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ASN REPORT

on the state of nuclear safety and radiation protection in France in 2015

The ASN (Nuclear Safety Authority) Report on the state of nuclear safety and radiation protection in France in 2015.

This report is specified in Article L. 592-31 of the Environment Code.

It was submitted to the President of the Republic, the Prime Minister and the Presidents of the Senate and the National Assembly, pursuant to the above-mentioned Article.

Summary

ASN actions

Activities regulated by ASN

On the whole, **2015** was satisfactory despite a **worrying** short-to-medium term **context**

FROM LEFT TO RIGHT:
Philippe CHAUMET-RIFFAUD - **Commissioner**; Margot TIRMARCHE - **Commissioner**; Jean-Jacques DUMONT - **Commissioner**; Pierre-Franck CHEVET - **Chairman**; Philippe JAMET - **Commissioner.**

Montrouge, 1st March 2016

2015 is similar to previous years: the nuclear safety and radiation protection situation is on the whole satisfactory.

The operating safety of the nuclear installations has in particular been maintained at a good level, although radiation protection requires particular vigilance, especially in the medical field, with about ten level 2 incidents occurring in 2015.

However, this positive evaluation for 2015 should be moderated as the context is a worrying one, with significant concerns for the future. This view is based on three observations:

- Safety and radiation protection challenges will grow over the period 2015-2020:
  - The possible continued operation of the 900 MWe reactors beyond their fourth periodic safety review is a key issue. The generic opinion from ASN on this subject will be issued no earlier than the end of 2018 after analysis of the studies yet to be produced by EDF.
  - The other main nuclear installations, in particular fuel cycle installations and research reactors, will need to undergo a periodic safety review during the same period. By the end of 2017, ASN will have to begin to process about fifty review files.
  - The improvements to the installations required following the Fukushima Daiichi accident must continue to be deployed, in particular for the fixed equipment of the "hardened safety core", required to supplement the mobile resources already in place.
  - The projects or construction sites for new installations, EPR, Cigéo, RJH, ITER are behind schedule. Safety is not generally a factor, except for the Flamanville EPR vessel anomaly, which is being given special treatment. This anomaly was discovered belatedly, following requests made by ASN, rather than at the initiative of the industrial firms concerned. A check is therefore required on the items that were manufactured in the past.
- The main industrial firms, Areva, CEA, EDF, who hold prime responsibility for the safety of their installations, are experiencing economic or financial difficulties. Wide-reaching reorganisations are in progress. Time will be needed for them to take full effect.
- In 2016, ASN and the Institute for Radiation Protection and Nuclear Safety (IRSN) did not obtain the additional human resources needed to meet these challenges. In these conditions, ASN will be giving priority to regulation of the installations in operation rather than the examination of new installations. A situation such as this is not however sustainable and ASN is once again asking for a review of its financing, to enable it to have appropriate resources able to meet its needs and those of IRSN.

This worrying context must encourage all stakeholders to exercise the greatest vigilance to ensure that safety remains a priority. For its part, ASN will be attentive to the technical and financial capacity of the industrial firms, as well as to ensuring that they maintain in-house skills that are vital for safety. It will also ensure that the necessary safety investments are made.

The European safety approach undergoes ambitious development

The Fukushima Daiichi accident focused attention on reinforcing the provisions of the international convention on nuclear safety, adopted after the Chernobyl accident. A policy declaration was issued in February 2015: it stipulates the reinforced safety objectives but imposes no new corresponding obligations. This result, which ASN deems disappointing, can be explained by the lack of a shared view of the level of safety to be reached. In these conditions, it is particularly important to maintain the momentum created in Europe in this field, as illustrated by the 2014 European Directive on nuclear safety, which sets more ambitious requirements than those of the international convention, and by the European radiation protection Directive of 2013.

European harmonisation of safety and radiation protection remains a priority for ASN, which will continue to participate actively in the work of ENSREG (European Nuclear Safety Regulators Group), a consultative body of the European Commission in the field of nuclear safety, and of WENRA (Western European Nuclear Regulators Association) and HERCA (Heads of the European Radiological protection Competent Authorities). The ASN Chairman was in fact the President of ENSREG in 2015.

ASN will in particular support projects to harmonise the management of emergency situations in Europe, more specifically with regard to the coordination of the population and environment protection measures to be taken by the various countries concerned by releases in the event of a severe nuclear accident.

The possible continued operation of ageing installations is a major issue

EDF wishes to extend the operating life of its reactors currently in service well beyond forty years, the service life posited at their initial design stage. In the future, this fleet would function alongside new EPR or equivalent type reactors, meeting considerably strengthened safety requirements. The continued operation of the current reactors beyond forty years must therefore be examined taking account of the existence of safer technology. There are then two objectives. The licensee must first of all demonstrate the compliance of the reactors with the applicable regulations, more specifically by analysing and processing the problems of equipment ageing and obsolescence. It must also improve their level of safety with respect to the requirements applicable to the new reactors.

On this point, ASN issued a position statement in 2013 on the list of topics to be examined more closely and the generic studies to be carried out in the run-up to the fourth periodic safety reviews for the 900 MWe reactors. In early 2016, it should give its opinion on the orientations adopted by EDF for the study and verification programmes associated with these reviews.

Tricastin reactor 1 will be the first in France to undergo its fourth ten-yearly in-service inspection, in 2019. This time-frame is particularly tight, given the scale of the analyses and work required. It raises numerous questions: EDF's ability to carry out the necessary studies, industrial capacity for performing the corresponding work, the ability of ASN and IRSN to mobilise the human resources needed to analyse the proposals and then check performance of the programme decided on.

ASN intends to issue a generic opinion in 2018 on the continued operation of the 900 MWe reactors beyond forty years. This general opinion will be drafted with the participation of the public. The subsequent periodic review of each reactor will entail a public inquiry as specified by the Energy Transition for Green Growth Act (TECV).

Installations other than power reactors (laboratories, waste plants and installations undergoing decommissioning) cover a wide variety of activities: research, fuel cycle, waste management, production of radiopharmaceuticals and industrial irradiators, etc. These installations are often ageing.

Several dozen of these installations will have to undergo a periodic review, often for the first time. For both ASN and IRSN, this already means a considerable increase in the workload, which will only get heavier in the coming years. Increased oversight, on a recently formalised basis, that is proportionate to the safety issues, will be a means of optimising how ASN and IRSN resources are used.

In any case, ASN will ensure that the upgrades specified further to these reviews are actually carried out, despite the economic, financial and budget constraints faced by the licensees.

The post-Fukushima Daiichi fixed equipment must be deployed

Learning the lessons from the Fukushima Daiichi accident has been an ASN priority since 2011. ASN issued prescriptions aimed at significantly reinforcing the safety of all the nuclear installations and it monitors their implementation. ASN in particular prescribed the deployment in each installation of a "hardened safety core" of material and organisational provisions which, in extreme conditions such as those which led to the Fukushima Daiichi disaster, would prevent a severe accident and, were it nonetheless to occur, would mitigate its consequences.

This "hardened safety core" comprises mobile equipment that can be connected to the installation in addition to fixed equipment, thus combining the advantages of the immediate availability of fixed equipment with the operational flexibility of mobile equipment. At the international level, numerous countries simply deployed mobile equipment. This mobile equipment has been fully deployed in France as in most other European countries. Deployment of the fixed equipment is more complex and will take longer.

Changing pressure equipment regulations

The Order of 12 December 2005 modified the regulations applicable to the manufacture of Nuclear Pressure Equipment (ESPN), mainly by reinforcing the substantiating documents required from the manufacturers concerning the quality of their products and by organising the intervention by approved technical inspection agencies.

More specifically owing to the extended substantiations it requires, this regulatory approach in particular enabled the vessel anomalies for the EPR under construction in Flamanville to be brought to light. Additional in-depth tests are to be carried out. They will make it possible to reach a decision on the acceptability of the parts concerned with respect to the safety requirements.

These observations also led to the initiation of a process to review the quality of ESPN manufactured by Areva over the past ten years.

However, implementing this regulation proved to be more complex than had been anticipated, as illustrated by the problems with evaluating the conformity of the replacement generators for reactor 3 at Le Blayais. In April 2015, work was started by ASN jointly with the Ministry responsible for the Environment and the industrial firms concerned in order to deal with these problems in depth and allow full application of the regulations, modified by the Order of 30th December 2015, which more specifically introduces a transitional system which comes to an end on 31st December 2018.

Eventual decommissioning of the current nuclear fleet will generate a very large quantity of very low level waste, which could be disposed of locally

Decommissioning of a Basic Nuclear Installation (BNI) is a lengthy and complex operation involving risks, which must be anticipated as of the design of the installation with preparations being made as soon as its final shutdown is decided.

The main BNI licensees will have to carry out major decommissioning programmes in the coming years.

EDF, which is already faced with the decommissioning of installations which have been shut down for several years, must now prepare for the eventual decommissioning of the fleet of reactors currently in service. This will result in an influx of radioactive waste, further increasing the need to boost long-lived waste storage capacity, pending the availability of disposal facilities. The large quantities of very low level waste will also raise a new question: to limit waste traffic, might it not be better to envisage several regional disposal facilities, rather than a single centralised one? ASN considers that this point needs to be evaluated and debated.

For its part, CEA is faced with the need to decommission numerous installations situated in civil or defence-related BNIs. The corresponding operations have fallen significantly behind schedule in recent years. Together with the Defence Nuclear Safety Authority, ASN considers that such a situation is prejudicial to safety and that the means necessary to remedy this situation must be deployed.

The operations begun by Areva on its La Hague site, to collect and package legacy waste, will also require considerable resources.

Long-lived waste disposal is behind schedule: storage capacity has to be re-assessed

For long-lived waste, underground disposal is the solution offering the best level of safety for the time-scale being considered. It is therefore considered internationally to be the reference solution.

The repeated extensions to the time needed for the preliminary design studies for the long-lived waste disposal project confirm the difficulty involved in such projects. It would in particular appear:
- that the schedule set by the Act covering development of the Cigéo project needs to be set back by five years;
- that the choice of a disposal site for Low Level, Long-Lived Waste disposal (LLW-LL) is still posing a problem.

Waste producers must reassess their storage capacities to provide the overall management system for these wastes with enough margin to deal with the uncertainties surrounding the actual availability of disposal solutions, without compromising nuclear safety. This essential extension of short-term storage capacity should not however deflect attention from the goal of long-term disposal.

In this respect, the studies for deep geological disposal of high and intermediate level long-lived waste are continuing, in particular with regard to the reversibility aspect, which addresses a two-fold requirement:
- adaptability of the installation to scientific and technological advances, as well as to the consequences of any changes in energy policy or industrial choices, which could lead to the disposal of non-reprocessed spent fuels;
- recoverability of the waste already emplaced, for a fixed period of time.

Legislative definition of the technical requirements linked to reversibility is a prerequisite for the creation of a disposal facility creation authorisation application file.

Radiation protection in the medical field remains a key issue

Regulation of dose management in medical imaging remains a major objective, in particular for computed tomography, owing to the significant contribution by this type of examination to the exposure of the French population, and for interventional radiology, owing to the major radiation-protection issues for the patients and professionals concerned by these rapidly developing procedures.

With regard to interventional radiology, ASN observes that certain urgent measures, which have been recommended for several years now, have still not been fully applied in all the medical structures concerned: increased numbers of medical physicists, training of the users, means allocated to persons competent in radiation protection, quality assurance and audits of professional practices. ASN considers that the system of dosimetric reviews for the most common or most heavily irradiating procedures must be pursued.

In the field of radiotherapy, ASN inspections were able to measure the progress made by the centres, even if there are still weaknesses in quality management and risk management. The new hypofractionated treatment techniques such as hadron therapy, which involve high energy levels in often very small volumes, are challenges for the coming years. ASN will ensure that the recommendations made in 2015 by its advisory committee for radiation protection – concerning the medical and forensic applications of ionising radiation using these new techniques – are implemented, in order to reinforce patient safety and protection.

The growth of new imaging and radiotherapy techniques requires a strengthening of initial university training and indeed continuing training in radiation protection, both for those prescribing the examinations and those performing them.

The new 2016-2019 national action plan for radon-related risk management will target homes and professional premises

It will allow improved monitoring of human exposure to radon in the home and in the workplace. Under ASN oversight, radon measurements taken by the approved laboratories will be input into a national database. On the basis of a nationwide map, it will now be mandatory to inform those buying or renting a home of the radon risk in the commune concerned.

It should be noted that close to former mining sites and their waste rock, radon exposure may prove to be a major risk for the occupants of certain buildings, as was shown by the case observed in Bessines (Haute-Vienne *département*[1]).

Safety and radiation protection benefit from a reinforced legislative framework

The TECV Act marks a significant step forward for safety and radiation protection: it extends the roles and powers of ASN and reinforces the role of IRSN, consolidates the Local Information Committees (CLI) and, more generally, the provisions concerning the information and involvement of the general public. It is an invaluable tool for optimising how we manage the period of unprecedented challenges today facing us.

1. Administrative region headed by a Prefect

The Nuclear Safety Authority

ASN was created by the 13th June 2006 Nuclear Security and Transparency Act. It is an independent administrative Authority responsible for regulating civil nuclear activities in France. It also contributes towards informing the citizens.

ASN is tasked, on behalf of the State, with regulating nuclear safety and radiation protection in order to protect workers, patients, the public and the environment from the hazards involved in nuclear activities.

ASN aims to provide efficient, impartial, legitimate and credible nuclear regulation, recognised by the citizens and regarded internationally as a benchmark for good practice.

Competence
Independence
Rigour
Transparency

ASN

Its roles

Regulating

ASN contributes to drafting regulations, by giving the Government its opinion on draft decrees and Ministerial Orders, or by issuing statutory resolutions of a technical nature.

Authorising

ASN examines all individual authorisation applications for nuclear facilities. It can grant all authorisations, with the exception of major authorisations for basic nuclear installations, such as creation and decommissioning. ASN also issues the licenses provided for in the Public Health Code concerning small-scale nuclear activities and issues authorisations or approvals for radioactive substances transport operations.

Monitoring

ASN is responsible for ensuring compliance with the rules and requirements applicable to the facilities or activities within its field of competence. Inspection is one of ASN's main means of monitoring, although it also has appropriate powers of enforcement and sanction.

Informing

Primarily through its website *www.asn.fr* and its *Contrôle* magazine, ASN informs the public and the stakeholders (Local Information Committees, environmental protection associations, etc.) of its activities and the state of nuclear safety and radiation protection in France.

In emergency situations

ASN monitors the steps taken by the licensee to make the facility safe. It informs the public of the situation. ASN assists the Government. It in particular sends the competent Authorities its recommendations concerning the civil security measures to be taken.

Regulation and monitoring of diverse activities and facilities

Nuclear power plants, radioactive waste management, nuclear fuel shipments, packages of radioactive substances, medical facilities, research laboratories, industrial activities, etc. ASN monitors and regulates an extremely varied range of activities and installations. This regulation covers:
- 58 nuclear reactors producing nearly 80% of the electricity consumed in France, along with the EPR reactor currently under construction;
- all French fuel cycle facilities, from fuel enrichment to reprocessing;
- several thousand facilities or activities which use sources of ionising radiation for medical, industrial or research purposes;
- several hundred thousand shipments of radioactive substances nationwide, every year.

The help of experts

When taking certain decisions, ASN calls on the expertise of technical support bodies. This is primarily the case with the Institute for Radiation Protection and Nuclear Safety (IRSN). The ASN Chairman is a member of the IRSN Board. ASN also requests opinions and recommendations from scientific and technical Advisory Committees of Experts (GPE).

Key figures in 2015

483	staff members
82%	management
268	inspectors
1,882	inspections of nuclear facilities, of shipments of radioactive substances, of the medical, industrial and research sectors, of approved organisations
16,694	inspection follow-up letters available on *www.asn.fr* as at 31st December 2015
330	technical opinions sent to ASN by IRSN
25	Advisory Committee meetings
2,958	authorisations and licenses
20	press conferences
78	information notices
36	press releases
6	accident simulation exercises
80.11	million euros total budget for ASN
85	million euros IRSN budget devoted to expert appraisal work on behalf of ASN

ASN organisation chart as at 31st December 2015

COMMISSION

Commissioners
Philippe CHAUMET-RIFFAUD
Jean-Jacques DUMONT
Philippe JAMET
Margot TIRMARCHE

Head of Private Office
Laurent FELBER

Chairman
Pierre-Franck CHEVET

DIRECTORY-GENERAL OFFICE

Deputy directors-general
Julien COLLET
Alain DELMESTRE
Jean-Luc LACHAUME

Adviser
Henri LEGRAND

Head of Staff
Ambroise PASCAL

Director-general
Jean-Christophe NIEL

Director for the Director-general
Loïc TANGUY

DEPARTMENTS

- **Nuclear power plant department (DCN)**
  Anne-Cécile RIGAIL
- **Nuclear pressure equipment department (DEP)**
  Rémy CATTEAU
- **Transport and sources department (DTS)**
  Vivien TRAN-THIEN
- **Waste, research facilities and fuel cycle facilities department (DRC)**
  Fabien SCHILZ
- **Ionising radiation and health department (DIS)**
  Jean-Luc GODET
- **Environment and emergency department (DEU)**
  Bénédicte GENTHON
- **International relations department (DRI)**
  Stéphane PAILLER
- **Communication and public information department (DCI)**
  Alain DELMESTRE

Office of Administration (SG)
Luc CHANIAL

Management and expertise office (MEA)
Alain RIVIÈRE

DIVISIONS

1 - Bordeaux division
Regional representative: N…
Regional head: Paul BOUGON

2 - Caen division
Regional representative: N…
Regional head: Guillaume BOUYT

3 - Châlons-en-Champagne division
Regional representative: N…
Regional head: Jean-Michel FÉRAT

4 - Dijon division
Regional representative: Thierry VATIN
Regional head: Marc CHAMPION

5 - Lille division
Regional representative: Vincent MOTYKA
Regional head: François GODIN

6 - Lyon division
Regional representative: Françoise NOARS
Regional head: Marie THOMINES

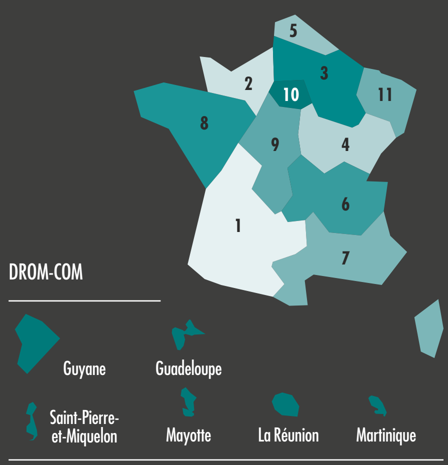
7 - Marseille division
Regional representative: N…
Regional head: Laurent DEPROIT

8 - Nantes division
Regional representative: Annick BONNEVILLE
Regional head: Pierre SIEFRIDT

9 - Orléans division
Regional representative:
Christophe CHASSANDE
Regional head: Pierre BOQUEL

10 - Paris division
Regional representative: Alain VALLET
Regional head: Bastien POUBEAU

11 - Strasbourg division
Regional representative: N…
Regional head: Sophie LETOURNEL



Division Caen and Orleans respectively involved in the Bretagne region and Ile-de-France region for control of the only BNIs. The Overseas *départements* and regions and the Overseas communities (DROM-COM) are under the responsibility of the Paris division.

Its organisation

The Commission

The Commission defines ASN general policy regarding nuclear safety and radiation protection. It consists of five Commissioners, including the Chairman.

Pierre-Franck CHEVET **Chairman**	Philippe CHAUMET-RIFFAUD **Commissioner**	Jean-Jacques DUMONT **Commissioner**	Philippe JAMET **Commissioner**	Margot TIRMARCHE **Commissioner**
DATE APPOINTED				
12th November 2012 for 6 years	10th December 2014 for 6 years	15th December 2010 for 6 years	15th December 2010 for 6 years	12th November 2012 for 6 years
APPOINTED BY				
President of the Republic			President of the Senate	President of the National Assembly

Impartiality

The Commissioners perform their duties in complete impartiality and receive no instructions either from the Government or from any other person or institution.

Independence

The Commissioners perform their duties on a full-time basis. Their mandate is for a six-year term. It is not renewable. The duties of a Commissioner can only be terminated in the case of impediment or resignation duly confirmed by a majority of the Commissioners. The President of the Republic may terminate the duties of a member of the Commission in the event of a serious breach of his or her obligations.

Competencies

The Commission issues resolutions and publishes opinions in ASN's *Official Bulletin*. The Commission defines ASN external relations policy both nationally and internationally. The Commission defines ASN regulatory policy. The Chairman appoints the nuclear safety inspectors, the radiation protection inspectors, the health and safety inspectors for the nuclear power plants and the staff responsible for verifying compliance with the requirements applicable to pressure vessels. The Commission decides whether to open an inquiry following an incident or accident. Every year, it presents the ASN *Report on the state of nuclear safety and radiation protection in France* to Parliament. Its Chairman reports on ASN activities to the relevant commissions of the French Parliament's National Assembly and Senate as well as to the Parliamentary Office for the Evaluation of Scientific and Technological Choices. The Commission drafts ASN internal regulations and appoints its representatives to the High Committee for Transparency and Information on Nuclear Security.

Commission figures in 2015

77 sessions

25 opinions

61 resolutions

Headquarters and the regional divisions

ASN comprises a headquarters and eleven regional divisions with competence for one or more administrative regions. This organisation enables ASN to carry out its regulation and monitoring duties over the entire country and in the overseas territories of France. The headquarters are organised thematically and are responsible at a national level for their fields of activity. The ASN regional divisions operate under the authority of the regional representatives, appointed by the ASN Chairman. They are ASN's representatives in the regions and contribute locally to ASN's public information role. The divisions carry out most of the direct inspections on nuclear facilities, radioactive substances transport operations and small-scale nuclear activities. In emergency situations, the divisions assist the Prefect of the *département*, who is in charge of protecting the general public, and supervise the operations carried out to safeguard the facility on the site.

ASN is adapting how it works to the unprecedented challenges being faced

Jean-Christophe NIEL
Director-general

Montrouge, 1st March 2016

Throughout the year, ASN inspects, authorises (or not), regulates, sanctions, investigates, reports, informs, trains its staff, and so on.

Several inspections are carried out daily; there were 1,882 in 2015. Nearly 8,000 small-scale nuclear sector notifications or licenses under the Public Health Code and 440 under Article 26 of Decree 2007-1557 of 2nd November 2007 were examined. ASN was notified of 1,682 incidents by health professionals, licensees and industry. In 2015, 77 meetings of the ASN commission led to the signing of 61 resolutions and 25 opinions. 114 information notices and press releases were published on the ASN website. The emergency centre was activated four times in a nuclear emergency situation and six times for emergency simulation exercises. Nearly 3,700 days of training were dispensed.

ASN's roles are thus broken down between monitoring (50%), authorisation/licensing (25%), regulation (10%), public information (10%) and management of emergency situations (5%).

ASN presented this breakdown to the entity responsible for informing the Government about the resources available for regulating nuclear safety and radiation protection and their development. The conclusions, drafted by this entity, consisting of the General Inspectorate for Finances, the General Council for the economy, industry, energy and technologies and the General Council for the environment and sustainable development, were submitted to the Government so that it could present its report to Parliament, pursuant to the 2015 Budget Act.

* * *

These figures show the scale of the day to day work done by ASN staff in their oversight of nuclear activities and exposure to ionising radiation.

In the field of nuclear safety, ASN oversaw and regulated the continued operation of Areva's Comurhex plant, the Ganil and four 900 MWe reactors operated by EDF.

In 2015, it issued a generic opinion on the third ten-yearly in-service inspections of the 1,300 MWe reactors and continued to examine the file regarding the service life extension of the 900 MWe reactors beyond their fourth ten-yearly in-service inspection, or in other words after forty years of operation.

ASN also issued an opinion on the cost of the deep geological radioactive waste disposal project (Cigéo). In another area ASN notified the licensees concerned, Areva and CEA, of its requirements with regard for the "hardened safety core".

It issued a position statement on the test programme designed to characterise the positive macrosegregation detected on the EPR vessel closure head and asked EDF to complete the reactor commissioning application file. It is continuing its work to ensure full application of the provisions concerning nuclear pressure equipment.

ASN has issued a number of prescriptions addressing a number of unsatisfactory situations, such as the recovery of legacy waste at La Hague, preventing the fire risk in the facility operated in Saclay by CIS bio international or the tightness of the Bugey reactor 5 containment.

Finally, in 2015, it prepared the iodine tablets renewal campaign for the populations living in the vicinity of the 19 French nuclear power plants. This campaign is part of a broader process to develop a protection culture among the populations concerned. It will take place throughout 2016, together with the public authorities, the associations and elected officials and will use the national education system as a means of spreading its message.

In the field of medical radiation protection, ASN drew up a 2015 summary of the steps taken to control ionising radiation doses delivered to patients. The results are mixed; they reveal the development of good practices, but inadequate human resources.

ASN published recommendations on the implementation of new radiotherapy techniques and diagnostic reference levels for medical imaging.

Certain health situations required particular attention. This was in particular the case with the Timone hospital in Marseille, or the four incidents rated level 2 on the INES scale, all of which were related to radiation-protection, or the nine incidents rated on the ASN-SFRO scale, notified to ASN in 2015.

In 2015, with the Energy Transition for Green Growth Act, ASN's roles were expanded. Under the Ordinance of 10th February 2016, it is now responsible for regulating source security. This provision will enter into force no later than 1st July 2017. In 2015, ASN continued preparatory work prior to taking charge of this new activity.

* * *

As recalled by the Commission in its editorial, ASN is facing unprecedented challenges. It is therefore adapting its working methods to ensure that they are proportionate to the corresponding risks.

Regulation and oversight tailored to the challenges

There are numerous forms of inspection: for the major issues, ASN carries out "in-depth" inspections, involving several members of ASN staff and experts from the Institute for Radiation Protection and Nuclear Safety (IRSN). These inspections can last several days in a given facility and usually concern a specific topic.

For subjects with more minor implications, ASN adapts its oversight according to the actual risks. Thus, in 2015, ASN experimented with a new form of inspection, which it first of all implemented for conventional radiological activities carried out by veterinarians on domestic animals. This was done in close collaboration with the Council of the order of veterinarians. For this activity, the radiation protection consequences are minor, but there are a very large number of facilities. The aim is to identify those facilities on which ASN needs to focus its efforts. It envisages extending this approach to other areas under its responsibility.

Another example of the proportionate approach to the small-scale nuclear sector in areas with limited potential consequences: the ASN regional divisions are carrying out targeted inspection campaigns, followed by communication, aimed at raising radiation-protection awareness among professionals. For example, in 2015, the Lille division inspected about twenty medical radiology surgeries and the Lyon division about twenty dental surgeries.

Revision of the regulations to cover all the risks

The regulation of Basic Nuclear Installations (BNI) is undergoing a major revision. This revision was recommended by the two Integrated Regulatory Review Service missions of 2006 and 2014. The regulations prior to the 2006 Act on Transparency and Nuclear Security (TSN) were fragmented and inconsistent; in particular, they must now incorporate the 350 safety requirements drawn up by WENRA (Western European Nuclear Regulators Association). Finally, in the integrated approach recommended by the TSN Act, this revision is needed to cover all the risks and detrimental effects of BNIs.

The aim is to produce clear, complete, coherent, up-to-date reference regulations which reflect the best safety standards. It is also to achieve regulation that is proportionate to the risks or detrimental effects, based on a technical vision of safety and radiation protection issues.

In order to facilitate the adoption of the regulatory changes and corresponding requirements, ASN initiated a process of information and periodic training targeting the licensees. In December 2015, the Marseille division for example convened the local licensees to review the results of application of the BNI order in the Provence - Alpes - Côte d'Azur region.

ASN also drafted a guide to explain the process behind the drafting of the regulatory texts. The implementation of the prescriptions of this guide will improve the definition of the objectives and broad outlines of new draft texts before their detailed preparation begins. It will help reinforce the analysis of their potential impacts, improve the organisation of exchanges with the stakeholders and systematically make provision for experience feedback from application of the texts. This guide is submitted to the public for consultation in March 2016.

In 2015, the ASN website also posted new procedures for promoting public involvement during the consultation processes, in particular for its draft regulatory resolutions.

BNI classification to reinforce the efficiency of regulation

The BNI regime applies to more than a hundred installations in France. It concerns a wide variety of installations: nuclear research or power reactors, radioactive waste disposal centres, fuel fabrication or reprocessing plants, laboratories, industrial irradiators, etc. The risks or detrimental effects associated with these installations also vary widely.

In 2015, to boost the effectiveness of its regulation and oversight, ASN classified the various BNIs according to their risks and adapted its regulation and oversight according to this classification. Following an initial implementation period of about eighteen months, it will draw the lessons from this new approach.

Again with the aim of ranking and prioritising its actions in accordance with the potential risks, an ASN 2015 guide specified the time-frame objectives for characterising and processing conformity deviations affecting equipment important for safety, but which do not make this equipment unavailable.

ASN is also continuing to deploy the remote-notification system and in the next few months it will be used for notifications concerning the Public Health Code, which in particular comprises the transport field. Notifications for the other fields (for example notification of significant events in the small-scale nuclear sector or in BNIs) and licenses under the Public Health Code will be added later.

Finally, the transposition of basic radiation protection standards and the revision of the BNI texts will reinforce the "graded approach" to regulation of the risks linked to the use of ionising radiation and protection of the population against natural sources of ionising radiation, radon in particular.

* * *

The credibility and pertinence of ASN's actions are built on the commitment of its personnel, their know-how and their rigorous approach. I would like to take this opportunity to thank them all. I would also like to extend my thanks to the teams from IRSN for their daily engagement at our side, as well as to the Advisory Committees of Experts who meet regularly, for their essential contributions to our most important decisions.

Significant events in 2015

ASN actions

Activities regulated by ASN

01 Nuclear activities: ionising radiation and health and environmental risks

Ionising radiation may be of natural origin or caused by human activities, referred to as nuclear activities.

The exposure of the population to naturally occurring ionising radiation is the result of the presence of radionuclides of terrestrial origin in the environment, radon emanations from the ground and exposure to cosmic radiation.

Nuclear activities are activities entailing a risk of exposure to ionising radiation, emanating either from an artificial source or from natural radionuclides. These nuclear activities include those conducted in Basic Nuclear Installations (BNIs) and the transport of radioactive substances, as well as in all medical, veterinary, industrial and research facilities where ionising radiation is used.

Ionising radiation is defined as radiation that is capable of producing ions – directly or indirectly – when it passes through matter. It includes X-rays, alpha, beta and gamma rays, and neutron radiation, all of which have different energies and penetration powers.

The effects of ionising radiation on living beings can be "deterministic" (health effects such as erythema, radiodermatitis, radionecrosis and cataracts, which are certain to appear when the dose of radiation received exceeds a certain threshold) or "probabilistic" (probability of occurrence of cancers in an individual, but no certainty). The protective measures against ionising radiation aim to avoid deterministic effects, but also to reduce the probability of occurrence of radiation-induced cancers, which constitute the main risk.

Understanding the risks linked to ionising radiation is based on health monitoring (cancer registers), epidemiological investigation and risk assessment via extrapolation to low doses of the risks observed at high doses. There are still however numerous uncertainties and unknowns, in particular with regard to radio-sensitivity, the effects of low doses, the radiological signature of cancers and certain non-cancerous diseases.

Exposure to ionising radiation in France

The entire French population is potentially exposed to ionising radiation, but to differing degrees, depending on whether the ionising radiation is of natural origin or the result of human activities.

On average, the exposure of an individual in France was estimated by the French Institute for Radiation Protection and Nuclear Safety (IRSN) at 4.5 millisieverts (mSv) per year in 2010, varying by a factor of up to 5 depending on the location.

The sources of this exposure are as follows:
- for about 1 mSv/year, naturally occurring radioactivity excluding radon, including 0.6 mSv/year for radiation of telluric origin, 0.3 mSv/year for cosmic radiation and 0.6 mSv/year for internal exposure from food;
- for about 1.4 mSv/year, radon, with considerable variation related to the geological characteristics of the land (a new map of the country was produced in 2011 according to the radon exhalation potential) and to the buildings themselves; in zones defined as high-priority, periodic measurements must be taken in places open to the public and in the workplace. A national action plan for the period 2011-2015 has been implemented; its results and a new plan for the period 2016-2019 will be published in 2016;
- for about 1.6 mSv/year (estimate for 2015), diagnostic radiological examinations, with a clear upwards trend (+ 23% from 2007 to 2012); particular attention must thus be paid to controlling the doses delivered to the patients;
- for about 0.02 mSv/year, the other artificial sources of exposure: past airborne nuclear tests, accidents affecting facilities, releases from nuclear installations.

Nuclear activity workers undergo specific monitoring (more than 350,000 individuals in 2014); in 2014, the annual dose remained below 1 mSv (annual effective dose limit for the public) for 96% of the workforce monitored, while 20 mSv (regulation limit for nuclear workers) was exceeded for eight individuals, as was the case in 2013; the collective dose has fallen by about 50% since 1996 while the population monitored has grown by about 50%. For workers in activity sectors entailing technological enhancement of naturally occurring radioactive materials, the doses received in 85% of cases are less than 1 mSv/year. In a number of known industrial sectors however, it is quite probable that this value will be occasionally exceeded.

Finally, aircrews are subject to particularly close monitoring owing to their exposure to cosmic radiation at high altitude. Of the recorded doses, 85% are between 1 mSv per year and 5 mSv per year, while 15% are below 1 mSv per year.

Outlook

2016 will more particularly be devoted to the transposition into French law of the new European basic radiation protection standards concerning exposure to radon; the new requirements will lead to increased communication about this risk and the organisation, collection and analysis of the results of measurements taken in the home.

With regard to the regular increase in doses delivered to patients through medical imaging procedures, ASN will continue with the measures it initiated in 2011 to maintain the engagement by the health authorities and health professionals at all levels, in particular by raising the awareness of the practitioners prescribing the examinations.

02 The principles and stakeholders in regulating nuclear safety, radiation protection and environmental protection

Nuclear activities must be carried out in compliance with the eight fundamental principles of the Environment charter, the Environment Code and the Public Health Code.

- the principle of nuclear licensee responsibility for the safety of its facility;
- the “polluter-pays” principle: the polluter responsible for the environmental damage bears the cost of pollution prevention and mitigation measures;
- the precautionary principle: the lack of certainty, in the light of current technical and scientific knowledge, should not delay the adoption of proportionate prevention measures;
- the participation principle: the populations must take part in drafting public decisions;
- the justification principle: a nuclear activity may only be carried out if justified by the advantages it offers by comparison with the exposure risks it can create;
- the optimisation principle: exposure to ionising radiation must be kept as low as is reasonably achievable;
- the limitation principle: the regulations set an individual’s ionising radiation exposure limits as a result of a nuclear activity (except for medical purposes);
- the prevention principle: anticipation of any environmental damage through rules and actions taking account of the best available techniques at an economically acceptable cost.

The nuclear activity regulators

The current French organisation for the regulation of nuclear safety and radiation protection was established by the 13th June 2006 Act on Transparency and Security in the nuclear field (TSN Act), as codified in the Environment Code.

Parliament defines the applicable legislative framework and monitors its implementation, in particular through its special commissions, which conduct hearings, or the Parliamentary Office for the Evaluation of Scientific and Technological Choices (OPECST), which has issued a number of reports on this subject and to which ASN presents its annual *Report on nuclear safety and radiation protection in France.*

On the advice of ASN, the Government defines the general regulations for nuclear safety and radiation protection. Again on the advice of ASN, it also issues major individual resolutions concerning BNIs (creation authorisation, etc.).

It is responsible for civil protection in an emergency.

In the current governmental organisation, the Minister for the Environment, Energy and the Sea is responsible for nuclear safety and, together with the Minister for Social Affairs and Health, for radiation protection.

In each *département*, the Prefect – as the State’s representative – is responsible for the population protection measures. The Prefect is also involved during various procedures to oversee local coordination and provide the Ministers or ASN with an opinion.

ASN is an independent administrative Authority created by the TSN Act. It is tasked with regulating nuclear activities and contributes to public information. It sends the Government proposals for regulatory texts and is consulted on the texts prepared by the Ministers. It clarifies the regulations through statutory resolutions. It issues certain individual authorisations and proposes others to the Government. Nuclear activities are monitored and inspected by the ASN staff and by organisations duly authorised by ASN. ASN contributes to France's European and international actions within its areas of competence. Finally, it provides its assistance for management of radiological emergencies.

ASN is run by a Commission of five full-time, irrevocable Commissioners, nominated for a non-renewable 6-year mandate by the President of the Republic, the President of the Senate and the President of the National Assembly.

ASN has head office departments and eleven regional divisions around the country. Its total workforce stands at 483 employees. In 2015, the ASN budget stood at €80 million.

On technical matters, ASN relies on the expertise provided by IRSN and by the Advisory Committees of Experts.

About 400 IRSN staff work on providing ASN with technical support. In 2015, IRSN thus devoted €85 million to this work, equally funded by a subsidy from the State and revenue from a tax paid by the licensees of the large nuclear installations.

In total, the State's budget for transparency and the regulation of nuclear safety and radiation protection amounted to €176 million in 2015.

ASN also convenes pluralistic working groups enabling all the stakeholders to contribute to drafting doctrines and action plans and monitor their implementation.

ASN is also committed to the field of research, in order to identify areas requiring further investigation in order to meet the medium to long term expert assistance requirements and improve nuclear safety and radiation protection. It has set up a scientific committee.

The 17th August 2015 Energy Transition for Green Growth Act (TECV) and the Ordinance of 10th February 2016 containing various nuclear safety provisions reinforced ASN's duties and regulatory powers.

The Ordinance of 10th February 2016 set up a sanctions committee within ASN, responsible for the application of administrative fines in the event of any breach of the regulations.

Consultative bodies

The organisation of nuclear security and transparency also includes consultative bodies, in particular the High Committee for Transparency and Information on Nuclear Security (HCTISN), an information, consultation and debating body dealing with the risks linked to nuclear activities, the High Council for Public Health (HCSP) which contributes to the definition of multi-year public health objectives, evaluates the attainment of national public health targets and contributes to their annual monitoring, as well as various commissions tasked with giving an opinion on draft regulatory texts, such as the High Council for the Prevention of Technological Risks.

Outlook

Faced with unprecedented challenges, ASN considers that a significant reinforcement of its human and financial resources and those of IRSN is essential. Despite the efforts made by the Government since 2014 (addition of 30 posts over three years and stabilisation of the budget), at a time of extreme budget restrictions, the current situation remains worrying.

03 Regulations

The specific legal framework for radiation protection is based on the international norms, standards or recommendations drawn up by various organisations, in particular the International Commission for Radiological Protection (ICRP), a non-governmental organisation, the International Atomic Energy Agency (IAEA) and the International Standard Organisation (ISO).

At a European level, under the EURATOM Treaty, various directives concern nuclear safety and radiation protection, in particular Council Directive 2013/59/Euratom setting the basic standards for health protection against the dangers arising from exposure to ionising radiation and Council Directive 2009/71/Euratom of 25th June 2009 setting a community framework for the nuclear security of nuclear installations, revised in July 2014.

At a national level, the legal framework for nuclear activities has been extensively modified in recent years, most latterly with the adoption of the 17th August Energy Transition for Green Growth Act (TECV) and the publication of the Ordinance of 10th February 2016 containing various nuclear-related provisions. The main texts are contained in the Public Health Code and the Environment Code. Other texts are more specialised, such as the Labour Code, which deals with radiation protection of workers, or the Defence Code, which contains provisions regarding defence-related nuclear activities or the prevention of malicious acts. Finally, various texts apply to certain nuclear activities but without being specific to them.

The activities or situations regulated by ASN include a number of different categories presented below, along with the relevant regulations.

Small-scale nuclear activities: this category covers the many fields that use ionising radiation, including medicine (radiology, radiotherapy, nuclear medicine), human biology, research, industry and certain veterinarian, forensic or foodstuff conservation applications.

The Public Health Code created a system of authorisation or notification for the manufacture, possession, distribution (including import and export), and utilisation of radionuclides. ASN grants the licenses and receives the notifications. The Ordinance of 10th February 2016 added a system of registration mid-way between authorisation/licensing and notification.

The general rules applicable to small-scale nuclear facilities are the subject of ASN statutory resolutions. Thus, in 2015, ASN expanded the list of activities requiring notification and specified the rules for registering and monitoring radioactive sources.

Exposure of individuals to radon: human protection is based primarily on the obligation of monitoring in geographical areas where the concentration of naturally occurring radon can be high. This monitoring is mandatory in certain premises open to the public and in the workplace. A strategy to reduce this exposure is necessary, should the measurements taken exceed the action levels laid down in the regulations. In 2015, ASN adopted two statutory resolutions concerning radon measurement.

Basic Nuclear Installations (BNIs): these are the most important nuclear facilities; they are the facilities of the nuclear electricity generating sector (nuclear power plants, main facilities of the “fuel cycle”), the large storage and disposal facilities for radioactive substances, certain research facilities and the large accelerators or irradiators. There are nearly 150 of them, spread over about 40 sites.

The legal regime for the BNIs is defined by section IX of Book V of the Environment Code and its implementing Decrees. This regime is said to be “integrated” because it aims to prevent or manage all risks and detrimental effects that a BNI is liable to create for humans and the environment, whether or not radioactive in nature. It in particular requires that the creation of a BNI be authorised by a decree issued on the advice of ASN and that ASN authorise start-up of the installation, stipulate requirements regarding its design and operation with respect to protection of the population and the environment and authorise delicensing of the installation.

The TECV Act modified the oversight of BNI decommissioning by making a distinction between final shutdown, decided on by the licensee, and decommissioning, the conditions of which are stipulated in a decree issued on the advice of ASN and based on a file submitted by the licensee, in compliance with the principle of immediate dismantling which is now enshrined in law.

ASN is working on a revision of the BNI general technical regulations: after publication of the Ministerial Order of 7th February 2012 setting the general rules applicable to BNIs, ASN thus initiated the publication of about fifteen statutory resolutions; in 2015, it adopted two resolutions concerning waste management and the content of the BNI safety analysis report. This system is supplemented by guides, which are not legally binding and which present ASN policy; twenty guides have so far been published.

Pressure equipment specially designed for BNIs is subject to special rules updated in 2015 by the publication of the Decree of 1st July 2015 and the order of 30th December 2015.

The transport of radioactive substances: the safe transport of radioactive substances is based on the “defence in depth” principle involving on the one hand the packaging and its content, which must withstand the foreseeable transport conditions, and on the other the means of transport and its reliability, plus the response measures deployed in the event of an incident or accident.

The regulations concerning the transport of radioactive materials are based on the IAEA recommendations integrated into the international agreements covering the various modes of dangerous goods transport. At a European level, the regulations are grouped into a single 24th September 2008 Directive, transposed into French law by an amended Order dated 29th May 2009, known as the “TMD Order”.

ASN is in particular responsible for approving package models for the most dangerous shipments.

Contaminated sites and soils: the management of sites contaminated by residual radioactivity warrants specific radiation protection measures, in particular if remediation is envisaged. Depending on the current and future uses of the site, decontamination objectives must be set and the removal of the waste produced during post-operation clean-out of the contaminated premises and remediation of soil must be managed, from the site up to storage or disposal.

In 2012, ASN published its doctrine for the management of sites contaminated by radioactive substances.

The Ordinance of 10th February 2016 created a system of active institutional controls for contaminated sites and soils.

Outlook

2016 will in particular be devoted to implementing the TECV Act and the Ordinance of 10th February 2016, with renovation of the regimes governing the small-scale nuclear sector, continued drafting of the BNI general technical regulations and definition of the framework applicable to the protection of radioactive sources against malicious acts.

This regulatory work by ASN will be carried out with a view to ensuring that the rules are more closely tailored to the particular issues and to continuing to support the stakeholders involved.

04 Regulation of nuclear activities and exposure to ionising radiation

In France, nuclear activity licensees are responsible for the safety of their activity.

They cannot delegate this responsibility, and must ensure permanent surveillance of both this activity and the equipment used. Given the risks for humans and the environment linked to ionising radiation, the State regulates nuclear activities, a task it has entrusted to ASN.

Control and regulation of nuclear activities is a fundamental responsibility of ASN. The aim is to verify that all licensees fully assume their responsibility and comply with the requirements of the regulations relative to radiation protection and nuclear safety, in order to protect workers, patients, the public and the environment from risks associated with radioactivity.

Inspection is the key means of monitoring available to ASN. It requires one or more ASN inspectors (nuclear safety inspectors, radioactive substance transport safety inspectors, labour inspectors and radiation protection inspectors) to go to a monitored site or department, or to carriers of radioactive substances. The inspection is proportionate to the level of risk presented by the installation or the activity and the way in which the licensee assumes its responsibilities. It consists in performing spot checks on the conformity of a given situation with regulatory or technical baseline requirements. After the inspection, a follow-up letter is sent to the person responsible for the inspected site or activity and published on *www.asn.fr*. Any deviations found during the inspection can lead to administrative or criminal penalties.

ASN has a broad vision of control and regulation, encompassing material, organisational and human aspects. Its oversight actions take the tangible form of resolutions, requirements, inspection follow-up documents, sanctions where applicable and assessments of safety and radiation protection in each sector of activity. ASN's monitoring actions are also carried out by other means such as examination of files, analysis of significant events, visits prior to commissioning of installations and measures to raise the awareness of professionals.

This arrangement is supplemented by systematic technical inspections in certain fields by approved organisations.

Significant events

1,882 inspections were carried out in 2015 by the 268 ASN inspectors. These 1,882 inspections represent 2,024 days of actual inspection in the field. This number is down by comparison with 2014 owing to a fall in ASN's inspection capacity due to high inspector turnover and the time needed to train the new inspectors.

ASN also experimented with verification methods that complement inspections with veterinarians in certain *départements*.

In 2015, ASN was notified of:
- 1,039 significant events concerning nuclear safety, radiation protection and the environment in BNIs; 938 of these events were rated on

the INES scale[1] (848 events rated level 0, 89 events rated level 1 and one event rated level 2). Of these events, 15 significant events were rated as "generic events" including one at level 1 on the INES scale;
- 66 significant events concerning the transport of radioactive substances, including 9 level 1 events and one level 2 event on the INES scale;
- 617 significant events concerning radiation protection in small-scale nuclear activities, including 153 rated on the INES scale (of which 25 were level 1 events and 2 were level 2 events).

In 2015, as a result of infringements observed, the ASN inspectors transmitted 14 infringement reports to the public prosecutor's offices, three of which were related to labour inspections in the NPPs.

ASN took eight administrative actions (formal notice, deposit of sums, etc.) against managers of nuclear activities. In 2015, ASN continued the process initiated for the first time in 2014, involving the deposit of a sum by the CIS bio international company for performance of work to manage the fire risk.

1. *International Nuclear and Radiological Event Scale.*

The Energy Transition for Green Growth Act of 17th August 2015 provides for a reinforcement of ASN's oversight resources and powers of sanction. Through the Ordinance of 10th February 2016, measures were added to the ASN administrative sanctions, giving its inspectors more graduated powers of inspection and sanction.

Outlook

In 2016, ASN intends to carry out about 1,800 inspections on BNIs, radioactive substances transport operations, activities employing ionising radiation, organisations and laboratories it has approved and activities involving pressure equipment. ASN will as a priority inspect the activities with potentially serious consequences, defined in consideration of the experience feedback from 2015.

At the same time, ASN will continue to revise the procedures for notification of significant events, taking into account the feedback from the events notification guide in small-scale nuclear activities and the changes in regulations in the BNI sector.

It will propose changes to the sanctions policy, pursuant to the provisions of the TECV Act and the Ordinance of 10th February 2016.

In the environment field, ASN will continue its regulatory work with a modification of the Order of 7th February 2012, more particularly to take account of changes to the regulations, such as the entry into force on 1st June 2015 of Directive 2012/18/EU of 4th July 2012 concerning major accidents involving dangerous substances, referred to as "Seveso 3". It will also complete the revision of the ASN resolution of 16th July 2013, referred to as the "Environment Resolution", a process which was started in 2015.

05 Radiological emergency and post-accident situations

Nuclear activities are carried out with the two-fold aim of preventing accidents and mitigating any consequences should they occur. Despite all the precautions taken, an accident can never be completely ruled out and the necessary provisions for dealing with and managing a radiological emergency situation must be planned for, tested and regularly revised.

Radiological emergency situations, arising from an incident or accident, which risk leading to an emission of radioactive substances or to a level of radioactivity, liable to affect public health, include:
- emergency situations occurring in a BNI;
- accidents involving Radioactive Material Transports (RMT);
- emergency situations occurring in the field of small-scale nuclear activities.

Emergency situations affecting nuclear activities can also comprise non-radiological risks, such as fire, explosion or the release of toxic substances.

ASN takes part in management of these situations, for questions concerning the regulation of nuclear safety and radiation protection and, drawing on the expertise of its technical support organisation, IRSN, performs the following four main assignments:
- ensure and verify the soundness of the steps taken by the licensee;
- advise the Government and its local representatives;
- contribute to the circulation of information;
- act as competent Authority within the framework of the international conventions.

The ASN emergency response organisation set up for an accident or incident in a BNI more specifically comprises:
- at the national level, an emergency centre in Montrouge, consisting of three Command Posts (PC):
  - a "Strategy" Command Post, consisting of the ASN Commission, which, in an emergency situation, could be called on to issue resolutions and impose prescriptions on the licensee of the installation concerned;
  - a Technical Command Post (PCT) in constant contact with its technical support organisation, IRSN, and with the ASN Commission. Its role is to adopt a stance for advising the Prefect, who acts as the director of contingency operations;
  - a Communication Command Post (PCC), located close to the Technical Command Post. The ASN Chairman or his representative acts as spokesperson, a role which is distinct from that of the head of the Technical Command Post.
- at the local level:
  - ASN representatives working with and advising the Prefect in his decisions and communications;
  - ASN inspectors present on the site affected by the accident.

Significant events

In 2015, the national emergency centre was activated for six national exercises as well as on three occasions after the licensee triggered the on-site emergency plan on the Cattenom NPP on 28th May, the Flamanville NPP in the night of 26th August and the former Brennilis NPP undergoing decommissioning, on 23rd September. In all three cases, the situation was brought under control by the licensee after a few hours and no radioactive substances were released. The ASN emergency centre was also activated as a preventive measure for a few hours on the evening of 9th October, for a situation concerning the Flamanville plant.

Local implementation of the national *"Major nuclear or radiological accident"* response plan, published in February 2014, was initiated in 2015, under the supervision of the Prefects of the defence and security zones. It should take account of the diversity of local situations and will first of all entail updating the existing planning measures according to the method proposed in the guide published by the Ministry for the Interior in late 2014.

In 2015, the new roles of the Steering committee for managing the post-accident phase of a nuclear accident or radiological emergency situation (Codirpa) formalised in a letter from the Prime Minister of 29th October 2014 giving ASN a new mandate for a five-year period, focused on monitoring, supporting and analysing the various processes involved in the preparation for the post-accident phase. The Codirpa working group on long-duration releases submitted its report in 2015. A new working group was set up in 2015 on waste management in a post-accident situation, involving members from Codirpa and from the French National Radioactive Material and Waste Management Plan (PNGMDR). The report from the pluralistic seminar on the economic assessment of the risk of a nuclear accident, held by ASN in October 2014, was released in 2015. ASN initiated the necessary steps to promote the development of research on this subject, nationally and internationally.

During their joint meeting in 2014, the HERCA (Heads of the European Radiological protection Competent Authorities) and WENRA (Western European Nuclear Regulators Association) associations adopted a common position for improved transboundary coordination of protection measures during the first phase of a nuclear accident. The position of HERCA and WENRA aims, in the event of an accident, to promote the rapid transmission of information between the countries concerned and the consistency of the population protection recommendations issued by the nuclear safety and radiation protection authorities.

HERCA and WENRA consider that in Europe evacuation should be prepared up to 5 km around the NPPs, and sheltering and ingestion of stable iodine tablets up to 20 km. A general strategy should be defined in order to be able to extend evacuation up to 20 km, and sheltering and ingestion of stable iodine tablets up to 100 km.

In the same way as in previous years, ASN, together with the General Secretariat for Defence and National Security, the General Directorate for civil security and emergency management and the Defence Nuclear Safety Authority (ASND), prepared the 2015 programme of six national nuclear and radiological emergency exercises concerning BNIs and radioactive substance transport operations.

Outlook

The local implementation of the national response plan for a major nuclear or radiological accident will be tested in 2016 and 2017 during half-day exercises based on a radioactive substances transport accident scenario. In 2016, ASN will also take part in a major exercise involving the Government.

In 2016, ASN will continue with the European initiatives taken with a view to harmonisation of actions to protect populations in an emergency situation and to develop a coordinated response by the safety and radiation protection Authorities in the event of a near or remote accident, more specifically as part of the HERCA/WENRA approach. In 2016, ASN will take part in organising a workshop on this approach, involving the European authorities in charge of civil protection.

ASN will ensure that the populations are extensively involved in the preparation of these emergency exercises and that the post-accident part and the international relations part are put to use.

Finally, in 2016, ASN will continue to draft a resolution on the obligations of BNI licensees relative to the preparation for and management of emergency situations and the content of the on-site emergency plan, aiming to clarify the provisions of Title VII of the Order of 7th February 2012 setting the general rules for BNIs.

A new national iodine tablets distribution campaign is being run in 2016, under ASN supervision, for the populations living in the zone covered by the off-site emergency plans, around NPPs operated by EDF. The purpose of this distribution is to achieve the widest possible overall population coverage, but also to make the populations and local elected officials (mayors) aware of the potential risk and the instructions to be followed.

06 From information to transparency and public participation

The TSN Act of 13th June 2006 defines transparency in the nuclear field as *"the set of provisions adopted to ensure the public's right to reliable and accessible information on nuclear security"* (Article L.125-12 of the Environment Code, formerly Article 1 of the TSN Act).

The TECV Act of 17th August 2015 reinforces the transparency provisions.

It gives official status to ASN's declaration on the state of nuclear safety and radiation protection in its annual report. The Act reinforces the licensees' obligations regarding the provision of information. The Act also comprises a range of provisions concerning BNI Local Information Committees (CLI). Each year, the Local Information Committees will hold at least one meeting open to the public and those situated in *départements* on the borders will include representatives of the foreign States concerned.

ASN is a driving force behind implementation of the provisions of these Acts that are fundamental for transparency and nuclear security. ASN considers that nuclear subjects are everyone's business and that all citizens should be able to reach their own opinions.

Significant events

On 15th April 2015, ASN presented its *Report on the state of nuclear safety and radiation protection in France* to the OPESCT. This report, which constitutes the reference document on the state of the activities regulated by ASN in France, is submitted each year to the President of the Republic, to the Government and to Parliament.

In 2015, ASN was called to regular hearings by Parliament on its activities, on subjects concerning nuclear safety and radiation protection and with regard to the Energy Transition for Green Growth Bill.

In 2015 ASN organised twenty national and regional press conferences. Pierre-Franck Chevet presented his New Year greetings to about thirty journalists from the national and international press. ASN also held a press conference attended by about forty journalists, to present the ASN annual report. The ASN regional divisions then held regional conferences to present the results of their activities for the year and the coming challenges for ASN.

The *www.asn.fr* website is the main outlet for ASN information. The content of the ASN website is available on mobile phones and tablets, but also on the main social networks. In 2015, ASN used the functions offered by Twitter to achieve the widest possible dissemination of its news. ASN also has a Facebook page. Lastly, ASN continued in 2015 to develop its network on Dailymotion, YouTube, Viadeo and LinkedIn.

ASN and IRSN presented the travelling exhibition entitled *"La sûreté nucléaire ? Question centrale !"* (Nuclear safety? A core question) in Dunkerque from 17th September to 21st December 2015 with the urban community of Dunkerque, the Gravelines CLI and the National Association of Local Information

Committees and Commissions (ANCCLI).

The TECV Act, passed in 2015, reinforces transparency:
- At the expense of the licensee, those living in the vicinity of a BNI must now be regularly informed of the nature of the accident risks, the envisaged consequences, the safety measures and the procedures to be followed.
- The BNI licensees' obligations to provide information shall be extended to all aspects concerning public health and security or protection of nature and the environment.
- CLIs are granted the official right to address all questions within their field of competence;
- The CLIs will also be able to visit the installations, either for a general presentation of their functioning or following an incident or accident to obtain an explanation of the causes and effects of the event.
- All the CLIs must also hold at least one public meeting per year.
- Lastly, the composition of the CLIs in *départements* situated on a national border shall be supplemented to ensure better representation of the neighbouring countries concerned.
- For nuclear power generating reactors undergoing a periodic safety review beyond their thirty-fifth year of operation, the provisions proposed by the licensee to reinforce the safety of its installation and correct the anomalies observed will be the subject of a public inquiry before ASN finalises its prescriptions.

Article L. 120-1 of the Environment Code provides for a procedure of public consultation via the Internet on draft regulatory texts having an impact on the environment. During the year 2015, three draft statutory resolutions and three draft guides thus underwent the public consultation process.

Depending on their potential impact, individual resolutions on nuclear safety and radiation protection may also undergo the public consultation process. During the year 2015, 43 draft individual resolutions were thus posted for public consultation on *www.asn.fr*.

Outlook

In 2016, ASN will actively contribute to implementing steps to reinforce nuclear transparency in accordance with the requirements of the TECV Act.

ASN will strengthen its general public information measures. It will reinforce transparency on the subjects under its responsibility, together with the other players and stakeholders.

ASN will also improve the conditions in which members of the public can express their opinion on the draft regulatory texts on *www.asn.fr*. ASN will also organise a consultation with stakeholders on the first results of the procedures enabling the public to participate in the development of its resolutions.

The iodine tablets information and distribution campaign for the populations living in the vicinity of EDF NPPs (400,000 homes) started at the beginning of 2016. Under the supervision of a pluralistic steering committee chaired by ASN, its purpose is to inform the population about the nuclear risk and about the appropriate steps to be taken, in particular the ingestion of iodine tablets.

07 International relations

ASN is involved in international cooperation, enabling it to contribute to reinforcing nuclear safety and radiation protection worldwide, while consolidating its competence and its independence.

Significant events

Europe is a priority for ASN actions. Several European directives set common requirements and standards across Europe in the fields of nuclear safety and radiation protection. ASN contributes to drafting these rules, in particular through ENSREG (European Nuclear Safety Regulators Group), which assists the European Commission.

The European Authorities carry out numerous initiatives aimed at harmonising nuclear safety and radiation protection regulations and practices. Two associations, WENRA and HERCA, bring together the heads of the European nuclear safety and radiation protection authorities respectively. These associations more particularly drew up a common approach to transboundary cooperation for the prevention and management of a nuclear accident.

Beyond Europe, ASN plays an active role in the work overseen by the UN's IAEA agency. IAEA defines safety standards, which are then used by its Member States to draft their own national regulations. These standards are also used as the basis for peer audit missions by the safety regulators and nuclear licensees. An IRRS (Integrated Regulatory Review Service) mission thus examined the French nuclear safety regulation system in November 2014.

Based on an ASN proposal, IAEA in 2015 revised the INES scale designed to inform the public about the severity of nuclear accidents, including accidents concerning patients. ASN also contributed to the IAEA report on the Fukushima Daiichi accident.

ASN also takes part in the work done by the Organisation for Economic Cooperation and Development's Nuclear Energy Agency (NEA), allowing the exchange of information, experience and practices between the national regulatory Authorities. In 2015, the NEA more specifically continued its work to analyse the lessons learned from the Fukushima Daiichi accident, published a green paper on defence in depth and organised a seminar on safety culture among the regulators. ASN also takes part in several ASN groups, one of which is devoted to inspection practices in the various Member States.

ASN plays an active role in the international MDEP (Multinational Design Evaluation Programme) initiative, the aim of which is to develop innovative approaches to pool the resources and knowledge of safety regulators tasked with evaluating and overseeing the construction of new reactors. ASN contributes in particular to the group devoted to the EPR reactor, as well as to the groups working on codes and standards, digital instrumentation and control and multinational inspection of nuclear component manufacturers.

ASN also works with many countries through bilateral agreements. ASN takes care to share its best practices and conversely to understand the methods used in other countries. Personnel exchanges are organised regularly, ranging from a few days to assignments lasting several years.

ASN is continuing with its commitment to international assistance programmes. The purpose of this assistance is to enable the countries concerned to acquire the safety and transparency culture that is essential for a national system of nuclear safety and radiation protection regulation. In 2015, ASN took part in projects for the benefit of the safety regulators of China, Ukraine, Vietnam and Morocco.

ASN acts as the national point of contact for international conventions on nuclear safety and the safety of spent fuel and radioactive waste management. These conventions are an important tool in reinforcing nuclear safety worldwide, in particular through the three-yearly meetings at which each country submits a report on the implementation of these conventions for peer review.

ASN is the competent Authority for the Convention on the Early Notification of a Nuclear Accident and the Convention on Assistance in the case of a Nuclear Accident or Radiological Emergency. The purpose of these conventions is to facilitate the circulation of information and cooperation between countries in the event of a nuclear accident.

Outlook

In 2016, ASN will continue to work on developing the European approach to nuclear safety and radiation protection.

At a national level, ASN will support the joint proposals from HERCA and WENRA on transboundary cooperation in the prevention and management of a nuclear accident. The work will continue together with the national departments in charge of disaster protection and emergency services.

At an international level, ASN will continue to urge the need to learn the lessons from all aspects of the Fukushima Daiichi accident, including organisational and human factors. The 7th review meeting of the contracting parties to the convention on nuclear safety will be held in 2016, for which ASN will coordinate drafting of the report. Finally, ASN will contribute to the examination initiated by INRA (International Nuclear Regulators Association) of the effectiveness of the international peer review arrangements (IRRS, OSART – Operational Safety Review Team, etc.).

08 Regional overview of nuclear safety and radiation protection

This chapter sets out the nuclear safety and radiation protection situation observed locally by ASN's eleven regional divisions in 2015.

Summary sheets present the BNIs and small-scale nuclear facilities (medical, industrial and research) and the local actions particularly representative of ASN's work in the regions.

09 Medical uses of ionising radiation

For more than a century, medicine has made use of various sources of ionising radiation, both for diagnostic purposes and for therapy. While their benefits and usefulness have long been medically proven, these techniques however contribute significantly to the exposure of the population to ionising radiation.

Behind exposure to natural ionising radiation, medical exposure represents the second source of exposure for the population and the leading source of artificial exposure. In 2014, according to IRSN, 226,013 people working in medical and veterinary fields involving the use of ionising radiation underwent dosimetric exposure monitoring. Medical and dental radiology concerns about 74% of the medical personnel exposed. More than 98% of the health professionals monitored in 2014 received an annual effective dose below 1 mSv. The annual effective dose limit of 20 mSv was exceeded on seven occasions and the annual dose limit for the extremities (500 mSv) was exceeded on one occasion.

In France, there are several thousand conventional or dental radiology devices, just over a thousand computed tomography facilities, more than a thousand facilities carrying out interventional radiology and fluoroscopy-guided procedures, 225 nuclear medicine units using unsealed sources for in vivo or in vitro diagnostics and for internal radiotherapy. In addition, as at the end of 2014, 176 external radiotherapy centres equipped with 476 treatment devices, handling some 175,000 patients every year, and 653 radiotherapists were identified.

The activities presenting the highest risk from the radiation protection standpoint require authorisation.

Nuclear medicine comprises about 700 specialist practitioners, along with another 1,000 physicians from other specialities working together in nuclear medicine units (interns, cardiologists, endocrinologists, etc.)

In 2015, ASN issued 663 authorisations, including 48% in computed tomography, 26% in nuclear medicine, 20% in external radiotherapy, 5% in brachytherapy and 1% for blood product irradiators.

In 2015 ASN published a number of reports on computed tomography, teleradiology, radiotherapy and nuclear medicine.

Significant Radiation Protection Events (ESR) in 2015

Since July 2015, the radiotherapy units have been able to carry out on-line notification of ESR on an on-line notification portal shared by the French Health Products Safety Agency (ANSM) and ASN. It will be extended to cover the entire medical sector in 2016.

After a gradual rise over the period 2007 to 2014, the number of ESR notified to ASN dipped slightly in 2015, down to 525: 220 concerned radiotherapy (mainly patient positioning anomalies) or brachytherapy, 123 nuclear medicine, 100 computed tomography and 22 interventional radiology. 64% of them concern patients. 6% of the ESR concern the workers, primarily in nuclear medicine.

A rise in the number of ESR rated 2 on the ASN-SFRO[1] scale should be noted. Nine ESR rated level 2 or 2+ were notified. These concern errors in the target volume to be treated, the side to be treated, the dose fractioning, patient identity or brachytherapy activity.

The events notified to ASN in 2015 show that the consequences with the most significance in radiation protection terms concern:
- for the workers; nuclear medicine and interventional radiology;
- for the patients; interventional radiology during lengthy, complex procedures, radiotherapy – in particular for hypofractionated treatments – and nuclear medicine, with radiopharmaceuticals administration errors;
- for the public and the environment; nuclear medicine, with leaks from radioactive effluent pipes and containments.

The lessons learned from the significant radiation protection events notified to ASN underline the need to increase the involvement of Persons Competent in Radiation protection (PCR) and medical physicists in the management of radiation protection, to develop the training of the professionals using ionising radiation, to implement procedures for quality management and safety and for the evaluation of professional practices.

1. *This scale is designed for communication with the public in comprehensible, explicit terms, concerning radiation protection events leading to unexpected or unforeseeable effects on patients undergoing an external radiotherapy medical procedure.*

The radiation protection situation in radiotherapy

The safety of radiotherapy treatments is a priority area of ASN regulation and oversight. ASN systematically inspects radiotherapy centres every two years. An annual inspection frequency is applied for the centres with vulnerabilities in terms of human resources or organisation and particular attention is paid to departments having undergone major modifications (organisational or material), and centres implementing new techniques.

ASN published recommendations on the implementation of new radiotherapy techniques. In May 2015, recommendations were sent to all radiotherapy units, in order to warn them of the occurrence of radiation protection events linked to radiotherapy external beam asymmetry and to improve its detection.

ASN observes a continuous improvement in the implementation of the quality and safety management requirements in radiotherapy departments while at the same time underlining the variability between centres. Even if quality systems are improving, they are not evaluated and take insufficient account of actual practices.

Risk management is now standard practice in radiotherapy departments, with the implementation and analysis of anomaly logs. However, efforts are still needed in the monitoring of the improvements made. ASN issued recommendations in 2015 to improve the support given to the radiotherapy units, reduce the complexity of the risk assessments and make them more operational.

With regard to brachytherapy, the departments benefit from the organisation set up for external radiotherapy, concerning both the deployment of a quality management system and the radiation protection of workers and patients. Although PCR resources are generally available and training is given, progress is still needed in the technical inspections and job description assessments.

The radiation protection situation in nuclear medicine

A positive point is the increasing importance being given to the radiation protection of workers, patients and the environment. Risk assessments and personnel dosimetry monitoring are now carried out satisfactorily. Medical physicists are now used as a matter of course and medical physics organisation plans have been drawn up. Waste and effluent management is based on management plans.

Efforts are required for job description assessments, training, technical inspection and the analysis of dosimetry data for optimisation purposes.

The radiation protection situation in conventional radiology and computed tomography

Owing to the significant contribution to the exposure of the French population by this type of examination, ASN has maintained the oversight of radiation protection in the computed tomography field as one of its priorities. In 2012, computed tomography procedures accounted for 71% of the mean effective dose received by the population, although they only represent 10% of the volume of procedures. In May 2015, ASN painted a mixed picture of the management of the doses of ionising radiation delivered to the patients, with the development of good practices, but inadequate human resources. In 2015, ASN also published recommendations on diagnostic reference levels for medical imaging.

Its inspections also show that improvements are needed, in particular with greater preliminary analysis of prescribed examinations, training in radiation protection of patients, optimisation of scanner examination protocols, analysis of dosimetry data and evaluation of professional practices.

The radiation protection situation in interventional radiology

ASN considers that the urgent measures it has been recommending for several years to improve the radiation protection of patients and professionals in the exercise of interventional practices, especially in the operating theatres, have still not been taken. These measures concern increasing the still insufficient medical physicist staff numbers, user training, quality assurance, organising professional practice audits, increasing the means allocated to PCRs, training medical professionals in patient radiation protection and the publication of best practices guides by the learned societies.

Outlook

Due to the implications – as much for the radiation protection of professionals, where dose limit overruns are still observed – as for that of patients, where significant radiation protection events are notified – and because of the shortcomings in the radiation protection culture of medical workers, particularly in operating theatres, ASN considers that the inspection of interventional radiology remains a national priority in its 2016 inspection programme.

10 Industrial, research and veterinary uses and source security

Small-scale nuclear activities stand out through their extreme heterogeneity and the very large number of licensees concerned. Industrial, research and veterinary uses of radioactive sources are mainly industrial irradiation, X-ray inspection of materials, checking of physical parameters such as dust levels or density, neutron activation and various detection techniques, plus trackers. Electrical devices emitting ionising radiation are used for similar purposes, as well as for veterinary diagnostic radiology.

ASN must therefore adapt its efforts to the radiation protection issues of these activities if it is to regulate them effectively. ASN is in particular attentive to overseeing the management of ionising radiation sources, monitoring their conditions of possession, utilisation and disposal and ensuring the accountability and monitoring of source manufacturers and suppliers.

Significant events

In 2015, with regard to the users, ASN examined and notified 218 new licenses, handled 1,017 license renewals or updates and revoked 396 licenses. In 2015, ASN granted 193 licences and renewed 256 licenses to use X-ray generating devices and issued 601 notification acknowledgements. With regard to the suppliers, 94 licence or license renewal applications were examined by ASN. ASN also carried out 410 inspections of users and suppliers.

ASN continued its verification of the withdrawal from service of smoke detectors using radioactive sources. In September 2015, it granted a license to the Orange company for the removal of all the lightning arresters installed on its network that contain radionuclides and for their storage on specified sites.

It is also encouraging the removal of radioactive lightning conductors.

In 2015, several incidents took place in the field of industrial radiography, including one rated 2 on the INES scale; it concerned the use of an X-ray generating device in a bunker, leading to the exposure of one person in Colomiers (Haute-Garonne *département*). Industrial radiography is an inspection priority for ASN, with nearly 100 inspections per year. ASN finds that the way the companies address the risk varies widely. Preparation of the interventions, dose forecast evaluations, coordination between ordering customers and service providers and the adoption of preventive measures warrant particularly close attention by the parties involved.

In the other fields, a level 2 incident was linked to the discovery of two radioactive sources in a laboratory of the National Institute for Health and Medical Research at Bordeaux University, leading to the exposure of several individuals.

ASN is concerned by the increase in the number of cases of abnormal radioactivity being detected in metals and consumer goods around the world and considers that France needs rapidly to implement a nationwide radioactivity detection strategy.

As part of its regulatory duties, ASN defined a clear regulatory framework in its resolution of 8th September 2015, concerning the registration of movements by and rules for monitoring radionuclides in the form of radioactive sources. ASN continued to draft texts aimed at defining the minimum radiation protection requirements for the design of X-ray generating devices, jointly with the stakeholders. With regard to industrial radiography, ASN continued the process initiated with the General Directorate for Labour, to reinforce requirements in the field of justification, given the existence of recognised alternative methods.

Finally, Act 2015-992 of 17th August 2015 on the Energy Transition for Green Growth, entrusted ASN with the regulation and oversight of the measures to be taken by those responsible for a nuclear activity in order to protect sources against malicious acts. ASN continued its work to prepare the implementing texts necessary for actual deployment of regulation and it reinforced its efforts being devoted to inventorying the existing facilities.

Outlook

A guide drawn up by ASN will be published in 2016, jointly with IRSN and the National Agency for Radioactive Waste Management (Andra), to help assess the protection means necessary when removing radioactive lightning conductors.

A report presenting the conclusions of the investigations carried out with the stakeholders to define standard scenarios for loss of source control, define technical recovery solutions and best practices in the event of an incident involving loss of control of a source, is also currently being drafted.

ASN will also continue its work to propose a draft resolution determining the technical requirements for ionising radiation generating devices distributed in France.

A draft resolution on the minimum technical rules for the design, operation and maintenance of cyclotrons should be the subject of consultations in 2016.

Finally, in 2016, ASN will continue to prepare regulatory texts to take account of source security when examining licensing applications, to define the requirements for protection against malicious acts concerning the most dangerous sources and to organise the regulation of source security.

ASN will continue to carry out its licensing and oversight duties, tailoring its efforts and the oversight procedures to the specific radiation protection implications of the particular activities.

11 Transport of radioactive substances

About 770,000 consignments of radioactive substances are transported each year in France. This corresponds to about 980,000 packages of radioactive substances, which represent just a few per cent of the total number of dangerous goods packages transported each year. 88% of the transported packages are intended for the health, non-nuclear industries or research sectors, of which about 30% is accounted for by the medical sector alone. The nuclear industry accounts for about 12% of the annual traffic of radioactive substances (for example, about 400 annual shipments of new fuel, 220 of spent fuel, about 50 for MOX fuels and about 100 for plutonium oxide powder).

The content of the packages varies widely: their radioactivity level varies from a few thousand becquerels for low-activity pharmaceutical packages, to trillions of becquerels for spent fuel. Their weight also varies from a few kilogrammes to about a hundred tonnes. Road

transport accounts for about 90% of radioactive substances shipments, rail 3% and sea 4%. Air transport is widely used for small and urgent packages over long distances, for example, low activity radiopharmaceutical products. All of these shipments can be international.

The main participants in transport arrangements are the consignor and the carrier. The consignor is responsible for package safety. ASN checks that transport safety regulations are correctly applied for radioactive and fissile substances used for civil purposes. The major risks in the transport of radioactive substances are the risks of irradiation, contamination, criticality, but also toxicity or corrosion. To prevent them, the radioactive substances in the packages must be protected from fire, mechanical impact, water ingress into the packaging facilitating criticality reactions, chemical reaction between package components, etc. Safety is thus based above all on the robustness of the package, which is the subject of rigorous regulatory requirements. Given the international nature of these shipments, the regulations are drawn up on the basis of recommendations issued under the aegis of the International Atomic Energy Agency (IAEA). Although all packages must comply with strict rules, only 3% require ASN approval.

Significant events

Since the publication of the BNI Order on 7th February 2012, radioactive substances internal transport operations must be covered by the installations' internal baseline requirements. In 2015, ASN continued to examine the general operating rules for internal transports at EDF and Areva La Hague. ASN also updated the guide intended for industrial firms wishing to submit a transport package approval application to ASN and opened it to public consultation in 2015.

In 2015, ASN issued 43 approval certificates.

ASN performs inspections at all the stages in the life of a package: from manufacture and maintenance of a packaging, to package preparation, shipment and reception. In 2015, ASN carried out 98 inspections in radioactive substance transport (all sectors considered).

ASN in particular inspected the manufacture of castings for the first TN G3 container designed to transport spent fuels from NPPs and the Manon package for the transport of radioactive sources. It inspected transhipment at the rail terminal in Valognes (Manche *département*) of vitrified waste packages from the reprocessing plant in Sellafield (Great Britain) and intended for Switzerland. An inspector from the competent Swiss Authority and representatives of HCTISN member associations took part in this inspection as observers.

ASN published the update of its guide for packages not requiring approval. When it inspected these packages and despite noting improvements, ASN also found that the designers of type A package models must continue to make efforts, notably on the representative nature of the tests performed and the associated safety case.

ASN's inspections reveal deficiencies in familiarity with regulations and responsibilities on the part of the transport players in the field of small-scale nuclear activities, the medical sector in particular.

In the event of an accident, management of an emergency involving transport should be able to mitigate the consequences for the public and the environment. In 2015, ASN carried out two inspections on the topic of preparedness for emergency situations and inspected the emergency plans put into place by the main industrial players in the sector. ASN took part in an emergency exercise simulating an accident in the Saône-et-Loire *département*, involving the services of the Prefect and the emergency services.

ASN must be notified of any deviation from the regulations or the safety files applicable to the transport of radioactive substances. In 2015, ASN began its update of the guide specifying the notification procedures.

In 2015, concerning the transport of radioactive substances, ASN was notified of 56 level 0 events, nine level 1 events and one level 2 event. In particular, in March 2015, an incident rated level 2 concerned a gamma ray projector containing a high-level source which was not in the safe position during shipment. More than half of the events are notified by the industrial stakeholders in the nuclear cycle (EDF and Areva in particular). About one fifth of the significant events concern radioactive pharmaceutical products. The small-scale nuclear sectors are the cause of relatively few transport events when compared with the corresponding traffic levels, probably owing to a lack of notification.

In 2015, ASN adopted a resolution requiring that companies transporting radioactive substances in full or in part on French territory notify ASN and carry out a radioactive substances transport accident emergency exercise.

Outlook

During its inspections in 2016, ASN will continue to focus on internal transports on nuclear sites, on the manufacture and maintenance of packages, on preparedness for emergency situations and on non-approved packages. It will implement the notification system for companies transporting radioactive substances.

12 EDF Nuclear Power Plants (NPPs)

ASN imposes stringent safety requirements on power reactors, the regulation and oversight of which mobilises nearly 200 of its staff and as many IRSN experts on a daily basis.

ASN is developing an integrated approach to regulation that covers not only the design of new installations, their construction, modifications, integration of feedback on events or maintenance problems, but also human and organisational factors, radiation protection, environmental protection, worker security and the application of labour legislation.

Significant events

Experience feedback from the Fukushima Daiichi accident

In the wake of the Fukushima Daiichi accident, ASN issued a set of resolutions requiring the operators of major nuclear facilities to perform stress tests. Further to these stress tests, ASN issued a range of resolutions in 2012, requiring EDF to take additional steps to reinforce the robustness of the NPPs to extreme situations, more specifically:

- a «hardened safety core» able to perform vital safety functions in the event of hazards or unforeseen circumstances exceeding those adopted for the general design of the facility;
- a Nuclear Rapid Intervention Force (FARN) which, using mobile means external to the site, can intervene on a nuclear site in a pre-accident or accident situation;
- a range of corrective measures or improvements, notably the acquisition of additional communication and radiological protection means, the deployment of additional instrumentation.

EDF first of all deployed temporary or mobile measures to enhance protection against the main situations of total loss of the heat sink or electrical power supplies. EDF initiated studies designed to deploy robust means on all the sites to protect against extreme hazards in order to deal with these situations.

NPP operating life extension

EDF must carry out a periodic safety review of its reactors every ten years. This review consists, on the one hand, of a detailed check on designs and equipment and, on the other, of a reassessment of safety by comparison with the most recent facilities and international best practices. On this occasion, EDF corrects the deviations detected and identifies the modifications it intends to make to reinforce the safety of its reactors. On a case by case basis, ASN then decides on the continued operation of each reactor, if necessary issuing additional prescriptions.

In 2015, ASN examined EDF's proposals for the continued operation of the 900 MWe nuclear reactors beyond their fourth ten-yearly in-service inspection. This is of particular importance as it runs contrary to the initial design hypotheses for a certain number of equipment items. The studies of the conformity of the installations and the management of equipment ageing must thus be reviewed, taking account of the deterioration mechanisms actually observed and the maintenance and replacement strategies implemented by the licensee.

In March 2015, ASN ruled on the generic aspects of the continued operation of the 1,300 MWe reactors beyond thirty years. ASN considers that the measures planned by EDF to assess the condition of these reactors and manage their ageing are acceptable. ASN also considers that the modifications identified by

EDF following this study phase will make a significant improvement to the safety of these installations.

In February 2015, ASN ruled on the orientations of the periodic safety review associated with the second ten-yearly in-service inspections of the 1,450 MWe reactors. ASN in particular considers that the safety objectives to be adopted for this review must be defined in the light of the objectives applicable to new reactors.

Flamanville 3 EPR

On 19th March 2015, ASN received the commissioning authorisation application for Flamanville 3. ASN considered that additional information was needed before it could rule on this application, more specifically the conformity of the as-built installation with the file submitted, the design of the systems or the accident studies.

Flamanville 3 EPR reactor vessel anomaly

In late 2014, Areva NP informed ASN that tests performed on a vessel head representative of that intended for the Flamanville EPR showed the presence of an area with a high carbon concentration leading to lower than expected mechanical properties. Measurements confirmed the presence of this anomaly in the closure head and bottom head of the Flamanville 3 EPR vessel.

This anomaly is linked to the presence of a high carbon concentration which results in mechanical properties that are not as good as expected. Areva NP sent ASN a file presenting the approach it plans to implement to demonstrate the sufficiency of the mechanical properties of the material used in the manufacture of the vessel closure head and bottom head for the future Flamanville EPR reactor. This approach will in particular be based on the future results of a programme of mechanical and chemical tests.

On 12th December 2015, ASN issued a position statement concerning the approach used to demonstrate the mechanical properties of the Flamanville 3 EPR vessel closure head and bottom head proposed by Areva NP. Subject to its observations and requests being taken into consideration, ASN considers that the approach proposed by Areva is acceptable in principle and has no objection to the initiation of the planned programme of tests.

ASN assessments

Nuclear Power Plants (NPPs)

ASN considers that management of reactor operation is on the whole satisfactory. It however considers that the involvement by the corporate head office departments in monitoring the application of the prescription documents by the NPPs needs to be improved. Management of external operating experience feedback is still not robust enough, both between the sites and with regard to EDF head office departments.

In 2015, EDF notified 586 significant safety events, 109 concerning radiation protection and 79 concerning protection of the environment. The number of safety incidents notified was slightly down compared to 2014 (-8%).

ASN considers that EDF's internal independent safety system fulfils its role of verification of the measures and decisions taken by the departments in charge of operating the installations. Greater traceability is however required of the elements substantiating this verification process on the one hand and the stances adopted on the other.

With regard to the periodic equipment tests, even though improvements by comparison with 2014 had been observed on the sites, efforts must be maintained with regard to management of the planning, preparation and performance of these tests. The process implemented for subsequent confirmation of the validity of the tests must be reinforced in order to promote a questioning attitude.

Concerning the performance of maintenance work, ASN observes that the number of quality defects found is on the whole stable. It observes that the maintenance workers still face constraints linked to the organisation of the work, the inadequate preparation of certain activities or the working conditions.

EDF has implemented a specific multi-year action plan designed to reinforce the management of activities scheduled and carried out during maintenance outages of nuclear power generating reactors. Even if this action plan has led to more serene management of the preparation and performance phases by the licensee, ASN considers that EDF must continue with its efforts over the long term, in particular in the light of the EDF industrial programme for the coming years.

ASN considers that EDF must continue its efforts concerning the identification and traceability of the deviations detected. The potential severity of certain generic conformity anomalies demonstrates that EDF needs to manage the operational processes contributing to maintaining the conformity of the installations with their design, construction and operating baseline requirements.

ASN considers that in 2015, the condition of the first containment barrier, consisting of the fuel cladding, is on the whole progressing, despite a few points to be improved. 2015 was marked by the shutdown of the Nogent 2 reactor before the normal end of its operating cycle following a significant increase in absorber cluster drop time. This increase was the result of the deformation of fuel assemblies, which were repaired.

ASN considers that the condition of the steam generators was improved by the replacement of the last steam generator equipped with tube bundles made of 600 MA alloy which was susceptible to corrosion. ASN considers that EDF's operating and maintenance strategy concerning steam generator clogging is appropriate.

ASN considers that the organisation set up by the plants to monitor activities and systems liable to have an impact on static and dynamic containment in the installations is on the whole satisfactory. The results of the ten-yearly inspections on the containments were satisfactory, with the exception of Bugey reactor 5, which needs to be repaired. ASN is also remaining vigilant concerning the evolution of the tightness of the double-wall containments, for which EDF has made prevention and surveillance commitments.

The inspections carried out in 2015 on emergency management confirmed the satisfactory organisation of the plants in this area. The crews who will implement the on-site emergency plans are adequately sized and all emergency crew members take part in an annual exercise. The preparedness for emergency situation management can however be improved, in particular concerning the management and utilisation of mobile equipment employed in an emergency situation and through lessons learned from the emergency exercises.

ASN notes that the relations between the sites and the departmental fire-fighting and emergency services are on the whole satisfactory and that the response organisation is generally not found to be wanting in the management of actual fires. Nonetheless, the observations made in previous years with regard to sectorisation, detection, management of calorific potential and fire permits, are still valid. The number of outbreaks of fire recorded for 2015 is higher than that for 2014.

ASN noted the personnel's higher level of expertise regarding the explosion risk but considers that EDF must devote greater effort to training and exercises for the response crews. ASN does however consider that insufficient account is taken of the lessons learned from events on all the reactors.

ASN considers that the organisation in place on the sites for managing skills, qualifications and training is on the whole satisfactory and that the management processes are generally well-documented and coherent. Generally speaking, the training programmes are run satisfactorily. Nonetheless, the range of training proposed by certain sites is not always adapted rapidly enough. Furthermore, the persons concerned do not always receive the scheduled training.

In general, EDF devotes significant investment to hiring and training, in order to anticipate the necessary renewal of skills. Given the expected departures and the work to be done by EDF in the coming years, ASN considers that EDF needs to continue its efforts with regard to hiring and training.

ASN considers EDF's approach for improved integration of organisational and human factors in the engineering departments to be pertinent. Nonetheless, EDF must continue with its efforts in order to achieve the expected effects.

ASN observes that the collective dosimetry on all the reactors was slightly down in 2015 by comparison with 2014 and that the regulation annual limit for external whole-body dosimetry was never exceeded in 2015. ASN notes that the collective dose has been stable for about ten years now, reflecting the increased volume of maintenance work in controlled areas, combined with continued optimisation efforts. ASN considers that weaknesses remain in the control of industrial radiography operations and that of the dispersion of contamination inside the reactor building continues to be inadequate, owing to worksite containment faults or a lack of signalling of contamination levels.

ASN considers that EDF's organisation for the nuisance and impact control of NPPs on the environment is satisfactory on most sites and is progressing, more specifically with improved assimilation of the regulations. Monitoring of discharge objectives and integration of operating experience feedback remain an area requiring progress. Waste management is on the whole progressing but could still be improved.

The ASN assessments of each NPP are detailed in chapter 8 of the report. The Penly, Fessenheim and Saint-Laurent-des-Eaux sites stand out positively in this general assessment, while Cruas and Gravelines are however under-performing.

Manufacturing of pressure equipment

ASN observes that the justifications and demonstrations provided by the manufacturers with regard to nuclear pressure equipment regulations are still regularly unsatisfactory. As of the first half of 2015, EDF and Areva therefore took organisational measures to improve their practices and bring them into line with the regulatory requirements. ASN considers this approach to be a positive one and will be attentive to ensuring that it is seen through to completion.

Outlook

In 2016, ASN will issue a ruling on the orientation of the generic studies to be carried out in preparation for the fourth periodic safety reviews of the nuclear reactors, after consulting the public on the draft additional requirements to be sent to EDF concerning its design and verification programme.

Monitoring the implementation of the material and organisational measures prescribed following the Fukushima Daiichi accident remains a priority for ASN. In 2016, ASN will be heavily involved in examining the design, construction and operating provisions adopted by EDF.

2016 will also see continued examination of the commissioning authorisation application for the Flamanville 3 EPR reactor. ASN will examine the detailed design of the reactor and will monitor the construction and the preparation for the start-up tests. It will examine the file that Areva intends to submit concerning the reactor vessel anomaly.

In 2016, ASN will continue the extensive work it initiated in 2015 with the manufacturers, licensees and organisations it approves, regarding the drafting of professional baseline requirements and conformity evaluation baseline requirements.

Finally, ASN will ensure that the ongoing reorganisation of the industrial players takes account of the safety issues and that the safety improvement measures already under way are continued.

13 Nuclear fuel cycle installations

The fuel cycle concerns all the steps involved in the fabrication of the fuel and then its reprocessing once it has been used in nuclear reactors.

The main plants in the cycle – Areva NC Tricastin (Comurhex and TU5/W), Eurodif, GB II, Areva NP Romans-sur-Isère (ex-FBFC and ex-Cerca), Mélox, Areva NC La Hague and Areva NC Malvési – are part of the Areva group. These plants include facilities which have BNI status.

Significant events

With regard to the uranium conversion installations, the production tool in the Areva NC Comurhex plant (BNI 105) is to be modernised with the construction then commissioning of the Comurhex II installations initially scheduled for 2015 and today planned for 2018, while the current plant, Comurhex I, will close by the end of 2017. Delays in the new plant led Areva NC to ask ASN for an operating extension for the former ICPE (Installation Classified on Environmental Protection grounds) plants. This operation of life extension of the Comurhex I plants from July 2015 to the end of 2017 was accepted in 2015 provided that work was done to reinforce them. This work in particular concerns the implementation of mitigation means to limit the consequences of a major hazardous gas leak in the Procédé buildings.

With regard to the back-end cycle, the most significant point concerns the status of the evaporation capacity in the UP2-800 plant at La Hague. In 2011, Areva NC brought to light several perforations of the shell of an evaporator used to concentrate fission product solutions in the R7 unit. This evaporator could not be returned to service and needs to be replaced. In mid-2012, the licensee sent ASN a file presenting the safety options it had selected for the design of the new evaporator, to replace the old one. Examination of this file continued in 2014, with installation of this new evaporator currently being envisaged for 2017. Furthermore, in October 2014 in the R2 unit, high corrosion rates were observed on the fission product solutions concentration evaporators. These rates are higher than the equipment design-basis and higher than those observed on the same equipment in the T2 unit. ASN asked the licensee to explain this difference between the R2 and T2 units and to analyse the impact of this accelerated corrosion mechanism on the safety of the plant's evaporator capacity for the coming years. In addition, given the safety issues associated with these evaporators, ASN prescribed an annual inspection of the condition of this equipment in order to prevent a possible accident. The situation of this equipment demands particularly high vigilance by ASN, which considers that this is a priority issue for 2016 in terms of safety on this site.

Concerning the integration of experience feedback from the Fukushima Daiichi accident, work is continuing on the fuel cycle installations. The ASN resolutions of 9th January 2015 prescribe the hazard levels and associated requirements for the "hardened safety core" and the deadlines for deployment of this "hardened safety core" in all fuel cycle installations.

Assessment and outlook

Cross-disciplinary aspects

With regard to the Areva group, ASN will be particularly vigilant in ensuring that the BNI licensees to be created as a result of the ongoing split-up of the group, are in full possession of the capabilities needed to meet their responsibilities. In particular, the engineering capability of the two groups resulting from the split-up of Areva as it currently stands shall be credible enough to make any modifications to the installations concerned and manage any internal crises.

Fuel cycle consistency

In 2016, ASN will start an examination of the new "Cycle impact" file covering the period 2016-2030 and aimed at anticipating the various emerging needs in order to manage the nuclear fuel cycle in France. ASN will in particular focus on monitoring the level of occupancy of the spent fuel underwater storage facilities (Areva and EDF). It asked EDF to examine the impact on the anticipated saturation dates for these storage facilities of the shutdown of a reactor, of a possible modification in the spent fuel reprocessing traffic, as well as the solutions envisaged for delaying this saturation. ASN considers that the saturation of the storage facilities must be anticipated (pools at La Hague and fuel building pools for the EDF reactors) and that Areva and EDF must very rapidly define a management strategy going beyond 2030.

Tricastin site

ASN will continue to monitor the reorganisation of the Tricastin platform to ensure that these major organisational changes within the group have no impact on the safety of the various BNIs on the site. It will also demand that the platform licensees meet their responsibilities and either complete the unification process scheduled for 2012 or abandon the pooling of the equipment that should be in the possession of each of them.

Romans-sur-Isère site

Areva NP still needs to carry out major conformity work on several buildings.

Given the malfunctions observed in recent years, ASN will pursue its heightened surveillance of the facility in 2016 in order to ensure that this licensee's nuclear safety performance is improved. It will be attentive to compliance with the deadlines for performance of the work defined in the facility's safety improvement plan and the revision of its safety baseline requirements. It will also be attentive to ensuring the implementation of the improvements planned as part of the stress tests.

The reports presenting the conclusions of the ten-yearly periodic safety reviews conducted on the two installations on the site, submitted at the end of 2014 for BNI 98 and at the end of 2015 for BNI 63, will be examined so that ASN can reach a conclusion on the conditions for the possible continued operation of these installations for the coming ten years.

La Hague site

ASN considers that efforts must be continued concerning the recovery and packaging of legacy waste from the La Hague plants.

With regard to the recovery of legacy waste, ASN will be attentive to ensuring that any changes in Areva's industrial strategy do not lead to any failure to comply with the ASN prescriptions concerning the recovery and removal of waste from silo 130 and the STE2 and HAO sludges. ASN had already issued prescriptions to this effect in 2010 for silo 130 and in 2014 for the entire waste Recovery and Packaging Programme (RCD). 2016 will thus be marked by ASN's verification of the licensee's implementation of the above-mentioned regulatory provisions.

14 Nuclear research and miscellaneous industrial facilities

The research and civil industrial BNIs not directly linked to the generation of electricity are operated by CEA, by other research organisations (for example the Institut Laue-Langevin – ILL, the ITER international organisation and the Ganil) or by industry (for example CIS bio international, Synergy Health and Ionisos, which operate radiopharmaceutical production facilities and industrial irradiators).

The safety principles applicable to these facilities are identical to those applied to power reactors and nuclear fuel cycle facilities, while taking account of their specificities with regard to risks and detrimental effects. To improve the way in which these specific risks and detrimental effects are taken into account and in accordance with the resolution of 29th September 2015, ASN placed the installations it regulates into three categories.

Significant events

With regard to the nuclear installations operated by CEA, the generic subjects which more specifically attracted the attention of ASN in 2015 were:
- monitoring of the periodic safety reviews, in particular concerning the integration of aspects common to the BNIs on a given site and the lessons learned from requirements added during examination of the CEA installations files with the lowest risks;
- waste management and decommissioning of CEA installations for which numerous projects are significantly behind schedule owing to changes in strategy.

2015 was marked by the requirement for post-Fukushima Daiichi "hardened safety cores" in certain CEA centres and installations. Their implementation will lead to a significant improvement in safety and will give CEA robust means for emergency diagnosis and management.

ASN underlined that the performance of these numerous reviews associated with the preparation of the final shutdown and decommissioning authorisation application files represents a major safety issue, which will require significant resources on the part of CEA. CEA's compliance with the deadlines for its major commitments was improved. CEA also agreed to give fresh impetus to this approach in order to share the main nuclear safety issues to be dealt with over the coming decade.

ASN considers that the level of safety in the facilities operated by CEA is on the whole satisfactory, in particular the operation of its experimental reactors. ASN considers that CEA must reinforce its surveillance and its oversight of external contractors in a context of large-scale subcontracting.

With regard to the other nuclear installations, ASN remains concerned by the radiopharmaceutical production facility operated by CIS bio international on the Saclay site.

CIS bio international is a key player on the French market for radiopharmaceutical products used for both diagnosis and therapy. The organisational improvement efforts in 2015 have not yet led to any tangible results, in particular concerning the simultaneous management of large-scale projects, operational stringency, deadline compliance and monitoring of operations conformity with the requirements defined by the licensee and by the regulations, which need to be reinforced. ASN still observes significant drift in the deadlines for transmission of significant event reports and in the actual implementation of the measures identified during the inspections. The deviations observed during inspections and in the root causes of events reveal persistent shortcomings in operational stringency, in maintenance and in the assessment of the scale of the anomalies. Equipment maintenance in particular needs to be improved.

Assessment and outlook

A wide variety of research and other facilities are regulated by ASN. ASN will continue to oversee the safety and radiation protection of these installations as a whole and compare practices per type of installation in order to choose the best ones and thus encourage operating experience feedback. ASN will also continue to develop a proportionate approach to the risks and detrimental effects of the installations, as classified by the resolution of 29th September 2015.

CEA

ASN considers that the "major commitments" approach implemented by CEA since 2006 is on the whole satisfactory. It will be attentive to the implementation of the new major commitments decided on in 2015.

Generally speaking, ASN will remain vigilant to ensuring compliance with the commitments made by CEA, both for its facilities in service and those being decommissioned. Similarly, ASN will remain vigilant to ensuring that CEA performs exhaustive periodic safety reviews of its facilities so that the examination can be conducted in satisfactory conditions and so that the safety of the facilities benefits from the necessary improvements. As necessary, it will request additional information for those CEA files it considers to be unacceptable, as was the case in 2015 with Masurca.

ASN will be particularly attentive to compliance with the deadlines for transmission of the decommissioning files for CEA's old facilities which have been or will shortly be shut down (in particular Phébus, Osiris, MCMF, Pégase). The Rapsodie reactor, the situation of which is described in Chapter 15, is also concerned as are the following waste processing facilities: the storage area (BNI 56) in Cadarache, the effluent treatment station (BNI 37) in Cadarache, the solid radioactive waste management area (BNI 72) in Saclay. The drafting of all these decommissioning files and then performance of these decommissioning operations represents a major challenge for CEA, for which it must make preparations as early as possible. Finally, ASN will monitor the preparation work for the decommissioning of the Osiris reactor shut down in in 2015.

In 2016, ASN intends to:
- continue with surveillance of the operations on the Jules Horowitz Reactor (RJH) construction site and prepare for examination of the future commissioning authorisation application by means of the advance examination process;
- begin examining the significant modification authorisation application for Masurca and examine the safety review file completed by CEA;
- complete its examination of the periodic safety review files for the LECI, Poséidon, LEFCA and LECA facilities and decide on the conditions for their possible continued operation.

Other licensees

ASN will continue to pay particularly close attention to ongoing projects, that is ITER and the commissioning of the Ganil extension.

ASN will finalise its examination of complete service entry of the "hardened safety core" for the High Flux Reactor (RHF), operated by the ILL, several years ahead of the other licensees.

Finally, in 2016, ASN will maintain its close surveillance of the radiopharmaceuticals production plant operated by CIS bio international, with regard to the following points:
- increased operational rigour and safety culture;
- performance of the prescribed work, supplemented in 2015, for continued operation of the plant following its last periodic safety review;
- post-operational clean-out work on the very-high level units shut down in the facility.

15 Safe decommissioning of basic nuclear installations

The term decommissioning covers all the activities performed after shutdown of a nuclear facility, in order to attain a final condition in which all the dangerous and radioactive substances have been removed. In 2015, about thirty nuclear facilities of all types were shut down or undergoing decommissioning in France.

Doctrine and regulations

In 2015, the principle of immediate dismantling (anticipated as of the design stage, initiated at shutdown of the installation, with the dismantling operations potentially taking a very long time) was enshrined in the TECV Act. This Act also renovates the decommissioning procedure by making a clearer distinction than before between final shutdown of the facility and its decommissioning. ASN is pleased to see the progress made on these points. For preparation of the texts required by the Act, ASN issued an opinion on 28th January 2016 on the draft decree updating the procedures surrounding final shutdown and decommissioning of BNIs.

In 2015, ASN also continued to update Guide No. 14 concerning clean-out of structures and Guide No. 6 on final shutdown and decommissioning of BNIs. Finally, ASN produced a draft guide on the management of contaminated soils in nuclear installations. These three guides will be opened for consultation with a view to publication in 2016.

Facilities

2015 was marked by two installation delicensing operations: the Siloé reactor in Grenoble, mainly used for technological irradiation of structural materials and nuclear fuels, in the resolution of 9th January 2015, and the Electromagnetic Radiation Laboratory (LURE) in Orsay, a powerful X-ray production research facility operated by the National Centre for Scientific Research, in the resolution of 27th October 2015.

Concerning the installations operated by EDF, ASN issued an authorisation in December 2015 for the beginning of operations to reprocess the residual sodium in the main vessel of the Superphenix reactor. Dismantling of the Chinon A3 heat exchangers continued. The preparatory work for dismantling of the Chooz A reactor vessel continued. Examination of the safety of the installations, examination of the dismantling strategy and the management of EDF waste and Andra's report on the technical feasibility of Low Level, Long-Lived waste (LLW-LL) disposal began in 2015. Finally, after observing shortcomings in the preparation for the work and the risk assessments by the Brennilis NPP, ASN asked EDF to revise all the organisational and human provisions concerned for management of the risks linked to hot spot work on the decommissioning worksites.

With regard to CEA's installations, ASN and ASND observed significant delays in the performance of the decommissioning operations and the recovery and packaging of legacy waste, with significant increases in the times envisaged for these operations and considerable delays in the transmission of the decommissioning files. ASN and ASND asked CEA to present a new decommissioning strategy for all the BNIs and individual installations located within defence BNIs.

In connection with its examination of the decommissioning authorisation application for the Phenix reactor, ASN issued a resolution on 8th January 2015 setting the requirements applicable to the reactor's "hardened safety core" and the management of emergency

situations. In 2015, the preparation work for the decommissioning of the Phenix plant continued. ASN sent its conclusions following the technical examination and the consultations with the Minister responsible for nuclear safety and issued its opinion on 22nd December 2015.

The legacy waste Recovery and Packaging Project (RCD) currently under way in the HAO silo and the organised disposal of hulls, which represent the first hold point in decommissioning of the spent fuel reprocessing plant operated by Areva NC at La Hague, continued. ASN authorised Areva NC to build the recovery and packaging unit in a resolution dated 10th June 2014. The civil engineering work for the construction of the recovery and packaging unit authorised by the resolution of 10th June 2014 continued in 2015.

Outlook

ASN's main actions in 2016 will concern the continued development of the regulatory framework for decommissioning and the close monitoring of certain installations:

- assist the Ministry for the Environment with completion of the modifications to the Decree of 2nd November 2007 following the TECV Act on decommissioning reform;

- complete and finalise the decommissioning procedure, structures clean-out and soil remediation guides for BNIs;
- implement actions with respect to the EDF decommissioning strategy and more particularly the decommissioning of the gas-cooled reactors;
- begin examination of the Areva and CEA decommissioning strategies;
- complete examination of the LAMA delicensing application;
- continue examination of the decommissioning files for AMI (Chinon), Comurhex and Eurodif (Tricastin), UP2-400 and STE2 (La Hague), the enriched uranium reprocessing units (ATUE) and Rapsodie (Cadarache), the Procédé and Support BNIs (Fontenay-aux-Roses);
- begin examination of the decommissioning files for the solid radioactive waste management zone (Saclay);
- examine the periodic safety review files for Superphenix and the fuel storage unit.

16 Radioactive waste and contaminated sites and soils

The management of radioactive waste is governed by the 28th June 2006 Programme Act on the sustainable management of radioactive materials and waste, today codified in the Environment Code. This Act sets a clear framework for management of all radioactive waste, in particular by requiring the adoption of a National Radioactive Materials and Waste Management Plan (PNGMDR) revised every three years.

Significant events

2015 was marked by the drafting of the 2016-2018 PNGMDR. This three-yearly plan presents the rules of the radioactive substances management policy nationwide, identifies new needs and determines the objectives to be achieved, more specifically in terms of studies and research to create new management solutions.

2015 was also marked by regulatory changes to the operational management of radioactive waste in the installations. ASN's resolution on waste management studies and the inventory of waste produced in the BNIs, clarifying the provisions of the BNI Order, was signed by the commission on 21st April 2015 and approved by the Minister responsible for nuclear safety. The public consultation concerning its application guide and that concerning the ASN resolution on the packaging of radioactive waste and acceptance of radioactive waste packages in disposal BNIs were also held in 2015.

Assessment and outlook

Generally speaking, ASN considers that the French radioactive waste management system, built around a specific legislative and regulatory framework, a National Plan for Radioactive Materials and Waste Management (PNGMDR) and an Agency for management of radioactive waste independent of the waste producers (Andra), is capable of regulating and implementing a structured and coherent national waste management policy. ASN considers that there must eventually be safe management for all waste, more specifically by means of a disposal solution. The update of the PNGMDR to be carried out in 2016 will be an opportunity to set new short and medium term objectives to ensure this.

Regulations concerning the management of radioactive waste

In 2016, ASN will finalise the resolution concerning the packaging of radioactive waste. It will draw up draft resolutions concerning radioactive waste disposal and storage installations and a draft guide for the application of the resolution on waste studies. ASN will also complete the guide for application of the resolution on waste management studies and the inventory of waste produced in the BNIs.

ASN will also be vigilant in ensuring that the work to transpose Directive 2013/59/Euratom of 5th December 2013, setting basic radiation protection standards, does not compromise the French policy in which there are no clearance levels for waste from BNIs, while reinforcing the monitoring of TENORM waste.

Licensee waste management strategies

ASN periodically assesses the strategies put into place by the licensees to ensure that each type of waste has an appropriate solution and that the range of solutions implemented form a coherent whole. ASN in particular remains attentive to ensuring that the licensees have the necessary treatment or storage capacity for managing their radioactive waste and anticipate sufficiently far in advance the construction of new facilities or renovation work on older facilities.

Low level, long-lived waste

With regard to low level, long-lived radioactive waste, ASN considers that progress in the creation of management solutions is essential. Andra's mid-2015 submission of the report required by the PNGMDR is a key and strategic step in the implementation of this solution. ASN considers that following the examination of this report in early 2016, new objectives must be set by the Government for the implementation of management solutions for these wastes. Moreover, depending on the results of this report, the waste procedures should on the one hand create new storage capacity to avoid delaying decommissioning operations and, on the other, speed up the deployment of alternative strategies if their waste is not compatible with the Andra project.

In 2016, ASN will begin its revision of the safety guide for the disposal of low level, long-lived radioactive waste This approach will be implemented within a pluralistic working group comprising all the stakeholders.

High and intermediate level, long-lived radioactive waste

With regard to the Cigéo project for the disposal of high and intermediate level, long-lived waste, 2016 will be marked by Andra's submission of the safety options file for Cigéo, more specifically containing the project's safety options, the technical retrievability options, a preliminary version of the waste acceptance specifications and a project development plan. This file will be the first overall safety file for the facility since 2009. It will in particular undergo an international peer review, under the aegis of IAEA, before ASN issues its opinion.

A Bill specifying the procedures for the creation of a deep geological reversible disposal facility for high and intermediate level, long-lived waste should be debated in Parliament in 2016. It should more specifically define the notion of reversibility. ASN will publish its reversibility policy in 2016.

The Cigéo project is entering the industrial phase in which the responsibilities of the various players and stakeholders will be required in particular to comply with the requirements of the Environment Code and the BNI regime.

ASN recommends that a re-evaluation be made of the cost of disposal of substances liable to be emplaced in a deep geological disposal facility but which are not yet part of the project's current inventory – spent fuel in particular.

Management of the former uranium mining sites and contaminated sites and soils

With regard to the former uranium mining sites, ASN will in 2016 attempt to address the concerns of the Regional Directorates for the Environment, Planning and Housing regarding the Areva Mines action plan for the management of mining waste rock. It will focus more specifically on the management of potentially sensitive cases, in particular with regard to the radon risk. It will ensure that any action taken is completely transparent and involves the local stakeholders. It will continue its work on the management of former mining sites, together with the Ministry responsible for the Environment.

With regard to contaminated sites and soils, ASN will continue in 2016 to give its opinion on contaminated site remediation projects, on the basis of the principles of its policy published in October 2012 and, together with the Ministry responsible for the Environment, will work on a revision of circular DGS/SDEA1/DGEC/DGPR/ASN 2008-349 of 17th November 2008 concerning the responsibility for certain radioactive waste and radioactive contamination sites on the basis of operating experience feedback.

ASN will also continue its involvement in international work on these topics, in particular within IAEA, ENSREG, WENRA, as well as bilaterally with its counterparts.

Energy Transition for Green Growth Act

Nine years after the TSN Act was passed on 13th June 2006, Act 2015-992 of 17th August 2015 on the Energy Transition for Geen Growth, known as the "TECV Act", marks a new step forward in nuclear legislation.

On the basis of the experience acquired with application of the framework set up in 2006 and extensive work to harmonise practices across Europe, to which France made a significant contribution, this supplements and consolidates this framework, while strengthening the regulatory powers of ASN.

These adaptations to nuclear legislation come on the one hand from the TECV Act itself – it contains a Title VI entitled "Reinforcing nuclear safety and information of the public" – and on the other from Ordinance 2016-128 issued by the President of the Republic on 10th February, concerning the grounds for an authorisation qualification provided for by this same TECV Act.

ASN is pleased to note that the legislative provisions introduced by these texts represent a number of advances in the regulation of nuclear safety and radiation protection and that they reinforce public information on these subjects.

It in particular notes the following positive points.

Enhanced transparency and information of the citizens

The law requires that each year, the Local Information Committees (CLI) hold at least one meeting open to the public and that the CLIs of BNIs situated in *départements* on the borders include representatives of the foreign States concerned. Moreover, the CLIs may ask to visit the facility, in order to understand its normal operation and any significant events rated at least 1 on the INES scale which may have occurred in it.

Without having to ask for it, those living in the vicinity of a BNI will, at the expense of the licensee, receive regular information about safety measures and the steps to be taken in the event of an accident. These population information operations will be regularly presented to the CLI.

Given the stakes associated with the continued operation of the nuclear reactors beyond forty years, the measures proposed by the licensee during the reactor periodic safety reviews performed after thirty-five years of operation, will be the subject of a public inquiry.

Finally, the public's right to information about the BNIs will be extended to all the risks and detrimental effects of the installations.

Evolution of the BNI authorisation system

The law states that depending on the stakes involved and their scale, BNI modifications shall be the subject of:
- either a modification of the creation (or decommissioning) authorisation decree, after a public inquiry;
- or an ASN authorisation, which may involve participation by the public;
- or notification of ASN by the licensee.

This more graduated system will thus allow processing appropriate to the risks and detrimental effects of the facility and its modifications.

Monitoring of the use of contractors and subcontracting

The law makes it possible to manage or limit the use of contractors or subcontracting for operation of BNIs. This involves on the one hand specifying those activities which are the direct responsibility of the licensee and which cannot be entrusted to contractors and, on the other, limiting the number of levels of subcontracting that can be authorised for the performance of certain activities.

The law also enshrines in the Environment Code the principle of prohibiting the licensee from delegating the surveillance of any outside parties performing an activity important for ensuring the protection of health, public security and the environment.

Evolution of the BNI shutdown and decommissioning system

The Act also enshrines in the Environment Code the principle of immediate dismantling of BNIs, that is dismantling as soon as possible after shutdown of the installation. It renovates the decommissioning procedure, by making a clearer distinction than previously between the following:

- final shutdown of the facility which is the responsibility of the licensee and must be notified to ASN;
- decommissioning of the facility, the procedures of which must be approved by the State on the basis of a file proposed by the licensee.

Shutdown of an installation for two consecutive years shall also be considered to be final.

Reinforcement of the ASN means of inspection and powers of sanction

The Ordinance of 10th February 2016 also reinforces ASN's means of inspection and powers of sanction.

ASN now in particular has the following options:

- It can prescribe measures to ensure the security of radioactive sources against malicious acts and verify correct application of these measures.
- It can order the payment of fixed and daily fines in the event of non-compliance with a formal notice. The administrative fines will be decided on by a sanctions committee, created within ASN and separate from the Commission, in order to maintain the principle of separation between the investigative and sentencing functions.
- It can extend the inspections carried out by its inspectors to activities important for the protection of health, public security and the environment, performed outside BNIs by the licensee, its suppliers, contractors, or subcontractors.
- It can have third-party assessments carried out at the expense of those inspected.
- Finally, it can ensure that research is tailored to the needs of nuclear safety and radiation protection.

Clarification of the organisation of the oversight of nuclear safety and radiation protection

ASN is in charge of the regulation and oversight of nuclear safety, radiation protection and nuclear activities.

The TECV Act incorporates into the Environment Code the existence and the duties of the French Institute for Radiation Protection and Nuclear Safety (IRSN). It recalls that ASN benefits from the technical support of IRSN and that these assessment activities are supported by research.

It also clarifies the relations between ASN and IRSN, indicating that ASN "guides IRSN's strategic programming" and that the ASN Chairman is an automatic and fully-fledged member of the Board of the institute.

It also mentions the principle of the publication of IRSN opinions.

Reinforced monitoring of former nuclear sites

Finally, the Ordinance of 10th February 2016 states that sites contaminated by radioactive substances and which present environmental risks could be subject to active institutional controls designed to protect the population. The party responsible for a site contaminated by a past or legacy nuclear activity, or its assigns, could be ordered to carry out remediation of the site.

Conclusion

ASN considers that the legislative provisions introduced by the TECV Act and the Ordinance of 10th February 2016 improve the regulation and oversight of nuclear safety and radiation protection by consolidating and modifying the framework set up by the TSN Act, so that it is more effective and more closely tailored to the actual issues. It also notes with satisfaction that transparency and public information have been reinforced.

The work to transcribe these provisions into the regulations has already started and will continue in the coming months.

Energy Transition for Green Growth Act

In the related chapters, these boxes present the changes brought about by the Act in the fields concerned.

01

Nuclear activities: ionising radiation and health and environmental risks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Ionising radiation may be of natural origin or caused by human activities, referred to as nuclear activities. The exposure of the population to naturally occurring ionising radiation is the result of the presence of radionuclides of terrestrial origin in the environment, radon emanations from the ground and exposure to cosmic radiation.

Nuclear activities are defined in the Public Health Code as *"activities involving a risk of exposure of persons to ionising radiation associated with the utilisation of artificial sources of radiation, whether substances or devices, or natural sources of radiation, whether natural radioactive substances or materials containing natural radionuclides…"* These nuclear activities include those carried out in Basic Nuclear Installations (BNI) and during the transport of radioactive substances, as well as in the medical, veterinary, industrial and research fields.

The various principles with which the nuclear activities must comply, particularly those of nuclear safety and radiation protection, are set out in chapter 3.

In addition to the effects of ionising radiation, BNIs are similar to all industrial installations in that they are the source of non-radiological risks and detrimental effects such as the discharge of chemical substances into the environment, or noise emission.

1. STATE OF KNOWLEDGE OF THE HAZARDS AND RISKS ASSOCIATED WITH IONISING RADIATION

Ionising radiation is defined as being capable of producing ions – directly or indirectly – when it passes through matter. It includes X-rays, alpha, beta and gamma rays, and neutron radiation, all of which being characterized by different energies and penetration powers.

1.1 Biological and health effects

Whether it consists of charged particles, for example an electron (beta radiation) or a helium nucleus (alpha radiation), or of photons (X rays or gamma rays), ionising radiation interacts with the molecules making up the cells of living matter and alters them chemically. Of the resulting damage, the most significant concerns the DNA of the cells and this damage is not fundamentally different from that caused by certain toxic chemical substances, whether exogenous or endogenous (resulting from cellular metabolism).

When not repaired by the cells themselves, this damage can lead to cell death and the appearance of harmful biological effects if tissues are no longer able to carry out their functions.

These effects, called "deterministic effects", have been known for a long time, as the first effects were observed with the discovery of X rays by W. Roentgen (in the early 1900's). They depend on the nature of the exposed tissue and are certain to appear as soon as the quantity of radiation absorbed exceeds a certain dose level. These effects include, for example, erythema, radiodermatitis, radionecrosis and cataract formation. The higher the radiation dose received by the tissue, the more serious the effects.

Cells can also repair the damage thus caused, although imperfectly or incorrectly. Of the damage that persists, that to DNA is of a particular type, because residual genetic anomalies can be transmitted by successive cellular divisions to new cells. A single genetic mutation is far from being sufficient to cause the transformation into a cancerous cell, but this damage due to ionising radiation may be a first step towards cancerisation.

The suspicion of a causal link between exposure to ionising radiation and the appearance of a cancer dates back to 1902 (observation of skin cancer in a case of radiodermatitis).

Subsequently, several types of cancers were observed in occupational situations, including certain types of leukemia, broncho-pulmonary cancers (owing to radon inhalation) and jawbone sarcomas. Outside the professional area, the monitoring for more than 60 years of a cohort of about 85,000 people irradiated at Hiroshima and Nagasaki has enabled the regular assessment of the morbidity[1] and mortality due to cancer following exposure to ionising radiation, and the description of the dose-effects relationships – which often form the basis

1. Number of persons suffering from a given disease for a given time – usually one year – in a population.

of current regulations. Other epidemiological work has revealed a statistically significant rise in cancers (secondary effects) among patients treated using radiotherapy and attributable to ionising radiation. We can also mention the Chernobyl accident which, as a result of the radioactive iodine released, caused in the areas near the accident an excess in the incidence of thyroid cancers in people irradiated during childhood.

The risk of radiation-induced cancer appears at different levels of exposure and is not linked to the exceeding of a threshold. It is revealed by an increase in the probability of cancer in a population of a given age and sex. These are then called probabilistic, stochastic or random effects.

The internationally established public health objectives related to radiation protection aim to prevent the appearance of deterministic effects and reduce the probabilities of cancers arising from exposure to ionising radiation, which are also known as radiation-induced (or radio-induced) cancers; the results of the studies as a whole seem to indicate that radio-induced cancers represent the predominant health risk associated with exposure to ionising radiation.

1.2 Evaluation of risks linked to ionising radiation

The monitoring of cancers in France is based on 14 general registers in metropolitan France (covering 18 *départements* and the greater Lille urban area) and 3 registers in the overseas French *départements*. In addition to this, there are 12 specialised registers: 9 *département* registers covering 16 continental *départements*, 2 national cancer registers for children under 15 years of age concerning malignant haemopathy and solid tumours, and 1 multicentric mesothelioma register for France as a whole.

The aim of the register for a given area is to highlight differences in spatial distribution, to reveal changes over time in terms of increased or reduced incidence in the different cancer locations, or to identify clusters of cases.

This method of monitoring aims to be descriptive but is unable to highlight any causal effect between an exposure to ionising radiation and cancers, given that other environmental factors may also be suspected. Furthermore, it should be noted that the *département* registers do not necessarily cover the areas close to the nuclear installations.

Epidemiological investigation supplements monitoring. The purpose of epidemiological surveys is to highlight an association between a risk factor and the occurrence of a disease, between a possible cause and an effect, or at least to enable such a causal relation to be asserted with a very high degree of probability. The intrinsic difficulty in conducting these surveys or in reaching a convincing conclusion when the illness is slow to appear or when the expected number of cases is low, which is the case with low exposure levels of a few tens of millisieverts (mSv) for example, must be borne in mind. Cohorts such as that of Hiroshima and Nagasaki have clearly shown an excess of cancers, with the average exposure being about 200 mSv; studies on nuclear industry workers published in recent years suggest risks of cancer at lower doses.

These results support the justification of radiological protection of populations exposed to low doses of ionising

TO BE NOTED

The conclusions of the ASN seminar on the risks of leukemia linked to exposure to ionising radiation

Within the framework of the ASN advisory committees of experts in radiation protection, ASN organised a seminar entitled *"Risks of leukemias and exposure to ionising radiation"* on 9th June 2015. It was attended by some 60 people, members of the GPRADE* and GPMED**, representatives of national and international research organisations, doctors, representatives of the institutions concerned, patients' associations and members of the ASN Scientific Committee. The aim was to review current knowledge on the risk of leukemia in children and adults with respect to exposure to ionising radiation, taking into account the radiation exposure characteristics (acute or chronic, external or internal, age at the time of exposure, etc.) and by synthesizing known or suspected risk factors other than radiation.

Noteworthy conclusions of the seminar were:
- the existence of sound proof that exposure to ionising radiation is a risk factor for leukemia;
- the importance of continuing to study the incidence rate of leukemia in infants and young children near nuclear installations, with particular attention to the 0-4 years age bracket, and including a fuller description of the local population (lifestyle and mode of exposure);
- the need for greater interdisciplinarity (epidemiology, medicine, dosimetry, statistics) and skills-sharing was also underlined. The development of national coverage through the cancer registers has improved the robustness of the epidemiological studies. This information should now be supplemented by a characterisation of the different types of leukemia and robust dosimetric data;
- lastly, the ongoing harmonisation of the study protocols at national and international levels with a view to conducting joint studies must be continued in order to have greater statistical weight, bringing increased confidence in the results.

** Advisory Committee for Radiation Protection for Industrial and Research Applications of Ionising Radiation and in the Environment.*
*** Advisory Committee of Experts for Radiation Protection for the Medical and Forensic Applications of Ionising Radiation.*

TO BE NOTED

The latest publication of the International Agency for Research on Cancer – IARC (2015) on cancer mortality rate of workers employed in the nuclear industry*

The publication in 2015 by the WHO (IARC, Lyon, *www.iarc.fr)* of the cancer mortality rate for French, American and British workers employed in the nuclear industry (fuel preparation, research, electricity production, spent fuel reprocessing) and having worn personal dosimeters, has provided greater insight into the external irradiation risks which, although low, accumulate over the working life. The studied population included nearly 300,000 workers, of which the French cohort comprised 59,000 workers from Areva NC, CEA and EDF.

The average monitoring time of these workers was twenty-seven years. The average dose is 25 mSv cumulated over the working life (fifteen years on average). The mean annual dose is less than 2 mSv. 94% of the individuals had a cumulative total of less than 100 mSv. Among the 6% of individuals whose cumulative dose exceeded 100 mSv, 75 % started working in the 1970's and their mean cumulative dose is 223 mSv.

A first publication in June 2015 showed an increase in the risk of leukemia as a function of the cumulative dose. A second publication in October 2015 shows that the risk of cancers other than leukemias also increases as a function of the cumulative dose, that is to say about 4% for an increase of 100 mSv.

These results were observed from a total of 66,600 deaths, of which 19,064 were due to cancers other than leukemias. From the estimated dose-risk relationship, it appears that the proportion of deaths that can be attributed to external exposure to radiation within this population of workers is about 1% of all the observed 19,064 deaths due to cancers other than leukemias.

The observed relationship is stable (little heterogeneity between the countries, small-amplitude variations in the sensitivity analyses). To evaluate the existence of a potential bias due to tobacco, lung cancers were excluded from the analysis; this exclusion had little impact on the risk estimate.

The dose-risk relationship observed is consistent with those observed in other studies, particularly those of the Hiroshima and Nagasaki survivors and shows that the risk at low doses spread over time does not differ from that observed for the same irradiation dose received in a few seconds.

** The new results concerning the risk of death by cancer other than leukemia were published in the* British Medical Journal*; those on the leukemia risk were published in the* Lancet.

radiation (nuclear industry workers, medical personnel, medical diagnostic exposure, etc.).

Low-dose risks are assessed for risk-management purposes by extrapolating the risks observed at higher doses. This calculation gives an estimate of the risks entailed by exposure to low doses of ionising radiation. For these estimates, the prudent hypothesis of a linear no-threshold relationship between exposure and the number of deaths from cancer has been adopted internationally. This hypothesis implies that there is no dose threshold below which one can assert that there is no effect. The legitimacy of these estimates and of this hypothesis nevertheless remains scientifically controversial, as very large scale studies would be necessary to further support the hypothesis.

On the basis of the scientific syntheses of UNSCEAR (see box page 49), the International Commission on Radiological Protection – ICRP (see publication ICRP 103, chapter 3, point 1.1.1) has published risk coefficients for death from cancer due to ionising radiation, showing a 4.1% excess risk per sievert (Sv) for workers and 5.5% per sievert for the general public.

The evaluation of the risk of lung cancer caused by radon (radon is a naturally occurring radioactive gas – a decay product of uranium and of thorium – which emits alpha particles and is classified by the IARC as a definite human carcinogen) is based on a large number of epidemiological studies performed directly in the home, in France and internationally. These studies have revealed a linear relationship, even at low exposure levels (200 becquerels per cubic metre (Bq/m^3)) over a period of 20 to 30 years. The World Health Organisation (WHO) has synthesised the studies and recommends a maximum annual exposure level of between 100 and 300 Bq/m^3 for the general public. The ICRP *(Publication 115)* compared the risks of lung cancer observed through studies on uranium miners with those observed on the general population and concluded that there was a very good correlation between the risks observed in these two conditions of exposure to radon. The ICRP recommendations confirm those issued by the WHO which considers that, after tobacco, radon constitutes the highest risk factor in lung cancer.

In metropolitan France, about 19 million people spread over some 9,400 municipalities are potentially exposed to radon. According to InVS (French Health Monitoring Institute) figures from 2007, between 1,200 and 2,900 deaths from lung cancer can be attributed each year to radon exposure in the home, that is to say between 4 and 10% of deaths due to cancer. A national action plan for managing radon-related risks has been implemented since 2004 on the initiative of ASN and is updated periodically (see point 3.2.2).

1.3 Scientific uncertainties and vigilance

The action taken in the fields of nuclear safety and radiation protection in order to prevent accidents and limit detrimental effects has led to a reduction in risks but not to zero risk, whether in terms of the doses received by workers or those associated with discharges and releases from BNIs. However, many uncertainties persist and require that ASN remains attentive to the results of the scientific work in progress, for example in radiobiology and radiopathology, with possible consequences for radiation protection, particularly with regard to management of risks at low doses.

One can mention, for example, several areas of uncertainty concerning radiosensitivity, the effects of low doses, the radiological signature of cancers and certain non-cancerous diseases observed in radiotherapy follow-ups.

1.3.1 Radiosensitivity

The effects of ionising radiation on personal health vary from one individual to the next. Since it was stated for the first time by Bergonié and Tribondeau in 1906, it is for example known that the same dose does not have the same effect when received by a growing child and when received by an adult.

The variability in individual radiosensitivity to high doses of ionising radiation has been extensively documented by radiotherapists and radiobiologists. High levels of radiosensitivity have been observed in subjects suffering from genetic diseases affecting the repair of DNA and cellular signalling; they could lead to “radiological burns”.

At low doses, there is both cell radiosensitivity and individual radiosensitivity, which could concern about 5 to 10% of the population. Recent methods of immunofluorescence of molecular targets for signalling and repairing DNA damage help to document the effects of ionising radiation at low doses, reducing the detection thresholds by a factor of 100. The biochemical and molecular effects of a simple X-ray examination then become visible and measurable. The results of the research work conducted using these new investigation methods must be confirmed in the clinical environment before being integrated into medical practices.

This then raises delicate issues, some of which go beyond the strict context of radiation protection:
- If tests for evaluating individual radiation hypersensitivity become available, should screening prior to any radiotherapy or repeated computed tomography examinations be recommended?
- Should one try to determine the degree of radiosensitivity of workers who could be exposed to ionising radiation?
- Should the general regulations provide for specific protection for persons concerned by high radiosensitivity to ionising radiation?

First X-ray of the hand of Mrs Roentgen, December 1895.

UNDERSTAND

UNSCEAR

The United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) was set up in 1955 during the 10th session of the General Assembly of the United Nations. It comprises representatives from 21 countries and reports to the General Assembly of the United Nations. It is a scientific organisation created to conduct global and regional studies and evaluations of exposure to radiation and its effects on the health of the exposed groups. The committee also studies the progress made in understanding the biological mechanisms whereby radiation influences health or the environment.

Latest publications since 2013:
- Sources, effects and risks of ionising radiation:
  - Vol. I - Annex A - Levels and effects of radiation exposure due to the nuclear accident after the 2011 great east-Japan earthquake and tsunami (2013).
  - Vol. II - Annex B - Effects of radiation exposure of children (2013).
- Development since the UNSCEAR 2013 report relative to the levels and effects of exposure to radiation due to the nuclear accident in Japan in March 2011 (Fukushima Daiichi).

These questions have ethical implications owing to the potential use of the results of individual radiation sensitivity tests, for example to discriminate between potential employees.

Whatever the case, there should be no unnecessary exposure of individuals to ionising radiation, in other words without justification. Children should receive particularly close attention in the event of exposure to ionising radiation for medical purposes.

After the publication in 2014 of the conclusions of the seminar ASN organised on 16th December 2013, ASN remains attentive to progress in the knowledge and international reflections (IRCP in particular) to prepare for the statutory resolutions that might or will have to be taken.

1.3.2 Effects of low doses

The Linear No-Threshold (LNT) relationship. This hypothesis of this relationship, adopted to model the effects of low doses on health (see point 1.2), albeit practical from the regulatory standpoint, and albeit conservative from the health standpoint, is not as scientifically well-grounded as might be hoped for: there are those who feel that the effects of low doses could be higher, while others believe that these doses could have no effect below a certain threshold, and some people even assert that low doses have a beneficial effect. Research in molecular and cellular biology is progressing, as are epidemiological surveys of large cohorts. But faced with the complexity of the DNA repair and mutation phenomena, and the methodological limitations of epidemiology, uncertainties remain and the public authorities must exercise caution.

Dose, dose rate and chronic contamination. The epidemiological studies performed on individuals exposed to the Hiroshima and Nagasaki bombings have given a clearer picture of the effects of radiation on health, concerning exposure due to external irradiation (external exposure) received in a few fractions of a second at high dose and high dose rate. The studies carried out in the countries most affected by the Chernobyl accident (Belorussia, Ukraine and Russia) were also able to improve our understanding of the effects of radiation on health caused by exposure through internal contamination (internal exposure) more specifically through radioactive iodine. Studies on nuclear workers have given a clearer picture of the risk due to chronic exposure established over many years, whether as a result of external exposure or internal contamination.

Hereditary effect. The appearance of possible hereditary effects from ionising radiation in humans remains uncertain. Such effects have not been observed among the survivors of the Hiroshima and Nagasaki bombings. However, hereditary effects are well documented in experimental work on animals: mutations induced by ionising radiation in embryonic germ cells can be transmitted to descendants. The recessive mutation of one gene on one chromosome will produce no clinical or biological indications as long as the same gene carried by the other counterpart chromosome is not affected. Although it cannot be absolutely ruled out, the probability of this type of event nonetheless remains low.

Environmental Protection. The purpose of radiation protection is to prevent or mitigate the harmful effects of ionising radiation on individuals, directly or indirectly, including in situations of environmental contamination. Over and beyond environmental protection aiming at the protection of humans and present or future generations, the protection of non-human species as such forms part of the environmental protection prescribed in the French constitutional Charter for the environment. This subject has been taken into consideration by the ICRP since 2007 (ICRP 103) and the practical means of dealing with the protection of nature in the specific interests of animal and plant species has been the subject of several publications since 2008 (ICRP 108, 114 and 124).

Blood cell irradiator.

1.3.3 Radiological signature of cancers

It is currently impossible to distinguish a radiation-induced cancer from a cancer that is not radiation induced. The reason for this is that the molecular lesions caused by ionising radiation seem no different to those resulting from the normal cellular metabolism, with the involvement of free radicals – oxygenated in particular – in both cases. Furthermore, to date, neither anatomopathological examinations nor research for specific mutations have been able to distinguish a radiation-induced tumour from a sporadic tumour.

It is known that in the first stages of carcinogenesis a cell develops with a particular combination of DNA lesions that enables it to escape from the usual verification of cellular division, and that it takes about ten to one hundred DNA lesions (mutations, breaks, etc.) at critical points to pass through these stages. All the agents capable of damaging cellular DNA (tobacco, alcohol, various chemical substances, ionising radiation, high temperature, other environmental factors, notably nutritional and free radicals of normal cellular metabolism, etc.) contribute to cellular aging, and ultimately to carcinogenesis.

Consequently, in a multi-risk approach to carcinogenesis, can we still talk about radiation-induced cancers? Yes we can, given the large volumes of epidemiological data which indicate that the frequency of cancers increases as the dose increases, but the approach is undoubtedly more complex, since in certain cases cancer results from an accumulation of lesions originating from different risk factors. However, the radiation-induced event can also in certain cases be the only event responsible (radiation-induced cancers in children).

Highlighting a radiation signature of cancers, that is to say the discovery of markers that could indicate whether a tumour has a radiation-induced component or not, would be of considerable benefit in the evaluation of the risks associated with exposure to ionising radiation.

The multifactorial nature of carcinogenesis pleads in favour of a precautionary approach with regard to all the risk factors, since each one of them can contribute to DNA impairment. This is particularly important in persons displaying high individual radiosensitivity and for the most sensitive organs such as the breast and the bone marrow, and all the more so if the persons are young. Here, the principles of justification and optimisation are more than ever applicable (see chapter 2).

2. THE DIFFERENT SOURCES OF IONISING RADIATION

2.1 Natural radiation

In France, exposure to the different types of natural radioactivity (cosmic or terrestrial) represents on average about 65% of the total annual exposure.

2.1.1 Natural terrestrial radiation (excluding radon)

Natural radionuclides of terrestrial origin are present at various levels in all the compartments of our environment, including inside the human body. They lead to external exposure of the population owing to gamma rays emitted by the uranium-238 and thorium-232 daughter products and by the potassium-40 present in the soil, but also to internal exposure by inhalation of particles in suspension and by ingestion of foodstuffs or drinking water.

The levels of natural radionuclides in the ground are extremely variable. The highest external exposure dose rates in the open air in France, depending on the region, range from a few nanosieverts per hour (nSv/h) to 100 nSv/h.

The dose rate values inside residential premises are generally higher owing to the contribution of construction materials (about 20% higher on average).

Based on assumptions covering the time individuals spend inside and outside residential premises (90% and 10% respectively), the average effective dose due to external exposure to gamma radiation of terrestrial origin in France is estimated at about 0.5 mSv per person per year.

The doses due to internal exposure of natural origin vary according to the quantities of radionuclides of the uranium and thorium families incorporated through the food chain, which depend on each individual's eating habits. According to UNSCEAR (2000), the average dose per individual is about 0.23 mSv per year. The average concentration of potassium-40 in the organism is about 55 Becquerels per kilogram, resulting in an average effective dose of about 0.18 mSv per year.

Waters intended for human consumption, in particular groundwater and mineral waters, become charged in natural radionuclides owing to the nature of the geological strata in which they spend time. The concentration of uranium and thorium daughters, and of potassium-40, varies according to the resource exploited, given the geological nature of the ground. For waters displaying high radioactivity, the annual effective dose resulting from daily consumption (2 litres/inhabitant/day) may reach several tens or hundreds of microsieverts (µSv).

2.1.2 Radon

Some geological areas have a high radon exhalation potential due to the geological characteristics of the ground (granitic bedrock, for example). The concentration measured inside homes also depends on the tightness of the building (foundations) and the ventilation of the rooms.

So-called "domestic" exposure to radon (radon in dwellings) was estimated by IRSN (French Institute for Radiation Protection and Nuclear Safety) through measurement campaigns followed by statistical interpretations (see *www.irsn.fr)*. The average radon activity value measured in France is 63 Bq/m^3, with about half the results being below 50 Bq/m^3, 9% above 200 Bq/m^3 and 2.3% above 400 Bq/m^3.

These measurements have allowed the French *départements* to be classified according to the radon exhalation potential of the ground (see map below).

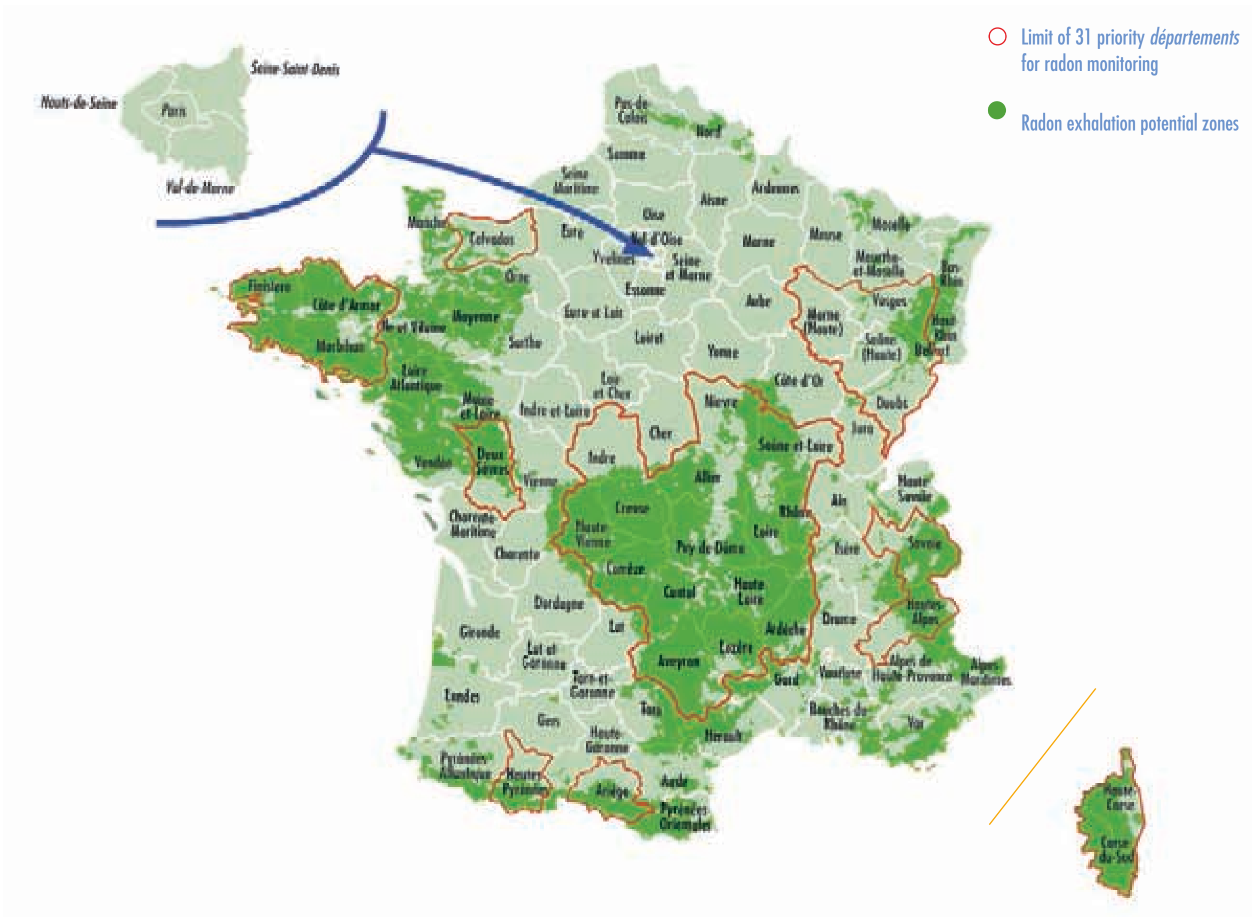
In 2011, IRSN published a new map of France considering the radon exhalation potential of the ground, based on data from the French Geological and Mining Research Office (BRGM).

2.1.3 Cosmic radiation

Les rayonnements cosmiques de composantes ionique The cosmic radiation from ionic and neutronic components is also accompanied by electromagnetic radiation. At sea level, the dose rate resulting from electromagnetic radiation is estimated at 32 nSv per hour and that resulting from the neutronic component at 3.6 nSv per hour.

Considering the average time spent inside the home (which itself attenuates the ionic component of the cosmic radiation), the average individual effective dose in a locality at sea level in France is 0.27 mSv per year, whereas it could exceed 1.1 mSv per year in a mountain locality situated at an elevation of about 2.800 metres.

RADON exhalation potential in metropolitan France (source: IRSN)



The average annual effective dose per individual in France is 0.33 mSv. It is lower than the global average value of 0.38 mSv per year published by UNSCEAR.

On account of the increased exposure to cosmic radiation due to extensive periods spent at high altitude, flight personnel must be subject to dosimetric monitoring. (see point 3.1.3).

2.2 Ionising radiation arising from human activities

The human activities involving a risk of exposure to ionising radiation, called nuclear activities, can be grouped into the following categories:
- operation of Basic Nuclear Installations;
- transport of radioactive substances;
- small-scale nuclear activities;
- disposal of radioactive waste;
- management of contaminated sites;
- activities enhancing natural ionising radiation.

2.2.1 Basic nuclear installations

Regulations classify nuclear facilities, called Basic Nuclear Installations (BNI), in various categories corresponding to more or less restrictive procedures, depending on the significance of the potential risks (see chapter 3, point 3).

The main BNI categories are:
- nuclear reactors;
- some particle accelerators;
- the plants that prepare, enrich or transform radioactive substances, particularly nuclear fuel production plants, irradiated fuel processing plants, and the facilities for processing and storing the radioactive waste produced by these plants;
- the installations intended for the processing, disposal, storage or use of radioactive substances, including waste, when the quantities involved exceed thresholds set by regulations.

The list of BNIs as at 31st December 2015 is given in appendix A.

Accident prevention and nuclear safety

The fundamental internationally adopted principle underpinning the specific organisational system and regulations applicable to nuclear safety is that of the responsibility of the licensee (see chapter 2). The public authorities ensure that this responsibility is fully assumed, in compliance with the regulatory requirements.

As regards the prevention of risks for workers, BNI licensees are required to implement all necessary means to protect workers against the hazards of ionising radiation, and more particularly to comply with the general rules applicable to all workers exposed to ionising radiation (work organisation, accident prevention, medical monitoring of workers, including those from outside contractors, etc.) (see chapter 3).

As regards protection of the population and the environment, the BNI licensee must also take all necessary steps to achieve and maintain an optimum level of protection. Discharges of liquid and gaseous effluents, whether radioactive or not, are in particular strictly limited (see chapter 4).

2.2.2 Transport of radioactive substances

When transporting radioactive substances, the main risks are those of internal or external exposure, criticality, as well as risks of a chemical nature. Safe transport of radioactive substances relies on an approach called defence in depth:
- The robustness of the packaging is the first line of defence. The packaging plays a vital role and must be able to withstand all foreseeable transport conditions.
- The reliability of the transport operations constitutes the second line of defence.
- Finally, the third line of defence consists of the response resources implemented to deal with an incident or accident.

2.2.3 Small-scale nuclear activities

Ionising radiation, whether emitted by radionuclides or generated by electrical equipments, is used in many areas, including medicine (radiology, radiotherapy, nuclear medicine, cell irradiators), biology, research, industry, but also for veterinary and forensic applications as well as for the conservation of foodstuffs.

The employer is required to take all necessary measures to protect workers against the hazards of ionising radiation. The facility licensee must also implement the provisions of the Public Health Code for the management of the ionising radiation sources in its possession (radioactive sources in particular) and, where applicable, manage the waste produced and limit discharges of liquid and gaseous effluents. In the case of use for medical purposes, patient protection issues are also taken into account (see chapter 3).

2.2.4 Radioactive waste management

Like all industrial activities, nuclear activities can generate waste, some of which is radioactive. The three fundamental principles on which strict radioactive waste management is based are the accountability of the waste producer, the traceability of the waste and public information.

The technical management provisions to be implemented must be tailored to the hazard presented by the radioactive waste. This hazard can be assessed primarily through two parameters: the activity level, which contributes to the toxicity of the waste, and the half-life, the time after which the activity level is halved.

Finally, management of radioactive waste must be determined prior to any creation of new activities or modification of existing activities in order to:
- ensure the availability of processing channels for the various categories of waste likely to be produced, from the front-end phase (production of waste and packaging) to the back-end phase (storage, transport and disposal);
- optimise the waste disposal routes.

2.2.5 Management of contaminated sites

Management of sites contaminated by residual radioactivity resulting either from a past nuclear activity or an activity which generated deposits of natural radionuclides warrants specific radiation protection actions, in particular if rehabilitation is envisaged.

Depending on the current or future uses of the site, decontamination objectives must be set and the removal of the waste produced during post-operation clean-out of the contaminated premises and remediation of the ground must be managed, from the site through to storage or disposal. The management of contaminated objects also follows these same principles.

2.2.6 Industrial activities resulting in the enhancement of natural ionising radiation

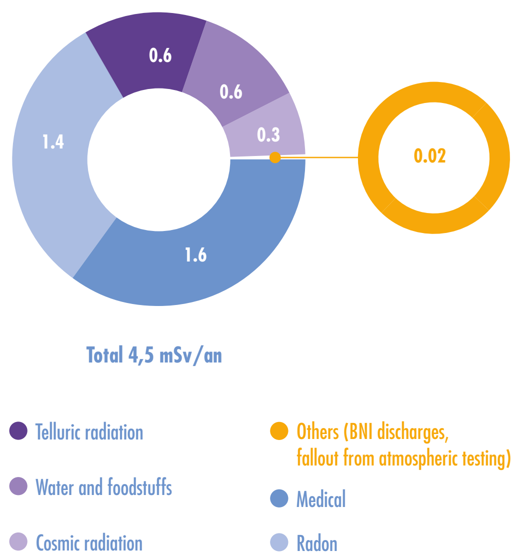
Exposure to ionising radiation of natural origin, when increased due to human activities, justifies measures to monitor or even to assess and manage the risk, if it is likely to create a hazard for the exposed workers and, where applicable, the neighbouring population.

Thus, certain professional activities now included in the definition of «nuclear activities» (see chapter 3), can significantly increase the exposure to ionising radiation of the workers and, to a lesser extent, of the populations in the vicinity of the locations where these activities are carried out, for example in the event of discharge of effluents into the environment. This is in particular the case with activities using raw materials or industrial residues containing natural radionuclides which are not used for their fissile or fertile radioactive properties.

The natural families of uranium and thorium are the main radionuclides found. The industries concerned include the phosphate mining and phosphated fertiliser manufacturing industries, the dye industries, in particular those using titanium oxide and those using rare earth ores such as monazite.

The radiation protection actions required in this field are based on the precise identification of the activities, the estimation of the impact of the exposure on the individuals concerned, and the implementation of corrective actions to reduce this exposure if necessary and monitoring.

DIAGRAM 1: The French population's exposure to ionising radiation (mSv/year)



Source: IRSN 2015.

3. MONITORING OF EXPOSURE TO IONISING RADIATION

Given the difficulty in attributing a cancer solely to the ionising radiation risk factor, "risk monitoring" is performed by measuring ambient radioactivity indicators (measurement of dose rates for example), internal contamination or, failing this, by measuring values (activities in radioactive effluent discharges) which can then be used – by modelling and calculation – to estimate the doses received by the exposed populations.

SOURCES AND ROUTES OF EXPOSURE to ionising radiation

External irradiation
internal contamination by inhalation of radioactive substances
Contaneous contamination

External irradiation
internal contamination by ingestion of contaminated foodstuffs
Contaneous contamination and involuntary ingestion

The entire population of France is exposed to ionising radiation of natural or anthropogenic origin, but to different extents across the country. The average exposure of the French population is estimated at 4.5 mSv (see diagram 1) per person per year, but this exposure is subject to wide individual variability, particularly depending on the place of residence and the number of radiological examinations received (source: IRSN 2015); the average annual individual effective dose can thus vary by a factor of up to 5 depending on the *département*. Diagram 1 represents an estimate of the respective contributions of the various sources of exposure to ionising radiation for the French population.

These data are however still too imprecise to allow identification of the most exposed categories or groups of individuals for each exposure source category.

3.1 Doses received by workers

3.1.1 Exposure of nuclear workers

The system for monitoring the external exposure of persons liable to be exposed to ionising radiation, working in BNIs or in small-scale nuclear facilities, has been in place for several decades. This system is primarily based on the mandatory wearing of a passive dosimeter by workers liable to be exposed and it is used to check compliance with the regulation limits applicable to workers: these limits concern, on the one hand, the total exposure (since 2003, the annual limit,

TABLE 1: Monitoring of external exposure of nuclear workers (year 2014)

Source: IRSN.

	NUMBER OF PERSONS MONITORED	COLLECTIVE DOSE (man-Sv*)	INDIVIDUAL DOSE > 20 mSv
Reactors and energy production (EDF)	25,179	6.57	0
Fuel cycle; decommissioning	8,934	2.28	0
Transport	602	0.09	0
Logistics and maintenance (contractors)	12,219	8.52	0
Others	20,949	6.85	0

TABLE 2: Monitoring of external exposure of workers in small-scale nuclear activities (year 2014)

Source: IRSN.

	NUMBER OF PERSONS MONITORED	COLLECTIVE DOSE (man-Sv*)	INDIVIDUAL DOSE > 20 mSv
Medicine	132,144	11.68	6
Dental	49,668	2.1	1
Veterinary	20,051	0.44	0
Industry	33,631	14.71	1
Research	13,122	0.40	0
Miscellaneous	24,150	1.42	0

* *Man-Sv (man-sievert): the SI unit for collective dose. For information, the collective dose is the sum of the individual doses received by a given group of persons.*

ASN inspectors inspect the dosimeters of the medical personnel at the Guingamp hospital centre.

TO BE NOTED

Results of dosimetry monitoring of worker external exposure to ionising radiation in 2014

(source: Occupational exposure to ionising radiation in France - 2014 results, IRSN, July 2015)

- Total population monitored: 359,646 workers.
- Monitored population for whom the dose remained below the detection threshold: 283,143 workers, or about 79%.
- Monitored population for whom the dose remained between the detection threshold and 1 mSv: 63,431 workers, or about 18%.
- Monitored population for whom the dose remained between 1 mSv and 20 mSv: 13,072 workers, or about 3.6%.
- Monitored population for whom the annual effective dose of 20 mSv was exceeded: 9 including 1 above 50 mSv.
- Collective dose (sum of individual doses): 56.3 man-Sv.
- Annual average individual dose in the population which recorded a dose higher than the detection threshold: 0.74 mSv.

Results of internal exposure monitoring in 2014

- Number of routine examinations carried out: 306,220 (of which fewer than 1% were considered positive).
- Population for which dose estimation was made: 553 workers.
- Number of special monitoring examinations or verifications performed: 5,524 (of which 16% were above the detection threshold).
- Population having recorded a committed effective dose exceeding 1mSv: 5 workers.

Results of cosmic radiation exposure monitoring in 2014 (civil aviation)

- Collective dose for 18,110 flight crew members: 32.6 man-Sv.
- Annual average individual dose: 1.8 mSv.

expressed in terms of effective dose, has been 20 mSv for 12 consecutive months), obtained by adding the dose due to external exposure to that resulting from any internal contamination; other limits, called equivalent dose limits, are defined for the external exposure of certain parts of the body such as the hands and the lens of the eye (see chapter 3).

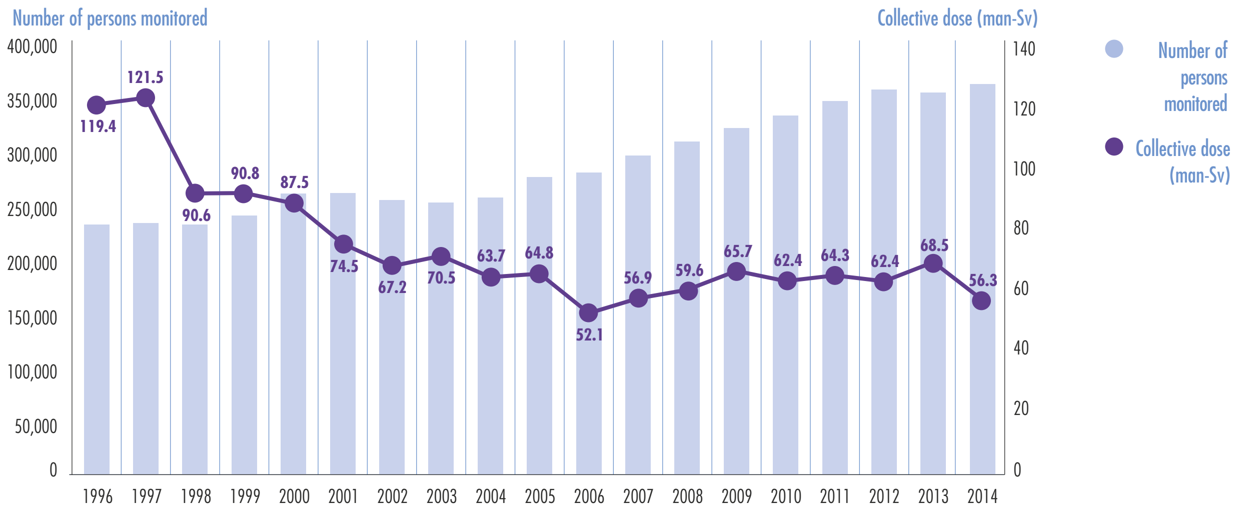
The recorded data allow the identification of the cumulative exposure dose for a given period (month or quarter) for each worker in nuclear activities, including workers from outside companies. The data are collected in the Ionising Radiation Exposure Monitoring Information System (SISERI) managed by IRSN and are published annually. The monitoring system does not include worker exposure to radon.

For each sector, tables 1 and 2 give the breakdown into the populations monitored, the collective dose and the number of times the annual limit of 20 mSv was exceeded. They clearly show a significant disparity in the breakdown of doses depending on the sector. For example, the medical and veterinary activities sector, which comprises a significant share of the population monitored (nearly two thirds of the total), in fact only accounts for about 28% of the collective dose. On the other hand, this sector accounts for seven of the eight reported exceedances of the 20 mSv annual dose limit, of which one approached 96 mSv, one was between 20 and 25 mSv and five were between 30 and 50 mSv).

The latest statistics show a slight but regular increase in the number of persons subject to dosimetric monitoring since 2005 (see diagram 2); the mark of 350,000 individuals was exceeded in 2012. This trend is largely due to the increase in the number of persons monitored in the fields of medical and veterinary activities. After a slight drop in 2013, the first since 2001, the year 2014 again showed a slight increase in the number of people monitored; it would thus seem that a plateau has been reached, a trend which remains to be confirmed in the coming years.

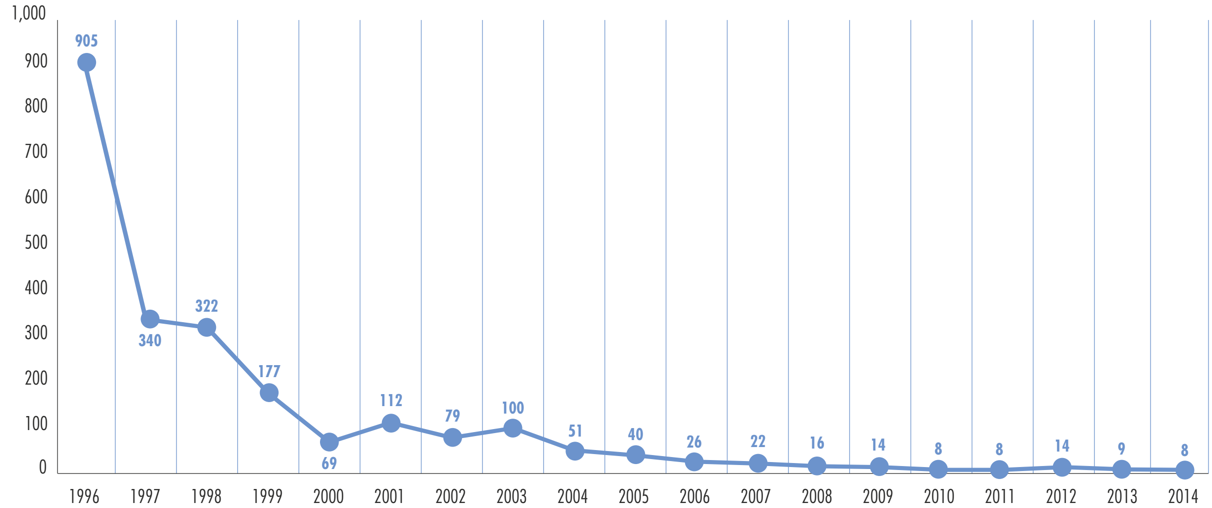
At the same time, the overall collective annual dose has decreased (by about 50% since 1996, whereas the number of people monitored has increased by about 50%). The collective dose did however display an upward trend between 2006 and 2009, followed by a levelling off over the 2009 -2013 period and then a drop in 2014 to reach 56.3 man-Sv.

DIAGRAM 2: Monitored population and collective dose trends, from 1996 to 2014



Source: IRSN.

DIAGRAM 3: Evolution of number of workers monitored, with an annual effective dose in excess of 20 mSv from 1996 to 2014



Source: IRSN.

The number of monitored workers whose annual effective dose exceeded 20 mSv has remained stable since 2013 (nine exceedances of the effective dose limit) (see diagram 3).

With regard to the dosimetry of the extremities (fingers and wrist), 27,068 workers were monitored in 2014 (i.e. 7.5% of the total number of persons monitored) and the total dose was 129 man-Sv. Out of all the persons monitored, there was one case where the 500 mSv regulatory equivalent dose limit at the extremities was exceeded (about 1,373 mSv for a medical worker).

The results of dosimetric monitoring of worker external exposure in 2014 published by IRSN in July 2015 show on the whole that the prevention system introduced in facilities where sources of ionising radiation are used is effective, because for more than 96% of the population monitored, the annual dose remained lower than 1 mSv (effective annual dose limit for the public as a result of nuclear activities). Exceedances of the regulatory limit values remain exceptional.

3.1.2 Worker exposure to TENORM (Technologically Enhanced Naturally Occurring Radioactive Materials)

Occupational exposure to enhanced natural ionising radiation is the result either of the ingestion of dust containing large amounts of radionuclides (phosphates, metal ore), or of the inhalation of radon formed by uranium decay (poorly ventilated warehouses, thermal baths) or of external exposure due to process deposits (scale forming in piping for example).

The results of the studies carried out in France since 2005 and published by ASN in January 2010, as well as the studies received since then, show that 85% of the doses received by workers in the industries concerned remained below 1 mSv/year. The industrial sectors in which worker exposure is liable to exceed 1mSv/year are the following: titanium ore processing, heating systems and recycling of refractory ceramics, maintenance of parts comprising thorium alloys in the aeronautical sector, chemical processing of zircon ore, mechanical transformation and utilisation of zircon and processing of rare earths.

3.1.3 Flight crew exposure to cosmic radiation

Airline flight crews and certain frequent flyers are exposed to significant doses owing to the altitude and the intensity of cosmic radiation at high altitude. These doses can exceed 1 mSv/year.

The "SIEVERT" observation system set up by DGAC (General Directorate for Civil Aviation), IRSN, the Paris Observatory and the Paul-Émile Victor French Institute for Polar Research *(www.sievert-system.com)*, is used to estimate flight crew exposure to cosmic radiation on the flights they make during the course of the year.

The doses received by 18,110 flight crew members were recorded in SISERI in 2014. The individual doses are less than 1 mSv in 15.3% of cases and between 1 mSv and 4 mSv in 84.7% of cases.

3.2 Doses received by the population

3.2.1 Doses received by the population as a result of nuclear activities

The automated monitoring networks managed nationwide by IRSN (*Téléray, Hydrotéléray* and *Téléhydro* networks) offer real-time monitoring of environmental radioactivity and can highlight any abnormal variation. In the case of an accident or incident leading to the release of radioactive substances, these measurement networks would play an essential role by providing data to back the decisions to be taken by the authorities and by notifying the population. In a normal situation, they contribute to the evaluation of the impact of BNIs (see chapter 4).

However, there is no overall monitoring system able to provide an exhaustive picture of the doses received by the population as a result of nuclear activities. Consequently, compliance with the population exposure limit (effective dose set at 1 mSv per year) cannot be controlled directly. However, for BNIs, there is detailed accounting of radioactive effluent discharges and radiological monitoring of the environment is implemented around the installations. On the basis of the data collected, the dosimetric impact of these discharges on the populations in the immediate vicinity of the installations is then calculated using models for simulating transfers to the environment. The dosimetric impacts vary, according to the type of installation and the lifestyles of the reference groups chosen, from a few microsieverts to several tens of microsieverts per year.

There are no known estimates for nuclear activities other than Basic Nuclear Installations, owing to the methodological difficulties involved in identifying the impact of the facilities and in particular the impact of discharges containing small quantities of artificial radionuclides resulting from the use of unsealed radioactive sources in research or biology laboratories, or in nuclear medicine units. To give an example, the impact of hospital discharges could lead to doses of a several tens of microsieverts per year for the most exposed persons, particularly for certain jobs in sewage networks and wastewater treatment plants (IRSN studies 2005 and 2015).

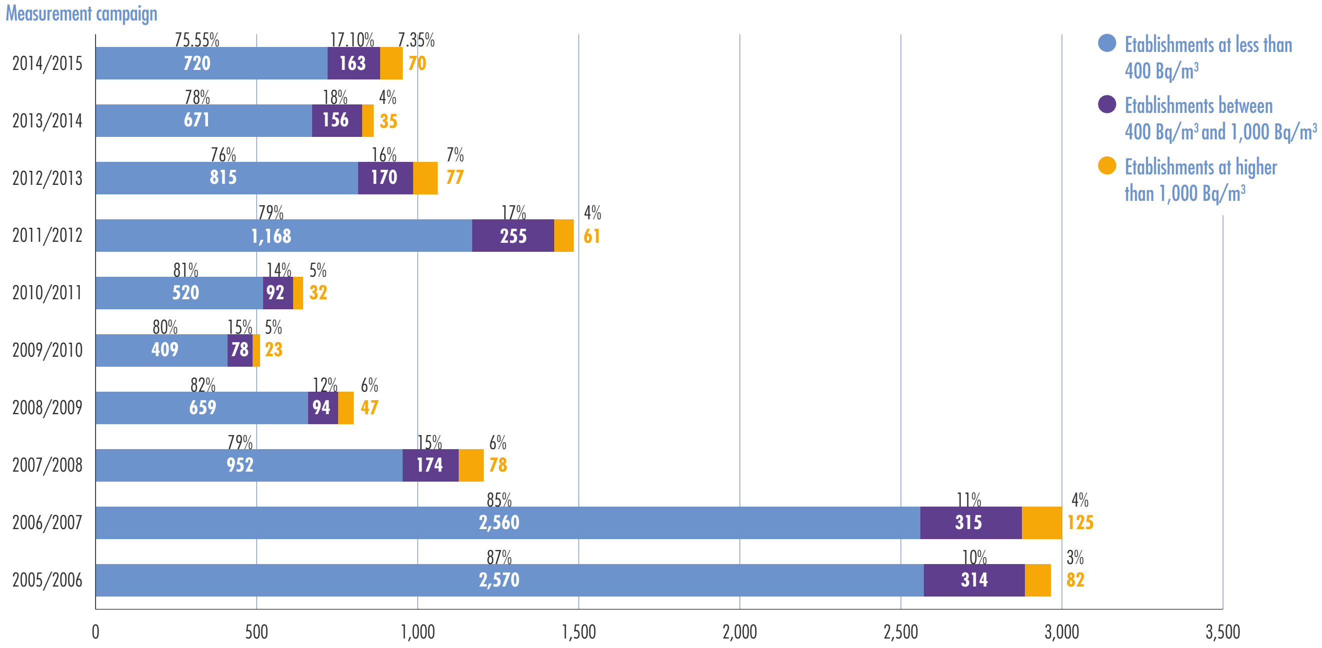
Situations inherited from the past, such as atmospheric nuclear tests and the Chernobyl accident, can make a marginal contribution to population exposure. Thus the average individual effective dose currently being received in metropolitan France as a result of fall-out from the Chernobyl accident is estimated at between 0.010 mSv and 0.030 mSv/year (IRSN 2001). That due to the fall-out from atmospheric testing was estimated in 1980 at about 0.020 mSv. Given a decay factor of about 2 in 10 years, current doses are estimated at well below 0.010 mSv per year (IRSN, 2006). With regard to the fall-out in France from the Fukushima Daiichi accident (Japan), the results published for France by IRSN in 2011 show the presence of radioactive iodine at very low levels, resulting in very much lower doses for the populations than those estimated for the Chernobyl accident, and having negligible impact.

3.2.2 Exposure of the population to NORM (Naturally Occurring Radioactive Materials)

Exposure due to natural radioactivity in drinking water. The results of the Regional Health Agencies' monitoring of the radiological quality of the tap water distributed to consumers between 2008 and 2009 (DGS/ASN/IRSN report published in 2011) showed that 99.83% of the population receives tap water whose quality complies at all times with the total indicative dose of 0.1mSv/year set by the regulations. This overall assessment can also be applied to the radiological quality of packaged mineral waters and spring waters produced in France (DGS/ASN/IRSN report published in 2013).

Exposure due to radon. Since 1999, it is compulsory to take periodic radon measurements in places open to

DIAGRAM 4: Results of radon measurement campaigns



Source: IRSN.

the public, especially in educational establishments and health and social institutions, due to the risk of lung cancer attributable to prolonged exposure to radon. Since August 2008, this compulsory monitoring has been extended to workplaces located in priority geographical areas.

Results of the measurement campaigns conducted since 2005 by organisations approved by ASN are presented in diagram 4. The percentages of the measurement results that exceed the action levels (400 and 1,000 Bq/m^3) remain comparable from one year to the next. A new ten-yearly screening cycle was started in 2009.

The results of the inspections in places open to the public are not appropriate for precisely assessing the doses linked to exposure of the general public due to the fact that exposure in the home accounts for the largest part of the doses received during one's lifetime. It should be noted that the data for the average activity concentrations of radon in the home date from the national radon exposure measurement campaign carried out in the years 1980-1990.

Over and beyond the regulatory aspects (see chapter 3), the management of radon risks formed the subject of an interministerial action plan for the period 2011-2015, coordinated by ASN. The results of this plan and the new action plan will be published in 2016 for the 2016-2019 period.

3.3 Doses received by patients

In France, exposure for medical purposes represents the greatest part of the artificial exposures of the public to ionising radiation. This medical exposure has been increasing over the last thirty years or so due to the rise in the number of radiological examinations – and computed tomography examinations in particular, to the ageing of the population, and to the strategies implemented to ensure better patient care, particularly in the context of patient monitoring after cancer treatment and coronary diseases. It has been regularly reviewed by IRSN since 2002.

The average effective dose per inhabitant resulting from diagnostic radiological examinations has been evaluated at 1.6 mSv for the year 2012 (IRSN report 2014) for some 81.8 million diagnostic procedures performed (74.6 million in 2007), i.e. 1,247 procedures for 1,000 inhabitants per year. It is to be noted that the individual exposure in 2012 is very varied. Thus, although about one third of the French population underwent at least one procedure (excluding dental procedures), 85% of that population was not exposed or received doses of less than 1 mSv.

The average effective individual dose increased by 23% between 2007 and 2012 (it was 1.3 mSv in 2007); it had already increased by 50% between 2002 and 2007 (IRSN/InVS report 2010). It must nevertheless be underlined that the methodologies used for the 2002-2007 period and the 2007-2012 period were not identical.

TABLE 3: Total number of procedures and associated collective effective dose for each imaging method (rounded values) in France in 2012

IMAGING METHOD	PROCEDURES		COLLECTIVE EFFECTIVE DOSE	
	NUMBERS	%	MSV	%
Conventional radiology (dentistry excluded)	44,175,500	54.0	18,069,200	17.7
Dental radiology	27,616,000	33.8	165,700	0.2
Computed Tomography	8,484,000	10.4	72,838,900	71.3
Diagnostic interventional radiology	377,000	0.5	3,196,400	3.1
Nuclear medicine	1,103,000	1.3	7,928,300	7.8
TOTAL	**81,755,500**	**100.0**	**102,198,500**	**100.0**

Source: IRSN.

Conventional radiology (54%), computed tomography (10.5%) and dental radiology (34%) account for the largest number of procedures. However, the contribution of computed tomography to the effective collective dose remains preponderant and more significant in 2012 (71%) than in 2007 (58%) whereas that of dental radiology remains very low (0.2%).

To give an example, thoracic and abdominal pelvic CT scans remain the most frequent (50% in 2012 vs 30% in 2007), more particularly in men after the age of 50 years (4.2% in 2012 vs 1.4% in 2007). Women underwent more conventional radiology procedures (mammograms and limb examinations) than men.

In adolescents, conventional radiology and dental procedures are more numerous (1,020 and 1,220 procedures respectively for 1,000 individuals in 2012). Despite their frequency in this population, dental radiology procedures represent only 0.5% of the collective dose.

It is noteworthy that in a sample of about 600,000 persons covered by health insurance, 44% underwent at least one diagnostic procedure in 2012. The analysis of the effective doses for these people who effectively underwent an examination shows that 70% of them received less than 1 mSv, 18% received between 1 and 10 mSv, 11% between 10 and 50 mSv and 1% more than 50 mSv. The substantial uncertainties in this study with regard to the average effective dose values per type of procedure must nevertheless be take into account, which justifies progressing in the dose estimates in the next exposure study of the general population.

Particular attention is required in order to control and reduce the doses linked to medical imaging, more specifically when alternative techniques can be used for a same given indication, because the multiplication of the most heavily irradiating examinations for the same person could lead to the effective dose value of several tens of millisieverts being reached; at this level of exposure, certain epidemiological surveys have revealed the occurrence of radiation-induced cancers.

Based on a sample of 100,000 children (1% of the French population), IRSN (2013 report) estimated that in 2010, one out of three children was exposed to ionising radiation for diagnostic purposes. The mean and median values for the effective dose are estimated at 0.65 mSv and 0.025 mSv respectively for all the children exposed. They are 5.7 mSv and 1.7 mSv respectively for children who have undergone at least one computed tomography procedure (1% of the population monitored).

Controlling the doses delivered to patients remains a priority for ASN, which has undertaken – in collaboration with the stakeholders (institutional and professional) – a programme of actions in various areas (quality and safety of practices/quality assurance, human resources/training, etc.).

3.4 Exposure of non-human species (animal and plant species)

The international radiation protection system was created to protect humans against the effects of ionising radiation. Environmental radioactivity is thus assessed with respect to its impact on human beings and, in the absence of any evidence to the contrary, it is today considered that the current standards also protect other species.

Protection of the environment from the radiological risk and more specifically the protection of non-human species, must however be guaranteed independently of the effects on humans. Pointing out that this objective is already incorporated in the national legislation, ASN will ensure that the impact of ionising radiation on non-human species be effectively included in the regulations and in the authorisations for nuclear activities as soon as evaluation methods are available. The opinion adopted by the GPRADE in September 2015, based on the IRSN appraisal report, is to be published in 2016.

4. OUTLOOK

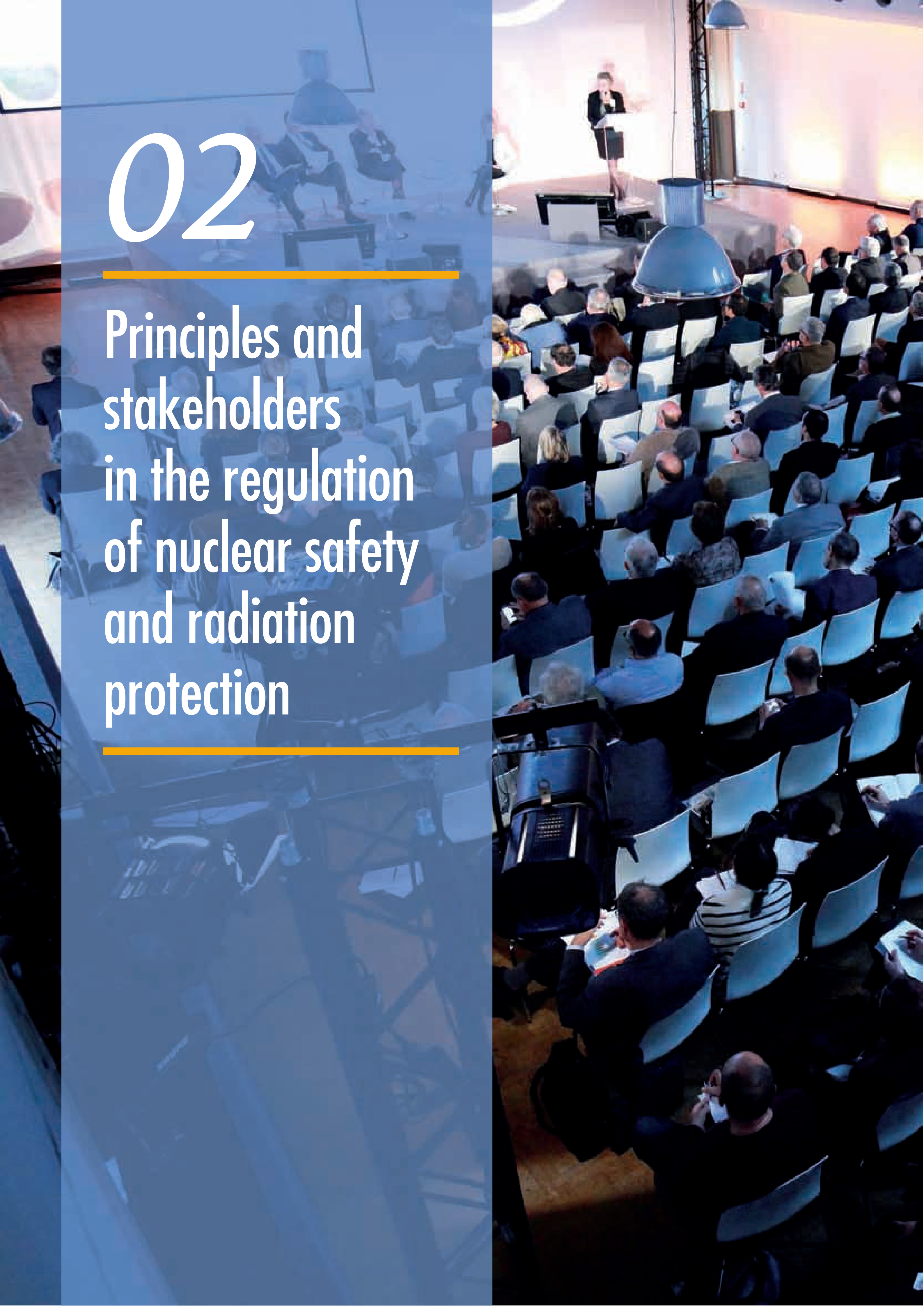
As in the preceding years, the review of worker exposure in 2014 published by IRSN confirms the stabilisation of the number of monitored workers whose annual dose exceeded 20 mSv at less than 10 cases, and the stabilisation at a low level of the collective dose following the reduction that began in 1996.

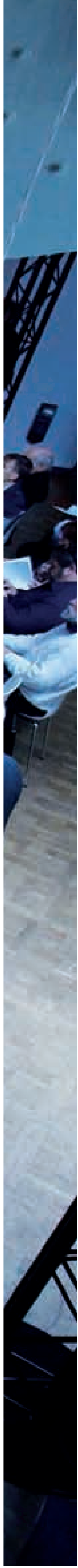
The Ordinance transposing the new requirements relative to radon exposure set out in European Directive 2013/59 defining the basic radiation protection standards, should make it possible to communicate more extensively to the general public on radon-related risks and to organise the collection and analysis of the results of measurements taken in the home. These are the main issues of the third National Action Plan 2016-2019 which is currently being finalised.

Regarding the question of the regular increase in doses delivered to patients during medical imaging examinations since 2002, which was confirmed by the results of the 2012 survey published in 2014, ASN will continue the actions it has undertaken since 2011 to maintain the mobilisation of the health authorities and health professionals at all levels. Raising awareness in doctors referring patients for examinations represents a new objective for the coming years.

02

Principles and stakeholders in the regulation of nuclear safety and radiation protection





Nuclear safety is defined in the Environment Code as *"the set of technical provisions and organisational measures – related to the design, construction, operation, shutdown and decommissioning of Basic Nuclear Installations (BNIs), as well as the transport of radioactive substances – which are adopted with a view to preventing accidents or limiting their effects". Radiation protection is defined as "protection against ionising radiation that is the set of rules, procedures and means of prevention and surveillance aimed at preventing or mitigating the direct or indirect harmful effects of ionising radiation on individuals, including in situations of environmental contamination".*

Nuclear safety and radiation protection obey principles and approaches that have been put in place progressively and continually enhanced by a process of feedback. The basic guiding principles are advocated internationally by the International Atomic Energy Agency (IAEA). In France, they are included in the Constitution or enacted in law, as well as now figuring in European Directives.

In France, the regulation of nuclear safety and radiation protection for civil nuclear activities is carried out by the French Nuclear Safety Authority, ASN, an independent administrative Authority, in liaison with Parliament and other State stakeholders, within the Government and the offices of the Prefects. This regulation is based on technical expert assessment services provided more particularly by the French Institute for Radiation Protection and Nuclear Safety (IRSN).

1. THE PRINCIPLES OF NUCLEAR SAFETY AND RADIATION PROTECTION

1.1 Fundamental principles

Nuclear activities must be carried out in compliance with the principles that underlie the legislative texts.

This primarily concerns:
- at the national level, the principles enshrined in the Environment Charter, which has the same value as the Constitution, and in the various codes (Environment Code and Public Health Code);
- at the European level, rules defined by Directives establishing a community framework for the safety of nuclear facilities and for the responsible and safe management of spent fuel and radioactive waste;
- at an international level, ten fundamental safety principles defined by IAEA (see box on page 66 and chapter 7, point 3.1) implemented by the Convention on Nuclear Safety (see chapter 7 point 4.1), which established the international framework for the oversight of nuclear safety and radiation protection.

These various measures of differing origins extensively overlap. They can be grouped into the eight main principles presented below.

1.1.1 Principle of licensee responsibility

This principle, defined in Article 9 of the Convention on Nuclear Safety, is the first of IAEA's fundamental safety principles. It stipulates that responsibility for the safety of nuclear activities entailing risks lies with those who undertake or perform them.

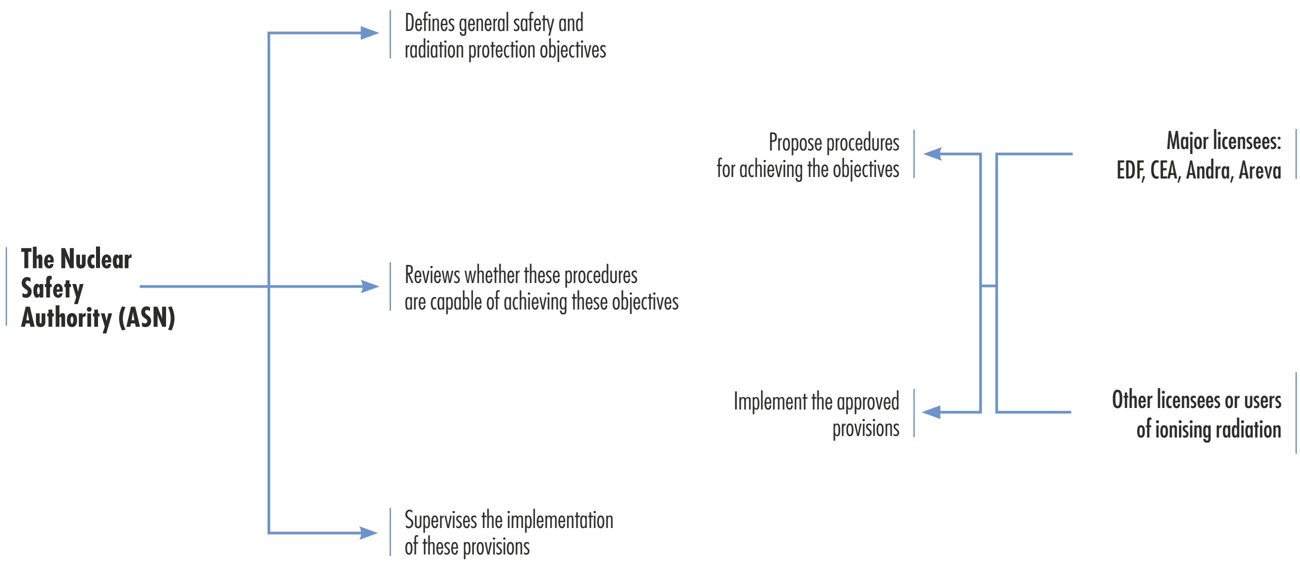
It applies directly to all nuclear activities.

1.1.2 "Polluter-pays" principle

The "polluter-pays" principle, stipulating the principle of the operator's responsibility, ensures that the costs of measures to prevent or reduce pollution are borne by those responsible for environmental damage. This principle is defined in Article 4 of the Environment Charter in these terms: *"An individual must contribute to reparation of the environmental damage he or she has caused".*

This principle entails the taxation of Basic Nuclear Installations (BNI) ("BNI" tax and contribution to IRSN), the taxation of radioactive waste producers (additional waste taxes), of disposal facilities (additional "disposal" tax) and of Installations Classified on Environmental Protection grounds (ICPE) (fraction of the General Tax on Polluting Activities – TGAP). These taxes are presented in greater detail in point 3.

RESPONSABILITY of licensees and responsibility of ASN



1.1.3 Precautionary principle

The precautionary principle, defined in Article 5 of the Environment Charter, states that: *"the absence of certainty, in the light of current scientific and technical knowledge, must not delay the adoption of effective and proportionate measures to prevent a risk of serious and irreversible damage to the environment"*.

Application of this principle results, for example, in the adoption of a linear, no-threshold dose-effect relationship where the biological effects of exposure to low doses of ionising radiation are concerned. This point is clarified in chapter 1 of this report.

1.1.4 Public participation principle

This principle allows public participation in the taking of decisions by public authorities. In line with the Aarhus Convention, it is defined in Article 7 of the Environment Charter as follows: *"Within the conditions and limits defined by law, all individuals are entitled to access environmental information in the possession of the public authorities and to take part in the taking of public decisions affecting the environment"*.

In the nuclear field, this principle leads in particular to the organisation of national public debates, which are mandatory prior to the construction of a nuclear power plant for example, as well as public inquiries, in particular during the examination of the files concerning the creation or decommissioning of nuclear facilities, to public consultation concerning draft resolutions with an impact on the environment, or to the basic nuclear installation licensee providing access to its file on the modification of its installation, which is liable to cause a significant increase in water intake or discharges into the environment of the installation.

1.1.5 The principle of justification

The principle of justification, defined in Article L. 1333-2 of the Public Health Code, states that: *"A nuclear activity or an intervention may only be undertaken or carried out if its individual or collective benefits, more specifically its health, social, economic or scientific benefits so justify, given the risks inherent in the human exposure to ionising radiation that it is likely to entail"*.

Assessment of the expected benefit of a nuclear activity and the corresponding drawbacks may lead to prohibition of an activity for which the benefit would not seem to outweigh the health risk. For existing activities, justification may be reassessed if the state of know-how and technology so warrants.

1.1.6 The principle of optimisation

The principle of optimisation, defined by Article L. 1333-2 of the Public Health Code, states that: *"The level of exposure of individuals to ionising radiation […], the probability of occurrence of this exposure and the number of persons exposed must be kept as low as is reasonably achievable, given the current state of technical knowledge, economic and social factors and, as necessary, the medical goal in question"*.

This principle, referred to as the ALARA (As Low As Reasonably Achievable) principle, leads for example to reducing the quantities of radionuclides present in the radioactive effluents from nuclear installations allowed in the discharge licenses, to requiring surveillance of exposure in the working environment in order to reduce it to the strict minimum and to ensuring that medical exposure as a result of diagnostic procedures remains close to the pre-determined reference levels.

1.1.7 The principle of limitation

The principle of limitation, defined in Article L. 1333-2 of the Public Health Code, states that: *"Exposure of an individual to ionising radiation […] may not increase the sum of the doses received beyond the limits set by regulations, except when the individual is exposed for medical or biomedical research purposes".*

The exposure of the general public or of workers as a result of nuclear activities is subject to strict limits. These limits include significant safety margins to prevent deterministic effects from appearing, as well as aiming at reducing to the lowest level possible the appearance of probabilistic effects in the long term.

Exceeding these limits leads to an abnormal situation and one which may give rise to administrative or legal sanction.

In the case of medical exposure of patients, no strict dose limit is set, provided that this voluntary exposure is justified by the expected health benefits to the person exposed.

1.1.8 The principle of prevention

To anticipate any environmental damage, the principle of prevention, defined in Article 3 of the Environment Charter, stipulates the implementation of rules and measures which must take account of *"the best available technology at an economically acceptable cost".*

In the nuclear field, this principle underlies the concept of defence in depth, presented below.

1.2 Some aspects of the safety approach

The safety principles and approaches presented below were gradually implemented and incorporate experience feedback from accidents. Absolute safety can never be guaranteed and despite all the precautions taken in the design, construction and operation of nuclear facilities, an accident can never be completely ruled out. The willingness to move forward and to create a continuous improvement approach is thus essential if the risks are to be reduced.

UNDERSTAND

The fundamental safety principles

IAEA establishes the following 10 principles in its publication "SF-1":

1. Responsibility for safety must rest with the person or organisation responsible for facilities and activities that give rise to radiation risks.
2. An effective legal and governmental framework for safety, including an independent regulatory body, must be established and sustained.
3. Effective leadership and management of safety must be established and maintained in organisations concerned with radiological risks, and in facilities and activities that give rise to such risks.
4. Facilities and activities that give rise to radiation risks must yield an overall benefit.
5. Protection must be optimised to provide the highest level of safety that can reasonably be achieved.
6. Measures for controlling radiation risks must ensure that no individual bears an unacceptable risk of harm.
7. People and the environment, both present and future, must be protected against radiation risks.
8. All practical efforts must be made to prevent and mitigate nuclear or radiation accidents.
9. Arrangements must be made for emergency preparedness and response for nuclear or radiation incidents.
10. Protective actions to reduce existing or unregulated radiation risks must be justified and optimised.

1.2.1 Safety culture

Safety culture is defined by the International Nuclear Safety Advisory Group (INSAG), an international nuclear safety consultative group reporting to the General Director of IAEA, as: *"that assembly of characteristics and attitudes in organisations and individuals which establishes that, as an overriding priority, nuclear plant safety issues receive the attention warranted by their significance".*

Safety culture therefore determines the ways in which an organisation and individuals perform their duties and accept responsibility, with safety in mind. It is one of the key fundamentals in maintaining and improving safety. It commits organisations and individuals to paying particular and appropriate attention to safety. At the individual level it is given expression by a rigorous and cautious approach and a questioning attitude making it possible to both obey rules and take initiative. In operational terms, the concept underpins daily decisions and actions relating to activities.

1.2.2 The "Defence in Depth" concept

The main means of preventing accidents and limiting their potential consequences is "the Defence in Depth". This consists in implementing material or organisational provisions (sometimes called lines of defence) structured in consecutive and independent layers, and which are capable of preventing the development of an accident. If one level of protection fails, the next level takes over.

An important element for the independence of the levels of defence is the use of different technologies ("diversified" systems).

The design of nuclear installations is based on a defence in depth approach. Five levels of protection are defined for nuclear reactors:

Level 1: Prevention of abnormal operation and system failures

This is a question firstly of designing and building the facility in a robust and conservative manner, integrating safety margins and planning for resistance with respect to its own failures or to hazards. It implies conducting the most exhaustive study possible of normal operating conditions to determine the severest stresses to which the systems will be subjected. It is then possible to produce an initial design basis for the facility, incorporating safety margins. The facility must then be maintained in a state at least equivalent to that planned for in its design through appropriate maintenance. The facility must be operated in an informed and careful manner.

Level 2: Keeping the installation within authorised limits

Regulation and governing systems must be designed, installed and operated such that the installation is kept within an operating range that is far below the safety limits. For example, if the temperature in a system increases, a cooling system starts up before the temperature reaches the authorised limit. Monitoring of the condition and correct operation of systems forms part of this level of defence.

Level 3: Control of accidents without core meltdown

The aim here is to postulate that certain accidents, chosen for their "envelope" characteristics (the most penalising in a given family) can happen, and to design and size backup systems to withstand those conditions.

Such accidents are generally studied with pessimistic hypotheses, that is to say the various parameters governing this accident are assumed to be as unfavourable as possible. The single-failure criterion is also applied, in other words, in the accident situation we also postulate the failure of any given component. As a result of this, the systems coming into play in the event of an accident (safeguard systems ensuring emergency shutdown, injection of cooling water into the reactor, etc.) comprise at least two redundant and independent channels.

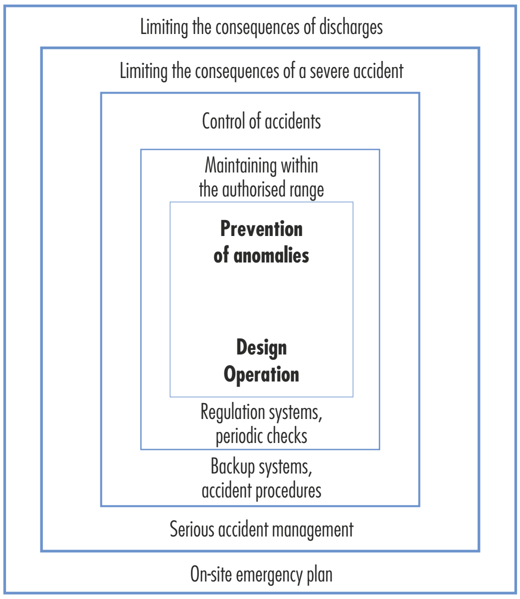
Level 4: Control of accidents with core meltdown

These accidents have been considered since the Three Mile Island accident (1979) and are now taken into account in the design of new reactors such as the EPR. The aim is to preclude such accidents or to design systems that can withstand them.

Level 5: Mitigation of the radiological consequences of significant releases

This requires implementation of the measures provided for in the emergency plans, including measures to protect the general public: shelter, taking of stable iodine tablets to saturate the thyroid and avoid fixation of released radioactive iodine, evacuation, restrictions on consumption of water and of agricultural products, etc.

THE 5 LEVELS of "Defence in Depth"



1.2.3 Positioning of barriers

To limit the risk of releases, several barriers are placed between the radioactive substances and the environment. Barriers must be designed to have a high degree of reliability and must be monitored to detect any weaknesses or failures. There are three such barriers for pressurised water reactors: the fuel cladding, the boundary of the reactor primary system, and the containment (see chapter 12).

1.2.4 Deterministic and probabilistic approaches

Postulating the occurrence of certain accidents and verifying that, thanks to the planned functioning of the equipment, the consequences of these accidents will remain limited, is known as a deterministic approach. This approach is simple to apply in principle and allows an installation to be designed (and its systems to be sized) with good safety margins, by using so-called "envelope" cases. The deterministic approach does not, however, lead to a realistic view of the most probable scenarios and does not rank risks satisfactorily, since it focuses attention on accidents studied with pessimistic assumptions.

The deterministic approach therefore needs to be supplemented by an approach that better reflects possible accident scenarios in terms of their probability, that is to say the probabilistic approach used in the "Probabilistic Safety Assessments" (PSA).

Thus for nuclear power plants, the level 1 Probabilistic Safety Assessments (PSA) consist in establishing event trees for each "initiating event" leading to the activation of a safeguard system (level 3 of defence in depth), defined by the failure (or the success) of the actions provided for in the reactor management procedures and the failure (or correct operation) of the reactor. The probability of each sequence is then calculated based on statistics on the reliability of systems and on the rate of success of actions (including data on "human reliability"). Similar sequences of events that correspond to the same initiating event are grouped into families, making it possible to determine the contribution of each family to the probability of reactor core meltdown.

Although the PSAs are limited by the uncertainties concerning the reliability data and the approximations in the modelling of the facility, they consider a broader set of accidents than the deterministic assessments and enable the design resulting from the deterministic approach to be verified and supplemented if necessary. They are therefore to be used as a complement to deterministic studies and not as a substitute for them.

The deterministic studies and probabilistic assessments constitute an essential element in the demonstration of nuclear safety that addresses equipment internal faults, internal and external hazards, and plausible combinations of these events.

To be more precise, the internal faults correspond to malfunctions, failures or damage to facility equipment, including as a result of inappropriate human action. Internal or external hazards correspond to events originating inside or outside the facility respectively and which can call into question the safety of the facility.

Internal faults include for example:
- loss of the electrical power supplies or the cooling systems;
- ejection of a rod cluster control assembly;
- rupture of a pipe in the primary or secondary system of a nuclear reactor;
- reactor emergency shutdown failure.

With regard to internal hazards, the following in particular must be considered:
- flying projectiles, notably those resulting from the failure of rotating equipment;
- pressure equipment failures;
- collisions and falling loads;
- explosions;
- fires;
- hazardous substance emissions;
- floods originating within the perimeter of the facility;
- electromagnetic interference;
- malicious acts.

Finally, external hazards more specifically comprise:
- the risks induced by industrial activities and communication routes, including explosions, hazardous substance emissions and airplane crashes;
- earthquakes;
- lightning and electromagnetic interference;
- extreme meteorological or climatic conditions;
- fires;
- floods originating outside the perimeter of the facility;
- malicious acts.

1.2.5 Operating experience feedback

Operating Experience Feedback (OEF), which contributes to defence in depth, is one of the essential safety management tools. It is based on an organised and systematic collection and analysis of the signals emitted by a system. It should enable the acquired experience to be shared (for implementation of preventive measures in a structure that learns from past experience). A first goal of Operating Experience Feedback (OEF) is to understand, and thus ensure progress in technological understanding and knowledge of actual operating practices, so that whenever pertinent, a fresh look can be taken at the design[1] (technical and documentary). As OEF is a collective process, a second goal is to share the resulting knowledge, by memorising and recording the anomaly, the lessons learned from it and how it

1. Technical and documentary design means all the designs of the components of the working activity: design of the machine, its operating procedure, its maintenance, how work is organised in relation to this machine, etc.

was rectified. A third goal of OEF is to act on working organisations and processes, on working practices (both individual and collective) and on the performance of the technical system.

Operating experience feedback encompasses events, incidents and accidents occurring both in France and abroad, whenever their assessment is relevant to enhancing nuclear safety or radiation protection.

1.2.6 Social, organisational and human factors

The importance of SOHF for nuclear safety, radiation protection and environmental protection

The contribution of humans and organisations to safety, radiation protection and environmental protection is decisive in the design, commissioning, operation and decommissioning of facilities, as well as in the transport of radioactive substances. Similarly, the way in which people and organisations manage deviations from the regulations, from the baseline requirements and from the state of the art, plus the corresponding lessons learned, is also decisive. Therefore, all those involved, regardless of their position in the hierarchy and their functions, make a contribution to safety, radiation protection and environmental protection, owing to their ability to adapt, detect and correct errors, rectify degraded situations and counter certain difficulties involved in the application of procedures.

ASN defines Social, Organisational and Human Factors (SOHF) as being all the aspects of working situations and of the organisation which have an influence on the work done by the operators. The elements considered concern the individual (training received, fatigue or stress, etc.) and the organisation within which he or she works (functional and hierarchical links, joint contractor work, etc.), the technical arrangements (tools, software, etc.) and, more broadly, the working environment with which the individual interacts. The working environment for instance concerns the heat, sound or light environment of the workstation, as well as the accessibility of the premises.

The variability in worker characteristics (vigilance varies with the time of day, the level of expertise varies according to the seniority in the position) and in the situations encountered (unexpected failure, social tension) explains that workers constantly need to adapt how they work so as to optimise effectiveness and efficiency. This performance must be achieved at an acceptable cost to the persons concerned (in terms of fatigue or stress) and they must also benefit from it (the feeling of a job well done, recognition by both peers and the hierarchy, development of new skills). Thus, an operating situation or a task achieved at very high cost to the operators is a potential source of risks: a small variation in the working context, human environment or working organisation can prevent the persons concerned from performing their tasks as expected.

Integration of SOHF

ASN considers that SOHF must be taken into account in a manner commensurate with the safety implications of the facilities and the radiation protection of workers during:

- the design of a new facility, equipment, software, transport package, or the modification of an existing one. ASN in particular wants to see design focusing on the human operator, through an iterative process comprising an analysis phase, a design phase and an evaluation phase. Therefore, the ASN resolution of 13th February 2014 concerning physical modifications to BNIs requires that *"the design of the physical modification envisaged shall, when it is applied and put into operation, take account of the interactions between the modified or newly installed equipment on the one hand and the users and their needs on the other"*.
- operations or activities performed by the workers during the commissioning, operation and decommissioning of nuclear facilities, as well as during the transportation of radioactive substances.

ASN also considers that the licensees must analyse the root causes (often organisational) of the significant events and identify, implement and assess the effectiveness of the corresponding corrective measures, on a long-term basis.

ASN's SOHF requirements

The Order of 7th February 2012 setting the general rules for BNIs, requires that the licensee define and implement an Integrated Management System (IMS) designed to ensure that the safety, radiation protection and environmental protection requirements are systematically taken into account in all decisions concerning the facility. The IMS specifies the steps taken with regard to organisation and resources of all types, in particular those adopted to manage the important activities. ASN thus asks the licensee to set up an IMS able to maintain and continuously improve safety, notably through the development of a safety culture.

2. THE STAKEHOLDERS

The organisation of the regulation of nuclear safety in France complies with the Convention on Nuclear Safety, Article 7 of which requires that *"Each Contracting Party shall establish and maintain a legislative and regulatory framework to govern the safety of nuclear installations"* and Article 8 of which requires that each Member State *"shall establish or designate a regulatory body entrusted with the implementation of the legislative and regulatory framework referred to in Article 7 and provided with adequate authority, competence and financial and human resources to fulfil its assigned responsibilities"*. These provisions were confirmed by the European Directive of 25th June 2009 concerning nuclear safety, the provisions of which were themselves reinforced by the amending Directive of 8th July 2014.

In France, the regulation of nuclear safety and radiation protection is primarily the responsibility of three parties: Parliament, the Government and ASN.

2.1 Parliament

Parliament's principal role in the field of nuclear safety and radiation protection is to make laws. Two major acts were therefore passed in 2006: the TSN Act of 13th June 2006, on transparency and security in the nuclear field; and the Programme Act of 28th June 2006, on the sustainable management of radioactive materials and waste.

In 2015, Parliament adopted the Energy Transition for Green Growth Act, an entire section of which is devoted to nuclear matters (Title VI entitled *"Reinforcing nuclear safety and information of the citizens"*). This Act reinforces the framework which was created in 2006.

Like the other independent administrative authorities and in application of the provisions of the Environment Code, ASN makes regular reports on its activity to Parliament, notably to the OPECST (Parliamentary Office for the Evaluation of Scientific and Technological Choices) and to the parliamentary commissions concerned.

The role of the OPECST is to inform Parliament of the consequences of the scientific or technological choices so that it can take informed decisions; to this end, the OPECST gathers information, implements study programmes and conducts evaluations. ASN regularly reports on its activities to the OPECST, particularly by submitting the annual *Report on the State of Nuclear Safety and Radiation Protection in France* to it each year.

ASN also reports on its activities to the Parliamentary Commission of the National Assembly and the Senate, notably on the occasion of hearings held by the commissions responsible for the environment or economic affairs.

The exchanges between ASN and elected officials are presented in more detail in chapter 6.

2.2 The Government

The Government exercises regulatory powers. It is therefore in charge of laying down the general regulations concerning nuclear safety and radiation protection. The Environment Code also tasks it with taking major decisions concerning BNIs, for which it relies on proposals or opinions from ASN. The Government can also call on consultative bodies such as the High Committee for Transparency and Information on Nuclear Safety (HCTISN).

The Government is also responsible for civil protection in the event of an emergency.

2.2.1 Ministers responsible for Nuclear Safety and Radiation Protection

On the advice of and, as applicable, further to proposals from ASN, the Minister responsible for Nuclear Safety defines the general regulations applicable to BNIs and those concerning the construction and use of Pressure Equipment (ESP) specifically designed for these installations (ESPN).

Also on the advice of and, as applicable, further to proposals from ASN, this same Minister takes major individual decisions concerning:
- the design, construction, operation and decommissioning of BNIs;
- the design, construction, operation, closure and decommissioning, as well as the surveillance of radioactive waste disposal facilities.

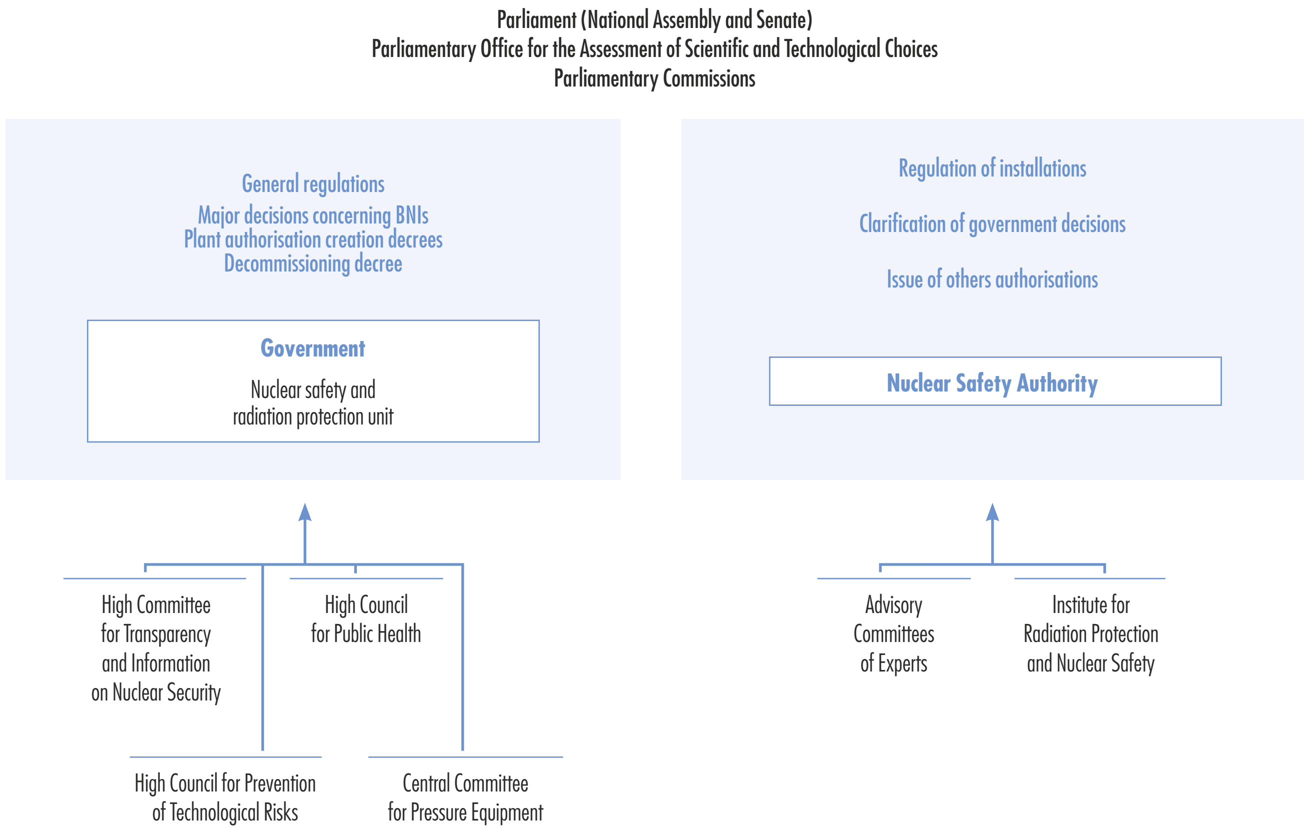
If an installation presents serious risks, the above-mentioned Minister can suspend the operation of an installation on the advice of ASN.

Furthermore, the Minister responsible for Radiation Protection defines – on the basis of ASN proposals if necessary – the general regulations applicable to radiation protection.

The regulation of worker radiation protection is the responsibility of the Minister for Labour.

The Ministers responsible for Nuclear Safety and for Radiation Protection approve the ASN internal regulations by means of an Interministerial Order. Each of them also approves ASN technical statutory resolutions and certain individual resolutions (setting BNI discharge limits, delicensing a BNI, etc.) affecting their own particular field.

REGULATION of nuclear safety and radiation protection in France



The Nuclear Safety and Radiation Protection Mission

The Nuclear Safety and Radiation Protection Mission (MSNR), within the General Directorate for Risk Prevention at the Ministry of the Environment, Energy and the Sea, is in particular tasked – in collaboration with ASN – with proposing Government policy on nuclear safety and radiation protection, except for defence-related activities and installations and the radiation protection of workers against ionising radiations.

Defence and Security High Official

The purpose of nuclear security, in the strictest sense of the term (IAEA definition, less wide-ranging than that of Article L 591-1 of the Environment Code) is to protect and monitor nuclear materials, their facilities and their transportation. It aims to ensure protection of the populations and environment against the consequences of malicious acts, in accordance with the provisions of the Defence Code.

This responsibility lies with the Minister for the Environment, Energy and the Sea, with the support of the Defence and Security High Official (HFDS) and more specifically the Nuclear Security Department (DSN). The HFDS thus acts as the nuclear security Authority, by drafting regulations, issuing authorisations and conducting inspections in this field, with the support of IRSN.

Although the two regulatory systems and approaches are clearly different, the two fields, owing to the specificity of the nuclear field, are closely linked. ASN and the HFDS are therefore regularly in contact with each other.

2.2.2 The Prefects

The Prefects are the State's local representatives. They are the guarantors of public order and play a particularly important role in the event of an emergency, in that they are responsible for measures to protect the general public.

The Prefects are involved in the various procedures presented in chapter 3. In particular, they send the Minister their opinion on the report and on the conclusions of the inquiry commissioner following the public inquiry into authorisation applications. At the request of ASN, they refer to the Departmental Council for the environment and health and technological risks for an opinion on the water intakes, discharges and other detrimental effects of BNIs.

2.3 ASN

The Nuclear Safety Authority (ASN), created by the TSN Act, is an independent administrative Authority which takes part in regulating nuclear safety, radiation protection and the nuclear activities mentioned in Article L. 1333-1 of the Public Health Code. Its roles are to regulate, authorise, monitor and support the public authorities in the management of emergency situations and to contribute to information of the public and transparency within its fields of competence.

ASN is run by a Commission of Commissioners and has departments placed under the authority of its Chairman. From a technical point of view, ASN relies on the expertise with which it is provided, notably by IRSN and by the Advisory Committees of Experts (GPEs).

2.3.1 Role and duties

Regulation

ASN is consulted on draft decrees and ministerial Orders of a regulatory nature dealing with nuclear safety as defined in Article L.591-1 of the Environment Code.

It can issue statutory resolutions of a technical nature to complete the implementing procedures for decrees and orders adopted in the nuclear safety or radiation protection field, except for those relating to occupational medicine. These resolutions must be approved by the Minister responsible for Nuclear Safety or the Minister responsible for Radiation Protection.

Approval orders and approved resolutions are published in the *Official Journal*.

Authorisation

ASN reviews BNI authorisation or decommissioning applications, issues opinions and makes proposals to the Government concerning the decrees to be issued in these fields. It defines the requirements applicable to these installations with regard to the prevention of risks, pollution and detrimental effects. It authorises commissioning of these installations and pronounces delicensing following completion of decommissioning.

Some of these ASN resolutions require approval by the Minister responsible for nuclear safety.

ASN issues the licenses, carries out registration and receives the notifications provided for in the Public Health Code concerning small-scale nuclear activities and issues licenses or approvals for radioactive substances transport operations.

The ASN resolutions and opinions defined by its Commission are published in its *Official Bulletin* on its website *(www.asn.fr)*.

Chapter 3 of this report describes ASN's roles in the fields of regulation and authorisation.

Control

ASN verifies compliance with the general rules and specific requirements for nuclear safety and radiation protection applicable to BNIs, to the pressure equipment designed specifically for such facilities and to the transport of radioactive substances. It also regulates the activities mentioned in Article L. 1333-1 of the Public Health Code and the ionising radiation exposure situations defined in Article L.1333-3 of the same Code.

ASN organises a permanent radiation protection watch throughout the national territory.

From among its staff, it appoints nuclear safety inspectors and radiation protection inspectors.

It issues the required approvals to the organisations participating in the verifications and in nuclear safety or radiation protection monitoring, as well as with regard to ESPN monitoring.

Ordinance 2016-128 of 10th February 2016, issued pursuant to authorisation by the Energy Transition for Green Growth Act, reinforces ASN's regulatory and sanction powers and broadens the scope of its competences.

The effect of ASN's reinforced regulation, policing and sanction powers will be to improve the effectiveness of the regulation of nuclear safety and radiation protection. These policing and sanction powers are extended to the activities performed outside BNIs and participating in the technical and organisational measures mentioned in the 2nd paragraph of Article L. 595-2 of the Environment Code, by the licensee, its suppliers, contractors or sub-contractors and in the same conditions as within the facilities themselves.

The sanctions commission set up within ASN will determine the administrative fines in order to comply with the principle of separation between the investigation, charging and sentencing functions instituted in French law and in international conventions with regard to the right to a fair trial. Chapter 4 of this report describes ASN actions in this field.

Emergency situations

ASN takes part in managing radiological emergency situations. It provides technical assistance to the competent Authorities for the drafting of emergency response plans, taking account of the risks resulting from nuclear activities.

When such an emergency situation occurs, ASN verifies the steps taken by the licensee to make the facility safe. It assists the Government with all matters within its field of competence and submits its recommendations on the medical or health measures or civil protection steps to be taken. It informs the general public of the situation, of any releases into the environment and their consequences. It acts as the competent Authority within the framework of international conventions, by notifying international organisations and foreign countries of the accident.

Chapter 5 of this report describes ASN actions in this field.

In the event of an incident or accident concerning a nuclear activity and pursuant to Decree 2007-1572 of 6th November 2007 concerning technical inquiries into accidents or incidents concerning a nuclear activity, ASN may carry out a technical inquiry.

Information

ASN participates in informing the public in its areas of competence. Chapter 6 of this report describes ASN actions in this field.

Research monitoring

The quality of ASN's resolutions and decisions relies primarily on robust technical expertise which, in turn, requires the best and most up-to-date knowledge. In this respect, Ordinance 2016-128 of 10th February 2016 issued pursuant to the Energy Transition for Green Growth Act, comprises measures giving ASN competence to monitor the adaptation of public research to the needs of nuclear safety and radiation protection.

Consequently, ASN is already concerned about the availability of the knowledge required to underpin the expertise it may need to call upon in the medium and long term. ASN is also attentive to the quality of research initiatives, with the prospect of them being integrated by the licensees into their safety cases and impact assessments.

ASN calls on a Scientific Committee to examine its proposed orientations concerning the research work to be conducted or taken further in the fields of nuclear safety and radiation protection. In a resolution dated 8th July 2014, the ASN Commission renewed for a further four years the mandates of the nine members of the Committee, appointed for their expertise in the field of research. Under the Chairmanship of Ashok Thadani, former head of research at the United States Nuclear Regulatory Commission (NRC), the Committee comprises Bernard Boullis, Jean-Claude Lehmann, Michel Schwarz, Patrick Smeesters, Michel Spiro and Victor Teschendorff, as well as Christelle Roy and Catherine Luccioni, appointed in 2015 following the departure of Marie-Pierre Comets. The Scientific Committee met twice in 2015.

On the basis of the work done by the Scientific Committee, ASN issued a first opinion in April 2012 underlining the importance it attaches to research, and identifying the initial research topics to be further investigated in the fields of nuclear safety and radiation protection.

A second opinion was issued in early 2015 on the research topics to be taken further in the following fields:
- waste packaging;
- deep geological disposal;
- transport of radioactive substances;
- severe accidents.

The Fukushima Daiichi nuclear accident also highlighted the need for more research in the field of nuclear safety. A call for projects in the field of nuclear safety was therefore issued by the French National Research Agency (ANR) under the Investing in the Future programme. ASN is a member of the steering committee for this call for projects.

SCIENTIFIC COMMITTEE

From left to right: Jean-Claude Lehmann, Michel Spiro, Christelle Roy, Ashok Thadani, Michel Schwarz, Bernard Boullis, Victor Teschendorff and Catherine Luccioni (not in photo: Patrick Smeesters).

ENERGY TRANSITION FOR GREEN GROWTH ACT

Ordinance 2016-128 of 10th February 2016, issued following authorisation by the Energy Transition for Green Growth Act, enables ASN:

- within BNIs, to exercise certain competencies concerning products and equipment entailing risks (for example equipment for explosive atmosphere), or chemical products;
- in order to back-up its resolutions, to resort to third party assessments, inspections and studies at the expense of the party being assessed or inspected, in a manner comparable to that used for ICPEs;
- to ensure that public research is tailored to the needs of nuclear safety and radiation protection.

2.3.2 Organisation

ASN Commission

The ASN Commission comprises five full-time Commissioners. Their mandate is for a period of six years and may not be renewed. The Commissioners perform their duties in complete impartiality and receive no instructions either from the Government or from any other person or institution. The President of the Republic may terminate the duties of a member of the Commission in the event of a serious breach of his or her obligations.

THE COMMISSION

From left to right: Jean-Jacques Dumont, Philippe Chaumet-Riffaud, Pierre-Franck Chevet, Philippe Jamet and Margot Tirmarche.

The Commission defines ASN strategy. More specifically, it is involved in developing overall policy, i.e. the doctrines and principles that underpin ASN's main missions of regulation, inspection, transparency, management of emergency situations and international relations.

Pursuant to the Environment Code, the Commission submits ASN's opinions to the Government and issues the main ASN resolutions. It decides on the public position to be adopted on the main issues within ASN's sphere of competence. The Commission adopts the ASN internal regulations which lay down its organisation and working rules, as well as its ethical guidelines. The Commission's resolutions and opinions are published in ASN's *Official Bulletin*.

In 2015, the ASN Commission met 77 times. It issued 25 opinions and 61 resolutions.

ASN central services

The ASN central services comprise an Executive Committee, an Office of Administration, a Management and Expertise Office and eight departments covering specific themes.

Under the authority of the ASN Director-General, the Executive Committee organises and manages the departments on a day to day basis. It ensures that the orientations determined by the Commission are followed and that ASN's actions are effective. It oversees and coordinates the various entities.

The role of the departments is the national management of the activities for which they are responsible. They take part in drafting the general regulations and coordinate the actions of the ASN regional divisions.

- The Nuclear Power Plant Department (DCN) is responsible for the regulation and monitoring of the safety of the NPPs in operation, as well as the safety of future power generating reactor projects. It contributes to development of regulation/monitoring strategies and ASN actions on subjects such as facility ageing, reactor service life, assessment of NPP safety performance, and harmonisation of nuclear safety in Europe.
  The DCN comprises six branches: “Hazards and Safety Reviews”, “Equipment and Systems Monitoring”, “Operation”, “Core and Studies”, “Radiation Protection, Environment and Labour Inspectorate” and “Regulation and New Facilities”.

- The Nuclear Pressure Equipment Department (DEP) is responsible for monitoring of safety of pressure equipment installed in BNIs. It monitors the design, manufacture and operation of nuclear pressure equipment and application of the regulations by the manufacturers and their subcontractors and by the nuclear licensees. It also monitors the approved organisations performing the regulation checks on this equipment.
  The DEP comprises four Branches: “Design – Manufacturing”, “In-service Monitoring” and “Relations with Divisions and Operations”.

- The Transport and Radiation Sources Department (DTS) is responsible for monitoring activities relating to sources of ionising radiation in the non-medical sectors and to transport of radioactive substances. It contributes to the development of technical regulations, to monitoring their application and to managing authorisation procedures (installations and equipment emitting ionising radiation in non-medical sectors, suppliers of medical and non-medical sources, accreditation of packaging and of relevant organisations). It is preparing to take charge of regulating radioactive source security.
  The DTS comprises two Branches: "Transport Monitoring" and "Radiation Protection and Sources" as well as a "Source Security" section.

- The Waste, Research Facilities and Fuel Cycle Department (DRC) is responsible for monitoring nuclear fuel cycle facilities, research facilities, nuclear installations being decommissioned, contaminated sites and radioactive waste management. It takes part in monitoring and inspecting the Bure underground research laboratory and the research facilities covered by international conventions, such as CERN or ITER.
  The DRC comprises four Branches: "Cross-discipline topics and Research facilities", "Fuel cycle facilities", "Management of Radioactive Waste" and "Decommissioning and Clean-out".

- The Ionising Radiation and Health Department (DIS) is tasked with regulating medical applications of ionising radiation and – in collaboration with IRSN and the various health authorities – with organising the scientific, health and medical watch with regard to the effects of ionising radiation on health. It contributes to the drafting of the regulations in the field of radiation protection, including with respect to natural ionising radiation, and the updating of health protection measures should a nuclear or radiological event take place.
  The DIS comprises two Branches: "Exposure in the Medical Sector" and "Exposure of Workers and the Public".

- The Environment and Emergency Department (DEU) is responsible for monitoring environmental protection and management of emergency situations. It establishes policy on nationwide radiological monitoring and on the provision of information to the public and helps to ensure that discharges from BNIs are as low as reasonably achievable, in particular by establishing general regulations. The DEU also contributes to defining the organisational framework of public authorities and nuclear operators where management of emergency situations is concerned and establishes ASN regulatory policy.
  The DEU comprises three Branches: "Safety and Emergency Preparedness", "Environment and Prevention of Nuisances" and "Development of Regulations".

- The International Relations Department (DRI) is in charge of ASN's bilateral and multilateral international relations. It develops exchanges with ASN's counterpart organisations in other countries, to gain understanding of their practices, to provide information about and explain the French approach and practices and to provide the countries concerned with useful information on the safety of French nuclear installations close to their borders.
  The DRI coordinates ASN representation within international bodies such as the European Union, IAEA or the OECD's Nuclear Energy Agency (NEA).

THE EXECUTIVE COMMITTEE

From left to right: Alain Delmestre, Jean-Christophe Niel, Jean-Luc Lachaume, Julien Collet and Ambroise Pascal (not in photo: Henri Legrand).

- The Communication and Public Information Department (DCI) is responsible for developing and implementing ASN's policy on communication and information regarding nuclear safety and radiation protection. It coordinates communication and information actions targeting different audiences, with a focus on handling requests for documentation, making ASN's position known and explaining regulations.
  The DCI comprises two Branches: "Public Information" and "Publications and Multimedia".

- The Office of Administration (SG) helps to provide ASN with the adequate, appropriate and long-term resources necessary for it to function. It is responsible for managing human resources, including with regard to skills, and for developing social dialogue. It is also responsible for ASN real estate policy and its logistical and material resources. It is in charge of ASN budget policy and ensures optimised use of its financial resources. Finally, it provides legal expertise for ASN as a whole.
  The SG comprises four Branches: "Human Resources", "Budget and Finance", "Logistics and Real Estate" and "Legal Affairs".

- The Management and Expertise Office (MEA) provides ASN with IT resources and a high level of expertise. It ensures that ASN's actions are coherent, by means of a quality approach and by overseeing coordination of the workforce.
  The MEA comprises three Branches: "Information Technology and Telephony", "Expertise and Research" and "Coordination and Quality".

THE DIRECTORS

From left to right: Luc Chanial, Anne-Cécile Rigail, Alain Rivière, Vivien Tran-Thien, Stéphane Pailler, Bénédicte Genthon, Jean-Luc Godet, Remy Catteau, Fabien Schilz and Alain Delmestre.

THE REGIONAL DIVISION HEADS

From left to right: Bastien Poubeau, Paul Bougon, Pierre Boquel, Sophie Letournel, Pierre Siefridt, Guillaume Bouyt, Jean-Michel Férat, Marie Thomines, François Godin, Laurent Deproit and Marc Champion.

ASN regional divisions

For many years, ASN has benefited from a regional organisation built around its eleven regional divisions. These regional divisions operate under the authority of the regional representatives. The director of the Regional Directorate for the Environment, Planning and Housing (DREAL) or of the Regional and inter-departmental Directorate for the Environment and Energy (DRIEE) in which the regional division in question is located, takes on this responsibility as regional representative. He or she is placed at the disposal of ASN to fulfil this role which is not exercised under the authority of the Prefect. This person is delegated with power of signature by the ASN Chairman for decisions at the local level.

The regional divisions carry out most of the direct inspections on the BNIs, on radioactive substance transport operations and on small-scale nuclear activities, and review most of the authorisation applications filed with ASN by the nuclear activity licensees within their regions. They are organised into two to four hubs, depending on the activities to be regulated in their territory.

In emergency situations, the regional divisions assist the Prefect, who is in charge of protecting the general public, and supervise the operations carried out to safeguard the facility on the site. To ensure preparedness for these situations, they take part in drawing up the emergency plans drafted by the Prefects and in periodic emergency exercises.

The regional divisions contribute to ASN's public information duty. They for example take part in the meetings of the Local Information Committees (CLIs) and maintain regular relations with the local media, elected officials, associations, licensees and local administrations.

ASN's regional divisions are presented in chapter 8 of this report.

2.3.3 Operation

Human resources

As at 31st December 2015, the total ASN workforce stood at 483, divided between the central services (263 staff members), the regional divisions (216 staff members) and various international organisations (4 staff members).

This workforce can be further broken down as follows:
- 388 tenured or contract staff members;
- 95 staff members seconded by public establishments (Andra, *Assistance publique – Hôpitaux de Paris*, CEA, IRSN, Departmental Fire and Emergency Response Service – SDIS).

TO BE NOTED

The State's regional reforms and ASN

Following the adoption by Parliament of the Act constituting the regional reorganisation of the Republic and then the Prime Minister's presentation to the Cabinet of Ministers on 31st July 2015 of the provisional list of the capitals of the new regions and the reorganisation of the local government administrations, ASN analysed the impact of these reforms on its regional organisation.

The ASN Commission and Director General's office, in close liaison with the regional divisions, thus initiated a review to take account of the new locations of the DREAL and the offices of the Prefects and the geographical situation of the new regional capitals.

ASN also asked the General Economic Council (CGE) to support this review process. The report submitted to it by the CGE at the beginning of 2016 will assist ASN in its own review and will help it reach a decision concerning its target organisation for the regions.

ASN maintains a diversified hiring policy in terms of profiles and experience, with the aim of ensuring that it has enough qualified and complementary human resources to perform its duties. In its opinion of 6th May 2014 concerning preparations for the Budget Bill for the period 2015-2017, it considered that 125 positions would need to be created by the end of 2017 in order to address the unprecedented safety challenges with which it is faced. Following budget discussions and decisions, it noted the 30 additional positions (10 per year) which had been granted to it for this same period.

In order to obtain the required experience and level of expertise, ASN sets up training programmes and procedures for integrating new arrivals and handing down specific know-how. It also aims to offer a variety of career paths, commensurate with its needs, based in particular on the experience of its staff.

Skills management

Competence is one of the four key values of ASN. The tutor system, initial and continuing training, whether general, linked to nuclear techniques, the field of communication, or legal matters, as well as day-to-day practices, are essential aspects of the professionalism of ASN staff.

Management of the skills of ASN personnel is based primarily on a technical training programme tailored to each staff member, based on training requirements that include minimum experience conditions.

Pursuant to the provisions of Articles L. 592-22 and L. 592-23 of the Environment Code, which more specifically state that *"ASN shall appoint nuclear safety inspectors […] and radiation protection inspectors […] from among its staff"* and Decree 2007-831 of 11th May 2007 setting the procedures for appointing and qualifying nuclear safety inspectors, which states that the *"nuclear safety inspectors and the staff responsible for checking nuclear pressure equipment […] are chosen for their professional experience and their legal and technical knowledge"*, ASN set up an official process for accrediting certain of its staff members to perform its inspections and, as necessary, carry out judicial policing roles. ASN also carries out labour Inspectorate duties in the nuclear power plants, pursuant to Article R. 8111-11 of the Labour Code. For each of the inspectors it qualifies, the accreditation decision taken by ASN is based on the adequacy of the skills acquired, both within and outside ASN, with those specified in the professional baseline requirements.

Furthermore, and in order to recognise the expertise and experience of its inspectors, ASN has set up a process enabling it to select senior inspectors from among its staff, to whom it can entrust inspections that are more complex or with more significant implications. As at 31st December 2015, 43 ASN nuclear safety and radiation protection inspectors were senior inspectors, or nearly 17% of the 273 ASN staff members holding at least one accreditation.

THE REGIONAL REPRESENTATIVES

From left to right: Thierry Vatin, Christophe Chassande, Alain Vallet, Vincent Motyka and Françoise Noars (not in photo: Annick Bonneville).

In 2015, nearly 3,700 days of training were provided to ASN staff through 204 sessions forming part of 119 different courses. The financial cost of the courses provided by organisations other than ASN, amounted to €430 k.

Social dialogue

ASN comprises various entities enabling it to maintain and develop high-quality social dialogue.

During the course of 2015, the ASN Social Dialogue Committee (SDC) met on four occasions, including one extraordinary session to address the possible impacts for ASN of the State's regional reforms. On other matters, numerous discussions were held with the personnel representatives: hiring and employment of contract staff at ASN, reorganisation or relocation of entities, discussions concerning tele-working, organisation of in-depth inspections, etc.

Complementing the action of the ASN SDC, the Joint Consultative Commission (CCP) – which has competence for contract staff – met three times, including one extraordinary session. Apart from examining how the tenure process defined in the 12th March 2012 Act is applied to ASN contract staff, the discussions primarily concerned hiring and employment at ASN for this personnel category.

Finally, the ASN Committee for Health, Safety and Working Conditions (CHSCT) met four times in 2015, including one extraordinary session in the presence of representatives from all the regional divisions, to discuss the possible impacts for ASN of the State's regional reforms. The discussions with the personnel representatives also covered a variety of subjects: methodology for drafting the ASN occupational risk assessment document (DU or DUER), in particular on the occasion of the launch of the questionnaire sent out to the staff to identify occupational hazards, the conditions for entering controlled-access areas by ASN inspectors, the radiation protection results

CHSCT meeting of 4th December 2015.

for 2014 and the evaluation of the general health, safety and working conditions situation at ASN for 2014.

Professional ethics

Three legislative texts set specific rules of professional ethics applicable to ASN:
- The Environment Code stipulates that as soon as the ASN Commission members are appointed, they shall draw up a declaration indicating the interests they hold or have held in the course of the previous five years in the areas falling under the competence of ASN. This declaration, which is filed at the ASN headquarters and is held at the disposal of the members of the Commission, is updated at the initiative of the Commissioner concerned as soon as any change occurs. No member of the Commission may, during their mandate, hold an interest that could affect their independence or impartiality (Article L. 592-6 of the Environment Code);
- The Act of 29th December 2011 relative to reinforcing the safety of medicines and health products, known as the "Medicines Act", establishes a modernised framework for professional ethics and sanitary expertise with which the Authorities involved in the area of health and sanitary safety must comply. For ASN, these particular ethical rules apply to its activity relative to the safety of health products. The declarations of interests of the persons concerned within ASN, and the members of the ASN Commission in particular, are published on *www.asn.fr.*
- The Act 2013-907 of 11th October 2013 concerning transparency in public life, requires that a declaration of the interests held as at the date of nomination and for the five years preceding this date be sent to the High Authority for Transparency in Public Life (HATVP), along with an exhaustive, accurate and true declaration of individual or common assets, more specifically by the members of independent administrative Authorities. For ASN, the members concerned are the members of the Commission.

Chapter 3 of the ASN's Rules of Procedure sets out the rules applicable to all ASN employees, focusing in particular on:
- observance of professional secrecy and duty of discretion;
- abuse of authority and breaches of the duty of integrity;
- conflicts of interest;
- guarantees of independence with regard to persons or entities subject to ASN oversight.

Financial resources

ASN's financial resources are presented in point 3.

In parallel with its request for additional staff expressed in its opinion of 6th May 2014, ASN considered that with regard to preparations for the Budget Bill for the period 2015-2017, it would need a €21 million budget increase by the end of 2017 in order to address the unprecedented safety challenges with which it is faced.

Following budget discussions and decisions, it duly noted the stability of its operating budget for this same period.

ASN management tools

<u>The Multi-year Strategic Plan</u>

The Multi-year Strategic Plan (PSP), produced under the authority of the ASN Commission, develops ASN's strategic lines for a period of several years. It is presented annually in an operational orientation document that sets the year's priorities for ASN, and which is in turn adapted by each entity into an annual action plan that is subject to periodic monitoring. This three-level approach is an essential part of ASN's development, organisation and management. The PSP for the period 2013-2015, entitled *"Taking up the challenges of nuclear safety and radiation protection: regulation, independence and transparency",* was extended for 2016 and comprises the following five strategic lines:
- enhance the legitimacy of ASN's resolutions and position statements;
- develop an efficient working environment and enhance skills;
- develop ASN's forward-looking, proactive approach;
- make the European hub a driving force for nuclear safety and radiation protection around the world;
- raise and fuel discussions and debates on the topic of nuclear safety and radiation protection.

The PSP is accessible on *www.asn.fr.*

<u>The ASN internal management system</u>

Within ASN, there are many forums for discussion, coordination and oversight.

These bodies, supplemented by the numerous cross-disciplinary structures, reinforce the safety culture of its staff through sharing of experience and the definition of coherent common positions.

Quality management system

To guarantee and improve the quality and effectiveness of its actions, ASN defines and implements a quality management system inspired by the ISO and IAEA international standards. This system is based on:
- an organisation manual containing organisation notes and procedures, defining the rules to be applied for each task;
- internal and external audits to check rigorous application of the system's requirements;
- listening to the stakeholders;
- performance indicators for monitoring the effectiveness of action taken;
- a periodic review of the system, to foster continuous improvement.

Internal communication

In the same way as human resources management, ASN's internal communication aims to foster the sharing of information and experience between teams and activities, by reinforcing the internal culture and reasserting the specific nature of ASN's remit, rallying the staff around the strategic orientations defined for their missions, and developing strong group dynamics.

2.4 The consultative and discussion bodies

2.4.1 The High Committee for Transparency and Information on Nuclear Security

The TSN Act created a High Committee for Transparency and Information on Nuclear Security (HCTISN), an information, discussion and debating body dealing with the risks inherent in nuclear activities and the impact of these activities on human health, the environment and nuclear safety.

The High Committee can issue an opinion on any question in these fields, as well as on controls and the relevant information. It can also deal with any issue concerning the accessibility of nuclear safety information and propose any measures such as to guarantee or improve nuclear transparency. It can be called on by the Government, Parliament, the local information committees or the licensees of nuclear facilities, with regard to all questions relating to information about nuclear safety and its regulation and monitoring.

The HCTISN's activities in 2015 are described in chapter 6.

TO BE NOTED

The French system for the oversight of nuclear safety and radiation protection was assessed by a team of 29 international experts under the supervision of IAEA.

In March 2015, ASN received the report from the IAEA peer review mission hosted from 17th to 28th November 2014. This Integrated Regulatory Review Service (IRRS) mission concerned all the activities regulated by ASN. It examined the strengths and weaknesses of the French nuclear safety and radiation protection oversight system with respect to IAEA standards.

The best practices identified by the IRRS team include:
- the involvement of the stakeholders in the regulatory processes and in the transparency of the decisions taken, as well as wide-ranging communication to promote participation in the regulatory activities and decisions;
- the independence of the ASN Commissioners and personnel in the performance of their regulatory duties;
- the coordination between the oversight organisations involved in emergency planning and the effective interaction with the licensees in this field.

The mission identified a few points worthy of particular attention or improvement, in particular:
- the regulatory framework for monitoring exposure in the medical field should be evaluated to ensure that there are no shortcomings and that the coordination between the organisations involved is appropriate;
- the system used by ASN to assess and modify its regulatory framework should be reinforced;
- all the processes ASN needs in order to perform its role should be specified in its integrated management system and implemented in full;
- new means must be examined in order to guarantee that ASN has the human and financial resources it needs for effective oversight of nuclear safety and radiation protection in the future.

ASN considers that the IRRS missions make a significant contribution to the international safety and radiation protection system. ASN is thus closely involved in hosting missions in France and in participating in missions in other countries. Commissioner Margot Tirmarche thus carried out an IRRS mission in Ireland in 2015.

In 2006, ASN hosted the first IRRS (Integrated Regulatory Review Service) mission concerning all the activities of a safety regulator, with a follow-up mission in 2009.

This audit is the result of the European Nuclear Safety Directive which requires a peer review mission every ten years.

The reports for the 2006, 2009 and 2014 IRRS missions are available for consultation on *www.asn.fr*.

2.4.2 The High Council for Public Health

The High Council for Public Health (HCSP), created by Act 2004-806 of 9th August 2004 concerning public health policy, is a scientific and technical consultative body reporting to the Minister responsible for Health.

The HCSP contributes to defining the multi-year public health objectives, reviews the attainment of national public health objectives and contributes to their annual monitoring. Together with the health agencies, it provides the public authorities with the expertise necessary for managing health risks and for defining and evaluating prevention and health safety policies and strategies. It also anticipates future developments and provides advice on public health issues.

2.4.3 The High Council for Prevention of Technological Risks

Consultation about technological risks takes place before the High Council for Prevention of Technological Risks (CSPRT), created by Order 2010-418 of 27th April 2010. Alongside representatives of the State, the Council comprises licensees, qualified personalities and representatives of environmental associations. The CSPRT, which takes over from the high council for classified facilities, has seen the scope of its remit extended to pipelines transporting gas, hydrocarbons and chemicals, as well as to BNIs.

The Government is required to submit Ministerial Orders concerning BNIs to the CSPRT for its opinion. ASN may also submit resolutions relating to BNIs to it.

2.4.4 The Central Committee for Pressure Equipment

The Central Committee for Pressure Equipment (CCAP), created by Article 26 of Decree 99-1046 of 13th December 1999 concerning Pressure Equipment (PE), is a consultative organisation reporting to the Minister responsible for the Environment.

It comprises members of the various administrations concerned, persons chosen for their particular competence and representatives of the pressure equipment manufacturers and users and of the technical and professional organisations concerned.

The Government and ASN are required to submit all questions concerning the legislative and regulatory aspects of nuclear pressure equipment (Ministerial Orders and certain individual resolutions concerning BNIs) to the CCAP. The accident files concerning this equipment are also copied to it.

2.4.5 Local Information Committees for the Basic Nuclear Installations

The Local Information Committees (CLI) for BNIs are tasked with a general duty of monitoring, information and consultation on the subject of nuclear safety, radiation protection and the impact of nuclear activities on humans and the environment, with respect to the site or sites which concern them. They may request expert assessments or have measurements taken on the installation's discharges into the environment.

The CLIs, whose creation is incumbent upon the President of the General Council of the *département*, comprise various categories of members: representatives of General Councils, of the municipal councils or representative bodies of the groups of communities and the Regional Councils concerned, members of Parliament elected in the *département*, representatives of environmental protection associations, economic interests and representative labour trade union and representative medical profession union organisations, and qualified personalities.

The status of the CLIs was defined by the TSN Act of 13th June 2006 and by Decree 2008-251 of 12th March 2008.

The activities of the CLIs are described in chapter 6.

2.5 Technical support organisations

ASN benefits from the expertise of technical support organisations to prepare its resolutions. This is primarily the case with the Institute for Radiation Protection and Nuclear Safety (IRSN). For several years now, ASN has been devoting efforts to ensuring greater diversification of its experts.

2.5.1 IRSN

IRSN was created by Act 2001-398 of 9th May 2001 and by Decree 2002-254 of 22nd February 2002 as part of the national reorganisation of nuclear safety and radiation protection regulation, in order to bring together public expertise and research resources in these fields. IRSN reports to the Ministers for the Environment, Health, Research, Industry and Defence.

Articles L.592-41 to L.592-43 of the Environment Code specify that IRSN is a State public industrial and commercial institution which carries out expert appraisal and research missions in the field of nuclear safety – excluding any responsibility as nuclear licensee. IRSN contributes to information of the public and publishes the opinions requested by a public authority or ASN, in consultation with them. It organises the publicity of scientific data resulting from the research programmes run at its initiative, with the exception of those relating to defence matters.

For the performance of its missions, ASN receives technical support from IRSN. As the ASN Chairman is now a member of the IRSN Board, ASN contributes to setting the direction of IRSN's strategic planning.

IRSN conducts and implements research programmes in order to build its public expertise capacity on the very latest national and international scientific knowledge in the fields of nuclear and radiological risks. It is tasked with providing technical support for the public authorities with competence for safety, radiation protection and security, in both the civilian and defence sectors.

IRSN also has certain public service responsibilities, in particular monitoring of the environment and of populations exposed to ionising radiation.

IRSN manages national databases (national nuclear material accounting, national inventory of radioactive sources, file for monitoring worker exposure to ionising radiation, etc.), and thus contributes to information of the public concerning the risks linked to ionising radiation.

IRSN workforce

As at 31st December 2015, IRSN's overall workforce stood at 1,700 employees, of which 400 are devoted to ASN technical support.

IRSN budget

The IRSN budget is presented in point 3.

A five-year agreement defines the principles and procedures for the technical support provided to ASN by the Institute. This agreement is clarified on a yearly basis by a protocol identifying the actions to be performed by IRSN to support ASN.

ENERGY TRANSITION FOR GREEN GROWTH ACT

This Act clarifies the organisation of the system built around ASN and IRSN:
- It enshrines the existence and duties of IRSN within a new section 6 of the Environment Code entitled "The Institute for Radiation Protection and Nuclear Safety" in Chapter II concerning "The Nuclear Safety Authority (ASN)" of Title IX of Book V of the Environment Code.
- It recalls that ASN benefits from IRSN technical support, indicating that this support comprises expert appraisal activities "supported by research".
- It clarifies the relations between ASN and IRSN, indicating that ASN *"guides IRSN's strategic decisions concerning this technical support"* and that the ASN Chairman is a member of the Board of the Institute.
- Finally, it also makes provision for the principle of the publication of IRSN opinions.

2.5.2 Advisory Committees of Experts

To prepare its resolutions, ASN relies on the opinions and recommendations of seven Advisory Committees of Experts (GPE), with competence for waste, nuclear pressure equipment, reactors, transport and laboratories and factories, medical radiation protection, radiation protection in non-medical sectors and the environment, respectively.

At the request of ASN, the GPE issue opinions on certain technical dossiers with significant consequences. They can also be consulted about changes in regulations or doctrine.

For each of the subjects covered, the GPEs examine the reports produced by IRSN, by a special working group or by one of the ASN departments. They issue an opinion backed up by recommendations.

The GPEs comprise experts nominated for their individual competence. They are open to civil society, to people from university and association backgrounds and from appraisal and research organisations. They can also be licensees of nuclear facilities or come from other sectors (industrial, medical, etc.). Participation by foreign experts can help diversify the approach to problems and provide the benefit of experience acquired internationally.

The desire to prevent any conflict of interest also led to Advisory Committee members being required to submit a declaration of interest and to the reinforcement of the internal operating rules of the Advisory Committees to ensure that experts with a direct interest in the subject being addressed do not take part in establishing the position of the Advisory Committee.

Since 2009, as part of its commitment to transparency in nuclear safety and radiation protection, ASN has published the GPE letters of referral, the opinions of the GPEs and ASN's position statements based on these opinions. IRSN for its part publishes the syntheses of the technical investigation reports it presents to the GPEs.

Advisory Committee for Waste (GPD)

The Advisory Committee for Waste (GPD) is chaired by Pierre Bérest and comprises 36 experts appointed for their competence in the nuclear, geological and mining fields.

In 2015, two plenary meetings were held, jointly with the Advisory Committee for Laboratories and Plants (GPU), along with one three-day bipartite meeting with German experts in Wolfenbüttel, during which a visit was made to the Asse II underground mine intended for the disposal of Low and Intermediate Level radioactive waste.

Advisory Committee for Nuclear Pressure Equipment (GPESPN)

Since 2009, the GPESPN has replaced the Standing Nuclear Section (SPN) of the CCAP. The GPESPN is chaired by Philippe Merle and comprises 28 experts appointed for their competence in the field of pressure equipment.

It held three plenary meetings in 2015.

Advisory Committee for Radiation Protection in Medical and Forensic Applications of Ionising Radiation (GPMED)

Chaired by Bernard Aubert, the GPMED comprises 30 experts appointed for their competence in the field of radiation protection of health professionals, the general public and patients and for medical and forensic applications of ionising radiation.

It held three meetings in 2015.

Advisory Committee for Radiation Protection for Industrial and Research Applications of Ionising Radiation and in the Environment (GPRADE)

Chaired by Jean-Paul Samain, the GPRADE comprises 27 experts appointed for their competence in the fields of radiation protection of workers (other than health professionals) and the public, for industrial and research applications using ionising radiation and for exposure to ionising radiation of natural origin, and protection of the environment.

In 2015, it held three meetings and a seminar.

Advisory Committee for Nuclear Reactors (GPR)

The Advisory Committee for Nuclear Reactors is chaired by Philippe Saint Raymond and comprises 34 experts appointed for their competence in the field of nuclear reactors.

In 2015, it held six plenary meetings, one of which lasted two days, two information meetings and visited a simulator at EDF.

Advisory Committee for Transport (GPT)

Since the death of its Chairman, Jacques Aguilar, and of one of its members, Alain Roulet, in 2015, the GPT comprises 25 experts appointed for their competence in the field of transport. The acting Chairman is held by the GPT Vice-Chairman, Jérôme Joly.

It held one information meeting in 2015.

Advisory Committee for Laboratories and Plants (GPU)

The Advisory Committee for Laboratories and Plants is chaired by Jérôme Joly and comprises 32 experts appointed for their competence in the field of laboratories and plants concerned by radioactive substances.

In 2015, it held three plenary meetings, two of which were organised jointly with the GPD.

2.5.3 The ASN's other technical support organisations

To diversify its expertise and benefit from other particular skills, ASN committed credits of €0.3 million in 2015.

In 2013, it also set up a framework agreement with expert appraisal organisations to ensure more dynamic use of a diversified panel of expertise.

In 2015, ASN continued or initiated collaboration with:
- CNAM-ErgoManagement: detailed examination of the steps taken by EDF to manage subcontracted engineering and design activities.
- the Ernst & Young et Associés company: environmental assessment of the 2016-2018 National Radioactive Materials and Waste Management Plan (PNGMDR) pursuant to the provisions of Article L. 122-4 of the Environment Code;
- the French National Institute for the Study of Industrial Environments and Risks (Ineris): assessment of the risk of thermal runaway by the contents of the SORG packaging.

2.6 The pluralistic working groups

ASN has set up several pluralistic working groups; they enable the stakeholders to take part in the development of doctrines, the definition of action plans or the monitoring of their implementation.

2.6.1 The pluralistic working group on the National Radioactive Materials and Waste Management Plan

Article L.542-1-2 of the Environment Code requires the production of a National Radioactive Materials and Waste Management Plan (PNGMDR), which is revised every three years and serves to review the existing management procedures for radioactive materials and waste, to identify the foreseeable needs for storage and disposal facilities, specify the necessary capacity of these facilities and the storage durations and, for radioactive waste for which there is as yet no final management solution, to determine the objectives to be met.

The Working Group (WG) tasked with producing the PNGMDR comprises environmental protection associations, experts, representatives from industry and regulatory authorities, alongside the radioactive waste producers and managers. It is co-chaired by the DGEC (General Directorate for Energy and the Climate) of the Ministry for the Environment, Energy and the Sea and by ASN.

The work of the PNGMDR WG is presented in greater detail in chapter 16.

2.6.2 The Steering Committee for Managing the Nuclear Post-Accident Phase

Pursuant to the Interministerial Directive of 7th April 2005, ASN, in association with the Ministerial departments concerned, is responsible for defining, preparing and implementing the steps necessary for managing a post-accident situation.

In order to develop a doctrine and after testing post-accident management during national and international exercises, ASN brought all the players concerned together within the Codirpa (Steering Committee responsible for Post-Accident Management). This committee, headed by ASN, has representatives from the ministerial departments concerned, the health agencies, associations, the CLI, and IRSN.

The work of the Codirpa is presented in greater detail in chapter 5.

2.6.3 The Steering Committee for Social, Organisational and Human Factors

ASN considers that there is a need to move forward with regard to the reflections and work being done on the human contribution and organisations to the safety of nuclear facilities and in 2012 it therefore decided to set up the Steering Committee for Social, Organisational and Human Factors (COFSOH) (see box below). The purpose of the COFSOH is on the one hand to allow exchanges between stakeholders on such a difficult subject as social, organisational and human factors and, on the other, to draft documents proposing common positions by the various members of the COFSOH on a given subject, along with guidelines for future studies to shed light on subjects that are insufficiently understood or which are lacking in clarity.

2.6.4 The other pluralistic groups

In 2015, the national committee responsible for monitoring the national plan for management of radon risks, chaired by ASN, carried out an assessment of the 2011-2015 national action plan and prepared the third plan for the period 2016-2019 (see chapter 1).

UNDERSTAND

ASN has set up a Steering Committee for Social, Organisational and Human Factors

Social, organisational and human factors received particular attention during the stress tests further to the Fukushima Daiichi accident. On completion of the various investigations, ASN indicated in January 2012 that it had identified three priorities in this area:
- renewal of the licensees' workforce and skills;
- -organisation of the use of subcontracting;
- research on these topics, for which programmes must be set up, at national or European levels.

Further to the stress tests, ASN has set up a pluralistic working group on these subjects, called the COFSOH (Steering Committee for Social, Organisational and Human Factors). In addition to ASN members, this Committee includes representatives of institutions and environmental protection associations, personalities chosen for their scientific, technical, economic, social, or information and communication expertise, persons in charge of nuclear activities, representatives of nuclear industry professional federations and representative employees' unions.

Nine plenary meetings of this Committee have been held since 2012. They allowed discussion of the following topics: subcontracting conditions and the relationship between client and subcontractors, the interaction between "managed safety" and "regulated safety", skills management at a time of workforce turnover and assessment of organisations or the use of pertinent OHF indicators to assess safety.

Since the beginning of 2013 and in parallel with the plenary meetings, the work of the COFSOH has been continuing through four working groups. The forty meetings held to date have addressed the following subjects:
- subcontracting in normal operating situations:
- management of emergency situations;
- interaction between managed safety and regulated safety;
- legal questions raised in connection with the subjects addressed in the other three working groups.

2.7 Other stakeholders

As part of its mission to protect the general public from the health risks of ionising radiation, ASN cooperates closely with other competent institutional stakeholders addressing health issues.

2.7.1 The National Agency for the Safety of Medication and Health Products

The National Agency for the Safety of Medication and Health Products (ANSM) was created on 1st May 2012. The ANSM, a public body reporting to the Ministry of Health, has taken up the duties of the AFSSAPS alongside other new responsibilities. Its key role is to offer patients equitable access to innovation and to guarantee the safety of health products throughout their life cycle, from initial testing through to monitoring after receiving marketing authorisation.

The Agency and its activities are presented on its website: *www.ansm.sante.fr.* The ASN-ANSM convention was renewed on 2nd September 2013.

2.7.2 French National Authority for Health

The French National Authority for Health (HAS), an independent administrative authority created by the French Government in 2004, is tasked primarily with maintaining an equitable health system and with improving patient care.

The Authority and its activities are presented on its website *www.has-sante.fr.* An ASN-HAS convention was signed on 4th December 2008.

2.7.3 French National Cancer Institute

Created in 2004, the French National Cancer Institute (INCa) is primarily responsible for coordinating activities in the fight against cancer.

TABLE 1: Advisory Committee meetings and visits in 2015

GPE	MAIN TOPIC	DATE
GPR	Informing EDF about the in-depth analysis of the event	8th January
GPMED	Conditions for Implementation of “New Techniques and Practices” in Radiotherapy	10th February
GPR	Management of activities subcontracted by EDF in PWRs in operation	11th February
GPRADE	Protection of non-human species and information about the work of the “Worker radiological surveillance” WG	13th February
GPR	Progress of the Flamanville 3 worksite and preparation for assessment of the commissioning authorisation application	5th March
GPU	Periodic safety review of the UP3 A plant (BNI 116) at La Hague operated by Areva NC (4th session: update of safety analyses)	18th March
GPR	Safety review guidelines associated with the fourth ten-yearly inspections of the 900 MWe reactors (VD4 900)	1st and 2nd April
GPT	New regulation cycle	23rd April
GPMED	Changes to Diagnostic Reference Levels	26th May
GPR	Visit to an EDF simulator at the CNEN in preparation for the GP of 18th June	3rd June
GPRADE	"Leukaemia risks and exposure to ionising radiation" seminar	9th June
GPESPN	Orientations chosen by EDF for updating of the regulation reference files for the fourth ten-yearly inspections of the 900 MWe reactors and continued operation up to VD4 + 20 years	10th June
GPR	Optimisation of radiation protection in EDF nuclear power plants	11th June
GPR	EPR project – Flamanville 3 – Review of organisational, human and technical resources for operation of the EPR reactor	18th June
GPU/GPD	Update of the EDF decommissioning strategy – 2013	30th June
GPU/GPD	EDF Waste management strategy	1st July
GPMED	Alpha therapy and imaging action plan	15th September
GPD	Meeting between the GPD and its German counterpart in Germany	14th and 16th September
GPESPN	In-service strength of 1,300 MWe reactors during the ten-year period following VD3	24th September
GPRADE	New internal regulations, protection of non-human species and transposition of Directive 2013/59/Euratom	25th September
GPR	Information meeting on the seismic hazard assessment made for the PWR "hardened safety core"	29th September
GPESPN	Analysis of the approach proposed by Areva to demonstrate the adequate toughness of the Flamanville 3 EPR vessel bottom head and vessel closure head domes.	30th September
GPR	EPR: examination of level 2 probabilistic safety assessments (PSA 2) and severe accidents (AG) for the Flamanville 3 reactor	15th October
GPRADE	Approval of the new internal regulations, discharge of radionuclides into the sewer networks, update of the Labour Code and information	26th November

The Institute and its activities are presented on its website: *www.e-cancer.fr.* An ASN-INCa convention was signed on 17th February 2014.

2.7.4 The French Health Monitoring Institute

The French Health Monitoring Institute (InVS), a public institute created in 1998, is tasked primarily with watching over all areas of public health and raising the alert where necessary.

The Institute and its activities are presented on its website: *www.invs.sante.fr.* An ASN-InVS convention was renewed on 24th January 2014.

3. FINANCING THE REGULATION OF NUCLEAR SAFETY AND RADIATION PROTECTION

Since 2000, all the personnel and operating resources involved in the performance of the responsibilities entrusted to ASN have been covered by the State's general budget.

In 2015, the ASN budget amounted to €80.11 million in payment credits. It comprised €40.85 million in ASN payroll credits and €39.26 million in operating credits for the ASN central services and its eleven regional divisions.

The total IRSN budget for 2015 amounted for its part to €220 million, of which €85 million were devoted to the provision of technical support for ASN. IRSN credits for ASN technical support are covered in part (€43 million) by a subsidy from the State's general budget allocated to IRSN and included in action 11 "Research in the field of risks" of programme 190 "Research in the fields of energy and sustainable development and spatial planning", of the interministerial "Research and higher education" mission. The rest (€42 million) is covered by a contribution from the nuclear licensees. This contribution was put into place by the budget amendment Act of 29th December 2010. Each year, ASN is consulted by the Government concerning the corresponding part of the State subsidy to IRSN and the amount of the annual contribution due from the BNI licensees.

In total, the State's 2015 budget for transparency and the regulation of nuclear safety and radiation protection in France amounted to €175.86 million: €80.11 million for the ASN budget, €85 million for IRSN technical support to ASN, €10.6 million for other IRSN missions and €0.15 million for the working of the HCTISN (French High Committee for Transparency and Information on Nuclear Security).

As shown in the table 3, these credits are split between five programmes (181, 217, 333, 218 and 190) to which must be added the annual contribution on behalf of IRSN.

To put this into perspective, the amount of the BNI Tax, paid to the general State budget, amounted in 2015 to €576.96 million.

This complex funding structure is detrimental to the overall clarity of the cost of regulation. It moreover leads to difficulties in terms of budgetary preparation, arbitration and implementation.

TABLE 2: Breakdown of licensee contributions

LICENSEE	AMOUNT FOR 2015 (MILLIONS OF EUROS)			
	INB TAXE	ADDITIONAL WASTE AND DISPOSAL TAXES	SPECIAL ANDRA CONTRIBUTION	CONTRIBUTION ON BEHALF OF IRSN
EDF	543.63	123.30	79.38	48.42
Areva Group	16.40	7.91	5.12	5.69
CEA	6.79	24.62	17.27	7.28
Andra	5.41	3.30	-	0.40
Others	4.73	2.06	-	0.73
TOTAL	**576.96**	**157.89**	**101.77**	**62.52**

TABLE 3: Budget structure of the credits allocated to transparency and the regulation of nuclear safety and radiation protection in France (January 2016)

				BUDGET RESOURCES				REVENUE
MISSION	PROGRAMME	ACTIONS	NATURE	INITIAL BUDGET ACT 2014		INITIAL BUDGET ACT 2015		BNI TAX 2015 (€M)
				AE (M€)	CP (M€)	AE (M€)	CP (M€)	
Ministerial mission **Ecology, sustainable development and spatial planning**	**Programme 181:** Risk Prevention	**Action 9:** Regulation of nuclear safety and radiation protection	Staff costs (including seconded employees	40.85	40.85	41.93	41.93	576.96
			Operating and intervention spending	13.32	18.34	12.93	17.94	
			TOTAL	**54.17**	**59.19**	**54.86**	**59.87**	
		Action 1: Prevention of technological risks and pollution	Operation of the HCTISN (High Committee for Transparency and Information on Nuclear Security)	0.15	0.15	0.15	0.15	
	Programme 217: Management and coordination of policies for ecology, energy and sustainable development and the sea	-	Operation of ASN's 11 regional divisions	13.35 (1)	13.35 (1)	13.35 (1)	13.35 (1)	
Ministerial mission **Oversight of government actions**	**Programme 333:** Resources shared by decentralised administrations	-		1.15	1.15	1.15	1.15	
Interministerial mission **Management of public finances and human resources**	**Programme 218:** Implementation and oversight of economic and financial policy	-	Operation of the ASN central services (2)	6.27	6.27	6.27	6.27	
			SUB-TOTAL	75.09	80.11	75.78	80.79	
Interministerial mission **Research and higher education**	**Programme 190:** Research in the fields of energy and sustainable development and spatial plannings	**Sub-action 11-2 (area 3):** French Institute for Radiation Protection and Nuclear Safety (IRSN)	IRSN technical support activities for ASN (3)	43.00	43.00	42.00	42.00	
		Sub-action 11-2 (3 others area): French Institute for Radiation Protection and Nuclear Safety (IRSN)		135.41	135.41	132.50	132.50	
Annual contribution to IRSN instituted by Article 96 of budget amendment Act 2010-1658 of 29th December 2010				41.95 (4)	41.95 (4)	42.95 (5)	42.95 (5)	
			SUB-TOTAL	220.36	220.36	217.45	217.45	576.96
			GRAND TOTAL	**295.45**	**300.47**	**293.23**	**298.24**	**576.96**

(1) Source: Budget Bills for 2013 and 2014 (annual performance project 2014 of programme 181).
(2) Source: 2006 Budget Bill (after deduction of transfer made under 2008 Budget Bill).
(3) Source: Budget Bills for 2015 and 2016 (annual performance project 2015 of programme 190).
(4) Out of a total contribution income of €53.10 million in 2014.
(5) Out of a total expected contribution income estimated at €59.90 million in 2015.

UNDERSTAND

BNI Tax, additional waste taxes, additional disposal tax, special Andra contribution and contribution to IRSN

Pursuant to the Environment Code, the ASN Chairman is responsible for assessing and ordering payment of the BNI tax, introduced under Article 43 of the 2000 Budget Act (Act 99-1172 of 30th December 1999). The revenue generated by this tax, the amount of which is set yearly by Parliament, came to € 576.96 million in 2015. The proceeds go to the central state budget.

Furthermore, for nuclear reactors and spent nuclear fuel reprocessing plants, the "Waste" Act creates three additional "research", "support" and "technological dissemination" taxes. The revenue from these taxes is allocated to funding economic development measures and research into underground disposal and storage by the National Agency for Radioactive Waste Management (Andra). The revenue from these taxes represented €157.89 million in 2015, of which €3.3 million were paid in 2015 to the municipalities and the local public cooperation bodies situated around the disposal centre.

In addition, since 2014, ASN has been tasked with assessing and ordering payment of the special contribution on behalf of Andra created by Article 58 of the 2013 budget amendment Act 2013-1279 of 29th December 2013, which will be payable up until the date of the deep geological disposal facility's creation authorisation. In the same way as the additional taxes, this contribution is due by BNI licensees, as of the creation of their facility and up until the delicensing decision. The revenue from this contribution represented €101.77 million in 2015.

Finally, Article 96 of Act 2010-1658 of 29th December 2010 creates an annual contribution on behalf of IRSN to be paid by BNI licensees. This contribution is in particular designed to finance the review of the safety cases submitted by the BNI licensees. The revenue from this contribution amounted to €62.52 million in 2015.

4. OUTLOOK

France is engaged in an ambitious energy transition policy defined by Act 2015-992 of 17 August 2015 concerning Energy Transition for Green Growth. This Act represents a milestone in the competence of ASN, by reinforcing its powers of regulation and sanction while at the same time developing transparency and public information and participation.

These new measures will be implemented in full in 2016.

Even if the Act stipulates that the share of nuclear energy in the production of electricity is to be halved by 2025, it will nonetheless remain considerable. The French nuclear NPP fleet will thus continue to be one of the largest in the world. Safety will continue to be enhanced, with reference to the requirements applicable to the new reactors and by learning the lessons from the Fukushima Daiichi accident.

In the light of the unprecedented safety challenges it faces, ASN recalls that in 2014 it asked for an additional 190 staff by the end of 2017 (125 for ASN, 65 for IRSN) and a budget increase of €36 million (€21 million for ASN, €15 million for IRSN). Even though the budget decisions made accorded it an additional 30 staff for the period 2015-2017 and maintained its operating credits, ASN nonetheless remains concerned by the inadequacy of these budgetary measures.

In the coming years, ASN will maintain strong ties – while retaining its full independence – with the other stakeholders involved in the oversight and information duties, in the field of nuclear safety and radiation protection. ASN will in particular promote the involvement of the stakeholders in pluralistic working groups, in particular the COFSOH.

When preparing its resolutions, ASN relies on the opinions and recommendations of seven Advisory Committees of Experts (GPE). ASN aims to continue to reinforce the guarantees of independence of the expertise on which it relies, and transparency in the process of drafting its resolutions and decisions.

Moreover, following the IRRS mission in November 2014, ASN will in 2016 continue with implementation of a specific action plan designed to address the recommendations made.

03

Regulations

Nuclear activities are highly diverse, covering any activity relating to the preparation or utilisation of radioactive substances or ionising radiation. Nuclear activities are covered by a legal framework that aims to guarantee that, depending on the nature of the activity and the associated risks, it will not be likely to be detrimental to safety, public health or the protection of nature and the environment.

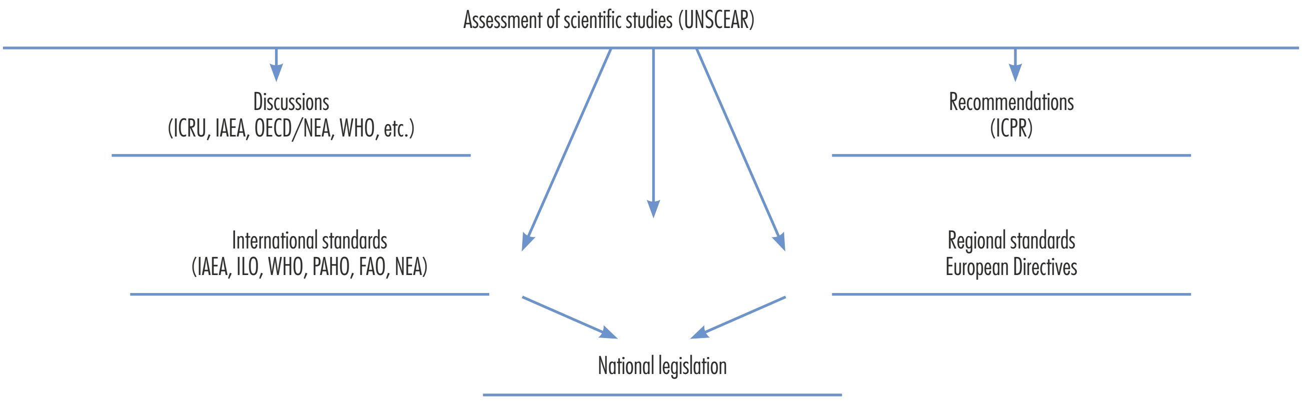
These activities are subject to the general provisions of the Public Health Code and, depending on their nature and the risks that they involve, to a specific legal system:
- the system for Installations Classified on Environmental Protection grounds (ICPE) for those activities covered by the list in Article L. 511-2 of the Environment Code (industrial activities using unsealed radioactive sources, depot, storage or disposal facilities for solid ore residues, etc.);
- the Basic Nuclear Installations (BNI) system specified in Article L. 593-1 of the Environment Code;
- the Secret Basic Nuclear Installations (SBNI) system, which is subject to the Defence Code;
- the small-scale nuclear activities system for the other activities (medical or industrial activities using ionising radiation or radioactive sources).

The transposition into French law of European Council Directive 2013/59/Euratom of 5th December 2013 setting basic standards for health protection against the hazards arising from exposure to ionising radiation, will renovate the general legal framework for nuclear activities by 2018.

1. THE GENERAL LEGAL FRAMEWORK APPLICABLE TO NUCLEAR ACTIVITIES

Nuclear activities are defined in Article L. 1333-1 of the CSP (Public Health Code). They are subject to various specific requirements aiming to protect individuals and the environment and apply either to all these activities, or only to certain categories. This set of regulations is described in this chapter.

DIAGRAM 1: Drafting of radiation protection doctrine and basic standards



1.1 The regulatory basis of nuclear activities

1.1.1 Radiation protection international baseline requirements

The specific legal requirements for radiation protection are based on various standards and recommendations issued internationally by various organisations. The following in particular can be mentioned:

- The International Commission on Radiation Protection (ICRP), a non-governmental organisation comprising international experts in various disciplines, publishes recommendations concerning the protection of workers, the general public and patients against ionising radiation, based on an analysis of the available scientific and technical knowledge, in particular that published by UNSCEAR. The latest ICRP recommendations were published in 2007 in ICRP Publication 103.
- The International Atomic Energy Agency (IAEA) regularly publishes and revises standards in the fields of nuclear safety and radiation protection. The basic requirements concerning protection against ionising radiation and the safety of radiation sources, based on the latest ICRP recommendations (Publication 103), were published in July 2014.
- The International Standard Organisation (ISO) publishes international technical standards constituting a major component of the radiation protection system. They form the interconnection between the principles, concepts, units of measurement and body of regulations for which they guarantee harmonised application.

At the European level, the EURATOM Treaty, in particular its Articles 30 to 33, defines the procedures for drafting EU provisions concerning protection against ionising radiation and specifies the powers and obligations of the European Commission with respect to their enforcement. The corresponding Euratom Directives are binding on the various countries, such as the new European Council Directive 2013/59/Euratom of 5th December 2013 setting basic standards for health protection against the hazards arising from exposure to ionising radiation. This Directive, published in the *Official Journal of the European Union* (JOUE) on 17th January 2014, repeals Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom and 2003/122/Euratom.

1.1.2 The Codes and the main Acts applicable to the regulation of nuclear activities in France

The legal framework for nuclear activities in France, which has been extensively modified since 2000, will once again be updated with the ongoing transposition of Directive 2013/59 Euratom: Ordinance 2016-128 of 10th February 2016 more specifically enabled the legislative provisions of Chapter III of Title III of Book III of the first part of the Public Health Code concerning radiation protection to be rewritten, while retaining the existing fundamental principles and requirements. The Articles of the Public Health Code mentioned in this chapter are those resulting from Ordinance 2016-128 of 10th February 2016.

TO BE NOTED

The new 2013/59/Euratom Directive of 5th December 2013

It supersedes the previous five Directives:

- Directive 89/618/Euratom of 27th November 1989 on informing the general public about health protection measures to be applied and steps to be taken in the event of a radiological emergency;
- Directive 90/641/Euratom of 4th December 1990 on the operational protection of outside workers exposed to the risk of ionising radiation during their activities in controlled areas;
- Directive 96/29/Euratom of 13th May 1996 laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionising radiation;
- Directive 97/43/Euratom of 30th June 1997 on health protection of individuals against the dangers of ionising radiation in relation to medical exposure, repealing Directive 84/466/Euratom;
- and Directive 2003/122/Euratom of 22nd December 2003 on the control of high-activity sealed radioactive sources and orphan sources.

It also takes account of the latest recommendations from the International Commission on Radiological Protection (ICRP 103) and the basic standards published by IAEA. The Member States have a period of four years in which to transpose this Directive (the transposition deadline is set for 6th February 2018). In November 2013, with the approval of the Government, ASN set up a transposition committee for this new Directive for which it now handles coordination and technical secretariat duties. The committee's first working priority was the legislative changes to be made, in particular to the Public Health Code. These changes were introduced through the Ordinance of 10th February 2016 as provided for in Article 128 of the Energy Transition for Green Growth Act 2015-992 of 17th August 2015.

Over and above these legislative subjects, ASN takes part in all the regulatory work initiated in 2014 to update the Public Health Code, the Labour Code and the Environment Code.

The Public Health Code

The provisions of Chapter III of Ordinance 2016-128 of 10th February 2016, concerning nuclear activities covered by the Public Health Code, enter into force at a date set by decree of the Council of State, and no later than 1st July 2017.

DIAGRAM 2: Various levels of regulation in the field of small-scale nuclear activities in France

ICRP, IAEA, HERCA	Orientation, Recommendations	**Not legally binding**
European Commission	Directives	
Parliament	Acts	
Government	Decrees and Orders	**Legally binding**
ASN/ Government approval	Technical Statutory Resolutions	
ASN	Individual Resolutions (Technical requirements)	
ASN	ASN Guides/BSR*	**Not legally binding**

** Basic Safety Rules.*

Article L. 1333-1 of the Public Health Code defines nuclear activities as *"activities comprising a risk of human exposure to ionising radiation related to the use either of an artificial source, whether substances or devices, or of a natural source, whether natural radioactive substances or materials containing natural radionuclides. They also include the steps taken to protect individuals from a risk following radioactive contamination of the environment or products from contaminated areas or manufactured from contaminated materials"*.

Article L.1333-2 of the Public Health Code defines the general principles of radiation protection (justification, optimisation and limitation), established internationally (ICRP) and incorporated into the IAEA requirements and into Directive 2013/59/Euratom. These principles, described in point 2 below, constitute guidelines for the regulatory actions for which ASN is responsible.

The scope of application of Chapter III of Title III of Book III of the first part of the Public Health Code includes the measures necessary to prevent or mitigate the risks in various radiological exposure situations: In addition to steps taken to protect individuals from a risk following radioactive contamination of the environment or from products from contaminated areas or manufactured from contaminated materials, the steps taken in a radiological emergency situation or in the event of exposure to a natural source of ionising radiation, radon in particular, are also concerned. All of these steps must now meet the justification and optimisation principles.

The administrative regime described in this chapter will change with the introduction of a simplified intermediate authorisation procedure, called the registration procedure, in addition to the existing notification and authorisation procedures. These changes will allow a graduated approach to risks to be adopted. A specific Article (L. 1333-7) defining the protected interests has been added. These interests are *"the protection of public health, salubrity and safety, as well as of the environment, against the risks or detrimental effects resulting from ionising radiation. The risks to be considered are not only those linked to the performance of the nuclear activity, but now also those linked to malicious acts, from creation of the activity to the phase following its cessation."*

The Public Health Code also institutes the radiation protection inspectorate, in charge of verifying compliance with its radiation protection requirements. This inspectorate, set up and coordinated by ASN, is presented in chapter 4. The Code also defines a system of administrative and criminal sanctions, described in the same chapter. Through the Ordinance of 10th February 2016, the Code was reinforced with the creation of a complete system of monitoring, policing and administrative and criminal sanctions, carried out primarily by ASN and the radiation protection inspectors, with reference to that mentioned in Chapter I of Title VII of Book I of the Environment Code.

Environment Code

The Environment Code defines various notions. According to Article L.591-1 of the Environment Code, nuclear security is a concept comprising *"nuclear safety, radiation protection, the prevention and fight against malicious acts, and also civil protection actions in the event of an accident"*. In some texts, however, the expression "nuclear security" remains limited to the prevention and mitigation of malicious acts.

Nuclear safety is *"the set of technical provisions and organisational measures - related to the design, construction, operation, shutdown and decommissioning of Basic Nuclear Installations (BNIs), as well as the transport of radioactive* *substances - which are adopted with a view to preventing accidents or limiting their effects"*[1].

Radiation protection is defined as *"the set of rules, procedures and prevention and surveillance means aimed at preventing or mitigating the direct or indirect harmful effects of ionising radiation on individuals, including in situations of environmental contamination"*. Article L. 593-42 of the Environment Code, created by Ordinance 2016-128 comprising various nuclear provisions, specifies that *"the general rules, prescriptions and measures taken in application of this Chapter and of Chapters V and VI for the protection of public health, when they concern occupational radiation protection, concern the collective protection measures which are the responsibility of the licensee and designed to ensure compliance with the principles of radiation protection defined in Article L. 1333-2 of the Public Health Code. They apply to the design, operation and decommissioning phases of the installation and are without prejudice to the obligations incumbent on the employer in application of Articles L. 4121-1 et seq. of the Labour Code"*

Nuclear transparency is defined as *"the set of provisions adopted to ensure the public's right to reliable and accessible information on nuclear security as defined in Article L. 591-1"*.

Article L. 591-2 of the Environment Code, stipulates the State's role in nuclear security: it *"defines the nuclear security regulations and implements the checks necessary for their application"*. The Ordinance of 10th February 2016 supplements this Article, stipulating that the State *"ensures that the regulations concerning nuclear safety and radiation protection and their oversight are assessed and improved, taking into account, where applicable, experience acquired in operation, lessons learned from the nuclear safety analyses carried out for the nuclear installations in operation, technological developments and the results of research on nuclear safety if they are available and relevant."* In accordance with Article L. 125-13 of the Environment Code, *"the State ensures that the public is informed of risks linked to nuclear activities defined in the first paragraph of Article L. 1333-1 of the Public Health Code and of their impact on individual health and safety as well as on the environment"*. The general principles applicable to nuclear activities are mentioned in turn in Articles L. 591-3 and L. 591-4 of the Environment Code. These principles are presented in point 1.1 of chapter 2.

Chapter II of Title IX of Book V of the Environment Code creates ASN, defines its general duties and attributions, and specifies its composition and operation. Its missions are presented in points 2.3.1 and 2.3.2 of chapter 2.

Chapter V of Title II of Book I of the Environment Code addresses information of the public about nuclear security. This subject is developed in greater detail in chapter 6.

Other codes or acts containing requirements specific to nuclear activities

The Labour Code defines specific requirements for the protection of workers, whether or not salaried, exposed to ionising radiation. They are presented in point 1.2.1 of this chapter.

Chapter II of Title IV of Book V of the Environment Code, which codifies Planning Act 2006-739 of 28th June 2006 concerning sustainable management of radioactive materials and waste, sets the framework for the management of radioactive materials and waste. It obliges the BNI licensees to make provision for the cost of managing their waste and spent fuel, and for decommissioning their facilities. Chapter 16 describes the main contributions of this act in detail.

Finally, the Defence Code contains various measures concerning protection against malicious acts in the nuclear field, or the regulation of defence-related nuclear activities and installations. They are presented in point 5.3 of this chapter.

The other regulations concerning nuclear activities

Some nuclear activities are subject to a variety of rules with the same goal of protecting individuals and the environment as the above-mentioned regulations, but with a scope that is not limited to the nuclear field alone. This for example includes international conventions (e.g. Aarhus Convention), European or Environment Code provisions concerning impact assessments, public information and consultation, and the regulations governing hazardous materials transport or pressure equipment. The applicability of some of these rules to nuclear activities is mentioned in the applicable chapters of this report.

Signed on 25th June 1998 in Aarhus (Denmark), the Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters (Aarhus Convention), was ratified by France on 8th July 2002 and entered into force in France on 6th October 2002. With the aim of helping to protect the right to live in a clean environment that guarantees health and wellbeing, the signatory States guarantee the right of access to information about the environment, public participation in the decision-making process and access to justice in environmental matters.

1. Nuclear safety, within the meaning of Article L. 591.1 of the Environment Code, is thus a more limited concept than that of the objectives of the BNI legal system as described in point 3 of this chapter.

ENERGY TRANSITION FOR GREEN GROWTH ACT

After a year-long debate, Parliament adopted the Energy Transition for Green Growth Act 2015-992 of 17th August 2015 (TECV). This Act comprises a Title devoted to nuclear matters (Title VI entitled *"Reinforcing nuclear safety and information of the public"*) and a number of provisions in Title VIII concerning the organisation of the regulation of nuclear safety and radiation protection.

The provisions to be considered concern:

Enhanced transparency and information of citizens

Reinforcing and expanding the roles of the Local Information Committees (CLI)

Provision is thus made for the following (Articles L. 125-17 to L. 125-26 of the Environment Code):

- organisation of an annual public meeting by the CLI, open to all;
- the possibility for the CLI to address any subject within its field of competence (monitoring, information and consultation concerning nuclear safety, radiation protection and the impact of nuclear activities on individuals and the environment);
- the possibility for the CLI Chairman to ask the licensee (who cannot refuse) to organise visits to the nuclear facilities;
- the possibility for the CLI Chairman to ask the licensee (who cannot refuse, subject to an assessment of "restoration of normal conditions of safety») to organise visits to the facilities after a "cooling off" period following an incident rated level 1 or higher on the INES scale;
- mandatory consultation of the CLI for any changes to the Off-site Emergency Plans (PPI);
- mandatory consultation of the CLI concerning information of the persons living within the perimeter of a PPI;
- in the case of sites located in a département on one of the country's borders, inclusion of members of neighbouring states in the composition of the CLI.

Reinforcement of certain information procedures

- with the principle of regular information, at the expense of the licensee, of persons living within the perimeter of a PPI (concerning the nature of the accident risks and the envisaged consequences, the safety measures and the steps to be taken in application of this plan) (Article L. 125-16-1 of the Environment Code);
- with the holding of a public inquiry on the measures proposed by the licensee during the periodic safety review of the NPP reactors after their 35th year of operation (Article L. 593-19 of the Environment Code).

Confirmation of the BNI system

Management of subcontracting

- The new Article L. 593-6-1 of the Environment Code confirms the rule preventing the licensee from delegating the surveillance of outside contractors performing an activity that is important for the protection of the interests mentioned in Article L. 593-1 of the Environment Code: This ban which is included in the BNI Order of 7th February 2012 now carries legislative weight.
- This same Article makes it possible for a Decree by the Council of State to circumscribe or limit the use of contracting or subcontracting for the performance of certain activities important for the protection of interests.

Evolution in the BNI authorisation system

- Articles L. 593-14 and L. 593-15 of the Environment Code use the same terminology as the regime of Installations Classified on Environmental Protection grounds (ICPE).
- The "substantial" modifications (previously referred to as "significant") correspond to those modifications requiring a new and complete authorisation procedure with public inquiry (Article L. 593-14 of the Environment Code).
- The "significant" modifications now correspond to modifications with a more limited impact on the protection of the interests mentioned in Article L. 593-1 of the Environment Code. Article L. 593-15 of the same code states that "significant" modifications are "depending on their importance" subject to authorisation by ASN or notification to it and that these "significant" modifications "may be opened to public consultation" (see point 3.3.5).

Renovation of the BNI final shutdown and decommissioning system

- The principle of immediate dismantling is enshrined in law (Article L. 593-25).
- The law differentiates between final shutdown and decommissioning of a BNI.
- The final shutdown of a BNI is the responsibility of the licensee, who must notify the Minister responsible for nuclear safety and ASN of the date no later than two years (or less if justified) prior to final shutdown. As of this date, the installation is considered to have final shutdown status and must be decommissioned (Article L. 593-26).
- Decommissioning (time-frame and procedures) is prescribed (and no longer authorised) by Decree (Article L. 593-28).
- Automatic transition to final shutdown for a facility which has ceased to function for two consecutive years (Article L. 593-24).

Clarification of the organisation of the oversight of nuclear safety and radiation protection by ASN and IRSN

The law enshrines the Institute for Radiation Protection and Nuclear Safety (IRSN) in the Environment Code (new Articles L. 592-41 to L. 592-45). It clarifies the organisation of the oversight of nuclear safety and radiation protection between ASN and IRSN.

The law gives IRSN *"research and expert assessment duties in the field of nuclear safety defined in Article L.491-1 of the Environment Code"* (that is nuclear safety, radiation protection, prevention and combating of malicious acts, and civil protection actions in the event of an accident).

The law requires that ASN draw on IRSN expertise in the performance of its regulation of nuclear safety and radiation protection. In order to guarantee that IRSN's expert assessment capacity matches ASN's requirements, the law requires that the latter offer guidance for IRSN's strategic programming with respect to this technical support and that its chairman be a member of the Institute's board.

Article L. 592-43 of the Environment Code introduces the principle of publication of all the opinions issued by IRSN at the request of ASN.

"Early" entry into force in French law of the protocols signed on 12th February 2004, reinforcing the Paris Convention of 29th July 1960 and the Brussels Convention of 31st January 1963 concerning civil liability in the field of nuclear energy.

By modifying Articles L. 597-2 et seq. of the Environment Code, the TECV Act reinforces the civil liability of the licensees in the event of damage linked to a nuclear activity. Without waiting for entry into force of the 2004 protocols related to their ratification by all the States of the European Union, this modification enforces certain provisions of the 2004 protocols, significantly re-evaluating the liability ceilings, which are raised from €23 million to €70 million for "low risk facilities" and from €91.50 million to €700 million for the other facilities. The law also extends its scope of application to new categories of installations (for example certain ICPE).

Relationship between the BNI System and the Energy Code

The Energy Code stipulates that authorisation is required for the operation of any electricity generating installation. For nuclear installations generating electricity, this authorisation is obtained independently of the commissioning authorisation granted by ASN pursuant to the Environment Code.

As the nuclear electricity generating capacity is capped at 63.2 gigawatts by law (Article L. 311-5-6 of the Energy Code), Article L. 311-5-5 of this same code stipulates that it is impossible to issue an operating authorisation pursuant to the Energy Code when this would have the effect of exceeding this maximum.

As the 63.2 GW cap corresponds to the installed power in France, commissioning of new nuclear power reactors would thus imply the need to revoke the generating authorisation for existing reactors up to the value of the power of the new reactor.

Revocation of the operating authorisation would lead to shutdown of the installation and, after a two-year period, would thereby lead to its final shutdown pursuant to Articles L. 593-24 and following of the Environment Code.

The same Article L. 311-5-6 of the Energy Code also stipulates that when a nuclear power installation is subject to the BNI System, the operating authorisation application in accordance with the Energy Code must be submitted no later than 18 months before commissioning (as determined in the Environment Code) and, in any case, no later than 18 months before the commissioning date mentioned in its creation authorisation decree.

An authorisation led to Ordinance 2016-128 of 10th February 2016 (see pages 42 and 43 of this report).

In line with the Aarhus Convention, Article 7 of the Environment Charter states that *"everyone has the right, within the conditions and limits defined by the law [...] to take part in the drafting of public decisions with an impact on the environment"*. Most of the resolutions issued by ASN, whether statutory or individual, fall within this category.

Articles L. 120-1 to L. 120-2 of the Environment Code set the conditions and limits for implementation of the principle of public participation in the statutory and individual resolutions with an impact on the environment. In both cases, these are "subsidiary" public participation procedures, in other words, procedures which apply if specific texts do not stipulate a particular procedure.

For statutory resolutions with an impact on the environment, Article L. 120-1 of the Environment Code, in force since 1st January 2013, requires that the draft resolution be made available to the public in electronic format for a time which may not be less than 21 days, except in the event of urgency relating to protection of the environment, public health or public order.

For individual resolutions with a direct or significant impact on the environment, Article L. 120-1-1 of the Environment Code, in force since 1st September 2013, requires that the draft resolution or, when the resolution is issued on request, the application file, be made available to the public in electronic format for a time that may not be less than 15 days except in the case of urgency relating to protection of the environment, public health, or public order.

ASN has adopted a structured approach towards implementing this procedure for public participation in the drafting of its resolutions (see chapter 6).

1.2 The regulations applicable to the various categories of individuals and the various situations involving exposure to ionising radiation

The various exposure levels and limits set by the regulations are presented in the appendix to this chapter.

1.2.1 General protection of workers

The Labour Code contains various specific provisions for the protection of workers, whether salaried or not, exposed to ionising radiation (Title V of Book IV of part IV) which supplement the general prevention principles. It establishes a link with the three radiation protection principles contained in the Public Health Code.

Its legislative part is only little affected by the transposition of Directive 2013/59/Euratom. However, it does require that the authorisations issued by ASN in accordance with the BNI Systems and the Public Health Code be examined on the basis of information concerning occupational exposure, thus making it necessary to clarify the responsibilities of the employer and those of the party responsible for a corresponding nuclear activity. Articles L.1333-27 of the Public Health Code and L.593-41 of the Environment Code were thus introduced. They specify that the general rules, prescriptions, means and measures aimed at protecting the health of workers from ionising radiation, implemented pursuant to the Public Health Code and BNI System, concern the collective protection measures to be taken by the party responsible for a nuclear activity and designed to ensure compliance with the radiation protection principles defined in Article L. 1333-2 of the Public Health Code. These measures concern the design, operation and decommissioning phases of the installation and are without prejudice to the obligations incumbent on the employer in application of Articles L. 4121-1 et seq. of the Labour Code.

A General Directorate for Labour/ASN joint Circular No. 4 of 21st April 2010 indicates the conditions of application of the provisions of the Labour Code concerning the radiation protection of workers.

Articles R. 4451-1 to R. 4451-144 of the Labour Code create a single radiation protection system for all workers (whether salaried or not) liable to be exposed to ionising radiation during the course of their professional activities. The transposition of Directive 2013/59 is an opportunity to update this regulatory part of the Labour Code, to take account of the work done in recent years at the request of the General Directorate for Labour (DGT) and ASN, in order to more closely tailor the requirements to the actual risks faced by the workers.

The following provisions of the Labour Code should be mentioned:
- application of the optimisation principle to the equipment, processes and work organisation (Articles R. 4451-7 to R. 4451-11), which leads to clarification of where responsibilities lie and how information is circulated between the head of the facility, the employer, in particular when he or she is not the head of the facility, and the person competent in radiation protection;
- the annual dose limit (Articles R. 4451-12 to 4451-15) set at 20 mSv for 12 consecutive months, barring waivers resulting from exceptional exposure levels justified in advance, or emergency occupational exposure levels;
- the dose limits for pregnant women (Article D. 4152-5) or more accurately for the unborn child (1 mSv for the period from the declaration of pregnancy up until birth).

The annual dose equivalent limit for the lens of the eye which is currently set at 150 mSv, will be lowered to 20 mSv on the occasion of the transposition of Directive 2013/59.

TO BE NOTED

Council Directive 2013/59/Euratom of 5th December 2013

For workers liable to be exposed to ionising radiation, the Directive introduces an annual effective dose limit of 20 mSv, to replace the value of 100 mSv over five consecutive years. As early as 2003, this limit had been incorporated into the Labour Code (20 mSv over 12 consecutive months). However, the equivalent dose limit of 150 mSv over 12 consecutive months for the lens of the eye will have to be modified and reduced to 20 mSv per year.

The new Euratom Directive will lead to modification of the existing PCR system, differentiating between consultancy and more operational duties. The radiation protection expert is responsible for giving the head of the company or the employer an opinion on questions concerning worker and public exposure, while the person responsible for radiation protection is tasked with operational implementation of radiation protection. ASN and the DGT have begun work on this subject.

The new Euratom Directive does not modify the general rules for the demarcation of monitored and controlled areas. However, on the basis of the opinions issued by the Advisory Committee of Experts for Radiation Protection for Industrial Applications and Research into Ionising Radiation and the Environment (GPRADE), and the Advisory Committee of Experts for Radiation Protection for the Medical and Forensic Applications of Ionising Radiation (GPMED), the DGT and ASN have already announced their intention during the course of the transposition work to update and simplify the existing system on the basis of a graduated approach to risk.

The same applies to the radiological monitoring of workers for which an assessment of the existing regulatory system was initiated in late 2013 in collaboration with the DGT and the Institute for Radiation Protection and Nuclear Safety (IRSN). The September 2015 publication of a "white paper" is available on the ASN website and proposes changes which will be studied at transposition of the new Euratom Directive. The main recommendations of the working group are as follows:
- repositioning of the ionising radiation risk in the employer's overall risk prevention strategy;
- adaptation of exposure monitoring to the working situations, thus ensuring that this monitoring is operational and controllable;
- broadening of access by persons competent in radiation protection to all dosimetry data, in order to ensure that they are more reactive and to strengthen their preventive role.

Zoning

Provisions concerning the demarcation of monitored areas, controlled areas and specially regulated areas (subject to special checks) were issued, regardless of the activity sector, by the Order of 15th May 2006 (published in the *Official Journal* of 15th June 2006). This Order also defines the health, safety and maintenance rules to be observed in these zones.

When defining the regulated zones, different levels of protection are taken into account: the effective dose for external exposure and, as applicable, internal exposure of the whole body; the equivalent doses for external exposure of the extremities and, as applicable, the dose rates for the whole body. A General Directorate for Labour/ASN joint circular of 18th January 2008 specifies the implementation procedures.

The Person with Competence in Radiation protection (PCR)

The PCR is placed under the responsibility of the employer and tasked with numerous radiation protection duties, including optimisation, implementation of radiological monitoring, information about risks, but also demarcation of regulated areas and job analyses.

Without waiting for the updating of the provisions of the Labour Code with regard to the PCR, in order to take account of the provisions of the new Directive 2013/59 concerning the "radiation protection expert / radiation protection officer" system (see box opposite), the Order of 26th October 2005 concerning PCR training procedures and trainer certification was repealed by the Order of 24th December 2013, on the basis of the recommendations issued by the Advisory Committee of Experts for Radiation Protection for the Medical and Forensic Applications of Ionising Radiation (GPMED) and the Advisory Committee of Experts for Radiation Protection for Industrial Applications and Research into Ionising Radiation and the Environment (GPRADE). The number of days of training was modified according to the potential risks, with an increase in the number of days for the most complex installations or those with the highest risk.

Dosimetry

The approval procedures for the organisations responsible for worker dosimetry are defined by the Order of 6th December 2003 as amended. The procedures for the medical monitoring of workers and the transmission of individual dosimetry data are specified by the Order of 21st June 2013 concerning the conditions for accreditation of organisations responsible for individual monitoring of worker exposure to ionising radiation and by the Order of 17th July 2013 concerning the medical monitoring passport and dosimetric monitoring of workers exposed to radiation. ASN delivers the required approvals to the dosimetry organisations and laboratories (see chapter 1).

Radiation protection checks

Technical control of sources and devices emitting ionising radiation, protection and alarm devices and measuring instruments, as well as ambient environment checks, can be entrusted to the French Institute for Radiation Protection and Nuclear Safety (IRSN), to the department with competence for radiation protection or to organisations approved under application of Article R. 1333-97 of the Public Health Code. The nature and frequency of the radiation protection technical checks are defined by ASN resolution 2010-DC-0175 of 4th February 2010.

These technical checks concern sources and devices emitting ionising radiation, the ambient environment, measuring instruments and protection and alarm devices, management of sources and of any waste and effluents produced. Some of these controls are carried out as part of the licensee's in-house inspection processes and some by outside organisations (the outside checks must be performed by IRSN or an organisation approved under Article R. 1333-97 of the Public Health Code – see point 2.1.4).

Radon in the workplace

(See point 2.3.1).

1.2.2 General protection of the general public

Apart from the special radiation protection measures included in individual nuclear activity licenses for the benefit of the general public and the workers, a number of general measures included in the Public Health Code help to protect the public against the dangers of ionising radiation.

Public dose limits

The annual effective dose limit (Article R. 1333-8 of the Public Health Code) received by a member of the public as a result of nuclear activities, is set at 1 mSv/year; the equivalent dose limits for the lens of the eye and the skin are set at 15 mSv/year and 50 mSv/year respectively. The calculation method for the effective and equivalent dose rates and the methods used to estimate the dosimetric impact on a population are defined by Ministerial Order of 1st September 2003.

Radioactivity in consumer goods and construction materials

The intentional addition of natural or artificial radionuclides in all consumer goods and construction materials is prohibited (Article R. 1333-2 of the Public Health Code). Waivers may however be granted by the Minister of Health after receiving the opinion of the French High Council for Public Health (HCSP) and ASN, except with respect to foodstuffs and materials placed in contact with them, cosmetic products, toys and personal ornaments. The Government Order of 5th May 2009 specifies the content of the waiver application file and the consumer information procedures stipulated in Article R. 1333-5 of the Public Health Code. This waiver arrangement was used in 2011 to cover the gradual phase-out of ionisation smoke detectors (see chapter 10) used in fire protection. This prohibition principle does not concern the radionuclides naturally present in the initial components or in the additives used to prepare foodstuffs (for example potassium-40 in milk) or for the manufacture of constituent materials of consumer goods or construction products (for example: uranium and its daughter products in granite).

Furthermore, the use of materials or waste from a nuclear activity is also prohibited, when they are contaminated or likely to have been contaminated by radionuclides, including by activation, as a result of this activity.

The Public Health Code comprises regulatory provisions (Article R. 1333-14) to limit the natural radioactivity in construction materials, if necessary, when this radioactivity is naturally present in the constituents used in their manufacture. This provision has never yet been applied. The transposition of the new Euratom Directive should further tighten up this restriction through an obligation to measure the radiation emitted.

Further to a proposal from ASN, the French High Committee for Transparency and Information on Nuclear Security (HCTISN) set up a working group for the information and consultation procedures in the event of a request for waivers concerning the ban on the intentional addition of radionuclides in consumer goods or construction products. This group should shortly resume its work, interrupted in 2014 owing to the renewal of the HCTISN (see chapter 6).

Radioactivity and the environment

A National Network for the Measurement of environmental radioactivity (RNM) was set up in 2002 (Article R. 1333-11 of the Public Health Code). A centralised system for collection of these measurements was implemented in 2009. The data collected must be used to help estimate the doses received by the population. The network's orientations are defined by ASN and it is managed by IRSN (ASN resolution 2008-DC-0099 of 29th April 2008, amended, on the organisation of a National Network for the Measurement of environmental radioactivity and setting the conditions for laboratory approval). To guarantee the quality of the measurements, the laboratories in this network must meet approval criteria, which in particular include participation in intercomparison benchmarking tests.

A detailed presentation of the RNM is given in chapter 4.

The radiological quality of water intended for human consumption

Pursuant to Article R. 1321-3 of the Public Health Code, water intended for human consumption is subject to radiological quality inspection. The monitoring procedures are specified in the Order of 12th May 2004. They form part of the sanitary monitoring carried out by the Regional Health Agencies (ARS). The Order of 11th January 2007 concerning water quality limits and benchmarks introduces four radiological quality indicators for water intended for human consumption. With regard to the transposition of Council Directive 2013/51/Euratom of 22nd October 2013 which sets requirements for protecting the health of the population with respect to radioactive substances in water intended for human consumption, the Order of 11th January 2007 was modified in 2015 by the Order of 9th December 2015 (Order modifying several Orders concerning water intended for human consumption issued pursuant to Articles R. 1321-2, R. 1321-3, R. 1321-7, R. 1321-20, R. 1321-21 and R. 1321-38 of the Public Health Code) thereby introducing a quality reference for radon in groundwater.

An Order of 9th December 2015 also sets procedures for measuring radon in water intended for human consumption, including packaged water, with the exception of natural mineral water, and in water used in a food company which does not come from the public mains supply, for the purposes of health checks pursuant to Articles R. 1321-10, R. 1321-15 and R. 1321-16 of the Public Health Code.

The indicators and the limits adopted are the total alpha activity (0.1 Bq/L), the total residual beta activity (1 Bq/L), the tritium activity (100 Bq/L) and the indicative dose (0.1mSv/year). The quality reference for radon is 100 Bq/L.

The circular from the General Directorate for Health (DGS) dated 13th June 2007, accompanied by recommendations from ASN, specifies the policy underpinning this regulation. It will need to be added to in order to take account of the transposition of Directive 2013/51.

Radiological quality of foodstuffs

Restrictions on the consumption or sale of foodstuffs may be necessary in the event of an accident or of any other radiological emergency situation.

In Europe, these restrictions are determined by Council Regulation 2016/52/Euratom of 15th January 2016, laying down maximum permitted levels of radioactive contamination of foodstuffs and livestock feedstuffs. The maximum permitted levels were defined to *"safeguard the health of the population while maintaining the unified nature of the market"*.

In the event of a confirmed nuclear accident, "automatic" application of this regulation cannot exceed a period of three months, after which it will be superseded by specific measures (see the regulation specific to the Chernobyl accident, the values of which are given in the appendix). Following the accident which struck Fukushima Daiichi on 11th March 2011, this system was activated by the European Commission on numerous occasions between 2011 and 2013, to take account of the changing radiological situation in the regions concerned[2]. For example, in the EU's first post-Fukushima regulation (297/2011 of 25th March 2011), the maximum permitted levels for 134/137Cs in milk were 1000 Bq/L as stipulated in Euratom regulation 3954/87. They were lowered a first time in April 2011 to 200 Bq/L and then a second time in April 2012 to 50 Bq/L, in line with the lowering of the maximum permitted levels in Japan.

Radioactive waste and effluents

Management of waste and effluents from BNIs and Installations Classified on Environmental Protection grounds (ICPEs) is subject to the provisions of the special regulations concerning these installations (for BNIs, see point 3.4.3). For the management of waste and effluents from other establishments, including hospitals (Article R. 1333-12 of the Public Health Code), general rules are established in ASN resolution 2008-DC-0095 of 29th January 2008. These effluents and waste must be disposed of in duly authorised facilities, unless there are special provisions for on-site organisation and monitoring of their radioactive decay (this concerns radionuclides with a radioactive half-life of less than 100 days).

French policy for the management of very low level waste in BNIs and facilities subject to the Public Health Code is clear and protective: it makes no provision for a "clearance level" for this waste (in other words a generic radioactivity level below which effluents and waste produced by a nuclear activity can be disposed of without control), but on the contrary ensures that they are managed in a special stream to ensure traceability. ASN considers that the use of clearance levels would have three major drawbacks:
- the difficulty in defining universal levels;
- the difficulty in controlling the clearance of this waste;
- and the incentive to dilute this waste in the environment.

With regard to the possibilities for reuse of the waste, ASN is not in favour of the reuse in consumer goods or construction products of waste that is or is likely to be contaminated. Waste from areas in which the production of nuclear waste is a possibility may only be reused within the nuclear sector.

2. European regulation (EU) 297/2011, then modified by regulations 351/2011, 506/2011, 657/2011, 961/2011, 1371/2011, 284/2012, 561/2012, 996/2012 and 495/2013.

1.2.3 Protection of persons in a radiological emergency situation

The general public is protected against the hazards of ionising radiation in the event of an accident or of radiological emergency situations through the implementation of specific actions (or countermeasures) appropriate to the nature and scale of the exposure. In the particular case of nuclear accidents, these actions were defined in the government Circular of 10th March 2000 which amended the Off-site Emergency Plans (PPI) applicable to BNIs, by expressing intervention levels in terms of doses. These levels constitute reference points for the public authorities (Prefects) who have to decide locally, on a case-by case basis, what action is to be taken.

Reference and intervention levels

The intervention levels were updated in 2009 by ASN statutory resolution 2009-DC-0153 of 18th August 2009, with a reduction of the level concerning exposure of the thyroid. Henceforth, the protection measures to be taken in an emergency situation, and the corresponding intervention levels, are:
- sheltering, if the predicted effective dose from the releases exceeds 10mSv;
- evacuation, if the predicted effective dose from the releases exceeds 50mSv;
- distribution of Thyroid Blocking stable Iodine (ITB) when the predicted equivalent dose to the thyroid from the releases is liable to exceed 50mSv.

The regulatory exposure limits set by the Labour Code do not apply to emergency workers. On the basis of the optimisation principle, "reference levels", comparable to guideline values to be considered for the performance of any intervention in circumstances such as these, are defined by the regulations (Article R. 1333-84 and R. 1333-86 of the Public Health Code). Two groups of emergency workers are thus defined:
- the first group comprises the personnel making up the special technical or medical response teams set up to deal with a radiological emergency. These personnel benefit from radiological surveillance, a medical aptitude check-up, special training and equipment appropriate to the nature of the radiological risk;
- the second group comprises personnel who are not members of the special response teams but who are called in on the basis of their expertise. They are given appropriate information.

The reference individual exposure levels for the participants, expressed in terms of effective dose, should be set as follows:
- the effective dose which may be received by personnel in group 1 is 100 mSv. It is set at 300 mSv when the intervention measure is aimed at protecting other people;
- the effective dose which may be received by personnel in group 2 is 10 mSv. In exceptional circumstances, volunteers informed of the risks involved in their acts may exceed the reference levels, in order to save human life.

Public information in a radiological emergency

The ways in which the general public is informed in a radiological emergency situation are covered by a specific EU Directive (Directive 89/618/Euratom of 27th November 1989 on informing the general public about health protection measures to be applied and steps to be taken in the event of a radiological emergency). This Directive was transposed into French law by Decree 2005-1158 of 13th September 2005 concerning the off-site emergency plans for certain fixed structures or installations, implementing Article 15 of Act 2004-811 of 13th August 2004 on the modernisation of civil protection.

Two implementing orders were published:
- the Order of 4th November 2005 concerning public information in the event of a radiological emergency situation;
- the Order of 8th December 2005 concerning the medical aptitude check-up, radiological surveillance and training or information of the personnel involved in managing a radiological emergency situation.

1.2.4 Protection of the general public in a long-term exposure situation

The contamination of sites by radioactive substances is the result of a nuclear activity in the remote or more recent past (use of unsealed sources, radium industry, etc.) or an industrial activity utilising raw materials containing non-negligible quantities of natural radionuclides of the uranium or thorium family (activity generating exposure to "enhanced" natural radiation, see point 2.3.2). Most of these sites are listed in the inventory sent out and updated periodically by the French National Agency for Radioactive Waste Management (Andra).

The contamination of the sites can also be the result of accidental releases of radioactive substances into the environment (see chapter 5).

These different exposure situations are qualified as "lasting exposure" in the Public Health Code (since 2007, ICRP publication 103 uses the expression "existing exposure situation"). For these situations, in accordance with the international texts, no exposure limit for the general public has been set at the regulatory level, as the management of these sites is chiefly based on a case-by-case application of the optimisation principle.

A guide on the management of sites potentially polluted by radioactive substances (published in December 2011), drafted under the coordination of ASN and the Ministry of the Environment, assisted by IRSN, describes how to deal with the various situations that could be encountered in the framework of the remediation of sites (potentially) contaminated by radioactive substances.

2. REGULATORY REQUIREMENTS APPLICABLE TO SMALL-SCALE NUCLEAR ACTIVITIES

The expression "small-scale nuclear" refers to medical, industrial and research applications of ionising radiation when not covered by the BNI or ICPE systems. This more specifically concerns the manufacture, possession, distribution – including import and export – and use of radionuclides or products and devices containing them.

2.1 Procedures and rules applicable to small-scale nuclear activities

The procedures and rules applicable to small-scale nuclear activities, if not the beneficiaries of an exemption, are described in section 3 of Chapter III of Title III of Book III of the first part of the Public Health Code. ASN issues licenses and approvals and is responsible for registration. Notifications are filed with the ASN regional divisions.

2.1.1 The licensing system

The licensing system applies indiscriminately to companies or facilities which have and use radionuclides on-site, and to those which trade in them or use them without directly possessing them.

The ASN license may be issued for a limited period and may in this case be renewed. The license application or notification is made with a form that can be downloaded from the *www.asn.fr* website or obtained from the ASN regional divisions. The conditions for filing license applications, established by Articles R. 1333-23 et seq. of the Public Health Code, are set out by ASN resolution 2010-DC-192 of 22nd July 2010, which establishes the content of the dossiers enclosed with the license application. The requirements applicable to the medical and non-medical fields are harmonised.

The forms implementing the resolutions have been available on-line since 2011 and are regularly updated.

It should be noted that the licenses issued under the authorisation systems for BNI, ICPE and Mining Code industries (for ICPE and Mining Code industries, the license is issued by the Prefect) constitute the authorisation for manufacturing or owning ionising radiation sources (see chapter 10), but do not constitute exemption from compliance with the provisions of the Public Health Code.

Licensing of medical applications and biomedical research

ASN issues licenses for the use of radionuclides, products or devices containing them, used in nuclear medicine, brachytherapy, and for irradiation of blood products, as well as for the use of particle accelerators in external radiotherapy and computed tomography devices. For medical applications and biomedical research, owing to specific patient radiation protection issues, the decision was taken not to use the clearance levels given in the Public Health Code; the licensing system thus comprises no exemptions.

Licensing of non-medical activities

ASN is responsible for issuing licenses for industrial and non-medical research applications. This concerns:
- the import, export and distribution of radionuclides and products or devices containing them;
- the manufacture, possession and use of radionuclides, products or devices containing them, devices emitting ionising radiation, the use of accelerators other than electron microscopes and the irradiation of products of any nature, including foodstuffs, with the exception of activities which are licensed under the terms of the Mining Code, the BNI legal system or that applicable to ICPEs.

The licence exemption criteria are given in the appendix to the Public Health Code (table A, appendix 13-8).

Exemption will be possible if one of the following conditions is met:
- the total quantity of radionuclides possessed is less than the exemption values in Bq;
- the radionuclide concentrations are less than the exemption values in Bq/kg.

2.1.2 The registration system

The Ordinance transposing Directive 2013/59/Euratom of 5th December 2013 introduces a simplified authorisation system known as "registration". This system can be utilised for nuclear activities representing serious risks or detrimental effects for the interests mentioned in Article L.1333-7, when these risks and detrimental effects can, in principle and in the light of the characteristics of these activities and the conditions of their implementation, be prevented by compliance with the general prescriptions. Utilisation of this new system will require relevant regulations and, for the activities concerned, the drafting of general prescriptions.

2.1.3 The notification system

The list of activities requiring notification pursuant to Article R.1333-19-1 of the Public Health Code was updated in 2009 by ASN resolution 2009-DC-0146 of 16th July 2009, supplemented by ASN resolution 2009-DC-0162 of 20th October 2009. As in low-dose medical radiology, radiology in veterinary practices is now included in the activities requiring notification. It is added to the list of non-medical activities requiring notification, pursuant to Article R.1333-19-3 of the Public Health Code.

ASN resolution 2009-DC-0146 of 16th July 2009 was modified in 2015 (ASN resolution 2015-DC-0531 of 10th November) in order to add X-ray generators used for irradiation of blood products.

ASN acknowledges receipt of the notification filed by the natural or artificial person responsible for the nuclear activity. As the maximum validity period for a notification has been abolished, a new notification for activities requiring regular notification only becomes necessary if significant changes have been made to the installation (replacement or addition of an appliance, transfer or substantial modification of the premises or change in party responsible for the nuclear activity).

Finally, the X-ray facilities used for forensic procedures (for example, radiological examination to determine the age of an individual, use of X-rays to detect objects hidden within the human body, etc.), are regulated by the licensing or notification system applicable to facilities designed for medical uses, depending on the type of equipment used (see point 2.2).

2.1.4 Licensing the suppliers of ionising radiation sources

ASN resolution 2008-DC-0109 of 19th August 2008 concerns the licensing system for the distribution, import and/or export of radionuclides and products or devices containing them. This resolution covers products intended for industrial and research purposes, but also health products: drugs containing radionuclides (radiopharmaceutical drugs, precursors and generators), medical devices (gamma-ray teletherapy devices, brachytherapy sources and associated applicators, blood product irradiators, etc.) and *in vitro* diagnosis medical devices (for radioimmunology assay).

ASN resolution 2008-DC-0108 of 19th August 2008 concerns the license to possess and use a particle accelerator (cyclotron) and the manufacture of radiopharmaceuticals containing a positron emitter.

2.1.5 Approval of radiation protection technical supervision organisations

Technical supervision of the radiation protection organisation, including supervision of the management of radioactive sources and any associated waste, is entrusted to approved organisations (Article R. 1333-97 of the Public Health Code). The conditions and procedures for approval of these organisations are set by ASN resolution 2010-DC-0191 of 22nd July 2010. ASN is responsible for issuing these approvals. The list of approved organisations is available on the ASN website (*www.asn.fr*). The nature and frequency of the radiation protection technical checks are defined in ASN resolution 2010-DC-0175 mentioned in point 1.2.1.

2.1.6 The rules for the design of facilities

ASN technical resolutions, subject to approval by the Ministers responsible for Radiation Protection, may be adopted to determine the design and operating rules for facilities in which sources of ionising radiation are used.

With regard to the design of the facilities, the *Union technique de l'électricité* (UTE) conducted a revision of standards NF-C 15-160 and the associated specific standards (general installation rules for X-ray generators). On the basis of this work, ASN has initiated an update of the design and layout rules for facilities inside which X-rays are produced and used. After several consultations of GPRADE and GPMED, ASN adopted resolution 2013-DC-0349 of 4th June 2013 laying down minimum technical rules for the design of facilities in which X-rays are present. This resolution entered into force on 1st January 2014, subject to certain provisions, for all facilities commissioned or for which the calculation parameters are modified. This resolution concerns industrial and scientific (research) facilities such as industrial radiography using X-rays in a bunker, veterinary radiology and medical facilities such as conventional radiology, dental radiology and scanners (see chapters 9 and 10).

This resolution also replaces the Order of 30th August 1991 determining the installation conditions to be met by X-ray generators.

On 23rd October 2014, ASN adopted resolution 2014-DC-0463 concerning minimum technical rules for the design, operation and maintenance of *in vivo* nuclear medicine facilities.

The new rules set out in the above-mentioned resolution of 23rd October 2014 replace rules existing since 1981; they mainly concern the rules for the ventilation of laboratories handling radiopharmaceuticals and hospital rooms reserved for patients who have received therapeutic treatment (in particular iodine-131).

2.1.7 Radioactive resources management rules

The general radioactive source management rules are contained in section 4 of Chapter III of Title III of Book III of the first part of the Public Health Code. These rules are as follows:
- No person may transfer or acquire radioactive sources without a license.
- Prior registration with IRSN is compulsory for the purchase, distribution, import and export of radionuclides as sealed or unsealed sources, or of products or devices containing them; this prior registration makes it possible to track the sources from their entry onto the market until the end of their life. ASN resolution 2015-DC-0521 of 8th September 2015 concerning the monitoring and registration procedures for radionuclides in the form of radioactive sources and products or devices containing them, clarified the regulatory framework with regard to the procedures for this registration of movements and for the monitoring rules concerning radionuclides in the form of radioactive sources (see chapter 10).
- Each establishment is required to ensure the traceability of radionuclides in the form of sealed or unsealed sources and of products or devices that contain them.
- ASN must be notified in the event of loss or theft of radioactive sources.
- Users of sealed sources are obliged to have the expired, damaged or end-of-life sources taken back by the supplier, who is obliged to recover them.

On this latter point, Decree 2015-231 of 27th February concerning the management of used sealed sources, which came into force on 1st July 2015, modified Articles R.1333-52 and R.1337-14 of the Public Health Code, in order to enable those in possession of sources to have the used sealed radioactive sources that have expired or reached the end of their service life recovered not only by their initial supplier, but also by any other authorised supplier of radioactive sources or, as a final resort, by Andra. The spirit of this modification is to address the difficulties experienced by those in possession of sources with regard to locating the original suppliers, the cost of recovery and the monopoly enjoyed by certain suppliers.

The conditions of implementation and payment of the financial guarantees incumbent on the source suppliers must be defined by an order from the Ministers responsible for Health and Finance (Articles R. 1333-53 and R. 1333-54-2 of the Public Health Code). In the absence of such an order, the particular licensing conditions established by the CIREA (Interministerial Commission on Artificial Radioelements) in 1990 are taken up as requirements in the licenses and are consequently applicable to the licensees.

2.2 Protection of persons exposed for medical and forensic purposes

Radiation protection for individuals exposed for medical purposes is based on two principles mentioned in paragraphs 1 and 2 of Article L. 1333-1 of the Public Health Code respectively: justification of the procedures and optimisation of exposure, which are under the responsibility of both the practitioners prescribing medical imaging examinations entailing exposure to ionising radiation and the practitioners carrying out these procedures. These principles cover all the diagnostic and therapeutic applications of ionising radiation, including radiological examinations requested for screening, occupational health, sports medicine and forensic purposes.

In medical imaging (see chapter 9), the final responsibility for exposure lies with the practitioners performing the exams. The rules applicable for the radiation protection of patients set out in the Public Health Code are different from those established for the protection of professionals, set out in the Labour Code, even if the competence of the physicians and professionals involved in delivering the dose must cover both domains.

2.2.1 Justification of practices

A written exchange of information between the prescribing practitioner and the practitioner carrying out the procedure exposing the patient should provide justification of the benefit of the exposure for each procedure. This "individual" justification is required for each procedure. Articles R. 1333-70 and R. 1333-71 of the Public Health Code respectively require the publication of "prescription of routine procedures and examinations" guides (also called *"indication guides"*) and "performance of procedures" guides (called *"procedure guides"*).

2.2.2 Optimisation of exposure

Optimisation in medical imaging (radiology and nuclear medicine) consists in delivering the lowest possible dose compatible with obtaining a quality image that provides the diagnostic information being sought. Optimisation in therapy (external radiotherapy, brachytherapy and nuclear medicine) consists in delivering the prescribed dose to the tumour to destroy cancerous cells while limiting the dose to healthy tissues to the strict minimum.

Standardised guides for conducting procedures using ionising radiation have been prepared and are regularly updated by health professionals, or are currently being prepared, to facilitate practical application of the optimisation principle (table 1).

TABLE 1: List of Referral Criteria for Imaging and Procedure Guides for the performance of medical procedures entailing exposure to ionising radiation

	SPECIALTIES				
	MEDICAL RADIOLOGY		NUCLEAR MEDICINE	RADIOTHERAPY	DENTAL RADIOLOGY
DOCUMENTS	Procedure guide	Referral criteria for imaging guide	Referral criteria for imaging and procedure guide	External radiotherapy procedure guide	Referral criteria for imaging and procedure guide
AVAILABLE ON	*www.sfrnet.org* *www.irsn.org*	*www.sfrnet.org* *www.irsn.org*	*www.sfmn.org*	*www.sfro.org*	*www.adf.asso.fr* *www.has-sante.fr*

Diagnostic reference levels

The Diagnostic Reference Levels (DRL) are one of the tools used for dose optimisation. As required in Article R. 1333-68 of the Public Health Code, the DRL are defined in the Order of 24th October 2011 concerning diagnostic reference levels in radiology and nuclear medicine. For radiology, this consists of dose values, while for nuclear medicine it consists of activity levels administered in the course of the most common or most heavily irradiating examinations. Depending on the type of examination, periodic measurements or readings shall be taken in each radiology and nuclear medicine unit.

Dose constraints

In the field of biomedical research, where exposure to ionising radiation is of no direct benefit to the persons exposed, dose constraints designed to optimise the doses delivered must be established by the medical doctors.

Medical radiation physics

The safety of radiotherapy and optimisation of the doses delivered to the patients in medical imaging require particular expertise in the field of medical physics. The employment of a Specialised Medical Radiation Physicist (PSRPM), formerly called a "radiophysicist", has been extended to radiology, having already been compulsory in radiotherapy and nuclear medicine.

The duties of the PSRPM were clarified and broadened by the Order of 19th November 2004. Thus the medical radiation physicists must ensure the appropriateness of the equipment, data and computing processes for determining and delivering the doses and activity levels administered to the patient in any procedure involving ionising radiation. In the field of radiotherapy, they guarantee that the radiation dose received by the tissues due to be irradiated matches that prescribed by the prescribing physician.

Furthermore, they estimate the dose received by the patient during diagnostic procedures and play a part in quality assurance including inspecting the quality of the medical devices.

Temporary criteria determining the conditions for the presence of radiation physicists in radiotherapy centres have been defined by decree (Decree 2009-959 of 29th July 2009). Since the end of the transitional period (May 2012), the criteria defined by the National Cancer Institute (INCa) are now applicable pursuant to Decree 2007-388 of 21st March 2007, and in particular the criterion concerning the obligatory presence of a radiation physicist during the treatment sessions.

Since 2005, heads of facilities have had to draw up plans for medical radiation physics, defining the resources allocated, primarily in terms of staffing, in the light of the medical procedures carried out in the establishment, the actual or probable patient numbers, existing dosimetry skills and resources allocated to quality assurance and control.

The conditions of training of the PSRPMs were updated by the Orders of 28th February and 6th December 2011.

In the same way as the physician or the radiographer, the PSRPM can be designated as the PCR by the employer in accordance with the Labour Code. In operating theatres using X-ray generators, optimisation of the doses delivered to the patients, which is the competence of the PSRPM, contributes to optimisation of the doses delivered to the professionals performing the procedure.

Radiotherapy quality assurance

The quality assurance obligations of radiotherapy centres, provided for in Article R.1333-59 of the Public Health Code, were specified by ASN resolution 2008-DC-0103 dated 1st July 2008, which mainly concerns the Quality Management System (QMS), the management's commitments as stipulated in the QMS, the documentary system, staff responsibility, the analysis of the risks incurred by the patients during the radiotherapy process, and the identification and handling of undesirable situations or malfunctions, whether organisational, human or equipment-related.

These obligations entered into force in September 2011.

Medical imaging quality assurance obligations also appear in the Public Health Code but have not yet been clarified by an ASN resolution. Faced with the regular increase in the doses of ionising radiation delivered to patients over the past decade, ASN intended to publish this resolution in 2017. This action is part of the Cancer Plan 3 adopted by the Minister responsible for Health in January 2014.

Maintenance and quality control of medical devices

Maintenance and quality control, both internal and external, of medical devices using ionising radiation (Articles R. 5211-5 to R. 5211-35 of the Public Health Code) have been mandatory since publication of the Order of 3rd March 2003. External quality control is entrusted to organisations approved by the Director General of the ANSM (French National Agency for the Safety of Medication and Health Products) who is responsible for issuing a decision defining the acceptability criteria, the monitoring parameters and the frequency of the inspections on the medical devices concerned. The published decisions are posted on the ANSM website.

Training and information

Additional major factors in the optimisation approach are the training of health professionals and the information of patients.

Thus the objectives and content of training programmes for personnel conducting procedures using ionising radiation, or who take part in these procedures, were defined in the Order of 18th May 2004. To ensure the traceability of the data on application of the justification and optimisation principles, the report on the procedure, written by the medical practitioner carrying out the examination, must provide information justifying the procedures and the operations carried out as well as the data used to estimate the dose received by the patient (Order of 22nd September 2006). These training courses were evaluated by ASN in 2012, and work is in progress to improve this training system, with updating of the Order by means of a resolution being planned for 2016.

Finally, before carrying out a diagnostic or therapeutic procedure using radionuclides (nuclear medicine), the physician must give the patient oral and written guidelines on radiation protection that are of use to him/herself, his/her relations, the public and the environment. In the case of a therapeutic nuclear medicine procedure, this information - which is contained in a written document – gives advice on day to day living such as to minimise external exposure of the patient's friends and family and the risk of any contamination, for example by specifying the number of days during which contact with the spouse and children must be limited. Recommendations (French High Public Health Council, learned societies) were distributed by ASN (January 2007) to enable the content of the information already sent out to be harmonised.

2.2.3 Forensic applications of ionising radiation

In the forensic field, ionising radiation is used in a wide variety of sectors such as occupational medicine, sports medicine or for investigative procedures required by the courts or insurance companies. The principles of justification and optimisation apply to both the person requesting the examinations and the person performing them.

In occupational medicine, ionising radiation is used for medical monitoring of workers (whether or not professionally exposed to ionising radiation, for example workers exposed to asbestos).

UNDERSTAND

The new Euratom Directive and the Public Health Code (radiation protection of patients)

The new Euratom Directive 2013/59 introduces the obligation to define a *"system for recognition of experts in medical physics"*. This requirement should lead to a forthcoming publication defining a status for medical physicists and dosimetrists (currently under preparation under the responsibility of the General Directorate for Health Care – DGOS). For radiotherapy, the Directive makes risk assessment, recording and analysis of undesirable events mandatory, along with their notification to the authorities, a system which is already in force in France.

For forensic applications of ionising radiation, the new Euratom Directive introduces a new terminology *("deliverable exposure of individuals for non-medical imaging purposes")* and should lead to a review of the existing arrangements, with more operational application of the justification principles.

2.3 Protection of persons exposed to a natural source of ionising radiation

2.3.1 Protection of persons exposed to radon

The regulatory framework applicable to management of the radon-related risk in premises open to the public (Article R. 1333-15 et seq. of the Public Health Code) introduces the following clarifications:
- The radon monitoring obligation applies in geographical areas in which radon of natural origin is likely to be measured in high concentrations and in premises in which the public is likely to stay for extended periods.
- The measurements are made by organisations approved by ASN, these measurements being repeated every 10 years and whenever work is carried out to modify the ventilation or the radon tightness of the building.

In addition to introducing action trigger levels of 400 and 1,000 Bq/m^3, the implementing Order of 22nd July 2004 concerning management of the radon risk in premises open to the public defined geographical zones and premises open to the public for which radon measurements are now mandatory:
- the geographical areas are the 31 départements classified as having priority for radon measurement (see chapter 1);
- the categories of premises open to the public cover teaching institutions, health and social institutions, spas and prisons.

The obligations of the owner of the facility are also specified when the action levels are found to have been exceeded. The Order of 22nd July 2004 was followed by the publication in the Official Journal of 22nd February 2005 of an opinion concerning the definition of the actions and work to be carried out in the event the action levels of 400 and 1000 Bq/m^3 are exceeded. The accreditation conditions for the organisations approved to carry out activity concentration measurements, the measurement conditions and the data transmission procedures are clarified by four ASN resolutions:
- ASN resolution 2009-DC-0134 of 7th April 2009, amended by resolution 2010-DC-0181 of 15th April 2010, sets the approval criteria, provides the detailed list of information to be enclosed with the approval application, and specifies the conditions of issue, verification and withdrawal of approval;
- ASN resolution 2009-DC-0136 of 7th April 2009 concerns the objectives, duration and content of the training programmes for the individuals carrying out radon activity concentration measurements.
- ASN resolution 2015-DC-0506 of 9th April 2015 concerning the conditions in which radon activity is measured, repealing resolution 2009-DC-0135 of 7th April 2009;
- ASN resolution 2015-DC-0507 of 9th April 2015 concerning the technical rules for the transmission of the radon measurement results produced by approved organisations and the conditions for access to these results, pursuant to the provisions of Article R. 1333-16 of the Public Health Code.

The list of approved organisations is published in the ASN *Official Bulletin* on *www.asn.fr.*

In the workplace, Article R. 4451-136 of the Labour Code also requires that the employer carry out radon activity measurements and take the necessary steps to reduce exposure when the results of the measurements reveal an average radon concentration higher than the levels set in an ASN decision. The Order of 7th August 2008 defines the workplaces in which these measurements are required and ASN resolution 2008-DC-0110 of 26th September 2008 specifies the reference levels above which the radon concentration must be reduced.

The transposition of European Directive 2013/59/Euratom will reinforce public and worker protection against the risk of exposure to radon. The Member States must thus:
- set a national reference level for radon concentrations inside buildings, not to exceed 300 Bq/m^3;
- encourage a survey of homes in which radon concentrations (annual average) exceed the reference level;
- ensure that information is made available both locally and nationally on exposure to radon inside buildings and the corresponding health risks, as well as on the importance of measuring exposure to radon and the technical means for lowering existing radon concentrations.

Ordinance 2016-128 of 10th February 2016 thus introduced new legislative provisions into the Public Health Code (which will come into force no later than 1st July 2017) and the Environment Code, to ensure lasting information of the population and to better estimate the exposure of the French population to radon. These new provisions aim to:
- consider the radon concentration as an indoor air quality parameter;
- set up a system of mandatory information of owners, new buyers of real estate and landlords, in areas with a high radon potential;
- collect the results of the radon measurements taken in homes, at the initiative of the owners or local authorities, in order to gain a clearer estimate of the exposure of the French population to radon.

2.3.2 Other sources of exposure to “enhanced” natural radiation

Professional activities which use materials which naturally contain radionuclides not used for their radioactive properties but which are liable to create exposure likely to harm the health of workers and the public (“enhanced” natural exposure) are subject to the provisions of the Labour Code (Articles R. 4451-131 to 135) and the Public Health Code (Article R. 1333-13).

The Order of 25th May 2005 defines the list of professional activities using raw materials naturally containing radionuclides, the handling of which can lead to significant exposure of the general public or of workers[3].

For these activities, the Public Health Code requires an estimation of the doses to which the general public is exposed on account of the installation or the production of consumer goods or construction materials (see chapter 1). In addition, and if protection of the public so warrants, it will also be possible to set radioactivity limits for the construction materials and consumer goods produced by some of these industries (Article R. 1333-14 of the Public Health Code). This latter measure complements the ban on the intentional addition of radioactive materials to consumer goods.

For the occupational exposure resulting from these activities, the Labour Code requires a dose assessment to be carried out under the responsibility of the employer. Should the dose limit of 1 mSv/year be exceeded, steps to reduce exposure should be taken. The above-mentioned Order of 25th May 2005 specifies the technical procedures for evaluating the doses received by the workers.

Finally, the Labour Code (Article R. 4451-140) stipulates that for aircrews likely to be exposed to more than 1 mSv/year, the employer must evaluate the exposure, take steps to reduce it (particularly in the event of a declared pregnancy) and inform the personnel of the health risks. The order of 7th February 2004 defines the procedures for implementing these measures. The transposition of the new Euratom Directive 2013/59/Euratom should lead to these activities being subject to the legal system for nuclear activities as defined in Article L. 1333-1 of the Public Health Code.

3. THE LEGAL SYSTEM APPLICABLE TO BASIC NUCLEAR INSTALLATIONS

Basic Nuclear Installations (BNIs) are installations which, due to their nature or to the quantity or activity of the radioactive substances they contain, are subject to particular provisions in order to protect the general public and the environment.

3. *This concerns: the combustion of coal in coal-fired power stations; the treatment of tin, aluminium, copper, titanium, niobium, bismuth and thorium ores; the production of refractory ceramics and the glasswork, foundry, iron and steel and metallurgy activities that use them; the production or use of compounds containing thorium; the production of zircon and baddaleyite, and the foundry and metallurgy activities that use them; the production of phosphated fertilisers and phosphoric acid; the treatment of titanium dioxide; the treatment of rare earths and the production of pigments containing them; the treatment of underground water by filtration for the production of water for human consumption and mineral waters and spas.*

UNDERSTAND

The new Euratom Directive and the Public Health Code (protection of the population)

The Euratom Directive does not modify the limits of public exposure to ionising radiation (1 mSv/year). It does however introduce:
- a new regulatory framework for regulating natural radioactivity in construction materials: new regulations will need to be prepared in France;
- the obligation of establishing a national radon action plan (already in place in France, see chapter 1) but also of reducing the reference level from 400 bq/m^3 to 300 bq/m^3.
- in the nuclear activities system, the need to include professional activities which use materials containing naturally-occurring radionuclides not used for their radioactive properties.

France already has a national radon action plan, which is part of the National Environmental Health Risks prevention Plan (PNSE) specified in Article L.1311-6 of the Public Health Code. The third national radon action Plan for the period 2016-2019 is currently under preparation. It will take account of the requirements of Appendix XVII of the Directive.

3.1 The legal bases

3.1.1 International conventions and standards

On proposals from member States, IAEA develops reference texts called “Safety Standards” describing safety principles and practices. They concern installation safety and radiation protection, the safety of waste management and the safety of radioactive substances transportation. Although these documents are not binding, they do nonetheless constitute references which are widely drawn on in the drafting of national regulations.

Several legislative and regulatory provisions relative to BNIs are derived from or take up international conventions and standards, and notably those of IAEA.

Two Conventions deal with safety (Convention on Nuclear Safety and Joint Convention on the Safety of Spent Fuel Management and the Safety of Radioactive Waste Management), while two others deal with the operational management of the consequences of any accidents (Convention on early notification of a nuclear accident and Convention on assistance in the case of a nuclear accident or radiological emergency). France is a contracting party to these four international Conventions. These Conventions are presented in detail in chapter 7.

The other conventions linked to nuclear safety and radiation protection

Other international conventions, the scope of which does not fall within the remit of ASN, may be linked to nuclear safety. Of particular relevance is the Convention on the Physical Protection of Nuclear Material, the purpose of which is to reinforce protection against malicious acts and against misappropriation of nuclear materials. This Convention entered into force in February 1987 and as at 15th September 2015, it comprises 153 contracting parties.

For France, these conventions are a tool to be used to reinforce nuclear safety, periodically presenting the international community with the status of the facilities concerned and the steps taken to ensure their safety.

3.1.2 European texts

Several European community texts apply to BNIs. The more important ones are described below.

The EURATOM Treaty

The EURATOM Treaty, which was signed in 1957 and came into force in 1958, aimed to develop nuclear power while protecting the general public and workers from the harmful effects of ionising radiation.

Chapter III of Title II of the EURATOM Treaty deals with health protection as linked to ionising radiation.

Articles 35 (implementation of means for checking compliance with standards), 36 (information to the Commission on environmental radioactivity levels) and 37 (information to the Commission on planned effluent discharges) deal with the issues of discharges and environmental protection.

The provisions regarding information of the Commission were integrated into Decree 2007-1557 of 2nd November 2007, amended, relative to Basic Nuclear Installations and to the regulation of the nuclear safety of the transport of radioactive substances, known as the "BNI Procedures Decree". In particular, the decrees authorising BNI creation, prescribing final shutdown, or authorising significant modifications to the facilities leading to an increase in discharge limit values, are only issued once the opinion of the Commission has been obtained.

The Directive of 25th June 2009 establishing a community framework for the nuclear safety of nuclear facilities, amended by Directive 2014/87/Euratom of 8th July 2014

Council Directive 2009/71/Euratom of 25th June 2009 creates an EU framework for nuclear safety and paves the way for the creation of a common legal framework for nuclear safety among all Member States.

This Directive defines basic obligations and general principles in this field. It strengthens the role of the national regulatory organisations, contributes to harmonising the safety requirements between the Member States in order to develop a high level of safety in the installations and encourages a high level of transparency on these issues.

It comprises stipulations regarding cooperation between nuclear regulators, in particular the creation of a peer review mechanism, staff training, regulation and inspection of nuclear installations and public transparency. In this respect, it reinforces cooperation between the Member States.

Finally, it takes account of the harmonisation work being carried out by the Western European Nuclear Regulators Association (WENRA), (see Chapter 7, point 2.8).

Directive 2014/87/Euratom of 8th July 2014 modifies Directive 2009/71/Euratom of 25th June 2009 and makes the following substantial improvements:
- concepts converging with those of IAEA (incident, accident, etc.);
- highlighting of the principles of "defence in depth" and "safety culture";
- clarification of responsibilities in the oversight of the safety of nuclear installations;
- the safety objectives for nuclear installations which stem directly from the safety requirements used by the WENRA association;
- a safety reassessment of each nuclear facility at least once every ten years;
- every 6 years, the organisation of peer reviews by the European counterparts on specific safety topics, conducted in the spirit of the stress tests performed in the aftermath of the Fukushima-Daiichi accident;
- the obligation for nuclear facility licensees and the nuclear safety authorities to inform local populations and the stakeholders.

These provisions significantly reinforce the community framework for oversight of the safety of nuclear facilities (see chapter 7, point 2.4). For those which require legislative weight, transposition is ensured by Articles L. 591-2 and L. 591-6 to L. 591-8 of the Environment Code, resulting from Ordinance 2016-128 of 10th February 2016 constituting various nuclear provisions, issued on the basis of the authorisation given in the Energy Transition for Green Growth Act of 17th August 2015 (TECV).

Directive of 19th July 2011 establishing a European community framework for the responsible and safe management of spent fuel and radioactive waste

Council Directive 2011/70/Euratom of 19th July 2011 establishes a European Community framework for the responsible and safe management of spent fuel and radioactive waste. It applies to the management of spent fuel and the management of radioactive waste, from production to disposal, when this waste is the result of civil activities. Like the Euratom Directive of 25th June 2009, it calls for each Member State to set up a coherent and appropriate national framework and sets various requirements for the States, the safety regulators and the licensees. By the 23rd August 2013 deadline set by this Directive for its transposition into the laws of the Member States, most of this Directive had been transposed into French law. The additional legislative measures necessary were implemented by Ordinance 2016-128 of 10th February 2016.

For the drafting of these two Directives, the institutions of the European Union benefit from the work done by the WENRA association (see Chapter 7, point 2.8).

3.1.3 National texts

The legal system applicable to the BNIs was revised in depth by Act 2006-686 of 13th June 2006 on transparency and security in the nuclear field, called the "TSN Act", and its application decrees, and in particular Decree 2007-1557 of 2nd November 2007, concerning BNIs and the regulation of nuclear safety in the transport of radioactive substances, called the "BNI Procedures Decree".

Since 6th January 2012, the provisions of the three main Acts that specifically concern BNIs – Act 2006-686 of 13th June 2006 on transparency and security in the nuclear field (called the "TSN Act"), Planning Act 2006-739 of 28th June 2006 relative to the sustainable management of radioactive materials and waste (called the "Waste Act"), and Act 68-943 of 30th October 1968 relative to civil liability in the field of nuclear energy (called the "RCN Act") - have been codified in the Environment Code.

Title VI and a few provisions of Title VIII of the TECV Act and Ordinance 2016-128 of 10th February 2016 constituting various nuclear provisions, make substantial modifications to the legislative framework for regulation of nuclear activities, BNIs in particular. ASN will again assist the Ministry responsible for the Environment with the drafting of regulatory texts clarifying these new legislative provisions and with drafting of the regulatory part of the Environment Code with regard to nuclear matters.

Environment Code

The provisions of Chapters III, V and VI of Title IX of Book V of the Environment Code underpin the BNI licensing and regulation system.

The legal system applicable to BNIs is said to be "integrated" because it aims to cover the prevention or control of all the risks and detrimental effects, whether or not radioactive, that a BNI could create for man and the environment.

About fifteen decrees specify the legislative provisions of Title IX of Book V of the Environment Code, in particular Decree 2007-830 of 11th May 2007 concerning the list of BNIs and Decree 2007-1557 of 2nd November 2007 as amended, concerning BNIs and the regulation of the nuclear safety of the transport of radioactive substances, known as the "BNI Procedures Decree" (see below).

ENERGY TRANSITION FOR GREEN GROWTH ACT

Ordinance 2016-128 of 10th February 2016 constituting various nuclear provisions, ensures the transposition of several Directives with respect to the TECV Act.

Issued on the basis of the authorisation given in the TECV Act, the Ordinance of 10th February 2016 comprises measures which, with respect to the Act, transpose the following European Directives into French law:
- Council Directive 2011/70/Euratom of 19th July 2011 establishing a European Community framework for the responsible and safe management of spent fuel and radioactive waste.
- Directive 2014/87/Euratom, modifying Directive 2009/71/Euratom of 25th June 2009 establishing a Community framework for the nuclear safety of nuclear facilities;
- Directive 2010/75/EU of 24th November 2010 (known as the "IED Directive") concerning industrial emissions;
- Directive 2012/18/EU of 4th July 2012 (known as the "Seveso III" Directive) on the control of major accident hazards involving dangerous substances.

The IED and Seveso III Directives are the two European environmental protection instruments applying to industrial installations. The purpose of the first is to reduce pollutant emissions during normal operation, while the second is designed to mitigate the consequences of a major accident on human health and the environment.

The provisions of Chapter II of Title IV of Book V of the Environment Code (drawn in particular from the codification of the "Waste Act") introduce a coherent and exhaustive legislative framework for the management of all radioactive waste.

"BNI Procedures Decree" of 2nd November 2007

Decree 2007-1557 of 2nd November 2007 concerning BNIs and regulation of the nuclear safety of the transport of radioactive substances, implements Article L. 593-43 of the Environment Code.

It defines the framework in which the BNI procedures are carried out and covers the entire lifecycle of a BNI, from its creation authorisation and commissioning, to final shutdown, decommissioning and delicensing. Finally, it determines the relations between the Minister responsible for Nuclear Safety and ASN in the field of BNI safety.

The Decree clarifies the applicable procedures for adoption of the general regulations and for issuing individual resolutions concerning BNIs. It defines how the Act is implemented with regard to inspections, policing and administrative or criminal sanctions. Finally, it defines the particular conditions for application of certain administrative systems within the perimeter of the BNIs.

In 2016, this Decree will be modified to take account of the changes brought about by the TECV Act and by Ordinance 2016-128 constituting various nuclear provisions. It will be codified in the Environment Code.

3.2 General technical regulations

The general technical regulations provided for by Article L. 593-4 of the Environment Code comprise all general texts setting technical rules for nuclear safety, whether ministerial Orders or ASN statutory resolutions. They are supplemented by circulars, Basic Safety Rules (BSR) and ASN guidelines, which are not binding.

Following the TSN Act of 13th June 2006, ASN began work on overhauling the general technical regulations applicable to BNIs, with the Order of 7th February 2012, called the "BNI Order", setting general rules for Basic Nuclear Installations, and about fifteen ASN statutory resolutions, some of which are still being drafted.

3.2.1 Ministerial Orders

The Order of 7th February 2012 setting out the general rules for basic nuclear installations, known as the «BNI Order» is a key milestone in the overhaul of the general technical regulations applicable to BNIs.

"BNI Order" of 7th February 2012

Issued pursuant to Article L. 593-4 of the Environment Code, the "BNI Order" defines the essential requirements applicable to the BNIs to protect the interests listed in the Act: public safety, health and sanitary conditions; protection of nature and the environment.

The BNI Order of 7th February 2012, modified by the order of 26th June 2013, applies throughout the existence of the facility, from design through to delicensing. It recalls the principle of "integrated safety", that is the protection of all the interests mentioned in Article L. 593-1 of the Environment Code (safety, public health and protection of nature and the environment) – in addition to simply preventing accidents – and of the "graded approach" (in other words the graduated nature of the requirements and oversight, which must be proportionate to the potential consequences of the issues being dealt with).

The BNI Order of 7th February 2012 addresses the following subjects:
- organisation and responsibility;
- the demonstration of nuclear safety;
- control of detrimental effects and the impact on health and the environment;
- pressure equipment designed specifically for BNIs;
- waste management;
- preparation and management of emergency situations.

In addition, the BNI Order of 7th February 2012 defines some particular provisions applicable to certain categories of installations or to certain activities within a BNI: nuclear power reactors, on-site transport of hazardous goods, decommissioning, storage of radioactive substances and radioactive waste disposal facilities.

It incorporates into French regulations the "reference levels" defined by WENRA, which has worked for several years on defining a common baseline of requirements. The work done by WENRA was built around the IAEA safety standards and the regulations or best practices employed in the Member States of the association. This work led to the definition of a range of requirements designed to harmonise the safety of the reactors in operation in Europe.

The provisions of the Order concerning the performance of probabilistic assessments, the practical preclusion of certain events, the qualification system for Elements Important for Protection (EIP) or the application of certain new rules drawn from the regulations applicable to ICPEs (except for large cooling towers) may require the revision of certain points of the safety case and in-depth analyses, which could entail the revision of certain construction or operating provisions. They will come into force at the next periodic safety review or the next significant modification of the BNI, or on the occasion of final shutdown and decommissioning of the facility taking place as of 1st July 2015.

3.2.2 ASN statutory resolutions

Pursuant to Article L. 592-20 of the Environment Code, ASN may issue statutory resolutions to clarify decrees and orders in the field of nuclear safety or radiation protection, which have to be approved by the Minister in charge of Nuclear Safety and Radiation Protection.

ASN has defined a programme for drafting these statutory resolutions aimed at clarifying the BNI Procedures Decree of 2nd November 2007 or the BNI Order of 7th February 2012. Even before being required by law, ASN has from the outset submitted its draft statutory resolutions to public consultation on *www.asn.fr* (see chapter 6, point 2.2).

It should be pointed out that ASN proposed that some of its statutory resolutions also be presented to the Higher Council for the Prevention of Technological Risks (CSPRT) (more specifically with regard to resolutions covering topics that the CSPRT examines within the context of the ICPE system) in order to ensure greater consistency between the requirements applicable to ICPEs and BNIs (see chapter 2, point 2.4.3).

Diagram 3 shows the degree of progress of the project to overhaul the general technical regulations applicable to BNIs.

In 2015, two resolutions were adopted to supplement the implementation procedures of the BNI Order of 7th February 2012.

ASN resolution 2015-DC-0508 of 21st April 2015 concerning the study of waste management and the inventory of waste produced in the BNIs

ASN resolution 2015-DC-0508 of 21st April 2015 concerning the study of waste management and the inventory of waste produced in the BNIs clarifies the rules applicable to management of the waste produced in BNIs, in particular:
- the contents of the waste management study stipulated in paragraph 3° of section II of Article 20 of the above-mentioned Decree of 2nd November 2007 and Article 6.4 of the above-mentioned Order of 7th February 2012;
- the procedures concerning the definition and management of the waste zoning plan mentioned in Article 6.3 of the above-mentioned Order of 7th February 2012;
- the contents and procedures for producing the waste inventory stipulated in Article 6.6 of the above-mentioned Order of 7th February 2012.

TO BE NOTED

General technical regulations applicable to BNIs

The BNI Order of 7th February 2012 brings about a fundamental but nonetheless gradual change in the technical regulatory framework applicable to BNIs, already clarified by a number of ASN statutory resolutions.

ASN, whose role is to draft or assist with the drafting of regulations, has begun to revise them with the aim of achieving clear, complete reference regulations reflecting the best safety standards but which are also proportionate to the safety and radiation protection issues.

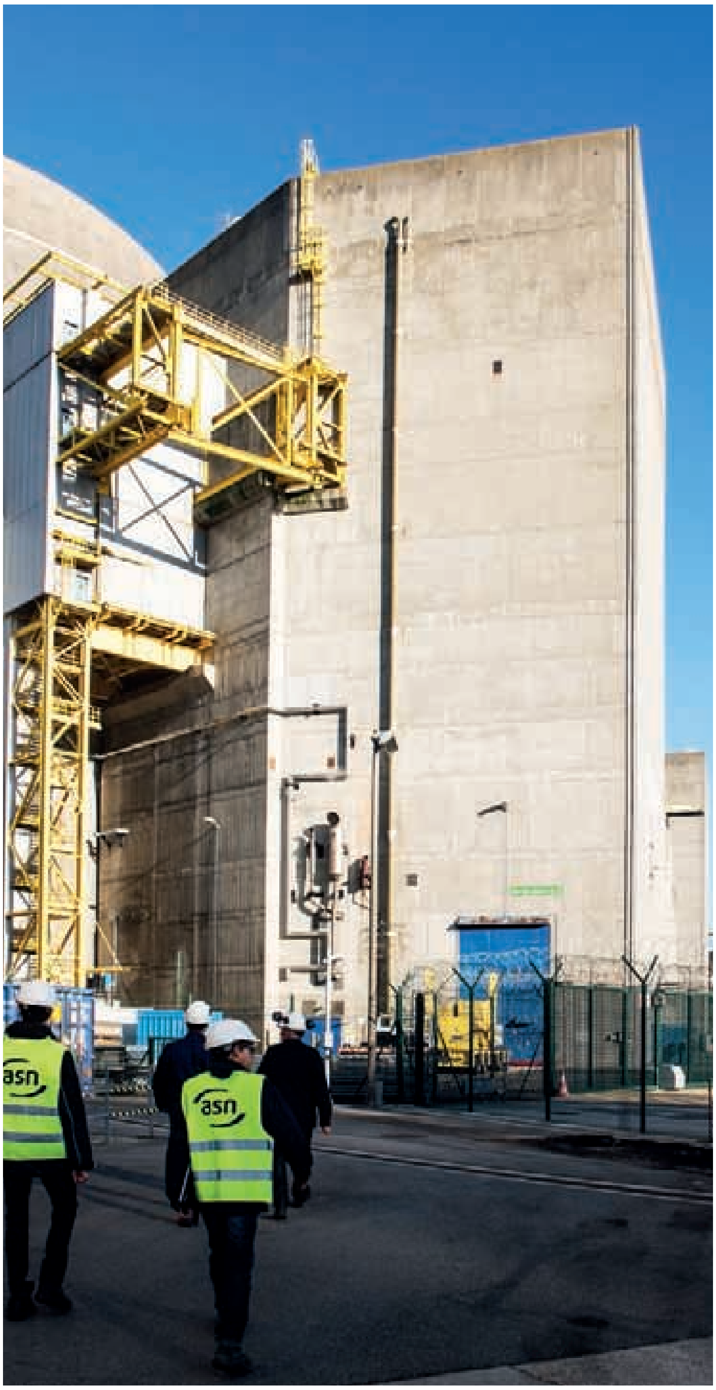
ASN thus carries out this work with the aim of involving all the stakeholders in the drafting of the regulations, given that broader consultation is a means of ensuring that the regulations will be appropriate and will be easier to understand and implement.

To ensure correct application of the regulations, ASN has also initiated a process to assist all the nuclear stakeholders through a series of seminars and meetings. ASN thus organises presentation and discussion sessions about the BNI Order, the latest being held in Marseille in October 2015.

ASN intends to continue and expand this support for all the nuclear stakeholders for the duration of the process to overhaul the general technical regulations applicable to BNIs, which should continue until 2017 (by which date all statutory resolutions and guidelines should be published).

After a few years, ASN will analyse experience feedback from application of the new regulations, to help guide subsequent choices.

A special section was created on *www.asn.fr* in which ASN makes a certain number of documents available, in particular presentation media for the seminar of 21st March 2014, number 197 of *Contrôle* magazine - which looks back at the various steps in the process to overhaul the general technical regulations applicable to BNIs, and provides a forum for the various stakeholders concerned by its implementation.



ASN inspection in Paluel NPP, November 2015.

ASN resolution 2015-DC-0532 of 17th November 2015 concerning the BNI safety analysis report

ASN resolution 2015-DC-0532 of 17th November 2015 concerning the BNI safety analysis report specifies the contents of the safety analysis report the licensee is required to transmit to ASN in its BNI creation or commissioning authorisation application file or in its BNI decommissioning file. The main provisions of this resolution more specifically concern:
- the objectives of the safety analysis report;
- the principles involved in drafting and updating the safety analysis report;
- compliance with the legislative and regulatory requirements;
- the description of the BNI and the measures designed to manage the risks it entails;
- the nuclear safety case (management of the risks presented by the installation);
- the design-basis study for the on-site emergency plan;
- particular operations such as the construction of the BNI, the management of radioactive sources and on-site transport operations;
- requirements specific to certain BNIs, in particular those which for example comprise one or more nuclear reactors.

This resolution supplements the statutory resolutions already in force and mentioned below:
- Resolution 2014-DC-0462 of 7th October 2014 concerning the control of the criticality risk in BNIs: It sets the technical rules applicable within BNIs in order to meet the goal of controlling the criticality risk. This resolution applies to all BNIs containing fissile material, except for those in which criticality is impossible owing to the physical-chemical characteristics of this material. Guidelines for implementation of this resolution should be published in 2016.
- Resolution 2014-DC-0444 of 15th July 2014 concerning PWR shutdowns and restarts stipulates that ASN approval is required to restart a reactor after a refuelling outage. It mainly defines the information to be sent to ASN by the licensee before, during and after the reactor outage, so that ASN can reach a decision on its restart and then remain informed of the overall results of the outage;
- Resolution 2014-DC-0420 of 13th February 2014 concerning physical modifications to BNIs: This resolution, which supplements the provisions of Chapter VII of Title III of the BNI Procedures Decree of 2nd November 2007, clarifies the provisions that the licensee of a BNI implements, on the one hand to assess and minimise the possible consequences for the protected interests of a physical modification to the facility and justify the acceptability of the remaining consequences and, on the other, to prepare for and then carry out this modification.
- Resolution 2014-DC-0417 of 28th January 2014 concerning the rules applicable to BNIs with regard to the management of fire risks: It sets the technical rules applicable within BNIs in order to meet the fire risk control objectives. In accordance with the defence in depth approach, the resolution defines requirements concerning measures to prevent the outbreak of fire, detection and fire-fighting measures and measures to prevent the propagation of a fire and mitigate its consequences.
- Resolution 2013-DC-0360 of 16th July 2013 concerning the control of detrimental effects and the health and environmental impact of BNIs: This resolution supplements the implementation conditions in Title IV of the BNI Order of 7th February 2012. Its main provisions concern methods for water intake and liquid or gaseous, chemical or radioactive discharges, the monitoring of water intake and discharges, environmental monitoring, prevention of detrimental effects and information to the regulatory authority and the public.
- Resolution 2013-DC-0352 of 18th June 2013 concerning public access to modification project files specified in Article L. 593-15 of the Environment Code: This specifies the implementation procedures for Article L. 593-15 of the Environment Code (and Article 26 of the BNI Procedures Decree of 2nd November 2007) which sets out the procedure for public access to the draft resolutions modifying the facility or its operating conditions which, without being significant, are nonetheless liable to cause a significant rise in water intake or environmental discharges. This public access procedure is run by the licensee (see chapter 6, point 2.2).
- Resolution 2012-DC-0236 of 3rd May 2012 supplementing certain conditions for application of ministerial decision JV/VF DEP-SD5-0048-2006 of 31st January 2006 which defines the conditions of use of spare parts in the main primary system and the main secondary systems of pressurized water nuclear reactors and specifies the documentation associated with each spare part. The resolution of 3rd May 2012 defines the technical and manufacturing surveillance documentation required for these components in order to establish consistency between these provisions and those applicable to the manufacture of pressure equipment.
- Resolution 2008-DC-0106 of 11th July 2008 concerning the use of internal authorisation systems in BNIs: The purpose of a system of internal authorisations is to reinforce the licensee's responsibility for nuclear safety and radiation protection. The regulations thus enable the licensee to carry out minor operations provided that it implements a system of reinforced and systematic internal controls, offering sufficient guarantees of quality, independence and transparency. Within this context, it is exempted from the notification procedure specified in Article 26 of the BNI Procedures Decree of 2nd November 2007. ASN authorises the use of such systems and monitors them.

3.2.3 Basic Safety Rules and ASN guides

ASN has drafted Basic Safety Rules (BSR) on a variety of technical subjects concerning BNIs. These are recommendations which specify safety objectives and describe practices ASN considers to be satisfactory. As part of the ongoing reorganisation of the general technical regulations applicable to BNIs, the BSR are gradually being replaced by ASN guides. Work is under way to identify the BSR which can be repealed and the guides needing to be updated.

The ASN guides collection was created as an educational tool for professionals. In 2015, it comprised twenty non-binding guides designed to affirm ASN doctrine, detail the recommendations, propose methods for achieving the objectives set in the texts and present methods and best practices stemming from experience feedback from significant events.

The ASN guides collection is presented in the appendix to this chapter.

3.2.4 French nuclear industry professional codes and standards

The nuclear industry produces detailed rules dealing with the state of the art and industrial practices. It groups these rules in "Industrial Codes". These rules allow concrete transposition of the requirements of the general technical regulations, while reflecting good industrial practice. They thus facilitate contractual relations between customers and suppliers.

In the particular field of nuclear safety, the Industrial Codes are drafted by the French association for NSSS equipment construction rules (AFCEN), of which EDF and Areva are members. The RCC Codes of design and construction rules have been drafted for the Design, Manufacture and Commissioning of Electrical Equipment (RCC-E), Civil Engineering (RCC-G) and Mechanical Equipment (RCC-M). A collection of in-service monitoring rules for mechanical equipment (RSE-M) has also been drafted.

These codes do not take the place of the regulations but are industrial tools which can be usefully employed as a basis for meeting the requirements of the regulations.

ASN's actions in this field are to oversee the drafting and updating of the codes and the acceptance of their usage in activities subject to its regulation.

ASN examines the codes drafting and utilisation processes, even if it does not carry out a complete analysis of their contents. It helps with the drafting and updating of codes in areas in which it considers that this would allow better implementation of the regulations.

ASN submits its comments on the use of the codes and, if it so deems necessary, sends requests for changes to the organisations responsible.

3.3 Plant authorisation decrees and commissioning licenses

Chapter III of Title IX of Book V of the Environment Code contains a creation authorisation procedure, which may be followed by a number of licensing operations throughout the life of a BNI, from its commissioning up to final shutdown and decommissioning, including any modifications made to the facility.

3.3.1 Safety options

Any industrial concern intending to operate a BNI may, even before starting the creation authorisation application procedure, ask ASN for an opinion on all or part of the safety options it has adopted for its installation. The applicant is notified of the ASN opinion and will produce any additional studies and justifications as necessary for a possible creation authorisation application. ASN generally asks a competent Advisory Committee to review the project.

The safety options will then be presented in the creation authorisation application file, in a preliminary version of the safety analysis report.

This preparatory procedure in no way exempts the applicant from the subsequent regulatory examinations but simply facilitates them.

3.3.2 Public debate

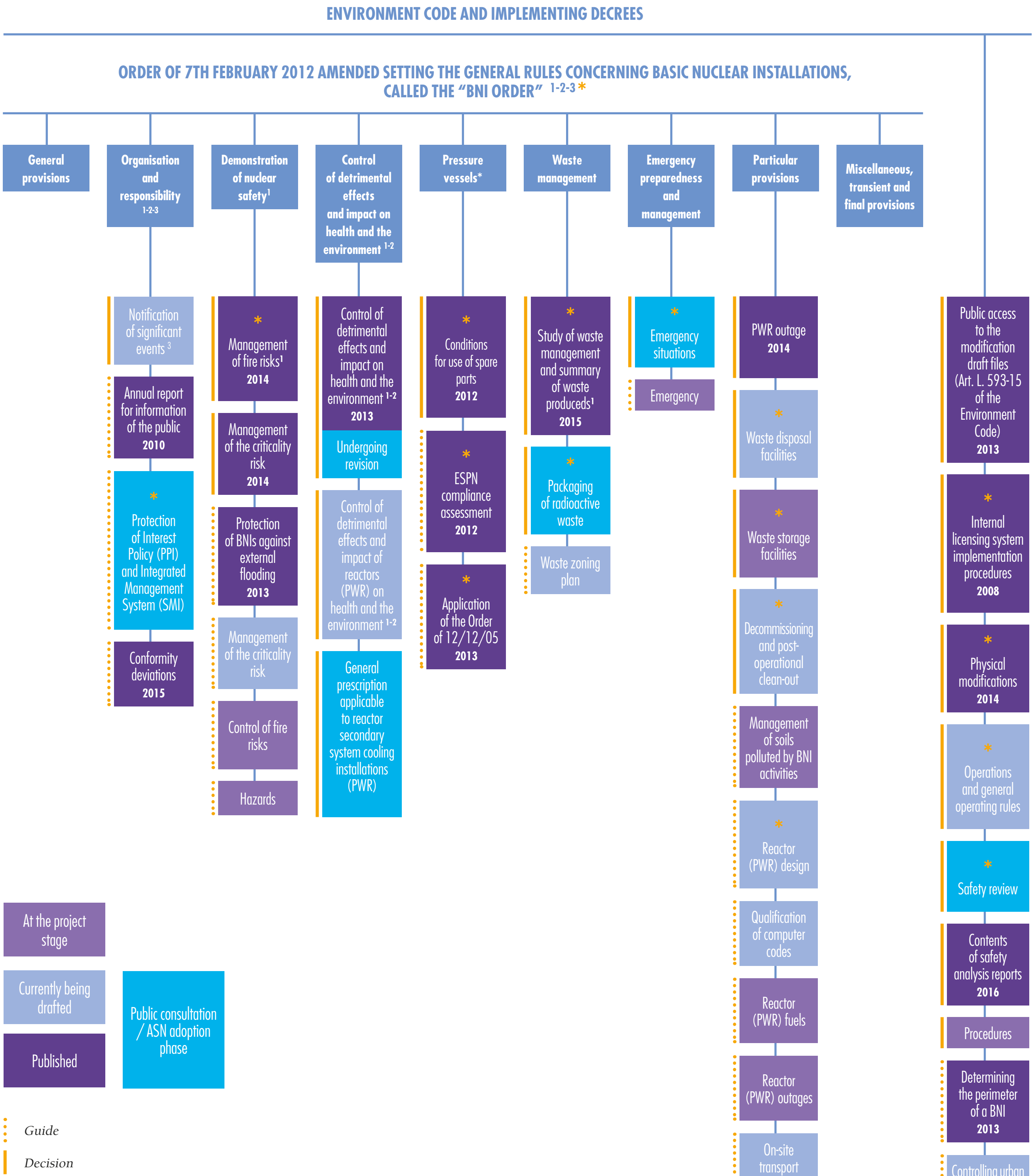
Pursuant to Articles L. 121-1 et seq. of the Environment Code, the creation of a BNI is subject to a public debate procedure when dealing with a new nuclear power generation site or a new site (other than for nuclear power generation) costing more than €300 million and, in certain cases, a new nuclear power generation site, or a new site (other than for nuclear power generation) costing between €150 million and €300 million (Article R. 121-1 of this same Code).

The public debate looks at the suitability, objectives and characteristics of the project.

3.3.3 The Creation Authorisation Decree

The creation authorisation application for a BNI is filed with the Minister responsible for Nuclear Safety by the industrial concern which intends to operate the facility, which thus acquires the status of licensee. The application is accompanied by a file comprising several items, including the detailed drawing of the installation, the impact assessment, the preliminary version of the safety analysis report, the risk management study and the decommissioning plan.

DIAGRAM 3: Status of progress of the overhaul of the general technical regulations applicable to BNIs, as at 18th January 2016



1. *Covering the scope of the Order of 31/12/1999*
2. *Covering the scope of the Order of 26/11/1999*
3. *Covering the scope of the Order of 10/08/1984*

* *Text concerned by the WENRA reference levels*

* *Title V entitled "Pressure equipment specially designed for Basic Nuclear Installations" of the BNI Order refers to the Order of 10th November 1999 concerning the monitoring of main primary system and main secondary system operations in pressurised water nuclear reactors and the Order of 12th December 2005 concerning nuclear pressure equipment.*

Drafts for modification of these Orders are currently being prepared.

ASN is responsible for reviewing the file, jointly with the Minister responsible for Nuclear Safety. This is followed by a period of parallel consultation of the public and technical experts.

The impact assessment is submitted for its opinion to the environmental authority of the Departmental Council for the Environment and Sustainable Development (CGEDD).

The public inquiry

Article L.593-8 of the Environment Code stipulates that the authorisation can only be granted after holding a public inquiry. The purpose of the inquiry is to inform the public and collect their opinions, suggestions and counterproposals, in such a way as to provide the competent authority with all the elements necessary for it then to make an informed decision.

The inquiry is carried out in accordance with the provisions of Articles L. 123-1 to L. 123-19 and R. 123-1 to R. 123-27 of the Environment Code. The Prefect opens the public inquiry at least in each of the communities of which any part is situated less than five kilometres from the perimeter of the installation. This inquiry lasts from a minimum of one month to a maximum of two months. The dossier submitted by the licensee in support of its authorisation application is made available in the public inquiry dossier. However, as the safety analysis report (containing the inventory of the risks the installation can present, the analysis of the measures taken to prevent these risks and a description of the measures designed to limit the probability of accidents and their effects) is a bulky document and is difficult for non-specialists to understand, it is supplemented by a risk control study, which itself comprises a non-technical summary of this study designed to make it easier to understand by the general public.

Furthermore, the procedures concerning BNIs subject to a public inquiry are within the scope of Decree 2011-2021 of 29th December 2011, determining the list of projects, plans and programmes to be communicated electronically to the general public under the experiment specified in section II of Article L. 123-10 of the Environment Code. This states that the Authority responsible for opening and holding the public inquiry shall communicate the main documents in the inquiry dossier to the general public in electronic format. This approach aims to make it easier for the public to become informed about the projects, in particular those who do not live in the places where the inquiry is being held. Using this means of providing access to information and the possibility of submitting observations in electronic format, as stipulated in Article R. 123-9 of the Environment Code since the publication of the above-mentioned Decree of 29th December 2011, aims to facilitate and improve the way in which the public can express their opinions. These recommendations came into force on 1st June 2012.

Construction of a BNI requires the issue of a building permit by the Prefect, according to procedures specified in Articles R. 421-1 et seq. and Article R. 422-2 of the Town Planning Code. Article L. 425-12 of the Town Planning Code, created by the TSN Act of 13th June 2006, states that *"when the project concerns a basic nuclear installation requiring creation authorisation pursuant to Article L. 593-7 of the Environment Code […], the work may not be performed before the closure of the public inquiry held prior to this authorisation."*

The creation of a Local Information Committee (CLI)

The TSN Act of 13th June 2006, now codified in Books I and V of the Environment Code, formally defined the status of the BNI Local Information Committees (CLI). The CLIs are presented in chapter 6.

The corresponding provisions can be found in sub-section 3 of section 2 of Chapter V of Title II of Book 1 of the Environment Code. The CLI can be created as soon as the BNI creation authorisation application is made. Whatever the case, it must be constituted once the authorisation decree has been issued.

The modifications made to the CLI's responsibilities by the TECV Act are detailed in chapter 6, point 2.3.1. The specific nature of the CLIs of BNIs located close to a border is taken into account because the Act enables foreign nationals to sit on these CLIs (this in particular concerns Germany, Belgium, Luxembourg and Switzerland).

Consultation of other European Union countries

Pursuant to Article 37 of the Treaty instituting the European Atomic Energy Community and to the BNI Procedures Decree of 2nd November 2007, the creation of a facility liable to discharge radioactive effluents into the environment can only be authorised after consulting the European Commission.

Consultation of technical organisations

The preliminary version of the safety analysis report appended to the creation authorisation application is transmitted to ASN, which may submit it for examination to one of the Advisory Committees reporting to it, following a report from IRSN.

Further to its investigation and the results of the consultations, ASN sends the Minister responsible for Nuclear Safety a draft decree proposal authorising or rejecting creation of the installation.

Creation Authorisation Decree

The Minister responsible for Nuclear Safety sends the licensee a preliminary draft Decree granting or refusing Creation Authorisation (DAC, see diagram 4). The licensee has a period of two months in which to present its observations. The Minister then obtains the opinion of ASN. ASN resolution 2010-DC-0179 of 13th April 2010 gives licensees and the

CLIs the possibility of being heard by the ASN Commission before it gives its opinion.

The creation authorisation for a BNI is delivered by a decree from the Prime Minister and countersigned by the Minister responsible for Nuclear Safety.

The Creation Authorisation Decree (DAC) establishes the perimeter and characteristics of the facility. It also specifies the duration of the authorisation, if applicable, and the installation commissioning deadline. It also specifies the essential elements required to protect public health and safety, or to protect nature and the environment.

The requirements defined by ASN for application of the Creation Authorisation Decree

For application of the DAC, ASN defines the requirements regarding the design, construction and operation of the BNI that it considers to be necessary for nuclear safety.

ASN defines the requirements regarding the BNI water intakes and effluent discharges. The specific requirements setting limits on the environmental discharges from the BNI under construction or in operation are subject to approval by the Minister responsible for Nuclear Safety.

3.3.4 Commissioning authorisation

Commissioning corresponds to the first utilisation of radioactive materials in the installation or the first operation of a particle beam.

Prior to commissioning, the licensee sends ASN a dossier comprising the updated safety analysis report of the "as-built" installation, the general operating rules, a waste management study, the on-site emergency plan and the decommissioning plan.

After checking that the installation complies with the objectives and rules specified in Chapter III of Title IX of Book V of the Environment Code and its implementing texts, ASN authorises commissioning of the installation and communicates this decision to the Minister responsible for Nuclear Safety and to the Prefect.

It also communicates it to the CLI.

3.3.5 BNI modifications

The BNI system, as modified by the TECV Act, makes provision for two cases when dealing with modifications to the facility or its operating conditions:

- "substantial" modifications to the facility (previously "significant" modifications of the facility), its authorised operating procedures or elements which led to its authorisation, specified in Article L. 593-14 of the Environment Code: these modifications are the subject of a procedure similar to that of a creation authorisation application in accordance with the procedure specified in Articles L. 593-7 to L. 593-12 of this same Code.
- As the regulatory texts currently stand, a modification is considered to be "substantial" in the cases mentioned in Article 31 of the BNI Procedures Decree of 2nd November 2007, that is:
  - a change in the nature of the installation or an increase in its maximum capacity;
  - a modification of the key elements protecting the interests mentioned in the first paragraph of Article L. 593-1 of the Environment Code, which appear in the authorisation decree;
  - the addition, within the perimeter of the facility, of a new BNI, the operation of which is linked to that of the facility in question.
- The other modifications are "significant» modifications to the installation, its authorised operating procedures, elements which led to its authorisation or its commissioning (they correspond to the former modifications subject to "Article 26 notification" of the BNI Procedures Decree of 2nd November 2007). Depending on their importance, they require either notification to ASN or authorisation by ASN under the terms of Article L. 593-15 of the Environment Code (the version resulting from the TECV Act). This same Article states that these modifications may be opened up for public consultation (public inquiry, public participation specified in Article L. 120-1-1 *via* the ASN website). Pending the update of the BNI Procedures Decree of 2nd November 2007 which will set criteria for differentiating between modifications requiring authorisation and those requiring notification, the "Article 26 notification" procedure of the BNI Procedures Decree remains in force. In accordance with this procedure, when a licensee envisages modifications to its facility or its operating conditions that are not considered to be substantial, it shall first of all notify ASN of them. It cannot make the modifications until a renewable period of at least six months has expired, unless ASN gives its express agreement. If it so considers necessary, ASN may stipulate requirements so that the envisaged modifications are reviewed or accompanied by additional measures to guarantee the protection of the interests mentioned in the first paragraph of Article L. 593-1 of the Environment Code.

UNDERSTAND

General Operating Rules

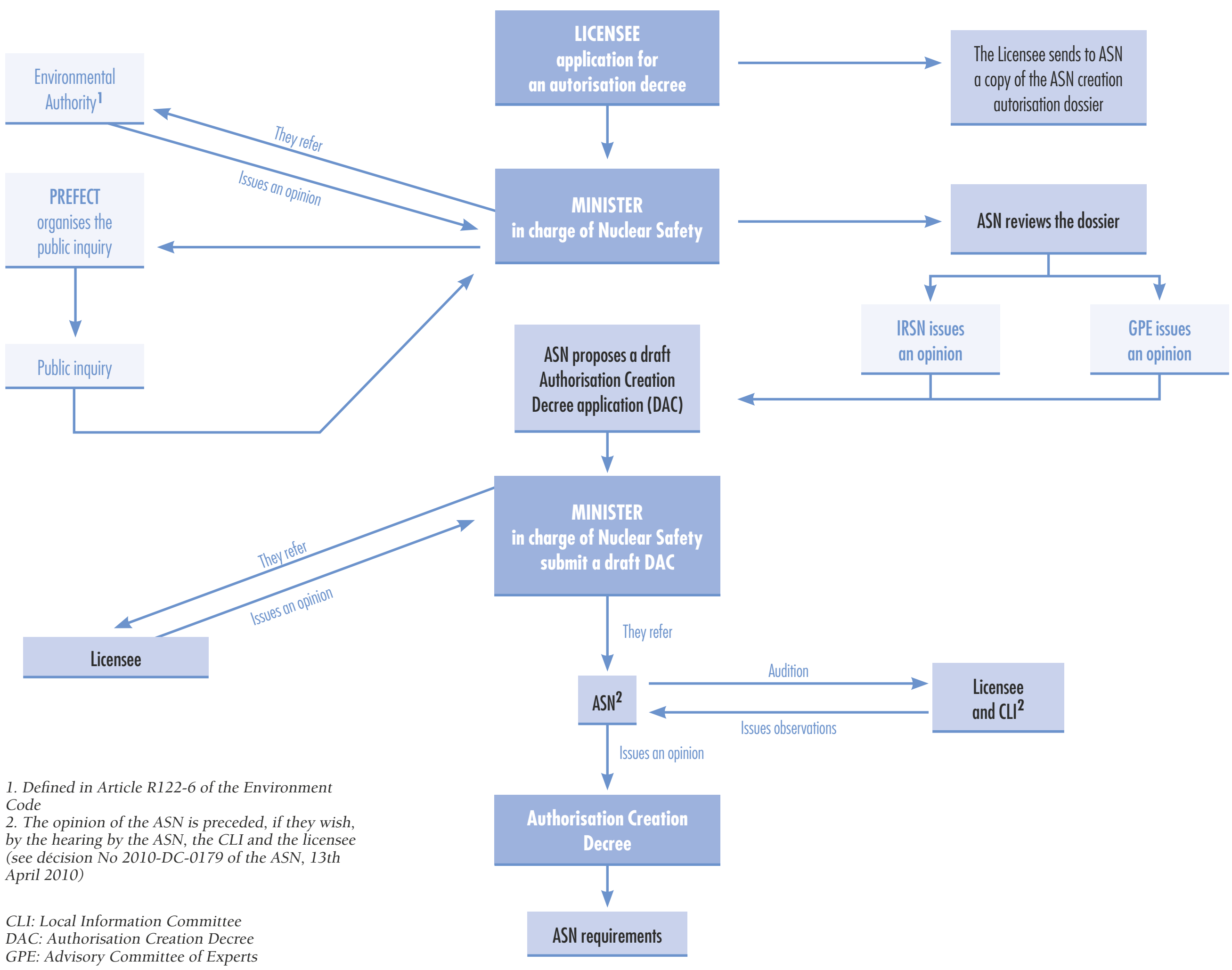
The General Operating Rules (RGE) are the "highway code" for nuclear reactors. They are drafted by the licensee and assessed by ASN prior to commissioning of the reactor and then each time a modification to the facility is liable to have an impact on this documentary baseline. They constitute an interface document between design and operation. They determine a set of specific rules, for which compliance guarantees that control of the reactor remains within the range covered by the nuclear safety case.

The procedure whereby the licensee gives the public access to the files for a BNI modification project that could cause a significant increase in its water intakes or effluent discharges to the environment, as specified by ASN resolution 2013-DC-0352 of 18th June 2013, remains in force (see chapter 6, point 2.2).

The other installations located within a BNI perimeter

The following co-exist within the perimeter of a BNI:
- the equipment and installations which are part of the BNI: they constitute an element of this facility necessary for its operation. Technically, depending on its type, this equipment may be considered comparable to classified installations but, as a part of the BNI, it is subject to the BNI system and BNI regulations.
- the equipment and installations which are not necessarily linked to the BNI. The "not necessary" equipment and installations on the Installations, Structures, Work and Fit-out subject to the Water Act (IOTA) or ICPE lists, situated within the perimeter of the BNI, remain subject to these systems, with ASN retaining competence for individual measures concerning this equipment and these installations and oversight thereof.

DIAGRAM 4: Creation authorisation procedure for a Basic Nuclear Installation defined in Chapter III of Title IX of Book V of the Environment Code



1. Defined in Article R122-6 of the Environment Code
2. The opinion of the ASN is preceded, if they wish, by the hearing by the ASN, the CLI and the licensee (see décision No 2010-DC-0179 of the ASN, 13th April 2010)

CLI: Local Information Committee
DAC: Authorisation Creation Decree
GPE: Advisory Committee of Experts

3.4 Particular requirements for the prevention of pollution and detrimental effects

3.4.1 The OSPAR Convention

The international OSPAR Convention (resulting from the merging of the Oslo and Paris conventions) is the mechanism whereby the European Commission and fifteen Member States, including France, cooperate to protect the marine environment of the North-East Atlantic. The strategic orientations for radioactive substances consist in *"preventing pollution of the maritime zone by ionising radiation by progressively and substantially reducing discharges, emissions and losses of radioactive substances. The ultimate aim is to achieve environmental concentrations that are close to the ambient values in the case of naturally occurring radioactive substances, and close to zero in the case of man-made radioactive substances"*. To achieve these objectives, the following are taken into account:
- the radiological impacts on humans and biota;
- the legitimate uses of the sea;
- technical feasibility.

Within the French delegation, ASN takes part in the work of the committee tasked with assessing application of this strategy.

3.4.2 The ESPOO Convention

The Convention on the assessment of environmental impacts in a transboundary context, more commonly called the "ESPOO Convention", requires that the contracting parties conduct an environmental assessment of the impacts of activities liable to have a transboundary environmental impact before licensing this activity and that they notify the neighbouring country concerned of this assessment. Certain nuclear facilities – such as NPPs, nuclear fuel production or enrichment facilities, radioactive waste disposal or reprocessing facilities – fall within the scope of this Convention.

The ESPOO Convention was adopted in 1991 and entered into force in September 1997.

3.4.3 ASN resolution 2013-DC-0360 of 16th July 2013 concerning the control of detrimental effects and the health and environmental impact of BNIs

Resolution 2013-DC-0360 of 16th July 2013 concerning the control of detrimental effects and the health and environmental impact of BNIs supplements the implementation procedures of Title IV of the BNI Order of 7th February 2012. Its main provisions concern methods for water intake and liquid or gaseous, chemical or radioactive discharges, the monitoring of water intake and discharges, environmental monitoring, prevention of detrimental effects and information of the regulatory authority and the public. With regard to environmental protection, the BNI Order of 7th February 2012 and the resolution of 16th July 2013 more specifically aim to address the following main objectives or issues:
- implement the integrated approach specified by law, whereby the BNI system governs all the risks, pollution and detrimental effects created by these installations;
- modify the regulations applicable to basic nuclear installations prior to 1st July 2013;
- incorporate into the regulations the requirements applicable to the BNI licensees by certain individual ASN decisions concerning water intake and effluent discharge, in order to create a more general and uniform framework;
- set binding unified principles and rules applicable to the BNIs;
- for BNIs, adopt requirements at least equivalent to those applicable to ICPEs and installations, structures, works and activities (IOTA) concerned by the list specified in Article L. 214-2 of the Environment Code, more specifically those of the Order of 2nd February 1998 concerning water intake and consumption and emissions of all types from installations classified on environmental protection grounds subject to authorisation, in accordance with the provisions of the BNI Order of 7th February 2012;
- adopt provisions, the implementation of which is such as to guarantee the quality of the steps taken by the BNI licensees for monitoring of their facilities (monitoring of effluents and of the environment);
- improve public information practices, making the corresponding steps taken by the licensees more legible.

3.4.4 BNI discharges

BNI discharges management policy

Like all industries, nuclear activities (nuclear industry, nuclear medicine, research installations, etc.) create by-products, which may or may not be radioactive. Steps are being taken to minimise their quantity through reduction at source.

The radioactivity discharged in effluents represents a marginal fraction of that which is confined in the waste.

The choice of the means of discharge (liquid or gaseous) is part of a more general approach aimed at mitigating the overall impact of the installation.

ASN makes sure that the BNI creation authorisation application explains the licensee's choices, in particular the reduction at source measures, the decisions taken between confinement, treatment or dispersal of substances, based on safety and radiation protection considerations.

The optimisation efforts encouraged by the authorities and made by the licensees have - for "equivalent operation" - resulted in these emissions being constantly reduced. ASN hopes that setting discharge limit values will encourage the licensees to maintain their discharge optimisation and management efforts. It ensures that discharges are kept to the minimum possible by using the best techniques available, and has undertaken a revision of the discharge limits in recent years.

The impact of BNI chemical discharges

The substances discharged can have an impact on the environment and the population owing to their chemical characteristics.

ASN considers that BNI discharges should be regulated in the same way as those of other industrial facilities. The TSN Act of 13th June 2006, codified in Books I and V of the Environment Code, and more broadly the general technical regulations concerning discharges and the environment, take this question into account. This integrated approach is little used abroad, where chemical discharges are often regulated by an Authority different from that in charge of radiological issues.

ASN wants the impact of chemical discharges on the populations and the environment to be as low as possible, in the same way as for radioactive substances.

The impact of thermal discharges from BNIs

Some BNIs, especially nuclear power plants, discharge cooling water into watercourses or the sea, either directly or after cooling in cooling towers. Thermal releases lead to a temperature rise in the receiving environment of up to several degrees.

The regulatory limits aim to prevent a modification of the receiving environment, in particular fish life, and to ensure acceptable health conditions if water is taken for human consumption downstream. These limits can thus differ according to the environment and the technical characteristics of each installation.

3.4.5 Prevention of accidental pollution

The BNI Order of 7th February 2012 and ASN resolution 2013-DC-0360 of 16th July 2013 concerning the control of detrimental effects and the health and environmental impact of BNIs, impose obligations designed to prevent, or in the event of an accident, to minimise direct or indirect discharges of toxic, radioactive, flammable, corrosive or explosive liquids into the sewer systems or the environment.

3.5 Requirements concerning radioactive waste and decommissioning

3.5.1 Management of BNI radioactive waste

The management of waste, whether or not radioactive, in the BNIs is regulated by ASN, notably to prevent and minimise – in particular at source – the production and harmfulness of the waste, more specifically by means of requirements concerning the design, classification, treatment and packaging.

In order to perform this regulation, ASN more specifically relies on a number of documents produced by the BNI licensees:
- the impact assessment, which is part of the creation authorisation application as described in Article 8 of the BNI Procedures Decree of 2nd November 2007;
- the waste management study, which is part of the commissioning authorisation application as described in Article 20 of the BNI Procedures Decree of 2nd November 2007, the contents of which are specified in Article 6.4 of the BNI Order of 7th February 2012. This study in particular includes an analysis of the waste produced or to be produced in the facility and the steps taken by the licensee to manage it, as well as the waste zoning plan;
- the waste summary specified in Article 6.6 of the BNI Order of 7th February 2012. This summary aims to verify that waste management complies with the provisions of the waste management study and to identify areas for improvement.

ASN resolution 2015-DC-0508 of 21st April 2015 concerning the study of waste management and the inventory of waste produced in the BNIs specifies the requirements concerning these documents and the operational waste management procedures.

3.5.2 Decommissioning

The legal framework for BNI decommissioning, in particular the modifications made by the TECV Act, are described in detail in chapter 15.

The final shutdown of a BNI is the responsibility of the licensee, who must notify the Minister responsible for Nuclear Safety and ASN no later than two years prior to final shutdown (this period may be shorter if so justified by the licensee). As of that date, the licensee is no longer authorised to operate its facility, which is considered to be finally shut down and must be decommissioned. Article L. 593-26 of the Environment Code states that until the decommissioning decree comes into force, the facility remains governed by the provisions of its Creation Authorisation Decree and the ASN prescriptions, which may be added to or modified if necessary.

Article L. 593-28 of the version of the Environment Code subsequent to the TECV Act, states that decommissioning of a nuclear facility must be prescribed by a decree, issued on the advice of ASN. The decommissioning file presented by the licensee undergoes the same consultations and inquiries as those applicable to a BNI creation authorisation application and in accordance with the same procedures.

This same article stipulates that the decommissioning decree in particular determines the characteristics of decommissioning, its completion deadline and, as necessary, the operations under the responsibility of the licensee after decommissioning.

Finally, Article L. 593-28 provides for the possibility of decommissioning a part of a BNI.

ASN has detailed the regulatory framework for BNI decommissioning operations in Guide No.6, which results from extensive work to clarify the administrative procedures while at the same time improving the extent to which nuclear safety and radiation protection are taken into account.

Installation delicensing

Following decommissioning, a nuclear installation can be delicensed. It is then removed from the BNI list and is no longer subject to the BNI system. To support its delicensing application, the licensee must provide a dossier demonstrating that the envisaged final state has indeed been reached and describing the state of the site after decommissioning (analysis of the state of the soil and remaining buildings or equipment, etc.). Depending on the final state reached, institutional controls may be implemented, according to the intended subsequent use of the site and buildings. These may contain a certain number of restrictions on use (to be used only for industrial applications for example) or precautionary measures (radiological measurements to be taken in the event of excavation, etc.). ASN can make the application of such institutional controls a prerequisite for delicensing.

3.5.3 The financing of decommissioning and radioactive waste management

Sections 1 and 2 of Chapter IV of Title IX of Book V of the Environment Code (previously Article 20 of the "Waste Act") create an arrangement for ring-fencing funds to meet the costs of decommissioning nuclear facilities and managing radioactive waste (see chapter 15, point 1.4). These arrangements are clarified by Decree 2007-243 of 23rd February 2007 concerning the secure financing of nuclear costs, modified by Decree 2013-678 of 24th July 2012 and the Order of 21st March 2007 concerning the secure financing of nuclear costs. The legal system created by these texts aims to secure the financing of nuclear costs, through implementation of the "polluter-pays" principle. It is therefore up to the nuclear licensees to ensure this financing, by setting up a portfolio of assets dedicated to the expected costs. This is done under the direct control of the State, which analyses the situation of the licensees and can prescribe measures should it be seen to be insufficient or inadequate. In any case, the nuclear licensees remain responsible for the satisfactory financing of their long-term costs.

It stipulates that the licensees must make a prudent assessment of the cost of decommissioning their installations or, for radioactive waste disposal installations, their final shutdown, maintenance and monitoring costs. They also evaluate the cost of managing their spent fuel and radioactive waste, according to Article L. 594-1 of the Environment Code. Pursuant to the Decree of 23rd February 2007, ASN issues an opinion on the consistency of the decommissioning and spent fuel and radioactive waste management strategy presented by the licensee with regard to nuclear safety.

From among the assets liable to be accepted to cover the provisions for the costs mentioned in Article L. 594-1 of the Environment Code (decommissioning of facilities, final shutdown, maintenance and monitoring costs, spent fuel and radioactive waste management costs), the Decree of 24th July 2013 identifies those which are mentioned by the provisions of the Insurance Code and those which are specific to the licensees of nuclear facilities. It makes certain types of debts acceptable (notably certain medium-term negotiable bonds and securitisation mutual funds) and, in certain conditions, unquoted stock; as a result of this extension, it more specifically clarifies the exclusion criteria for unquoted intra-group stock. It sets the maximum value of the assets within a given category or from the same issuer and determines new ceilings for assets that have become acceptable.

3.6 Particular requirements for pressure equipment

Pressure equipment is subject to the provisions of Chapter VII of Title V of Book V of the Environment Code, resulting from Act 2013-619 of 16th July 2013 comprising various provisions to adapt to European Union law in the field of sustainable development.

Most of the provisions with regard to pressure equipment of Decree 2015-799 of 1st July 2015 concerning products and equipment entailing a risk, which sets the procedures for application of this Chapter VII, will come into force on 19th July 2016. Until that date, the regulatory provisions in force are those defined by Decree 99-1046 of 13th December 1999 concerning pressure equipment and by its implementing tests. The principles of these regulations are those of the new approach pursuant to the European Pressure Equipment Directive.

Pressure equipment specially designed for BNIs, known as "Nuclear Pressure Equipment" (ESPN) is subject to both the BNI system and the pressure equipment system. For this equipment, specific Orders stipulate the provisions defined by the above-mentioned Decree of 13th December 1999 and finally the Order of 30th December 2015 concerning nuclear pressure equipment, most of which will come into force on 19th July 2016.

Nuclear pressure equipment is designed and produced by the manufacturer under its own responsibility. The manufacturer is required to comply with the main security and radiation protection requirements contained in the regulations and to have the conformity of its nuclear pressure equipment assessed by an independent, competent third-party organisation approved by ASN. The equipment in operation must be monitored and maintained by the licensee under ASN control and must undergo periodic technical inspections by ASN-approved organisations. The list of approved organisations and the associated approval decisions are available on the *www.asn.fr* website.

ASN is responsible for monitoring the organisations it approves.

Section II of Article L. 593-33 of the Environment Code gives ASN competence to issue individual resolutions and check the in-service monitoring of non-nuclear pressure equipment installed in a BNI.

Table 2 summarises the texts applicable to the pressure equipment present in BNIs.

4. REGULATIONS GOVERNING THE TRANSPORT OF RADIOACTIVE SUBSTANCES

4.1 International regulations

For the safe transport of radioactive substances, the International Atomic Energy Agency (IAEA) has issued Safety Requirements document TS-R-1 *"Regulations for the Safe Transport of Radioactive Material"*. ASN takes part in the work being done within IAEA concerning the transport of radioactive substances.

This basis specific to radioactive substances is used in the drafting of the "modal" transport safety regulations in force for dangerous goods: the ADR agreement (European Agreement on the international transport of Dangerous goods by Road) for road transport, the regulations concerning International Rail transport of Dangerous goods (RID) for rail transport, the regulations for the transport of Dangerous goods on the Rhine (ADNR) for river transport, the International Maritime Dangerous Goods code (IMDG) for maritime transport and the technical instructions of the ICAO (International Civil Aviation Organisation) for air transport.

Directive 2008/68/EC of 24th September 2008 establishes a common framework for all aspects of dangerous goods transport by road, rail and inland waterways within the European Union.

The regulations derived from the IAEA recommendations specify the package performance criteria. The safety functions to be assured are containment, radiation protection, prevention of thermal hazards and criticality.

The level of safety of the package is tailored to the potential danger of the transported content: a certain number of resistance tests representative of the risks entailed by the transport operation, including the risk connected with the content of the package, are associated with each type of package.

The regulations also define the scope of intervention of the public authorities and the associated safety requirements for each type of package (see chapter 11, point 2).

4.2 National regulations

The "modal" regulations are transposed in full into French law and are made applicable by Interministerial Orders based on the provisions of the Transport Code, especially its Articles L. 1252-1 and following. ASN is in contact with the Administrations responsible for the various modes of transport (General Directorate for Infrastructure, Transport and the Sea (DGITM), General Directorate for Risk Prevention (DGPR) and General Directorate for Civil Aviation (DGAC)) and attends the French Interministerial Commission for the Carriage of Dangerous Goods (CITMD).

Directive 2008/68/EC of 24th September 2008 is transposed into French law by a single order covering all land transport on the national territory. This is the Order of 29th May 2009 as amended concerning the transport of dangerous goods by land, known as the "TMD" Order. This text has replaced the former "ADR", "RID" and "ADNR" modal orders since 1st July 2009.

Other orders specific to a mode of transport apply to the transport of radioactive substances:
- the Order of 12th May 1997 as amended, concerning the technical conditions for the operation of aircraft by a public air transport operator (OPS1);
- the Order of 23rd November 1987 as amended, division 411 of the Regulation concerning the Safety of Ships (RSN);
- the Order of 18th July 2000 as amended, regulating the transport and handling of dangerous goods in sea ports.

TABLE 2: Regulations applicable to pressure equipment

<table>
<tr><th rowspan="2"></th><th colspan="2">NUCLEAR PRESSURE EQUIPMENT</th><th rowspan="2">NON-NUCLEAR PRESSURE EQUIPMENT</th></tr>
<tr><th>PWR REACTOR MAIN PRIMARY AND SECONDARY SYSTEMS</th><th>OTHER NUCLEAR PRESSURE EQUIPMENT</th></tr>
<tr><th rowspan="2">GENERAL PROVISIONS</th><td colspan="3">Chapter VII of Title V of Book V of the Environment Code;
Title I, IV and V of Decree 99-1046 of 13th December 1999</td></tr>
<tr><td>Title I and IV of the Order of 12th December 2005

As of 19/07/2016:
Titles I and IV of the Order of 30th December 2015</td><td>Title I and IV of the Order of 12th December 2005

As of 19/07/2016:
Titles I and IV of the Order of 30th December 2015</td><td></td></tr>
<tr><th>MANUFACTURING PROVISIONS</th><td>Title II of the Order of 12th December 2005

As of 19/07/2016:
Title II of the Order of 12th December 2015</td><td>Title II of the Order of 12th December 2005

As of 19/07/2016:
Title II of the Order of 12th December 2015</td><td>Title II of Decree 99-1046 of 13th December 1999

As of 19/07/2016:
Articles R.557-9-1 and following of the Environment Code</td></tr>
<tr><th>OPERATING PROVISIONS</th><td>Title III of Decree 99-1046 of 13th December 1999
Order of 10th November 1999</td><td>Title III of Decree 99-1046 of 13th December 1999
Title III of the Order of 12th December 2005</td><td>Title III of Decree 99-1046 of 13th December 1999
Order of 15th March 2000</td></tr>
</table>

The regulations require approval of the package models for certain radioactive substances transport operations (see chapter 11). These approvals are issued by ASN.

Article R. 1333-44 of the Public Health Code also requires that companies transporting radioactive substances in France be subject to either notification or licensing by ASN. On 12th March 2015, ASN issued a resolution (2015-DC-0503) creating a system of notification for all companies transporting radioactive substances on French territory.

Implementation of the regulations on the safe transport of radioactive substances is checked by nuclear safety inspectors duly appointed by ASN.

5. REQUIREMENTS APPLICABLE TO CERTAIN RISKS OR CERTAIN PARTICULAR ACTIVITIES

5.1 Contaminated sites and soils

The tools and the approach to be followed for management of polluted sites and soils are described in detail in chapter 16. On 4th October 2012 ASN published a doctrine on the management of sites contaminated by radioactive substances based on several principles. These principles are applicable to all sites polluted by radioactive substances. ASN's prime objective is to achieve the most thorough cleanout possible, aiming for complete removal of the radioactive pollution to allow unrestricted use of the cleaned out premises and land. Nevertheless, when this objective cannot be technically achieved, justification must be given and appropriate measures implemented to guarantee the compatibility of the site's condition with its actual or planned use.

The modifications made by the TECV Act in this field are described in detail in chapter 16.

5.2 ICPEs utilising radioactive substances

The ICPE system comprises objectives that are similar to those for BNIs, but it is not specialised and applies to a large number of installations involving risks or detrimental effects of all types.

Licensing by the Prefect, registration or simple notification is required for ICPEs according to the scale of the hazards they represent.

For installations requiring licensing, this license is issued by order of the Prefect following a public inquiry. The license comprises requirements which may be subsequently modified by a further order.

The list of ICPEs is given in column A of the appendix to Article R. 511-9 of the Environment Code. It defines the types of installations subject to the system and the applicable thresholds.

The ICPE list was modified following the publication of Decree 2014-996 of 2nd September 2014 with regard to the “1700” sections linked to the use of radioactive substances (it deletes section 1715 and creates sections 1716 for radioactive substances in unsealed form, 2797 for radioactive waste and 2798 for temporary management of waste resulting from a nuclear or radiological accident). At the end of 2015, four sections of the ICPE list concerned radioactive materials:

- section 1716 for radioactive substances in unsealed form;
- section 2797 for radioactive waste;
- section 2798 for the temporary management of waste resulting from a nuclear or radiological accident;
- section 1735 which requires licensing of repositories, storage or disposal facilities for solid residues of uranium, thorium or radium ore, as well as their processing by-products not containing uranium enriched with isotope 235 and for which the total quantity exceeds one ton.

The following three points of the Decree of 2nd September 2014 should be noted in particular:

- The activities and installations for the management of radioactive waste [pursuant to Council Directive 2011/70/Euratom of 19th July 2011 establishing a European community framework for the responsible and safe management of spent fuel and radioactive waste] are subject to licensing.
- Only radioactive substances in unsealed form with potential environmental implications are subject to the ICPE system; all sealed sources are subject to the Public Health Code.

Transport truck leaving Valognes, September 2015.

- The license or notification issued in accordance with section 1715 continues to carry the same value as a license or notification under the Public Health Code, until a new license is obtained under the Public Health Code or, failing which, for a maximum period of five years, in other words no later than 4th September 2019.

In accordance with Article L. 593-3 of the Environment Code, a facility located within the perimeter of a BNI, recorded in a section of the ICPE list but necessary for operation of the BNI, is subject to the BNI system.

By virtue of Article L.1333-9 of the Public Health Code, the licences issued to ICPEs in accordance with the Environment Code for the possession or use of radioactive sources, take the place of the licences required under the Public Health Code. However, except for the provisions concerning procedures, the legislative and regulatory provisions of the Public Health Code apply to them.

5.3 The regulatory framework for protection against malicious acts in nuclear activities

Malicious acts include theft or misappropriation of nuclear materials, acts of sabotage and attacks from outside the BNIs. These last two points must be considered in the procedures subject to the Environment Code and regulated and monitored by ASN. In this respect, in its safety analysis report, the licensee must present an assessment of the accidents liable to occur in the facility, regardless of the cause of the accident, including if it results from a malicious act. This assessment, which mentions the effects of accidents and the steps taken to prevent them or mitigate their effects, is taken into account when determining whether or not the creation authorisation can be granted. The most important risk prevention or mitigation measures can be the subject of ASN requirements.

However, ASN is not responsible for either determining the malicious threats to be considered, nor for regulating and monitoring the physical protection of nuclear facilities against malicious acts. The threats to be considered when examining malicious acts are defined by the Government (General Secretariat for Defence and National Security – SGDSN).

With regard to protection against malicious acts, two arrangements instituted by the Defence Code apply to certain nuclear activities:
- Chapter III of Title III of Book III of the first part of the Defence Code defines the measures to protect and monitor nuclear materials. This concerns the following fusible, fissile or fertile materials: plutonium, uranium, thorium, deuterium, tritium, lithium-6, as well as chemical compounds comprising one of these elements, except ores. To prevent the dissemination of these nuclear materials, their import, export, production, possession, transfer, use and transport are subject to licensing.
- Chapter II of Title III of Book III of the first part of the Defence Code defines a system for protection of establishments which *"if unavailable, would risk significantly compromising the nation's combat or economic potential, its security or its capacity for survival"*. The TSN Act of 13th June 2006 supplemented Article L. 1332-2 of the Defence Code in order to enable the administrative authority to apply this system to facilities comprising a BNI *"when the destruction of or damage to (this BNI) could constitute a serious danger for the population"*. This protection system requires that the licensees take the protective measures stipulated in a particular protection plan prepared by them and approved by the administrative authority. These measures in particular include effective surveillance, alarm and material protection measures. If the plan is not approved and in the event of persistent disagreement, the decision is taken by the administrative authority.

With regard to nuclear activities outside the scope of national defence, these systems are monitored at the national level by the Defence and Security High Official (HFDS) at the Ministry responsible for Energy.

Within a joint working group, ASN and HFDS hold regular discussions about the accidents included in the safety analysis reports as well as how some of them could be the result of a malicious act or an act of terrorism. In this respect, analysis of accident occurrences and the steps taken to prevent them ensure that the regulation authorisation processes carried out pursuant to the Defence Code are consistent with those resulting from the Environment Code.

For radioactive sources which are not nuclear materials as specified above and which are not used in facilities subject to the protection obligations specified in the Defence Code, there are at present no arrangements for monitoring the steps taken by those in possession of these sources to prevent any malicious acts. Yet, such acts involving some of these sources could have serious consequences. This is why, in 2008, the Government adopted the principle of obligations to take preventive measures applicable to the holders, with implementation thereof being monitored by ASN. Legislative measures were therefore included in the TECV Act and Ordinance 2016-128 (see chapter 10, point 4.6).

5.4 The particular system for defence-related nuclear activities and installations

The provisions concerning defence-related nuclear facilities and activities were codified in the Defence Code (creation of a sub-section 2 entitled *"Defence-related nuclear facilities and activities"* in Chapter III of Title II of Book III of the first part of the legislative part) by Ordinance 2014-792 of 10th July 2014 implementing Article 55 of Act 2013-1168 of 18th December 2013 concerning military planning for the years 2014 to 2019 and constituting various provisions concerning defence and national security.

Pursuant to Article L. 1333-15, defence-related nuclear facilities and activities are:
- Secret Basic Nuclear Installations (SBNI);
- military nuclear systems;
- defence-related nuclear experimentation sites and installations;
- the former nuclear experimentation sites in the Pacific;
- transport of fissile or radioactive materials involved in nuclear weapons and naval nuclear propulsion activities.

A large number of the provisions applicable to nuclear activities governed by ordinary law also apply to defence-related nuclear activities and installations; for example, they are subject to the same general principles as all nuclear activities governed by ordinary law and the requirements of the Public Health Code, including the system of licensing and notification of small-scale nuclear activities, and they concern defence-related nuclear activities and installations in the same conditions as the ordinary law activities, except for the fact that the licenses are granted by the Delegate for Nuclear Safety and Radiation Protection for National Defence Installations and Activities (DSND), reporting to the Minister of Defence and the Minister of Industry. Oversight of these activities and installations is the responsibility of the personnel of the Defence Nuclear Safety Authority (ASND) headed by the DSND.

Other provisions are specific to defence-related nuclear activities and facilities. They are subject to particular information rules in order to comply with specific defence requirements. Similarly, the installations on the list of BNIs, but which are fall within the perimeter of an SBNI, by order of the Prime Minister, are not subject to the BNI system but to a special system defined by the Defence Code and implemented by the ASND (see section 2 of Chapter III of Book III of the first part of the Defence Code).

When nuclear facilities are no longer necessary for the purposes of national defence, they are delicensed and transferred to the BNI system. The Tricastin SBNI has thus initiated a delicensing process, which should lead to registration by ASN of new BNIs, the first of which will be registered in 2016.

ASN and ASND maintain very close relations to ensure consistency between the systems for which they are responsible.

6. OUTLOOK

With regard to radiation protection, ASN plays an active role in the transposition of the Euratom Directive on basic standards. Since November 2013 it has acted as secretary for the transposition committee. Over and above these legislative subjects, dealt with by Ordinance, ASN takes part in all the regulatory work initiated in 2014 to update the Public Health Code, the Labour Code and the Environment Code.

With regard to BNIs, in 2016 ASN will be continuing the considerable work to overhaul the general regulations applicable to BNIs, as part of a gradual but nonetheless significant process of evolution. The regulations will thus be updated. They will include the WENRA "reference levels" and best practices, in order to create a framework that is clear, complete and uniform.

In the end, about twenty statutory resolutions and as many guides will supplement and clarify the BNI Order of 7th February 2012 in order to create a common regulatory foundation applicable to all BNIs, in line with the best European standards. As part of the overhaul of the general technical regulations applicable to BNIs, the basic safety rules are gradually being replaced by ASN guides. The work to identify the basic safety rules that can be repealed and the guides to be updated will continue in 2016.

Following on from the process it began in 2014, ASN will continue to support all the nuclear stakeholders. A specific heading has been created on *www.asn.fr* in which ASN gives access to a certain number of documents and provides a forum for expression by the various stakeholders concerned by its implementation.

After the hearing given to the licensees by the ASN Commission on 26th May 2015, ASN set up a process to evaluate the existing regulations and analyse feedback about the implementation of the texts already published. In 2016, ASN will continue its discussions with the licensees concerning the work to overhaul the general technical regulations applicable to BNIs.

Following the August 2015 adoption of the Energy Transition for Green Growth Act, which comprises a title devoted to nuclear aspects, and the 10th February 2016 publication of the Ordinance provided for in this Act, ASN will take part in the work concerning the implementing decrees. This will be an opportunity to initiate the codification of the regulatory part of the BNI system.

APPENDIX

The collection of ASN guides

N°1	Final disposal of radioactive waste in deep geological formations (February 2008)
N°2	Transport of radioactive materials in airports (February 2006)
N°3	Recommendations for drafting annual information reports for the public concerning Basic Nuclear Installations (October 2010)
N°4	Auto-assessment of risk exposure of patients receiving external radiotherapy (January 2009)
N°5	Management of radiotherapy safety and quality of treatment April 2009)
N°6	Final shutdown, decommissioning and delicensing of Basic Nuclear Installations in France (June 2010)
N°7	Civil transport of radioactive packages or substances on the public highway: • Volume 1: Shipment certification and approval applications (February 2013). • Volume 2: Package models safety file, European "Package Design Safety Report" guide (September 2012). • Volume 3: Conformity of package models not requiring approval (November 2015)
N°8	Evaluation of nuclear pressure vessel conformity (September 2012)
N°9	Determining the perimeter of a BNI (October 2013)
N°10	Local involvement of CLIs in the 3rd ten-year outage of the 900 MWe reactors (June 2010)
N°11	Notification and codification of criteria relative to significant radiation protection events excluding BNIs and radioactive material transport operations (October 2009)
N°12	Notification and codification of criteria related to significant safety, radiation protection or environmental events applicable to BNIs and radioactive material transport operations (October 2005)
N°13	Protection of Basic Nuclear Installations against external flooding (January 2013)
N°14	Acceptable complete clean-out methodologies in BNIs in France (June 2010)
N°15	*Control of activities in the vicinity of BNIs (draft)*
N°16	Significant radiation protection event affecting a radiotherapy patient: declaration and classification on the ASN-SFRO scale (October 2010)
N°17	Contents of radioactive substance transport incident and accident management plans (December 2014)
N°18	Disposal of effluents and waste contaminated by radionuclides, produced in facilities licensed under the Public Health Code (January 2012)
N°19	Application of the Order of 12th December 2005 relating to nuclear pressure equipment (February 2013)
N°20	Drafting of the Medical Physics Organisation Plan (POPM) (April 2013)
N°21	Processing of non-compliance with a requirement defined for an Element Important for Protection (EIP) (January 2015)
N°22	*Safety requirements for the design of pressurised water reactors (draft)*
N°23	*Definition and modification of the waste zoning plan for BNIs (draft)*
N°24	*Management of soils polluted by BNI activities (draft)*
N°25	*Participation of stakeholders in drafting an ASN statutory resolution or an ASN guide (draft)*

Regulation exposure limits and dose levels

ANNUAL EXPOSURE LIMITS contained in the Public Health Code and in the Labour Code

<table>
<tr><th>REFERENCES</th><th>DEFINITIONS</th><th>VALUES</th><th>OBSERVATIONS</th></tr>
<tr><td colspan="4">ANNUAL LIMITS FOR THE GENERAL PUBLIC</td></tr>
<tr><td rowspan="3">Article R.1333-8
of the Public Health Code.</td><td>• Effective Dose</td><td>1 mSv/year</td><td rowspan="3">• These limits comprise the sum of effective or equivalent doses received as a result of nuclear activities.
These are limits that must not be exceeded.</td></tr>
<tr><td>• Equivalent dose for the lens of the eye</td><td>15 mSv/year</td></tr>
<tr><td>• Equivalent dose for the skin (average dose over any area of 1 cm² of skin, regardless of the area exposed)</td><td>50 mSv/year</td></tr>
<tr><td colspan="4">WORKER LIMITS FOR 12 CONSECUTIVE MONTHS</td></tr>
<tr><td rowspan="3">Article R. 4451-13
of the Labour Code</td><td>Adults
• Effective dose
• Equivalent dose for the hands, forearms, feet and ankles
• Equivalent dose for the skin (average dose over any area of 1 cm² of skin, regardless of the area exposed)
• Equivalent dose for the lens of the eye</td><td>20 mSv
500 mSv
500 mSv
150 mSv</td><td rowspan="3">• These limits comprise the sum of effective or equivalent doses received. These are limits that must not be exceeded.
• Exceptional waivers are accepted:
- When justified beforehand, they are scheduled in certain working areas and for a limited period, subject to special authorisation. These individual exposure levels are planned according to a ceiling limit which is no more than twice the annual exposure limit value.
- Emergency occupational exposure is possible in an emergency situation, in particular to save human life.</td></tr>
<tr><td>Pregnant women
• Exposure of the child to be born</td><td>1 mSv</td></tr>
<tr><td>Young people from 16 to 18 years old*:
• Effective dose
• Equivalent dose for the hands, forearms, feet and ankles
• Equivalent dose for the skin
• Equivalent dose for the lens of the eye</td><td>6 mSv
150 mSv
150 mSv
50 mSv</td></tr>
</table>

** Only if covered by waivers, such as for apprentices.*

OPTIMISATION LEVELS for patient protection (Public Health Code)

<table>
<tr><th>REFERENCES</th><th>DEFINITIONS</th><th>VALUES</th><th>OBSERVATIONS</th></tr>
<tr><td colspan="4">DIAGNOSTIC EXAMINATIONS</td></tr>
<tr><td>Diagnostic reference level
Article R.1333-68,
Order of 16th February 2004</td><td>Dose levels for standard diagnostic examinations</td><td>E.g.: entrance dose of 0.3 mGy or dose area product (DAP)
25 cGy.cm² for an antero-posterior thorax radiograph</td><td>• The diagnostic reference levels, the dose constraints and the dose target levels are used by applying the principle of optimisation. They are simply guidelines
• The reference levels are created for standard patients by dose levels for typical radiology examinations and by the radioactivity levels of radiopharmaceutical products in diagnostic nuclear medicine</td></tr>
<tr><td>Dose constraint
Article R.1333-65,
Order of 7th November 2007</td><td>Used when exposure offers no direct medical benefit to the person exposed</td><td></td><td>The target dose level (specialists talk of a target volume in radiotherapy) is used to adjust the equipment</td></tr>
<tr><td colspan="4">RADIOTHERAPY</td></tr>
<tr><td>Target dose level
Art. R.1333-63</td><td>Dose necessary for the target organ or tissue (target organ or target-tissue) during radiotherapy (experimentation)</td><td></td><td>The target dose level (specialists talk of a target volume in radiotherapy) is used to adjust the equipment</td></tr>
</table>

APPENDIX

INTERVENTION TRIGGER LEVELS in cases of radiological emergencies (Public Health Code)

REFERENCES	DEFINITIONS	VALUES	OBSERVATIONS
PROTECTION OF THE GENERAL PUBLIC			
Intervention levels Art. R.1333-80, Order of 14th October 2003, Circular of 10th March 2000	Expressed in effective dose (except for iodine), these levels are designed to assist with the relevant response decision to protect the general public: • sheltering • evacuation • administration of a stable iodine tablet (equivalent dose for the thyroid)	 10 mSv 50 mSv 50 mSv	The Prefect can make adjustments to take account of local factors.
PROTECTION OF PARTICIPANTS			
Reference levels Art. R.1333-86	These levels are expressed as effective dose: • for the special teams for technical or medical intervention • for the other participants	 100 mSv 10 mSv	This level is raised to 300 mSv when the intervention is designed to prevent or reduce exposure of a large number of people.

LIMIT VALUES for the consumption and sale of foodstuffs contaminated in the event of a nuclear accident

MAXIMUM PERMITTED LEVELS OF RADIOACTIVE CONTAMINATION FOR FOODSTUFFS (BQ/KG OR BQ/L)	BABY FOOD	DAIRY PRODUCTS	OTHER FOODSTUFFS EXCEPT THOSE OF LESSER IMPORTANCE	LIQUIDS INTENDED FOR CONSUMPTION
Strontium isotopes, particularly strontium-90	75	125	750	125
Iodine isotopes, particularly iodine-131	150	500	2,000	500
Plutonium isotopes and alpha-emitting transuranian elements, particularly plutonium-239 and americium-241	1	20	80	20
Any other radionuclide with a half-life of more than 10 days, in particular caesium-134 and caesium-137	400	1,000	1,250	1,000

Source: Council regulation 2016/52/Euratom of 15th January 2016.

MAXIMUM PERMITTED LEVELS of radioactive contamination in livestock feedstuffs (caesium-134 and caesium-137)

ANIMAL CATEGORIES	BQ/KG
Pork	1,250
Poultry, lamb, veal	2,500
Others	5,000

Source: Council regulation 2016/52/Euratom of 15th January 2016.

GUIDELINE LEVELS in Bq/kg

RADIONUCLIDES	FOODSTUFFS INTENDED FOR GENERAL CONSUMPTION	BABY FOOD
Plutonium-238, plutonium-239, plutonium-240, americium-241	10	1
Strontium 90, ruthenium 106, iodine 129, iodine 131, uranium 235	100	100
Sulphur 35, cobalt 60, strontium-89, ruthenium-103, caesium-134, caesium-137, cerium-144, iridium-192	1,000	1,000
Tritium, carbon-14, technetium-99	10,000	1,000

Source: Codex alimentarius, July 2006.

04

Regulation of nuclear activities and exposure to ionising radiation

In France, nuclear activity licensees are responsible for the safety of their activity. They cannot delegate this responsibility, and must ensure permanent surveillance of both this activity and the equipment used. Given the risks linked to ionising radiation for humans and the environment, the State regulates nuclear activities, a task it has entrusted to ASN.

Regulation and monitoring of nuclear activities is a fundamental duty of ASN. The aim is to verify that all licensees fully assume their responsibility and comply with the requirements of the regulations relative to radiation protection and nuclear safety, in order to protect workers, patients, the public and the environment from risks associated with radioactivity.

Inspection is the key means of monitoring available to ASN. Inspection involves one or more ASN inspectors going to the site or department being inspected or to carriers of radioactive materials. The inspection is proportionate to the level of risk presented by the installation or the activity and the way in which the licensee assumes its responsibilities. It consists in performing spot checks on the conformity of a given situation with regulatory or technical baseline requirements. After the inspection, a follow-up letter is sent to the head of the inspected site or activity and published on *www.asn.fr.* Any deviations found during the inspection can lead to administrative or criminal sanctions.

ASN is developing a broader view of regulation, concerning both the material and the organisational and human aspects. Its regulatory duties entail the issue of resolutions, prescriptions, inspection follow-up documents, plus penalties as applicable, along with assessments of safety and radiation protection in each activity sector.

1. VERIFYING THAT THE LICENSEE ASSUMES ITS RESPONSIBILITIES

1.1 The principles of ASN's oversight duties

ASN aims to ensure that the principle of licensee responsibility for nuclear safety and radiation protection is respected.

ASN applies the principle of proportionality when determining its actions, so that the scope, conditions and extent of its regulatory action is commensurate with the health and environmental safety implications involved.

Regulation is part of a multi-level approach and is carried out with the support of the Institute for Radiation Protection and Nuclear Safety (IRSN).

It applies to all the phases in the performance of the activity, including the decommissioning phase for nuclear facilities:
- before the licensee exercises an activity subject to authorisation, by reviewing and analysing the files, documents and information provided by the licensee to justify its project with regard to safety and radiation protection. This verification aims to ensure that the information and demonstration supplied are both relevant and sufficient;
- during exercise of the activity, by visits, inspections, verification of licensee operations entailing significant potential consequences, review of reports supplied by the licensee and analysis of significant events. This verification comprises sampling and the analysis of justifications provided by the licensee with regard to the performance of its activities.

To consolidate the effectiveness and quality of its actions, ASN is adopting an approach involving continuous improvement of its regulatory practices. It uses the experience feedback from forty years of nuclear activity inspections and the exchange of best practices with its foreign counterparts.

1.2 The scope of regulation of nuclear activities

Article L. 592-21 of the Environment Code states that ASN must regulate compliance with the general rules and particular requirements of safety and radiation protection, applicable to:
- licensees of BNIs;
- those in charge of the construction and operation of Pressure Equipment (PE) used in BNIs;
- those in charge of radioactive substances transport;

- those in charge of activities entailing a risk of exposure of individuals and workers to ionising radiation;
- those in charge of implementing ionising radiation exposure monitoring measures.

In this chapter, these persons are called the “licensees”. ASN also regulates the organisations and laboratories it approves to take part in the inspections and to guarantee safety and radiation protection, as well as carrying out labour inspection duties in the NPPs (see chapter 12).

In addition, Article 30 of Ordinance 2016-128 of 10th February 2016 issued further to Article 128 of the Energy Transition for Green Growth Act of 17th August 2015 (TECV) expanded the scope of ASN regulation to suppliers, contractors and subcontractors of licensees, including outside BNIs.

Although historically based on verifying the technical conformity of facilities and activities with regulations or standards, regulation today also covers a broader field incorporating Social, Organisational and Human Factors (SOHF). It takes account of individual and collective behaviour and attitudes, management, organisation and procedures, relying on a variety of sources: significant events, inspections, relations with the stakeholders (personnel, licensees, contractors, trade unions, occupational physicians, inspection services, approved organisations, and so on).

2. ENSURING THAT REGULATION IS PROPORTIONATE TO THE IMPLICATIONS

ASN organises its regulatory work in a way that is proportionate to the implications of the activities. The licensee is the key player in the regulation of its activities. The performance of certain inspections by organisations and laboratories offering the necessary guarantees as validated by ASN approval, contributes to this action.

2.1 Definition of the implications

In order first of all to take account of the health and environmental implications and the licensees’ safety and radiation protection performance, and secondly the large number of activities it has to oversee, ASN periodically identifies and directly inspects the activities and topics with major potential consequences: It conducts permanent oversight of subjects entailing potential risks, which are systematically examined on a yearly basis, and also identifies topical subjects requiring more particular attention in any given year. For example, in 2015, the inspections focused on the following topics or activities:

- earthquake, environment, radiation protection and management of ageing for nuclear power plants; SOHF

ASN inspection in the Arronax cyclotron (Saint-Herblain), July 2015.

(training and maintaining skill levels), fire and monitoring of stakeholders in the fuel cycle facilities;
- industrial radiography, fields requiring high-level sealed sources and suppliers of sources for the industrial small-scale nuclear sector;
- computed tomography and teleradiology for the medical small-scale nuclear sector;
- on-site transport within BNIs, training of transport operators, SOHF, maintenance of packaging and preparedness for emergency situations involving the transport of radioactive substances.

In order to identify these activities and topics, ASN relies on current scientific and technical knowledge and uses the information collected by both itself and IRSN: results of inspections, frequency and nature of incidents, major modifications made to facilities, review of files, feedback of data concerning doses received by workers, information resulting from checks by approved organisations. It can revise its priorities further to significant events that have occurred in France or elsewhere in the world.

2.2 Checks performed by the licensees

The operations that take place in the BNIs and which have the highest potential safety and radiation protection implications require prior authorisation by ASN (see chapter 3).

2.2.1 Operations subject to a licensee internal authorisation procedure

ASN considers that the operations taking place in the BNIs with the highest nuclear safety and radiation protection implications must require its prior authorisation. However, it considers that operations for which the nuclear safety and radiation protection implications are limited must remain the responsibility of the licensee. For intermediate operations presenting potential consequences in terms of safety and radiation protection that are significant but do not compromise the safety scenarios used in BNI operation or decommissioning, ASN allows the licensee to assume direct responsibility for them, provided that it sets up a system of enhanced, systematic internal checks, offering sufficient guarantees of quality, independence and transparency. The decision on whether or not to carry out the operations must be the subject of a formal authorisation issued by the licensee's duly qualified staff. This organisation is called the "internal authorisations system". It is presented to the Local Information Committee (CLI). The system of internal authorisations is governed by the Decree of 2nd November 2007 and the resolution of 11th July 2008.

An internal authorisations system must thus be approved beforehand by an ASN resolution defining:
- the nature of the operations which can be covered by an internal authorisation;
- the process used to approve the operations, more specifically with an opinion issued prior to any operation by a body within the company that is independent from the people directly in charge of operation;
- identification of the persons qualified to issue the internal authorisations;
- the procedures for periodically informing ASN of the operations planned or completed.

ASN checks the proper application of the internal authorisations systems by means of inspections, examination of the periodic reports transmitted by the licensees and counter-analysis of the files. It may temporarily or definitively suspend an internal authorisations system at any moment if it considers that implementation is not satisfactory.

2.2.2 Internal monitoring of radiation protection by the users of ionising radiation sources

The aim of internal monitoring of radiation protection is to ensure regular assessment of the radiological safety of the activities using sources of ionising radiation. This monitoring is performed under the responsibility of the licensees. It may be carried out by the Person Competent in Radiation protection (PCR), appointed and mandated by the employer, or be entrusted to IRSN or to organisations approved by ASN. It does not replace either the periodic checks required by the regulations, or the inspections conducted by ASN. It for example concerns the performance of the protection systems, monitoring of the ambient atmosphere in regulated areas, or checks on medical appliances before they enter service or after modification.

2.2.3 Inspection of radioactive substances transport

For the transport of radioactive substances, the consignor is responsible for demonstrating that the package model used ensures compliance with the safety requirements set by the regulations, as well as being suitable for the contents to be transported. The following are subject to ASN approval: package models with the highest potential safety implications, in particular those intended for the transport of very high-level radioactive substances or those for which the content is liable to create a criticality risk (see chapter 11). These packages, and those which are not subject to approval, are regularly inspected by ASN in order to verify the measures adopted by the consignors.

2.3 ASN approval of organisations and laboratories

Article L. 592-21 of the Environment Code states that ASN must issue the necessary approvals to the organisations taking part in the inspections and in ensuring the nuclear safety and radiation protection watch. Depending on the health or safety implications of a nuclear activity or a facility category, ASN may rely on the results of checks carried out by independent organisations and laboratories it has approved and which it monitors via second level checks.

ASN thus approves organisations so that they can perform the technical inspections required by the regulations in the fields within its scope of competence:
- radiation protection checks;
- measurement of radon activity concentration in premises open to the public;
- assessment of nuclear pressure equipment conformity and inspection of equipment in service.

The checks carried out by these organisations contribute to ASN's overview of all nuclear activities.

In order to approve the applicant organisations, ASN ensures that they perform the inspections in accordance with their technical, organisational and ethical obligations and in compliance with the rules of professional good practice. Compliance with these provisions should enable the required level of quality to be obtained and maintained.

ASN ensures that benefit is gained from the approval, in particular through regular exchanges with the organisations it has approved and the mandatory submission of an annual report, in order to:
- turn operating experience feedback to good account;
- improve the approval process;
- improve the conditions of intervention by the organisations.

In 2014, the Organisations Approved for Radiation protection Inspections (OARP) carried out more than 74,000 inspections, for which the breakdown per type of source and per field is given in the following table.

The main deviations recorded during these inspections concern administrative checks. The deviations linked to organisational oversight mainly concern a failure to comply with the frequency of performance of internal checks. Analysis of the past five years of OARP annual reports shows an overall reduction in the number of deviations recorded.

ASN also approves laboratories to conduct analyses requiring a high level of measurement quality if the results are to be usable. It thus approves laboratories:
- for monitoring environmental radioactivity (see point 4);
- for worker dosimetry (see chapter 1).

The list of approvals issued by ASN is kept up to date on *www.asn.fr* (*"Bulletin officiel de l'ASN/agréments d'organismes"* section).

As at 31st December 2015, the following are approved by ASN:
- 43 organisations tasked with radiation protection checks, 10 approvals or approval renewals were delivered in 2015;
- 50 organisations tasked with measuring radon activity concentration in buildings. Ten of these organisations can also carry out measurements in cavities and underground structures, while 8 are approved to identify sources and means of radon ingress into buildings. In 2015, ASN issued 24 new approvals or approval renewals;
- 13 organisations tasked with the monitoring of worker internal dosimetry, 7 for external monitoring and 2 for monitoring exposure associated with natural radioactivity). In 2015, ASN issued 4 new approvals or approval renewals;
- 7 organisations tasked with nuclear pressure equipment inspections;
- 61 laboratories for environmental radioactivity measurements covering 864 approvals, of which 248 are approvals or approval renewals delivered during 2015.

ASN gives the General Directorate for Health (DGS) an opinion on the approval of the laboratories analysing radioactivity in water intended for human consumption.

It gives the Ministers responsible for Nuclear Safety and Transport an opinion on the approval of the organisations responsible for:
- training the drivers of vehicles transporting radioactive substances (class 7 hazardous materials);
- organising safety adviser examinations for transport of dangerous goods by road, rail or navigable waterway;
- certifying the conformity of packaging designed to contain 0.1 kg or more of uranium hexafluoride (initial and periodic checks);
- approval of the types of tankers[1];
- the initial and periodic checks of tankers for transport of class 7 hazardous substances by land.

1. For each new type of tanker, an organisation approved by ASN must issue a type approval certificate.
This certificate confirms that the tanker has been checked by the organisation, that it is suitable for the intended purpose and that it complies with the requirements of the regulations. When a series of tankers is manufactured with no change to the design, the certificate is valid for the entire series.

TABLE 1: Number of radiation protection inspections performed in 2014 by organisations approved for radiation protection inspections

TYPE OF SOURCE / FIELD	MEDICAL	VETERINARY	RESEARCH / TEACHING	NON-BNI INDUSTRIAL	BNI	TOTAL
SEALED SOURCES	1,175	9	3,500	14,455	21,021	**40,160**
UNSEALED SOURCES	456	5	2,097	672	4,798	**8,028**
MOBILES GERI*	2,595	278	22	608	5	**3,508**
FIXED GERI	7,697	963	709	6,364	167	**15,900**
PARTICLE ACCELERATOR	383	0	58	220	6	**667**
DENTAL	6,000					**6,000**
TOTAL	**18,306**	**1,255**	**6,386**	**22,319**	**25,997**	**74,263**

** Generator of ionising radiation*

TO BE NOTED

ASN reinforces the graduated approach for regulation of industrial small-scale nuclear activities

In 2015, ASN re-assessed its inspection priorities for industrial small-scale nuclear activities, following a detailed analysis of the characteristics of these activities. ASN thus modified the list of activities with potentially high risks, for example adding veterinary activities other than conventional radiology or the use of electrical generators of neutrons. It also identified activities for which inspections are not necessary if there is nothing to suggest deterioration of radiation protection in a given facility.

ASN also experimented oversight methods in addition to inspection, among veterinarians in certain *départements*. This for example consisted in analysing documents (answers to the auto-evaluation questionnaire or substantiating documentation) sent by the veterinarians when requested by ASN.

3. REINFORCING THE EFFICIENCY OF ASN'S MEANS OF REGULATION

The licensee is required to provide ASN with the information it needs to meet its regulatory responsibilities. The volume and quality of this information should enable ASN to analyse the technical demonstrations presented by the licensee and target the inspections. It should also allow identification and monitoring of the milestones in the operation of a nuclear activity.

ASN's regulatory action takes the form of reviews of files, pre-commissioning visits, inspections, and consultation with professional organisations (trade unions, professional orders, learned societies, etc.).

3.1 Assessment of the files submitted by the licensee

The purpose of the files supplied by the licensee is to demonstrate compliance with the objectives set by the general technical regulations, as well as those that it has set for itself. ASN is required to check the completeness of the data and the quality of the demonstration.

The review of these files may lead ASN to accept or to reject the licensee's proposals, to ask for additional information or studies or to ask for work to be done to bring the relevant items into conformity.

3.1.1 Analysing the information supplied by Basic Nuclear Installation (BNI) licensees

Reviewing the supporting documents produced by the licensees and the technical meetings organised with them are one of the forms of control carried out by ASN.

Whenever it deems necessary, ASN seeks the advice of technical support organisations, primarily IRSN. The safety review implies cooperation by numerous specialists, as well as efficient coordination, in order to identify the essential points relating to safety and radiation protection.

IRSN assessment relies on research and development programmes and studies focused on risk prevention and on improving our knowledge of accidents. It is also based on in-depth technical discussions with the licensee teams responsible for designing and operating the plants. For the more important issues, ASN requests the opinion of the competent Advisory Committee of Experts (GPE). For other matters, IRSN examines the safety analyses and gives its opinion directly to ASN. ASN procedures for requesting the opinion of a technical support organisation and, where required, of an Advisory Committee, are described in point 2.5.2 of chapter 2.

At the design and construction stage, ASN – aided by its technical support organisation – examines the safety analysis reports describing and justifying basic design data, equipment design calculations, utilisation rules and test procedures, and quality organisation provisions made by the prime contractor and its suppliers. ASN also checks the construction and manufacture of structures and equipment, in particular PWR Main Primary Systems (MPS) and Main Secondary Systems (MSS). In accordance with the same principles, it checks the packages intended for the transport of radioactive substances.

Once the nuclear facility has been commissioned, following ASN authorisation, all changes to the facility or its operation made by the licensee that could affect security, public health and safety, or the protection of nature and the environment, are notified to ASN. Moreover, the licensee must perform periodic safety reviews to update the assessment of the facility, taking into account any changes in techniques and regulations, and experience feedback. The conclusions of these reviews are submitted by the licensee to ASN, which can issue new prescriptions in order to tighten the safety requirements (see chapter 12 point 2.9.4).

Other data submitted by BNI licensees

The licensee submits routine activity reports and summary reports on water intake, liquid and gaseous discharges and the waste produced.

Similarly, there is a considerable volume of information on specific topics such as fire protection, PWR fuel management strategies, relations with contractors, and so on.

3.1.2 Review of the applications required by the Public Health Code

ASN is responsible for reviewing applications to possess and use ionising radiation sources in the medical and industrial sectors. ASN also deals with the specified procedures for the acquisition, distribution, import, export, transfer, recovery and disposal of radioactive sources. It in particular relies on the inspection reports from the approved organisations and the reports on the steps taken to remedy nonconformities detected during these inspections.

In addition to the internal inspections carried out under the responsibility of the facilities and the periodic checks required by the regulations, ASN carries out its own verifications. In this respect it directly carries out checks during the procedures for issue (pre-commissioning inspections) or renewal (periodic inspections) of the authorisations to possess and use radiation sources granted on the basis of Article R. 1333-23 of the Public Health Code. The authorisation notifications can only be issued if the requests submitted by ASN following the checks have been taken into account. These checks are in particular designed to compare the data contained in the files with the actual physical reality (sources inventory, check on the conditions of production, distribution and utilisation of the sources and the devices containing them). They also enable ASN to ask the facilities to improve their in-house provisions for source management and radiation protection.

3.2 Regulation of facilities and activities

ASN regulates nuclear activities and facilities in order to check that the licensees and those responsible for nuclear activities comply with the regulatory requirements and conditions specified in their authorisation license.

3.2.1 The types of facilities and activities regulated

Regulation and monitoring of Basic Nuclear Installations

Safety covers the technical and organisational measures taken at all stages in the operation of nuclear facilities (design, creation, commissioning, operation, final shutdown, decommissioning) to prevent or mitigate the risks for safety, public health and the environment (see chapter 3). This notion thus includes the measures taken to optimise waste and effluent management.

The safety of nuclear installations is based on the following principles, defined by the International Atomic Energy Agency (IAEA) in its fundamental safety principles for nuclear installations (Safety series No. 110) and then to a large extent incorporated into the European Directive on Nuclear Safety of 8th July 2014, which modifies that of 2009:

- responsibility for nuclear safety lies primarily with the licensee;
- the organisation responsible for regulation and oversight is independent of the organisation responsible for promoting or using nuclear power. It must have responsibility for licensing, inspection and formal notice, and must have the authority, expertise and resources necessary for performance of the responsibilities entrusted to it. No other responsibility shall compromise or conflict with its responsibility for safety.

In France, pursuant to the Environment Code, ASN is the body that meets these criteria.

The Energy Transition for Green Growth Act (TECV) makes provision for expanding the scope of regulation and monitoring by ASN beyond the activities of the licensee, to enable the inspectors to carry out inspections at the suppliers' and the contractors' or subcontractors', including outside the BNIs, when they carry out activities important for the protection of individuals and the environment.

In its regulatory duties, ASN is required to look at the equipment and hardware in the installations, the individuals in charge of operating it, the working methods and the organisation, from the start of the design process up to decommissioning. It reviews the steps taken concerning nuclear safety and the monitoring and limitation of the doses received by the individuals working in the facilities, and the waste management, effluents discharge monitoring and environmental protection procedures.

Regulation of pressure vessels

Numerous systems in nuclear facilities contain or carry pressurised fluids. In this respect they are subject to the regulations applicable to pressure equipment, which include ESP and ESPN (see chapter 3, point 3.6).

The Environment Code states that ASN is the administrative Authority with competence for issuing individual resolutions and checking the in-service monitoring of the pressure equipment installed within the perimeter of a BNI.

Pressure equipment operation is regulated. This regulation in particular applies to the in-service surveillance programmes, non-destructive testing, maintenance work, disposition of nonconformities affecting these systems and periodic post-maintenance testing of the systems.

ASN also assesses the regulatory conformity of the most important new nuclear pressure equipment items. It approves and monitors the organisations responsible for assessing the conformity of the other nuclear pressure equipment.

Regulation and monitoring of the transport of radioactive substances

Transport comprises all operations and conditions associated with movements of radioactive substances, such as packaging design, manufacture, maintenance and repair, as well as the preparation, shipment, loading, carriage, including storage in transit, unloading and reception at the final destination of the radioactive substance consignments and packages (see chapter 11).

The safety of transport of radioactive substances is ensured by three main factors:
- primarily, the robustness of package design and the quality of package construction;
- the reliability of transport and of certain special vehicle equipment;
- an efficient emergency response in the event of an accident.

Regulation and monitoring of activities comprising a risk of exposure to ionising radiation

In France, ASN fulfils this role by drafting and monitoring technical regulations concerning radiation protection (see chapter 3, point 1).

TABLE 2: Methods of ASN regulation of the various radiation protection players

	REVIEW/ AUTORISATION	INSPECTION	OPENNESS AND COOPERATION
Users of ionising radiation sources	• Review of the dossiers required by the Public Health Code (Articles R. 1333-1 to R. 1333-54) • Pre-commissioning inspection • Registration of notification or delivery of the authorisation	• Radiation protection inspection (Article L. 1333-17 of the Public Health Code)	• Jointly with the professional organisations, drafting of guides of good practices for users of ionising radiation
Bodies approved for radiation protection inspections	• Review of application files for approval to perform the inspections specified in Article R. 1333-95 of the Public Health Code and Articles R. 4451-29 to R. 4452-34 of the Labour Code • Organisation audit • Delivery of approval	• Second level inspection: - in-depth inspections at head office and in the branches of the organisations - unannounced field inspections	• Jointly with the professional organisations, drafting of rules of good practices for performance of radiation protection inspections

The scope of ASN's regulatory role in radiation protection covers all the activities that use ionising radiation. ASN exercises this duty, where applicable, jointly with other State services such as the Labour Inspectorate, the Inspectorate for Installations Classified on Environmental Protection Grounds (ICPE), the departments of the Ministry of Health and the French National Agency for Medicines and Health Products Safety (ANSM). This action directly concerns either the users of ionising radiation sources, or organisations approved to carry out technical inspections on these users.

The methods of regulating the radiation protection players are presented in table 2.

Regulating the application of Labour Law in the nuclear power plants

Labour inspection in the NPPs has been ensured from the outset by the administration tasked with technical oversight under the authority of the Minister responsible for Labour; the competence of ASN is now codified in Article R. 8111-11 of the Labour Code. The nineteen NPPs in operation, the nine reactors undergoing decommissioning and the EPR reactor under construction at Flamanville are the responsibility of the ASN labour inspectorate. The regulation of safety, radiation protection and labour inspection very often covers common topics, such as worksite organisation or the conditions of use of outside contractors (see chapter 12).

The ASN labour inspectors have four essential duties:
1. checking application of all aspects of labour legislation (health, occupational safety and work conditions, occupational accident inquiries, quality of employment, collective labour relations);
2. advising and informing the employers, employees and personnel representatives about their rights, duties and labour legislation;
3. informing the administration of changes in the working environment and any shortcomings in the legislation;
4. facilitating conciliation between the parties.

The ASN labour inspectors also have powers of decision concerning authorisation applications (firing of personnel representatives, waivers to regulations in terms of work or rest times, health and safety).

These duties are based on international standards (International Labour Organisation (ILO) Convention No. 81) and national regulations. ASN carries them out in liaison with the other Government departments concerned, mainly the departments of the Ministry responsible for Labour.

ASN has set up an organisation enabling it to deal with these issues. The action of the ASN labour inspectors (6.2 full-time equivalent – FTE) in the field has increased markedly since 2009, particularly during reactor outages, with inspection visits, advisory roles at the meetings of the Committee for Health, Safety and Working Conditions (CHSCT) and the Inter-company Committee on Safety and Working Conditions (CIESCT), as well as the regular discussions with the social partners.

3.2.2 Inspection objectives and principles

The inspection carried out by ASN is based on the following principles:
- The inspection aims to detect any deviations indicative of a possible deterioration in facility safety or the protection of individuals or the environment and any non-compliance with the legislative and regulatory requirements the licensee is required to apply.
- The inspection is proportionate to the level of risk presented by the facility or activity.
- The inspection is neither systematic nor exhaustive, is based on sampling and focuses on subjects with the greatest potential consequences.

3.2.3 Inspection resources implemented

To ensure greater efficiency, ASN's action is organised on the following basis:
- inspections, at a predetermined frequency, of the nuclear activities and topics of particular health and environmental significance;
- inspections on a representative sample of other nuclear activities;
- systematic technical inspections of all facilities by approved organisations.

Activities of more limited significance or with particularly high volume are inspected by the approved organisations, but can also be the subject of targeted inspections by ASN.

The inspections may be unannounced or notified to the licensee a few weeks before the visit. They take place mainly on the site or during the course of the relevant activities (work, transport operation). They may also concern the head office departments or design and engineering departments at the major licensees, the workshops or engineering offices of the subcontractors, the construction sites, plants or workshops manufacturing the various safety-related components.

ASN uses various types of inspections:
- standard inspections;
- in-depth inspections, which take place over several days, concern a number of topics and involve about ten or so inspectors. Their purpose is to carry out detailed examinations and they are overseen by senior inspectors;
- inspections with sampling and measurements which are designed to check discharges by means of samples that are independent of those taken by the licensee;
- event-based inspections carried out further to a particularly significant event;
- worksite inspections, ensuring a significant ASN presence on the sites on the occasion of reactor outages or particular work, especially in the construction or decommissioning phases;
- inspection campaigns, grouping inspections performed on a large numbers of similar installations, following a predetermined template;
- reinforced inspections, which consist in conducting an in-depth examination of a targeted topic with a larger team of inspectors than for a routine inspection.

Labour inspectorate duties lead to various types of interventions[2], focusing in particular on:
- checking application of the Labour Code by EDF and outside contractors in the NPPs (verification operations that include inspections);
- participation in meetings of the CHSCT, CIESCT and inter-firm Health, Safety and Working Conditions Committee (CISSCT) (EPR construction site);
- performance of inquiries further to requests, complaints or information, after which the inspectors can issue resolutions.

ASN sends the licensee an inspection follow-up letter officially documenting:
- deviations between the situation observed during the inspection and the regulations or documents produced by the licensee pursuant to the regulations.
- anomalies or aspects warranting additional justifications.

Some inspections are carried out with the support of an IRSN representative specialised in the facility visited or the topic of the inspection.

ASN inspectors

To meet its objectives, ASN has inspectors designated and accredited by the ASN Chairman, in accordance with the conditions defined by Decree 2007-831 of 11th May 2007, subject to them having acquired the requisite legal and technical skills through professional experience, mentoring or training courses.

The inspectors take an oath and are bound to professional secrecy. They exercise their inspection activity under the authority of the ASN Director-General and benefit from regularly updated practical aids (inspection guides, decision aids) to assist them in their inspections.

As part of its continuous improvement policy, ASN encourages the exchange and integration of best practices used by other inspection organisations:
- by organising international exchanges of inspectors between Safety Authorities, either for the duration of one inspection or for longer periods that could extend to a secondment of up to three years. Thus, after having observed its advantages, ASN has adopted the concept of in-depth inspections described earlier. However, it did not opt for the system involving a resident inspector on a nuclear site, as ASN considers that its inspectors must work within a structure large enough to allow sharing

2. The intervention is the representative unit of activity normally used by the labour inspectorate.

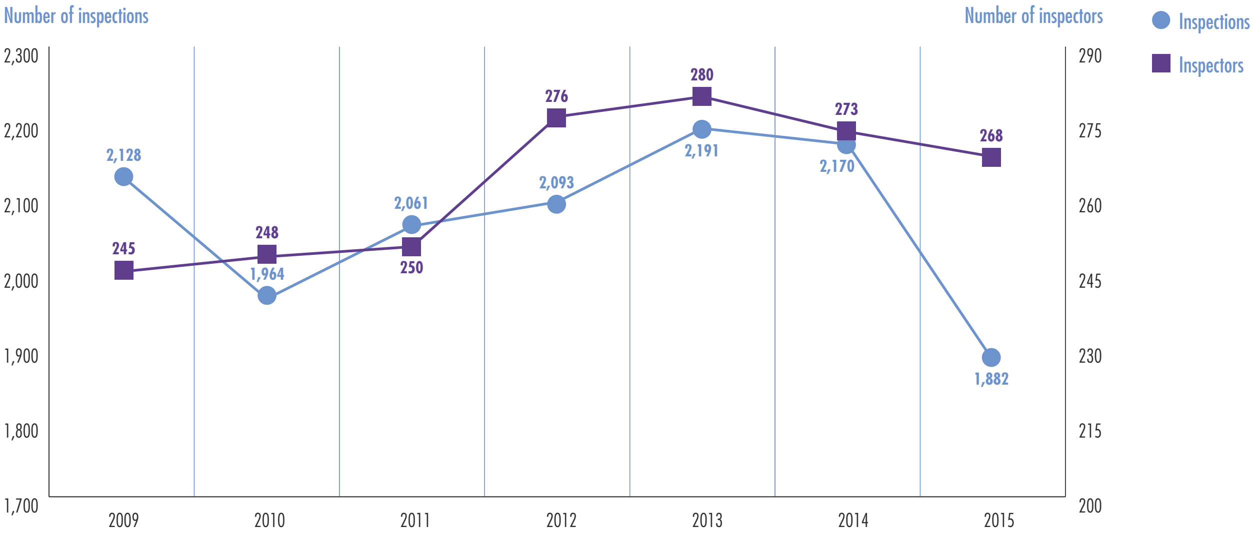
TABLE 3: Breakdown of inspectors per inspection domain (as at 31st December 2015)

TYPE OF INSPECTOR	DEPARTMENTS	DIVISIONS	TOTAL
Nuclear safety inspector (BNI)	85	98	183
of which nuclear safety inspector (transport)	*8*	*38*	*46*
Staff responsible for oversight of pressure equipment	19	32	51
Radiation protection inspector	42	101	143
Labour inspector	1	12	13
Number of inspectors all domains	117	151	268

TABLE 4: Trend in number of inspections performed from 2009 to 2015

	NUMBER OF INSPECTIONS CARRIED OUT					
YEAR	BNI	PE	RMT	NPX	OA-LA	TOTAL
2015	591	67	98	1,003	123	1,882
2014	686	87	113	1,159	125	2,170
2013	678	86	131	1,165	131	2,191
2012	726	76	112	1,050	129	2,093
2011	684	65	100	1,088	124	2,061
2010	665	72	92	1,002	133	1,964
2009	709	105	94	1,081	139	2,128

GRAPH 1: Trend in the number of ASN inspections and inspectors from 2009 to 2015



of experience and that they must take part in checks on different licensees and facilities in order to acquire a broader view of this field of activity. These guidelines also allow greater clarity in the exercise of the respective responsibilities of the licensee and the inspector;

- by taking on inspectors trained in other inspection practices. ASN encourages the integration into its departments of inspectors from other regulatory authorities, such as the Regional Directorate for the Environment, Planning and Housing (DREAL), ANSM, Regional Health Agencies (ARS), etc. It also proposes organising joint inspections with these authorities concerning the activities within their joint field of competence;
- by encouraging its staff to take part in inspections on subjects in different regions and domains, notably to ensure the uniformity of its practices.

Table 3 presents the headcount of inspectors as at 31st December 2015. Some inspectors operate in several inspection areas, and all the operational entity heads and their deputies fulfil both managerial and inspection functions.

Most of the inspections are carried out by inspectors assigned to the regional divisions, who represent 56% of the ASN inspectors. The 117 inspectors assigned to the departments take part in the ASN inspection effort within their field of competence; they represent 44% of the inspector headcount and performed 13% of the inspections in 2015.

Since 2009, ASN has carried out about 2,000 inspections every year, including about 37% in BNIs and activities linked to pressure equipment, 58% in small-scale nuclear activities, Approved Organisations and Laboratories (OA-LA) and 5% for the transport of radioactive substances (see table 5).

In 2015, 1,882 inspections were carried out, including 591 in the BNIs, 67 in activities linked to Pressure Equipment, 98 in radioactive substances transport activities, 1,003 in activities employing ionising radiation and 123 in approved organisations and laboratories. These 1,882 inspections represent 2,024 days of coordination of inspections in the field. This number is down by comparison with 2014 owing to a fall in ASN's inspection capacity due to high inspector turnover and the time needed to train the new inspectors.

Graph 1 shows the trend in the number of inspections and inspectors between 2009 and 2015.

ASN inspections programme

To guarantee a distribution of the inspection resources proportionate to the safety and radiation protection implications of the various facilities and activities, each year ASN drafts a forecast inspections schedule, taking into account the inspection implications (see point 2.1). This schedule is not communicated to the licensees or to those in charge of nuclear activities.

ASN ensures qualitative and quantitative monitoring of performance of the programme and the follow-up given to the inspections through periodic reviews. They enable the inspected activities to be assessed and contribute to the continuous improvement of the inspection process.

Information relative to the inspections

ASN informs the public of the follow-up to the inspections by posting the inspection follow-up letters on-line at *www.asn.fr.*

Moreover, for each in-depth inspection, ASN publishes an information notice on *www.asn.fr*.

3.2.4 Inspection of Basic Nuclear Installations (BNIs) and pressure equipment

In 2015, 658 inspections were carried out to check BNIs and pressure equipment, more than 21% of which were unannounced.

These inspections can be broken down into 330 inspections in the NPPs, 261 in the other BNIs (fuel cycle facilities, research facilities, facilities undergoing decommissioning, etc.) and 67 for pressure equipment. In the BNIs, an in-depth inspection was carried out in 2015 in the Bugey NPP, on the topic "Safety management and organisation".

The inspection breakdown by family of topics is shown in graph 2. The topics related to nuclear safety and social, organisational and human factors represent more than 50% of the BNI inspections. 10% of the inspections are devoted to environmental monitoring topics and to waste and effluents in the BNIs.

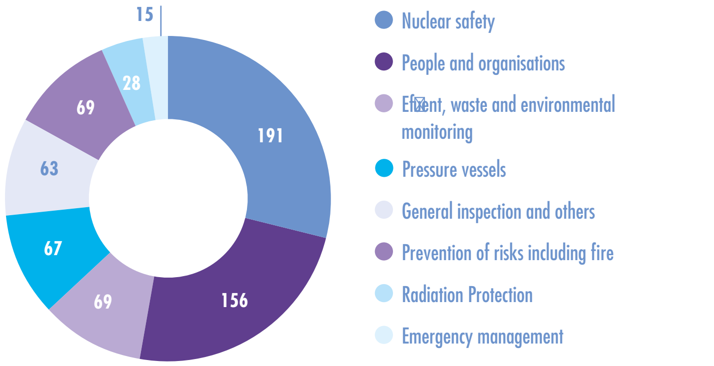
Of the 330 inspections carried out in the NPPs in 2015, nearly one third covered topics related to maintenance and operation. Social, organisational and human factors, the environment and the prevention and management of hazards are the other topics most widely inspected by ASN.

The ASN labour inspectors also carried out 583 interventions during the 174 inspection days in the NPPs.

In 2015, the 261 inspections carried out in the LUDD sites (laboratories, plants, waste and decommissioning) primarily concerned the "general inspection" and "status of systems, equipment and buildings" (checks, tests, ageing, works, etc.)" topics.

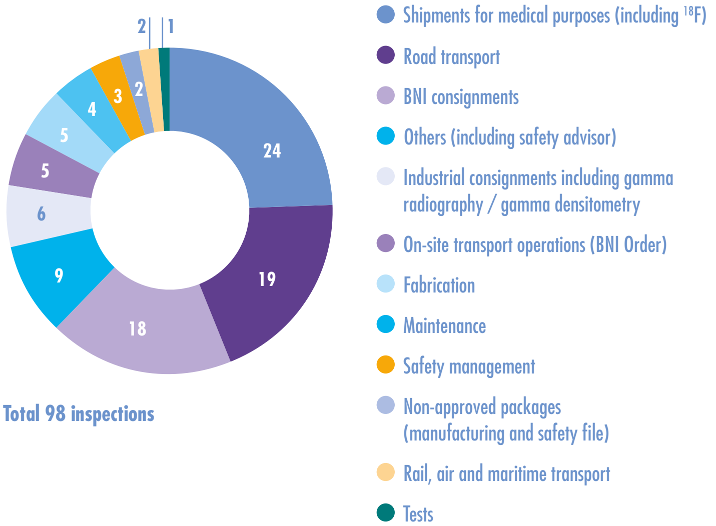
With regard to pressure equipment, ASN carried out 67 inspections in 2015 including 42 in the field of in-service monitoring of equipment, 18 on monitoring of recognised inspection services and 7 in the field of inspecting the design and manufacture of nuclear pressure equipment. ASN's Nuclear Pressure Equipment Department has received ISO 17020 accreditation from the French accreditation committee (Cofrac).

GRAPH 2: Breakdown of BNI inspections in 2015 by topic



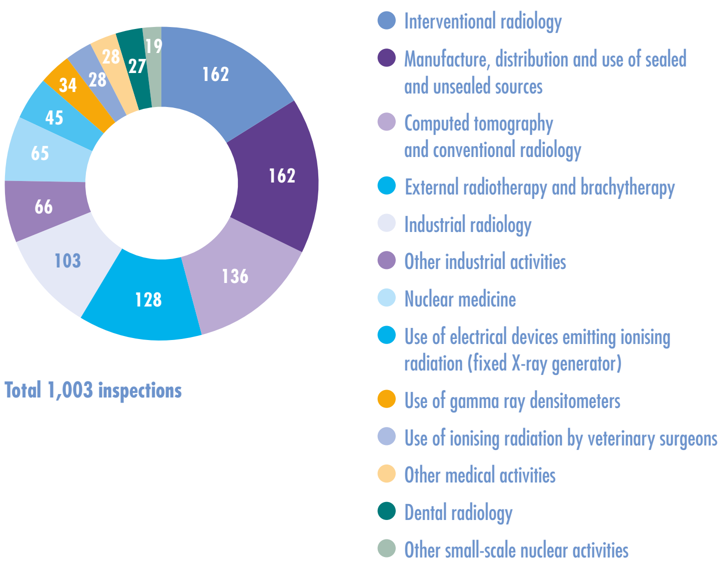
Total 658 inspections

GRAPH 3: Breakdown of radioactive substances transport inspections in 2015



Total 98 inspections

GRAPH 4: Breakdown of small-scale nuclear activity inspections in 2015 per type of activity



Total 1,003 inspections

3.2.5 Inspection of radioactive substances transport

ASN carried out 98 inspections on transport activities, 46% of which were unannounced; their breakdown into topics is illustrated in graph 3.

More than 49% of the inspections were carried out on the topic of "consignments" in industry, BNIs and the medical sector. Road carriage on the one hand and the other modes of transport on the other, account for 19% and 7% respectively of the inspections performed.

3.2.6 Inspection of small-scale nuclear activities

ASN organises its inspection activity so that it is proportionate to the radiological issues involved in the use of ionising radiation, and consistent with the actions of the other inspection services.

In 2015 ASN carried out 1,003 inspections – one fifth of which were unannounced – in some of the 50,000 or so nuclear facilities and activities in the sector. These inspections were more specifically divided among the medical (54%), industrial or research (41%) and veterinary (3%) sectors.

Medical or industrial activities entailing a high risk of human exposure are the most frequently inspected. Thus, 453 inspections were carried out in radiology and radiotherapy and 65 in nuclear medicine.

In addition, of the 410 inspections of industrial activities using ionising radiation, 162 concerned the manufacture, distribution and utilisation of sealed and unsealed sources and 103 concerned industrial radiography.

The breakdown of small-scale nuclear sector inspections according to the various activity categories is described in graph 4.

3.2.7 Inspection of ASN approved organisations and laboratories

ASN carries out a second level of inspection on approved organisations and laboratories. In addition to reviewing the application file and issuing the approval, this comprises surveillance such as the following:

- approval audits (initial or renewal audit);
- checks to ensure that the organisation and operation of the entity concerned comply with the applicable requirements;
- checks, which are usually unannounced, to ensure that the organisation's staff work in satisfactory conditions.

In 2015, ASN carried out 123 inspections on approved organisations and laboratories, 50% of which were unannounced, which can be broken down as follows:
- 76 inspections of organisations carrying out radiation protection technical checks;
- 28 inspections of organisations assessing nuclear pressure equipment conformity and carrying out in-service monitoring of operational equipment;
- 8 inspections of organisations measuring the activity concentration of radon;
- 11 inspections of laboratories approved for taking environmental radioactivity measurements.

3.2.8 Checks on exposure to Radon and Naturally occurring Radioactive Materials (NORM)

ASN also monitors radiation protection in premises where exposure of individuals to natural ionising radiation can be enhanced owing to the underlying geological context (radon in premises open to the public) or the characteristics of the materials used in industrial processes (non-nuclear industries).

Monitoring exposure to radon

Article R. 1333-15 of the Public Health Code and Article R. 4451-136 of the Labour Code provide for the radon activity concentration to be measured either by IRSN or by ASN approved organisations.

These measurements are to be taken between 15th September of a given year and 30th April of the following year.

For the 2015-2016 measurement campaign, the number of approved organisations is indicated in table 5.

Monitoring exposure to natural ionising radiation in non-nuclear industries

The Order of 25th May 2005 provides the list of professional activities (ore or rare earth processing industries, spas and facilities treating groundwater for human consumption) requiring monitoring of human exposure to natural ionising radiation, owing to the fact that the materials used contain natural radionuclides and are likely to generate doses that are significant from the radiation protection standpoint.

Monitoring natural radioactivity in water intended for human consumption

Monitoring the natural radioactivity in water intended for human consumption is the role of the ARS. The procedures for these checks take account of the recommendations issued by ASN and are taken up in the DGS Circular of 13th June 2008.

The results of the checks are jointly analysed and utilised by ASN and the services of the Ministry of Health.

3.3 Lessons learned from significant events

3.3.1 Anomaly detection and analysis

History

The international Conventions ratified by France (Article 9v of the Joint Convention on the safety of spent fuel management and on the safety of radioactive waste management of 5th September 1997; Article 19vi of the Convention on Nuclear Safety of 20th September 1994) require that BNI licensees, on account of the defence in depth principle, implement a reliable system for early detection of any anomalies that may occur, such as equipment failures or errors in the application of operating rules.

Based on twenty years of experience, ASN felt that it would be useful to transpose this approach, which was initially limited to nuclear safety, to radiation protection and protection of the environment. ASN thus drafted two guides defining the principles and reiterating the obligations binding on the licensees with regard to notification of incidents and accidents:
- guide No. 12 of 21st October 2005 contains the requirements applicable to BNI licensees and to carriers. It concerns significant events affecting nuclear safety of BNIs, radioactive material transports, radiation protection and protection of the environment;

TABLE 5: Number of organisations approved for measuring radon levels

	APPROVAL UNTIL 15TH SEPTEMBER 2016	APPROVAL UNTIL 15TH SEPTEMBER 2017	APPROVAL UNTIL 15TH SEPTEMBER 2018	APPROVAL UNTIL 15TH SEPTEMBER 2019	APPROVAL UNTIL 15TH SEPTEMBER 2020
Level 1 option A*	25	10	1	5	9
Level 1 option B**	4	5	0	0	1
Level 2***	6	1	0	0	1

** Workplace and premises open to the public for all building types*
*** Workplace, cavities and underground structures (except buildings)*
**** Represents complementary investigations*

- guide No. 11 of 7th October 2009, updated in July 2015, is intended for those in charge of nuclear activities as defined in Article L. 1333-1 of the Public Health Code and the heads of the facilities in which ionising radiation is used (medical, industrial and research activities using ionising radiation).

These guides can be consulted on the ASN website, *www.asn.fr.*

What is a significant event?

Detection of events (deviations, anomalies, incidents, etc.) by those in charge of the activities using ionising radiation, and implementation of corrective measures decided after analysis, play a fundamental role in accident prevention. The nuclear licensees detect and analyse several hundred anomalies each year for each EDF reactor and about fifty per year for any given research facility.

Prioritising the anomalies should enable the most important ones to be addressed first. ASN has defined a category of anomalies called "significant events". These are events that are sufficiently important in terms of safety or radiation protection to justify rapid notification of ASN, with a more complete analysis subsequently being sent to it. Significant events must be notified to it, as specified in the Order of 7th February 2012 (Art. 2.6.4), the Public Health Code (Articles L. 1333-3 and R. 1333-109 to R. 1333-111) and the Labour Code (Article R. 4451-99).

The criteria for notifying the public authorities of events considered to be "significant" take account of the following:
- the actual or potential consequences for workers, the public, patients or the environment, of events that could occur and affect nuclear safety or radiation protection;
- the main technical, human or organisational causes that led to the occurrence of such an event.

This notification process is part of the continuous safety improvement approach. It requires the active participation of all licensees (users of ionising radiation, carriers, etc.) in the detection and analysis of deviations.

It enables the authorities:
- to ensure that the licensee has suitably analysed the event and taken appropriate measures to remedy the situation and prevent it happening again;
- to analyse the event in the light of the experience available to other parties in charge of similar activities.

The purpose of this system is not to identify or penalise any individual person or party. Moreover, the number and rating on the INES scale (International Nuclear and Radiological Event Scale) of the significant events which have occurred in a nuclear facility are not on their own indicators of the facility's level of safety. On the one hand, a given rating level is an over-simplification and is unable to reflect the complexity of an event and, on the other, the number of events listed depends on the level of notification. The trend in the number of events does not therefore reflect any real trend in the safety level of the facility concerned.

3.3.2 Implementation of the approach

Event notification

In the event of an incident or accident, whether or not nuclear, with actual or potential significant consequences for the safety of the facility or the transport operation, or which is liable to harm people, property or the environment through significant exposure to ionising radiation, the licensee or person responsible for the nuclear activity is obliged to notify ASN and the state representative in the *département* without delay.

According to the provisions of the Labour Code, employers are obliged to declare significant events affecting their workers. When the head of a facility carrying out a nuclear activity calls in an external contractor or non-salaried worker, the significant events affecting salaried or non-salaried workers are notified in accordance with the prevention plans and the agreements concluded pursuant to Article R. 4451-8 of the Labour Code.

The notifying party assesses the urgency of notification in the light of the confirmed or potential seriousness of the event and the speed of reaction necessary to avoid an aggravation of the situation or to mitigate the consequences of the event. The notification time of two working days, tolerated in the ASN notification guide, does not apply when the consequences of the event require intervention by the public authorities.

ASN analysis of the notification

ASN analyses the initial notification to check the implementation of immediate corrective measures, to decide whether to conduct an on-site inspection to analyse the event in depth, and to prepare for informing the public if necessary.

Within two months of the notification, it is followed by a report indicating the conclusions the licensee has drawn from analysis of the events and the steps it intends to take to improve safety or radiation protection and prevent the event from happening again. This information is taken into account by ASN and its technical support organisation, IRSN, in the preparation of the inspection programme and when performing the BNI periodic safety reviews.

ASN ensures that the licensee has analysed the event pertinently, has taken appropriate steps to remedy the situation and prevent it from recurring, and has circulated the operating experience feedback.

ASN's review focuses on compliance with the applicable rules for detecting and notifying significant events, the immediate technical, organisational or human measures taken by the licensee to maintain or bring the installation into a safe condition, and the pertinence of the submitted analysis.

ASN and IRSN subsequently examine the operating feedback from the events. The assessment by ASN, the significant event reports and the periodic reviews sent by the licensees constitute the basis of operating experience feedback. This experience feedback can lead to requests for improvement of the condition of the facilities and the organisation adopted by the licensee, as well as for changes to the regulations.

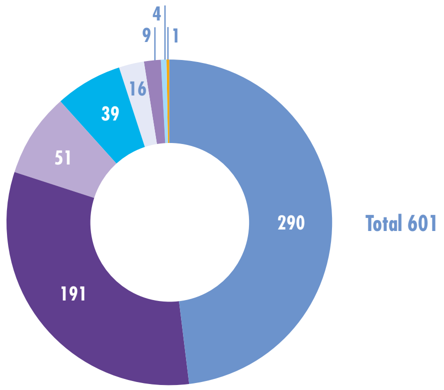
Operating experience feedback comprises the events which occur in France and abroad if it is pertinent to take them into account in order to reinforce safety or radiation protection.

3.3.3 Technical inquiries held in the event of an incident or accident concerning a nuclear activity

ASN has the authority to carry out an immediate technical inquiry in the event of an incident or accident in a nuclear activity. This inquiry consists in collecting and analysing all useful information, without prejudice to any judicial inquiry, in order to determine the circumstances and the identified or possible causes of the event, and draw up the appropriate recommendations if necessary. Articles L. 592-35 and following of the Environment Code give ASN powers to set up a commission of inquiry, determine its composition (ASN staff and people from outside ASN), define the subject and scope of the investigations and gain access to all necessary elements in the event of a judicial inquiry.

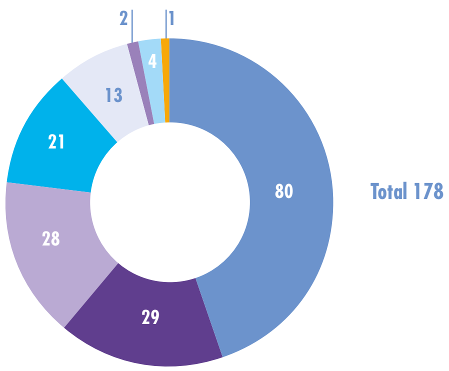
Decree 2007-1572 of 6th November 2007 on technical inquiries into accidents or incidents concerning a nuclear activity specifies the procedure to be followed. It is based on the practices established for the other investigation bureaus and takes account of the specific characteristics of ASN, particularly its independence, its ability to impose prescriptions or penalties if necessary and the concurrence of its investigative and other duties.

GRAPH 5: Events involving safety in NPPs, notified in 2015



- Deviation from Operational Technical Specifications (STE) or event which could lead to a deviation
- Other significant events which could affect safety
- Automatic reactor trip
- Transition to shutdown state in accordance with STE or accident procedures
- Design, manufacturing or assembly anomaly
- Inadvertent start-up of a protection or safeguard system
- Event or anomaly specific to the primary or secondary system
- Event which caused or could cause multiple failures

GRAPH 6: Events involving safety in BNIs other than NPPs notified in 2015

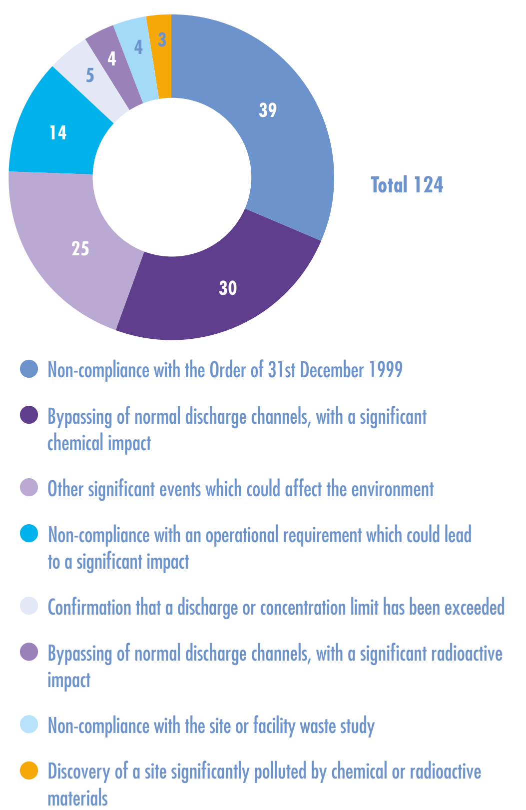


- Event which led to safety limit(s) being exceeded
- Other significant events which could affect safety
- Event actually or potentially affecting the containment of hazardous materials
- Inadvertent start-up of a protection or safeguard system
- Fault, deterioration or failure which affected a safety function
- On-site or off-site hazard affecting the availability of important equipment
- Event which caused or could cause multiple failures
- Event affecting a safety function and potentially constituting an accident precursor

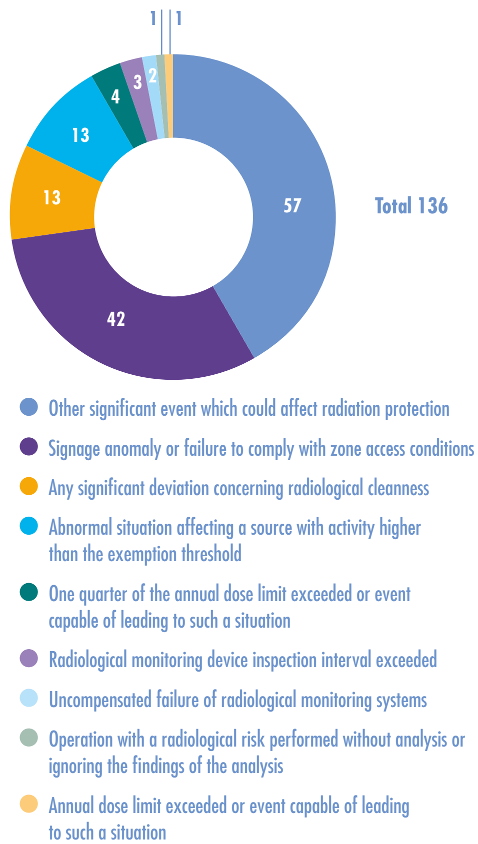
TABLE 6: Rating of significant events on the INES scale between 2010 and 2015

		2010	2011	2012	2013	2014	2015
BNI	Level 0	790	848	920	905	872	848
	Level 1	94	89	110	103	99	89
	Level 2	2	1	2	2	0	1
	Level 3 et +	0	0	0	0	0	0
	TOTAL BNI	**886**	**938**	**1,032**	**1,010**	**971**	**938**
NPX (medical and industry)	Level 0	121	81	118	130	157	126
	Level 1	37	15	33	22	34	25
	Level 2	1	1	1	2	4	2
	Level 3 et +	0	0	0	0	0	0
	TOTAL NPX	**159**	**97**	**152**	**154**	**195**	**153**
RMT	Level 0	53	25	52	50	60	56
	Level 1	9	2	6	1	3	9
	Level 2	0	0	1	0	0	1
	Level 3 et +	0	0	0	0	0	0
	TOTAL RMT	**62**	**27**	**59**	**51**	**63**	**66**
	TOTAL	**1,107**	**1,062**	**1,243**	**1,215**	**1,229**	**1,157**

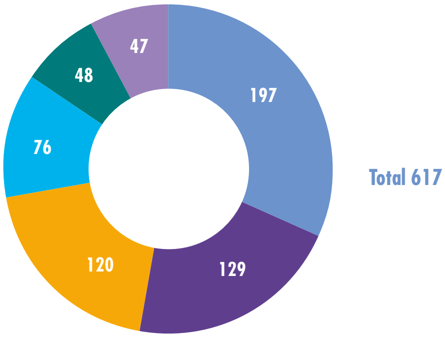
GRAPH 7: Significant environment-related events in BNIs notified in 2015



GRAPH 8: Events involving radiation protection in BNIs notified in 2015



GRAPH 9: Events involving radiation protection (other than BNIs and RMT) notified in 2015



- Concerning one or more patients (therapeutic purposes)
- Concerning one or more patients (diagnostic purposes)
- Concerning the general public
- Loss, theft or discovery of radioactive sources or substances
- Other event concerning radiation protection
- Concerning one or more workers

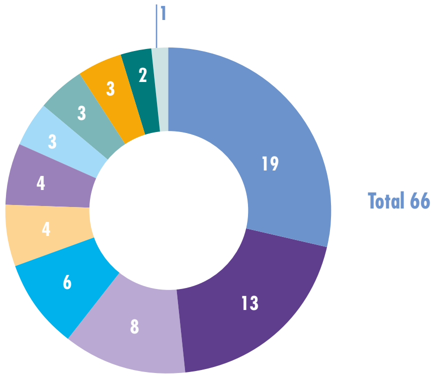
3.3.4 Statistical summary of events

In 2015, ASN was notified of:
- 1,039 significant events concerning nuclear safety, radiation protection and the environment in BNIs; 938 of these events were rated on the INES scale (848 events rated level 0, 89 events rated level 1 and 1 event rated level 2). Of these significant events, fifteen were rated as "generic events" including one at level 1 on the INES scale;
- 66 significant events concerning the transport of radioactive substances, including 9 events rated level 1 and 1 event rated level 2 on the INES scale;
- 617 significant events concerning radiation protection in small-scale nuclear activities, including 153 rated on the INES scale (of which 25 were level 1 events and 2 were level 2 events).

The general trend of rising numbers of significant events observed in recent years is slowing down. The trends must be differentiated according to the sector concerned. Between 2010 and 2015, despite fluctuations in certain years, the number of significant events notified in BNIs increased by about 8%. Over the same period, the number of significant events notified rose continuously in the small-scale nuclear activities sector, with an increase of about 25%, but remained relatively stable in transports.

As indicated earlier, these data must nevertheless be used with caution: they do not in themselves constitute a safety indicator. ASN encourages the licensees to notify incidents, which contributes to transparency and the sharing of experience.

GRAPH 10: Events involving the transport of radioactive substances notified in 2015



- Non-compliance with regulation requirements for the transport of radioactive materials which had or could have had significant consequences
- Non-compliance with one of the regulation limits applicable to the intensity of radiation or to contamination
- Any other event liable to affect the safety of transport and considered to be significant by the licensee or by ASN
- Shipment of a package even though the consignee is not in a position to receive the shipment
- Loss or theft of a radioactive substances package during transport
- Repetitive event, even if minor, affecting a safety function, for which the cause has not been identified or which is liable to constitute an incident precursor
- Hazard resulting either from natural phenomena or from human activities, actually or potentially affecting transport safety
- Inadvertent discovery of a package of radioactive substances from a shipment for which no loss was notified
- Event which affected one or more of the barriers placed between the radioactive material and humans, with actual or potential dispersion of these substances or significant exposure of persons to ionising radiation
- Fault, deterioration or failure which affected a safety function, with actual or potential significant consequences
- Event, regardless of the severity, if liable to lead to erroneous or deliberately misleading interpretations in the media or among the public

The distribution of significant events rated on the INES scale is specified in table 6. The INES scale is not applicable to patients, who are rated on the ASN-SFRO[3] scale of significant events affecting one or more radiotherapy patients, and is described in chapter 9.

3. This scale is designed for communication with the public in comprehensible, explicit terms, concerning radiation protection events leading to unexpected or unforeseeable effects on patients undergoing an external radiotherapy medical procedure.

Likewise, the significant events concerning the environment but involving non-radiological substances are not covered by the INES scale.

Such events are classified as “out of INES scale” events.

Graphs 5 to 10 describe in detail the significant events notified to ASN in 2015, differentiating between them according to the various notification criteria for each field of activity.

3.4 Heightening the awareness of professionals and cooperating with the other administrations

Regulation is supplemented by awareness programmes designed to ensure familiarity with the regulations and their application in practical terms appropriate to the various professions. ASN aims to encourage and support initiatives by the professional organisations who implement this approach by issuing best practice and professional information guides.

Awareness-raising also involves joint actions with other administrations and organisations which oversee the same facilities, but with different prerogatives. One could here mention the labour inspectorate, the medical devices inspectorate by the ANSM, the medical activities inspectorate entrusted to the technical services of the Ministry of Health, or the oversight of small-scale nuclear activities at the Ministry of Defence entrusted to the Armed Forces General Inspectorate (CGA), jointly with ASN. In June 2015, the cooperation protocol between CGA and ASN was renewed.

3.5 Information about ASN’s regulatory activity

ASN attaches importance to coordinating government departments and informs the other departments concerned of its inspection programme, the follow-up to its inspections, the penalties imposed on the licensees and any significant events.

To ensure that its inspection work is transparent, ASN informs the public by placing the following on its website *www.asn.fr*:
- inspection follow-up letters for all the activities it inspects;
- approval authorisations or rejections;
- incident notifications;
- the results of reactor outages;
- its publications on specific subjects (*Contrôle* magazine, etc.).

4. MONITORING THE IMPACT OF NUCLEAR ACTIVITIES AND RADIOACTIVITY IN THE ENVIRONMENT

4.1 Monitoring discharges and the environmental and health impact of nuclear activities

4.1.1 Monitoring of discharges

Monitoring discharges from BNIs

The monitoring of discharges from an installation is essentially the responsibility of the licensee. The prescriptions regulating discharges stipulate the minimum checks that the licensee is required to carry out. The monitoring focuses on the liquid and gaseous effluents (monitoring of the activity of discharges, characterisation of certain effluents prior to discharge, etc.) and on the environment around the facility (checks during discharge, samples of air, milk, grass, etc.). The results of this monitoring are recorded in registers transmitted to ASN every month.

The BNI licensees also regularly transmit a certain number of discharge samples to an independent laboratory for additional analysis. The results of these “cross-checks” are sent to ASN. This programme of cross-checks defined by ASN is a way of ensuring that the accuracy of the laboratory measurements is maintained over time.

Finally, through dedicated inspections, ASN ensures that the licensees comply with the regulatory provisions that apply to them regarding control of discharges. These generally unannounced inspections are run with the support of specialised, independent laboratories mandated by ASN. Effluent and environmental samples are taken for radiological and chemical analyses. Since 2000, ASN has carried out ten to thirty inspections – with sampling – every year (21 in 2014).

Accounting of BNI discharges

The rules for accounting of discharges, both radioactive and chemical, are set in the general regulations by ASN resolution 2013-DC-0360 of 16th July 2013 relative to control of the detrimental effects and the impact of Basic Nuclear Installations on health and the environment. These rules are set so that the discharge values notified by the licensees are never underestimated.

For discharges of radioactive substances, accounting is not based on overall measurements, but on an analysis per radionuclide, introducing the notion of a “reference

ASN environment inspection at the Nogent-sur-Seine NPP, December 2011

spectrum", listing the radionuclides specific to the type of discharge in question.

The principles underlying the accounting rules are as follows:
- radionuclides for which the measured activity exceeds the decision threshold for the measurement technique are all counted;
- the radionuclides of the «reference spectrum" for which the measured activity is below the decision threshold (see box) are considered to be at the decision threshold level.

UNDERSTAND

With regard to the measurements

- The Decision Threshold (SD) is the value above which it is possible with a high degree of confidence to conclude that a radionuclide is present in the sample.
- The Detection Limit (LD) is the value as of which the measurement technique is able to quantify a radionuclide with a reasonable degree of uncertainty (the uncertainty is about 50% at the LD).

In general LD ☒2 x SD.

For the measurement results on chemical substances, the Quantification Limit (LQ) is equivalent to the LQ used to measure radioactivity.

Reference spectra

For the NPPs, the reference spectra of discharges comprise the following radionuclides:
- Liquid discharges: tritium, carbon-14, iodine-131, other fission and activation products (manganese-54, cobalt-58, cobalt-60, Ag-110m, Tellurium-123m, antimony-124, antimony-125, caesium-134, caesium-137);
- Gaseous discharges: tritium, carbon-14, iodines (iodine-131, iodine-133), other fission and activation products (cobalt-58, cobalt-60, caesium-134, caesium-137), noble gases: xenon-133, xenon-135 (permanent discharges from ventilation networks, krypton-85, Xenon-131m, xenon-133 (when draining "RS" tanks), argon-41, xenon-133, xenon-135 (at decompression of reactor buildings).

For discharges of chemical substances with an emission limit value set by an ASN prescription, when the concentration values measured are below the quantification limit, the licensee is required by convention to declare a value equal to half the quantification limit concerned.

Monitoring discharges in the medical sector

Pursuant to ASN resolution 2008-DC-0095 of 29th January 2008, radioactivity measurements are taken on the effluents coming from the places that produce them. In hospitals that have a nuclear medicine department, these measurements chiefly concern iodine-131 and technetium-99m. In view of the difficulties encountered in putting in place the permits to discharge radionuclides into the public sewage networks, as provided for by the Public Health Code, ASN has created a working group involving administrations, "producers" (nuclear physicians, researchers) and sanitation professionals. The report from this working group will propose recommendations for making the regulations more efficient.

In the small-scale industrial nuclear sector, few plants discharge effluents apart from cyclotrons (see chapter 10). The discharge permits stipulate requirements for the discharges and their monitoring, which are subject to particular scrutiny during inspections.

TABLE 7: Radiological impact of BNIs since 2009 calculated by the licensees on the basis of the actual discharges from the installations and for the most exposed reference groups (data provided by the nuclear licensees). The values calculated by the licensee are rounded up to the next higher unit

LICENSEE/SITE	MOST EXPOSED REFERENCE GROUP / DISTANCE TO SITE IN km	ESTIMATION OF RECEIVED DOSES, IN mSv					
	[POPULATION] [(a)]	2009	2010	2011	2012	2013	2014
Andra / CSA	CD24 bridge / 2.1 [Child] [Adult 2012]	5.10^{-6}	2.10^{-6}	3.10^{-6}	1.10^{-5}	1.10^{-6}	2.10^{-6}
Andra / Manche	Hameau de La Fosse / 2.5 [Adult]	6.10^{-4}	4.10^{-4}	4.10^{-4}	4.10^{-4}	3.10^{-4}	3.10^{-4}
	Fisherman Goury / 8 [Adult]	8.10^{-8}	8.10^{-8}	7.10^{-8}	2.10^{-8}	2.10^{-8}	2.10^{-7}
Areva / FBFC	Ferme Riffard / 0.2 [Adult]	8.10^{-4}	1.10^{-3}	6.10^{-4}	6.10^{-4}	5.10^{-4}	3.10^{-4}
Areva / La Hague	Digulleville / 2.8 [Child, Adult (2012)]	8.10^{-3}	$1. 10^{-2}$	9.10^{-3}	9.10^{-3}	2.10^{-2}	2.10^{-2}
	Fisherman Goury / 6 [Adult, Child (2009, 2013, 2014)]	4.10^{-3}	5.10^{-3}	5.10^{-3}	5.10^{-3}	6.10^{-3}	7.10^{-3}
Areva / Tricastin (Areva NC, Comurhex, Eurodif, Socatri, SET)	Les Prés Guérinés / 1.5 [Adult] Les Girardes / 1.2 Adult (2012, 2013,2014)	5.10^{-4}	*	*	3.10^{-4}	3.10^{-4}	3.10^{-4}
	Clos de Bonnot / 0.1 [Adult (2012, 2013, 2014)]	8.10^{-4}	7.10^{-4}	5.10^{-4}	2.10^{-4}	2.10^{-4}	3.10^{-4}
CEA / Cadarache	Saint-Paul-Lez-Durance / 4.5 [Adult]	2.10^{-3}	2.10^{-3}	3.10^{-3}	2.10^{-3}	2.10^{-3}	2.10^{-3}
CEA / Fontenay-aux-Roses	Fontenay-aux-Roses / 1.5 [Child]	5.10^{-6}	4.10^{-6}	1.10^{-5}	3.10^{-5}	3.10^{-5}	1.10^{-4}
CEA / Grenoble [(b)]	Fontaine / 1 (gaseous discharges) and Saint-Egrève / 1.4 (liquid discharges) [Infant, Adult (2008, 2011, 2012, 2013)]	5.10^{-7}	3.10^{-7}	2.10^{-9}	2.10^{-8}	5.10^{-9}	(c)
CEA / Marcoule (Atalante, Centraco, Phénix, Mélox, CIS bio)	Codolet [Adult / 2] [Child 2013]	4.10^{-4}	3.10^{-4}	3.10^{-4}	2.10^{-4}	2.10^{-4}	2.10^{-3}
CEA / Saclay	Christ de Saclay [Fischerman / 1]	4.10^{-4}	7.10^{-4}	6.10^{-4}	1.10^{-3}	2.10^{-3}	2.10^{-3}
EDF / Belleville-sur-Loire	Neuvy-sur-Loire / 1.3 [Adult] [Infant 2013] Les Buteaux / 1.8 [Infant 2014]	7.10^{-4}	6.10^{-4}	8.10^{-4}	8.10^{-4}	7.10^{-4}	4.10^{-4}
EDF / Blayais	Le Bastion / 1.1 [Adult, Fischerman (2009, 2010, 2011, 2012, 2013, 2014)]	5.10^{-4}	6.10^{-4}	6.10^{-4}	2.10^{-4}	2.10^{-3}	6.10^{-4}
EDF / Bugey	Saint-Etienne d'Hières sud / 0.6 [Adult (2011, 2012)] [Infant (2013)] / Les Figuiers-Vernas / 2.1 [Infant 2014]	5.10^{-4}	4.10^{-4}	5.10^{-4}	6.10^{-4}	4.10^{-4}	2.10^{-4}
EDF / Cattenom	Garche Nord (2012), Warpich (2009, 2010, 2011, 2013, 2014) / 1.5 [Adult, Infant (2009, 2010, 2011, 2013, 2014)]	3.10^{-3}	3.10^{-3}	3.10^{-3}	3.10^{-3}	5.10^{-3}	8.10^{-3}
EDF / Chinon	Le Neman / 1.25 [Adult] [Infant (2013)] / Le Boirot / 1.7 [Infant 2014]	4.10^{-4}	4.10^{-4}	5.10^{-4}	5.10^{-4}	3.10^{-4}	2.10^{-4}
EDF / Chooz	Les Pirettes (gymnasium) / 0.8 [Adult , Infant (2009, 2013)] / Le Paviot-Ile Graviat / 1.5 [Infant 2014]	1.10^{-3}	1.10^{-3}	1.10^{-3}	9.10^{-4}	2.10^{-3}	7.10^{-4}
EDF / Civaux	Ervaux Sud / 0.7 [Adult] [Infant (2013)] / Le Peu / 1.9 [Infant 2014]	7.10^{-4}	1.10^{-4}	7.10^{-4}	9.10^{-4}	2.10^{-3}	8.10^{-4}
EDF / Creys-Malville	Ferme de Chancillon [Adult (2010, 2011, 2012) Infant (2013) / 0.85] / Le Poulet / 3.7 [Infant 2014]	8.10^{-6}	$6. 10^{-5}$	$7. 10^{-4}$	7.10^{-4}	2.10^{-4}	2.10^{-4}
EDF / Cruas-Meysse	Ferme de Grimaud, 1.25, Serres (2009,2010,2011,2012) / 1.5 [Adult (2008, 2011, 2012), Infant (2009, 2010, 2012, 2013)] / Les Roches / 2.4 [Infant 2014]	5.10^{-4}	5.10^{-4}	5.10^{-4}	4.10^{-4}	4.10^{-4}	2.10^{-4}
EDF / Dampierre-en-Burly	La Maison Neuve (2008), Les Serres (2009, 2010, 2011, 2012, 2013) / 0.7 [Adult] [Infant 2013] / La Ronce / 1.6 [Infant 2014]	1.10^{-3}	1.10^{-3}	2.10^{-3}	1.10^{-3}	9.10^{-4}	4.10^{-4}
EDF / Fessenheim	Cité EDF(Koechlin) [Adult (2010, 2011, 2012)] [(Infant 2013)]/ 1.2 / Nambsheim / 3.5 [Infant 2014]	8.10^{-5}	1.10^{-4}	$8. 10^{-5}$	1.10^{-4}	1.10^{-4}	4.10^{-5}
EDF / Flamanville	La Berquerie (2013) /0.8, Hameau es Louis (2009, 2010, 2011, 2012) / 0.8 [Adult, Pêcheur (2009, 2010, 2011, 2012, 2014)] [Infant (2013)]	9.10^{-4}	9.10^{-4}	2.10^{-3}	6.10^{-4}	7.10^{-4}	5.10^{-4}
EDF / Golfech	Pascalet / 0.9, Labaquière (2009, 2010, 2011, 2012, 2013) / 1 [Adult] [Infant (2013, 2014)]	8.10^{-4}	9.10^{-4}	8.10^{-4}	7.10^{-4}	6.10^{-4}	2.10^{-4}

LICENSEE/SITE	MOST EXPOSED REFERENCE GROUP / DISTANCE TO SITE IN km	ESTIMATION OF RECEIVED DOSES, IN mSv					
	[POPULATION] [(a)]	2009	2010	2011	2012	2013	2014
EDF / Gravelines	Petit-Fort-Philippe / 1.5, Espace Culturel Decaestecker (2009, 2010, 2011, 2012, 2013) / 1.1 / [Adult, Fisherman (2009, 2010, 2011, 2012, 2013)] / Gravelines / 1.8 [Fisherman, Adult 2014]	1.10^{-3}	1.10^{-3}	2.10^{-3}	4.10^{-4}	6.10^{-4}	8.10^{-4}
EDF / Nogent-sur-Seine	Port Saint-Nicolas 2.25, Maison de l'Eclusier (2009, 2010, 2011, 2012, 2013) / 1 [Adult] [Infant (2013, 2014)]	6.10^{-4}	9.10^{-4}	8.10^{-4}	6.10^{-4}	1.10^{-3}	5.10^{-4}
EDF / Paluel	Le Tôt / 1.5 [Adult, Fisherman (2009, 2010, 2011, 2012)] Conteville / 1 [Adult, Fisherman] / Saint-Sylvain / 1.4 [Adult 2014]	6.10^{-4}	7.10^{-4}	8.10^{-4}	5.10^{-4}	9.10^{-4}	9.10^{-4}
EDF / Penly	Saint-Martin Plage / 1.1, Vassonville (2009, 2010, 2011, 2012) / 0.7 [Adult, Fisherman (2009, 2010, 2011, 2012)] Penly / 0.8 [Adult, Fisherman 2013] / Biville sur Mer [Adult, Fisherman 2014]	9.10^{-4}	1.10^{-3}	1.10^{-3}	6.10^{-4}	7.10^{-4}	4.10^{-4}
EDF / Saint-Alban	Les Crès [Adult / 1.45] [Infant (2013)] / Saint-Pierre de Bœuf / 2.3 [Infant 2014]	4.10^{-4}	4.10^{-4}	4.10^{-4}	4.10^{-4}	4.10^{-4}	2.10^{-4}
EDF / Saint-Laurent-des-Eaux	Port au Vin [Adult / 0.75] [Infant (2013)] / Le Cavereau / 2.3 [Infant 2014]	3.10^{-4}	3.10^{-4}	3.10^{-4}	2.10^{-4}	2.10^{-4}	2.10^{-4}
EDF / Tricastin	Clos du Bonneau / 1.25, Le Trop Long (2009, 2010, 2011, 2012, 2013) / 1.35 [Adult (2014), [Infant (2009, 2010, 2011, 2012, 2013)]	7.10^{-4}	9.10^{-4}	7.10^{-4}	7.10^{-4}	5.10^{-4}	2.10^{-4}
Ganil / Caen	IUT / 0.6 [Adult]	3.10^{-3}	$<3.10^{-3}$	$<3.10^{-3}$	$<3.10^{-3}$	$<2.10^{-3}$	$<2.10^{-3}$
ILL / Grenoble	Fontaine / 1 (gaseous discharges) and Saint-Egrève (liquid discharges) / 1.4 [Infant]	1.10^{-4}	1.10^{-4}	5.10^{-5}	1.10^{-4}	2.10^{-4}	3.10^{-4}

a: until 2008, for installations operated by EDF, only "adult" figures are calculated. From 2009 to 2012, the dose of the most exposed reference group of each site for the two age classes (adult or infant) is mentioned. As of 2013, the dose of the reference group is provided for three age classes (adult, child, infant) for all the BNIs.
b: because the outfall for the liquid discharges is geographically distant from the stack, two impact calculations are performed. One reflects the aggregate of maximum impact of gaseous discharges plus maximum impact of liquid discharges. The other corresponds to an actual reference group.
c: as the site has no longer had radioactive discharges since 2014, the radiological impact caused by radioactive discharges is thus nil for the year 2014.

For the year 2014, CEA did not give the total dose for each site, but estimations of the doses calculated per radionuclide with a threshold of 0.01 µSv (when the estimated impact is below 0.01 µSv, the value given is < 0.01 µSv). On the basis of these data, the impact for each site was evaluated taking account of the value of 0.01 µSv for radionuclides for which the impact was declared to be lower than this threshold.
** Information not provided by the licensee.*

4.1.2 Evaluating the radiological impact of the facilities

In accordance with the optimisation principle, the licensee must reduce the radiological impact of its facility to values that are as low as possible under economically acceptable conditions.

The licensee is required to assess the dosimetric impact of its activity. As applicable, this obligation is the result of Article L. 1333-8 of the Public Health Code, or the regulations concerning BNI discharges (Article 5.3.2 of ASN resolution 2013-DC-0360 of 16th July 2013 concerning control of detrimental effects and the impact of basic nuclear installations on health and the environment). The result must be compared with the annual dose limit for the public (1 mSv/year) defined in Article R.1333-8 of the Public Health Code. This regulation limit corresponds to the sum of the effective doses received by the public as a result of nuclear activities.

In practice, only traces of artificial radioactivity are detectable in the vicinity of the nuclear facilities; most measurements taken during routine surveillance are below the decision threshold or reflect the natural radioactivity. As these measurements cannot be used for dose estimations, models for the transfer of radioactivity to humans must be used, on the basis of measurements of discharges from the installation. These models are specific to each licensee. They are detailed in the installation's impact assessment. During its assessment, ASN verifies that these models are conservative, in order to ensure that the impact assessments will in no case be underestimated.

In addition to the impact assessments produced on the basis of discharges from the facilities, the licensees are required to carry out environmental radioactivity monitoring programmes (water, air, earth, milk, grass, agricultural produce, etc.), more specifically to verify compliance with the hypotheses of the impact assessment and to monitor changes in the radioactivity in the various compartments of the environment around the facilities (see point 4.1.1).

An estimation of the doses from BNIs is presented in table 7. For each site and per year, this table gives the effective doses received by the most exposed reference population groups.

The doses from BNIs for a given year are determined on the basis of the actual discharges from each installation for the year in question. This assessment takes account of the discharges through the identified outlets (stack, discharge pipe to river or seawater). It also includes diffuse emissions and sources of radiological exposure to the ionising radiation present in the facilities. These elements are the "source term".

The estimate is made in relation to one or more identified reference groups. These are uniform groups of people (adults, infants, children) receiving the highest average dose out of the entire population exposed to a given installation, following realistic scenarios (taking into account the distance from the site, meteorological data, etc.). All of these parameters, specific to each site, explain most of the differences observed between sites and from one year to another.

For each of the nuclear sites presented, the radiological impact remains far below, or at most 1% of the limit for the public (1 mSv per year). Therefore in France, the discharges produced by the nuclear industry have an extremely small radiological impact.

4.1.3 Monitoring imposed by the European Union

Article 35 of the EURATOM Treaty requires that the Member States establish the facilities needed to carry out continuous monitoring of the level of radioactivity in the air, water and soil and to ensure compliance with the basic standards of health protection for the general public and workers against the hazards of ionising radiation. All Member States, whether or not they have nuclear facilities, are therefore required to implement environmental monitoring arrangements throughout their territory.

By virtue of the provisions of this same Article 35, the European Commission also has the right to access these monitoring facilities, in order to check their operation and effectiveness. During its verifications, the European Commission gives an opinion on the means implemented by the member states to monitor radioactive discharges into the environment and the levels of radioactivity in the environment around nuclear sites and over the national territory.

It gives its assessment of the monitoring equipment and methodologies used, and of the organisational setup.

Since 1994, the Commission has carried out the following inspections:
- the La Hague reprocessing plant and Andra's Manche repository in 1996;
- Chooz NPP in 1999;
- Belleville-sur-Loire NPP in 1994 and 2003;
- the La Hague reprocessing plant in 2005;
- the Pierrelatte nuclear site in 2008;
- the old uranium mines in the Limousin *département* in 2010;
- the CEA site at Cadarache in 2011.

4.2 Environmental monitoring

In France, many parties are involved in environmental radioactivity monitoring:
- the nuclear facility licensees, who perform monitoring around their sites;
- ASN, IRSN (whose roles defined by Decree 2002-254 of 22nd February 2002 include participation in radiological monitoring of the environment), the Ministries (General Directorate for Health (DGS), General Directorate for Food (DGAL), General Directorate for Competition Policy, Consumer Affairs and Fraud Control (DGCCRF, etc.), the State services and other public players performing monitoring duties nationwide or in particular sectors (foodstuffs for example, monitored by the Ministry responsible for Agriculture);
- the approved air quality monitoring associations (local authorities), environmental protection associations and the CLIs.

The French National Network for environmental radioactivity Monitoring (RNM) brings all these players together. Its primary aim is to collate and make available to the public all the regulatory environmental measurements taken on French territory, by means of a dedicated website *www.mesure-radioactivité.fr*. The quality of these measurements is guaranteed by subjecting the measuring laboratories to an approval procedure.

4.2.1 The purpose of environmental monitoring

The licensees are responsible for monitoring the environment around their facilities. The content of the monitoring programmes to be implemented in this respect (measurements to be taken and frequency) is defined in ASN resolution 2013-DC-0360 of 16th July 2013 concerning the control of detrimental effects and the impact on health and the environment of basic nuclear installations and in the individual prescriptions applicable to each installation (Creation Authorisation Decree, discharge licensing orders or ASN resolutions), independently of the additional measures that can be taken by the licensees for the purposes of their own monitoring.

This environmental monitoring:
- helps gives a picture of the radiological and radio-ecological state of the facility's environment through measurement of parameters and substances regulated by the prescriptions, in the various compartments of the environment (air, water, soil) as well as in the various biotopes and the food chain (milk, vegetables, etc.): a zero reference point is identified before the creation of the facility and environmental monitoring throughout the life of the facility enables any changes to be tracked;
- helps verify that the impact of the facility on health and the environment is in conformity with the impact assessment;
- detects any abnormal increase in radioactivity as early as possible;

- ensures there are no facility malfunctions, including by analysing the ground water and checking licensees' compliance with the regulations;
- contributes to transparency and information of the public by transmitting monitoring data to the RNM.

4.2.2 Content of monitoring

All the nuclear sites in France that produce discharges are subject to systematic environmental monitoring. This monitoring is proportionate to the environmental risks or drawbacks of the facility, as presented in the authorisation file, particularly the impact assessment.

The regulatory monitoring of the BNI environment is tailored to each type of installation, depending on whether it is a power reactor, a plant, a research facility, a waste disposal facility, etc. The minimum content of this monitoring is defined by the Order of 7th February 2012 setting the general rules for BNIs and by the above-mentioned ASN resolution of 16th July 2013. This resolution obliges BNI licensees to have approved laboratories take the environmental radioactivity measurements required by regulations.

Depending on specific local features, monitoring may vary from one site to another. Table 8 gives examples of the monitoring performed by an NPP and by a research centre or plant.

When several facilities (whether or not BNIs) are present on the same site, joint monitoring of all these installations is possible, as has been the case, for example, on the Cadarache and Tricastin sites since 2006.

These monitoring principles are supplemented in the individual requirements applicable to the facilities by monitoring measures specific to the risks inherent in the industrial processes they use.

Each year, in addition to sending ASN the monitoring results required by the regulations, the licensees transmit nearly 120,000 measurements to the national network for environmental radioactivity monitoring.

4.2.3 Environmental monitoring nationwide by IRSN

IRSN's nationwide environmental monitoring is carried out by means of measurement and sampling networks dedicated to:
- air monitoring (aerosols, rainwater, ambient gamma activity);
- monitoring of surface water (watercourses) and groundwater (aquifers);
- monitoring of the human food chain (milk, cereals, fish, etc.);
- terrestrial continental monitoring (reference stations located far from all industrial facilities).

It uses several approaches for this:
- continuous on-site monitoring using independent systems (remote-monitoring networks) providing real-time transmission of results. This includes:
  - the *Téléray* network (ambient gamma radioactivity in the air) which uses a system of continuous measurement monitors around the whole country. The density of this network is being increased around nuclear sites within a radius of 10 to 30 km around BNIs;
  - the *Hydrotéléray* network (monitoring of the main watercourses downstream of all nuclear facilities and before they cross national boundaries);
  - continuous sampling networks with laboratory measurement, for example the atmospheric aerosols radioactivity monitoring network;

Measurement of radioactivity in the environment during an emergency exercise at Chooz, by a representative from CEA Saclay (radiation protection), September 2014.

UNDERSTAND

The regional radiological findings approach

The purpose of the regional radiological findings produced by IRSN is, over an extensive area (covering several departments), to establish an updated baseline of the levels of radioactivity in certain environmental compartments that are characteristic of the area in question. Depending on the scale of the findings and the environment studied, emphasis is placed on typical agricultural crops and livestock production for the area concerned, fishery products or the natural bio-indicators.

This baseline aims to take into account firstly of the radiological «background noise» associated with the natural radioactivity and the persistence of old atmospheric fallout (nuclear weapons tests and the Chernobyl accident) and secondly of the influence of current or past discharges from any nuclear installations present in the area. In the event of discharges related to an incident or accident, this baseline would serve as a comparison benchmark and help orient the deployment of reinforced monitoring.

Since the regional radiological findings approach was initiated in 2008, seven radiological findings (Val de Loire, Rhone Valley, North-East area, Nord-Normandie, New Caledonia, "persistence zones" findings, mining radiological findings) have been published or are being drafted.

The corresponding reports are available on the IRSN website, *www.irsn.fr,* or the RNM website, *www.mesure-radioactivite.fr*

- processing and measurement in a laboratory of samples taken from the various compartments of the environment, whether or not close to facilities liable to discharge radionuclides.

Every year, IRSN takes more than 25,000 samples in all compartments of the environment (excluding the remote-measurement networks).

The radioactivity levels measured in France are stable and situated at very low levels, generally at the detection sensitivity threshold of the measuring instruments. The artificial radioactivity detected in the environment results essentially from fallout from the atmospheric tests of nuclear weapons carried out in the 1960s, and from the Chernobyl accident. Traces of artificial radioactivity associated with discharges can sometimes be detected near installations. To this can be added very local contaminations resulting from incidents or past industrial activities, and which do not represent a health risk.

On the basis of the nationwide radioactivity monitoring results and in accordance with the provisions of ASN resolution 2008-DC-0099 of 29th April 2008, as amended, IRSN regularly publishes a report on the radioactive status of the French environment. The first issue of this report, published at the beginning of 2013, covered the year 2010 and the first half of 2011. The second issue of this report, published at the end of 2015, corresponds to the period 2011-2014.

In addition to the publication of the above-mentioned radiological status reports, IRSN also produces regional radiological findings to provide more precise information about a given area (see box).

4.3 Measurement quality

Articles R.1333-11 and R.1333-11-1 of the Public Health Code require the creation of a National Monitoring Network (RNM) and a procedure to have the radioactivity measurement laboratories approved by ASN. The RNM working methods were defined by the above-mentioned ASN resolution of 29th April 2008.

This network is being deployed for two main reasons:
- to ensure the transparency of information on environmental radioactivity by making the results of this environmental monitoring and information about the radiological impact of nuclear activities in France available to the public on a specific website *(www.mesure-radioactivite.fr);*
- to pursue the implementation of a quality assurance policy for environmental radioactivity measurements by setting up a system of laboratory approvals granted by ASN resolution, pursuant to Article l. 592-21 of the Environment Code.

The approvals cover all components of the environment, water, soils or sediments, all biological matrices (fauna, flora, milk), aerosols and atmospheric gases. The measurements concern the main artificial or natural, gamma, beta or alpha emitting radionuclides, as well as the ambient gamma dosimetry (see table 9). The list of the types of measurements covered by an approval was extended by ASN resolution 2015-DC-0500 of 26th February 2015, approved by the Order of 3rd June 2015, which modifies the above-mentioned ASN resolution of 29th April 2008, in order to incorporate into the RNM the results of the foodstuffs health checks carried out on behalf of the DGAL and the DGCCRF.

In total, about fifty types of measurements are covered by approvals. There are just as many corresponding inter-laboratory comparison tests. These tests are organised by IRSN in a 5-year cycle, which corresponds to the maximum approval validity period.

4.3.1 Laboratory approval procedure

ASN resolution 2008-DC-0099 of 29th April 2008, modified by resolution 2015-DC-0500 of 26th February 2015, specifies the organisation of the national network and sets the approval arrangements for the environmental radioactivity measurement laboratories.

TABLE 8: Example of radiological monitoring of the environment around BNIs

ENVIRONMENT MONITORED OR TYPE OF INSPECTION	CATTENOM NPP (RESOLUTION 2014-DC-0415 OF 16TH JANUARY 2014)	AREVA DE LA HAGUE FACILITY (ORDER OF 10TH JANUARY 2003 AMENDED BY THE ORDER OF 8TH JANUARY 2007)
Air at ground level	• 4 continuous sampling stations for atmospheric dust on fixed filter with daily measurement of total β activity (β_G) γ spectrometry if $\beta_G > 2$ mBq/m^3 Monthly γ spectrometry on grouped filters per station • 1 continuous sampling station downwind of the prevailing winds, with weekly measurement of atmospheric ^{3}H	• 5 stations continuously sampling atmospheric dust on a fixed filter, with daily measurements of the total α activity (α_G) and total β activity (β_G). γ spectrometry if α_G ou $\beta_G > 1$ mBq/m^3 Monthly α spectrometry (Pu) on grouped filters per station • 5 continuous sampling stations for halogens on specific adsorbent with weekly γ spectrometry to measure iodines • 5 continuous sampling stations with weekly measurement of atmospheric ^{3}H • 5 continuous sampling stations with bi-monthly measurement of atmospheric ^{14}C • 5 continuous measurement stations for ^{85}Kr activity in the air
Ambient γ radiation	• Continuous measurement with recording: - 4 detectors at 1 km - 10 detectors on the site boundary - 4 detectors at 5 km	• 5 detectors with continuous measurement and recording • 11 detectors with continuous measurement at the site fencing
Rain	1 continuous sampling station under the prevailing winds with bi-monthly measurement of β_G and ^{3}H	• 2 continuous sampling stations including one under the prevailing winds with weekly measurement of α_G, β_G and ^{3}H. γ spectrometry if significant α_G or β_G
Liquid discharge receiving	• Sampling from the river upstream of the discharge point and in the good mixing area for each discharge Measurement of β_G, potassium (K)* and ^{3}H • Continuous sampling in the river at the good mixing point Measurement of ^{3}H (daily average mixture) • Annual samples from aquatic sediments, fauna and flora upstream and downstream of the discharge point with γ spectrometry, measurement of free ^{3}H and, in fish, organically bound ^{14}C and ^{3}H • Periodic sampling from a stream and in the dam adjoining the site with measurements of β_G, K, ^{3}H	• Daily seawater samples from 2 points on the coast, with daily measurements (γ spectrometry, ^{3}H) at one of these points and for each of the 2 points, α and γ spectrometry and β_G, K, ^{3}H and ^{90}Sr measurements • Quarterly seawater samples at 3 points offshore with γ spectrometry and β_G, K, ^{3}H measurements • Quarterly samples of beach sand, seaweed and limpets at 13 points with γ spectrometry + ^{14}C measurements and α spectrometry for the seaweed and limpets at 6 points • Sampling of fish, crustaceans, shellfish and molluscs in 3 coastal zones of the Cotentin with α and γ spectrometry and ^{14}C measurement • Quarterly sampling of offshore marine sediments at 8 points with α and γ spectrometry and ^{90}Sr measurement • Weekly to six-monthly sampling of water of 19 streams adjacent to the site, with α_G, β_G, K and ^{3}H measurements • Quarterly sampling of sediments from the 4 main streams adjacent to the site, with γ and α spectrometry • Quarterly sampling of aquatic plants from 3 streams adjacent to the site, with γ spectrometry and ^{3}H measurement
Groundwater	• Monthly sampling at 4 points, bi-monthly at 1 point and quarterly at 4 points with β_G, K and ^{3}H measurement	• 5 sampling points (monthly check) with α_G, β_G, du K and ^{3}H measurements
Water for consumption	• Annual sampling of water intended for human consumption, with β_G, K and ^{3}H measurements	• Periodic sampling of water intended for human consumption at 15 points, with α_G, β_G, K and ^{3}H measurement
Soil	• 1 annual sample of topsoil with γ spectrometry	• Quarterly samples at 7 points with γ spectrometry and ^{14}C measurement
Vegetation	• 2 grass sampling points, including one under the prevailing winds, monthly γ spectrometry and quarterly ^{14}C and C measurements. • Annual campaign for the main agricultural crops, with γ spectrometry, ^{3}H and ^{14}C measurements	• Monthly grass sampling at 5 points and quarterly at 5 other points with γ spectrometry and ^{3}H and ^{14}C measurements Annual α spectrometry at each point • Annual campaign for the main agricultural crops, with α and γ spectrometry, ^{3}H, ^{14}C and ^{90}Sr measurements
Milk	• 2 sampling points, situated 0 to 10 km from the facility, including one under the prevailing winds, with monthly γ spectrometry, quarterly ^{14}C measurement and annual ^{90}Sr and ^{3}H measurement	• 5 sampling points (monthly check) with γ spectrometry, K, ^{3}H, ^{14}C and ^{20}Sr measurement

α_G = total α ; β_G = total β
** Measurements of total concentration of potassium and by spectrometry for ^{40}K*

The approval procedure includes:
- presentation of an application file by the laboratory concerned, after participation in an Inter-laboratory Comparison Test (ILT);
- review of it by ASN;
- review of the application files – which are made anonymous – by a pluralistic approval commission which delivers an opinion on them.

The laboratories are approved by ASN resolution, published in its official bulletin. The list of approved laboratories is updated every six months.

UNDERSTAND

The national network's website: *www.mesure-radioactivite.fr*

In order to meet the transparency goal, the RNM launched a website in 2010 to present the environmental radioactivity monitoring results and information on the health impact of nuclear activities in France. In order to guarantee the quality of the measurements, only those taken by an approved laboratory or by IRSN may be communicated to the RNM.

The website is organised around three topics (radioactivity, the national network and the measurements map) and can be used to obtain information about radioactivity (what is radioactivity? how is it measured? what are its biological effects?), about the national monitoring network (operation, network participants, laboratory approval procedure), plus access to a database containing all the radioactivity measurements taken nationwide (almost 600,000 measurements). The RNM management report is also available on it.

ASN considers that the launch of the RNM website is a decisive step forward in terms of transparency. It however considers this to be just a first step in providing the public with environmental radioactivity monitoring information, and ensures that the expectations of the general public and web users about how they would like this website to develop are identified and taken into account. A panel of users was set up in 2012 to test the website. This feedback led ASN and IRSN to decide to initiate an overhaul of the site, in order to add functions and information enabling the public to understand and interpret the environmental radioactivity measurement results transmitted to the RNM.

After approval by the RNM steering committee in November 2014, the overhaul of the site was started in 2015. The new version of the *www.mesure-radioactivite.fr* site should be on-line during the course of 2016.

4.3.2 The approval commission

The approval commission is the body which is tasked with ensuring that the measurement laboratories have the organisational and technical competence to provide the network with high-quality measurement results. The commission is authorised to propose approval, rejection, revocation or suspension of approval to ASN. It issues a decision on the basis of an application file submitted by the candidate laboratory and its results in the inter-laboratory comparison tests organised by IRSN.

The commission presided over by ASN comprises qualified persons and representatives of the State services, laboratories, standardising authorities and IRSN. ASN resolution 2013-CODEP-DEU-2013-061297 of 12th November 2013, appointing candidates to the environmental radioactivity measurement laboratories approval commission, renewed the mandates of the commission's members for a further five years.

4.3.3 Approval conditions

Laboratories seeking approval must set up an organisation meeting the requirements of standard NF EN ISO/IEC 17025 concerning the general requirements for the competence of calibration and test laboratories.

In order to demonstrate their technical competence, they must take part in Inter-laboratory Comparison Tests (ILTs) organised by IRSN. The ILT programme, which now operates on a five-yearly basis, is updated annually. It is reviewed by the approval commission and published on the national network's website (*www.mesure-radioactivite.fr*).

Up to 70 laboratories sign up for each test, including a number of laboratories from other countries.

To ensure that the laboratory approval conditions are fully transparent, precise assessment criteria are used by the approval commission. These criteria are published on *www.mesure-radioactivite.fr*.

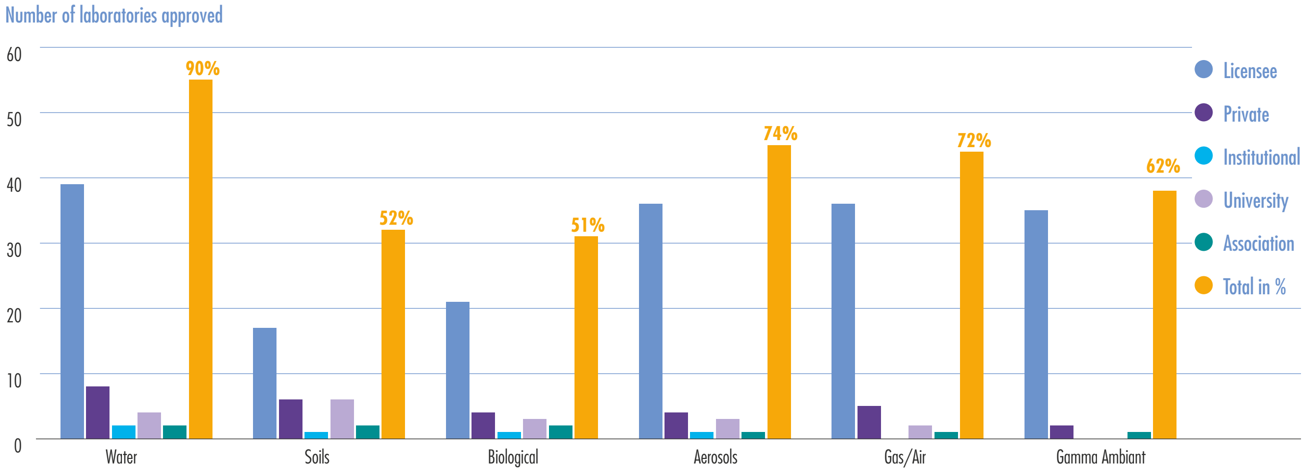
In 2015, IRSN organised four ILTs; 58 ILTs since 2003 have covered nearly 50 types of approval. The most numerous approved laboratories (55) are in the field of monitoring of radioactivity in water. About thirty to forty laboratories are approved for measurement of biological matrices (fauna, flora, milk), atmospheric dust, air, or ambient gamma dosimetry. 32 laboratories deal with soils and sediments. Although most laboratories are competent to measure gamma emitters in all environmental matrices, only about ten of them are approved to measure carbon-14, transuranic elements or radionuclides of the natural chains of uranium and thorium in water, soil and sediments and the biological matrices (grass, plant crops or livestock breeding, milk, aquatic fauna and flora, etc.).

TABLE 9: Approval chart and forecast five-year Inter-Laboratory Test (ILT) programme

		TYPE 1			TYPE 2		TYPE 3		TYPE 4		TYPE 5		TYPE 6		TYPE 7	
Code	Radioactive measurements category	Sea water	Water		Soil matrices		Biological matrices		Aerosols on filter		Gas air		Ambient environnment (soil/air)		Foodstuffs	
..-01	γ emitting radionuclides > 100 keV			1_01		2_01		3_01		4_01		5_01		-	milk	7_01
..-02	γ emitting radionuclides < 100 keV			1_02		2_02		3_02		4_02		5_02		-	milk	7_02
..-03	Total alpha			1_03		-		-		4_03		-		-	-	-
..-04	Total bêta			1_04		-		-		4_04		-		-	-	-
..-05	^{3}H			1_05		2_05		3_05		-		5_05: Cf. water		-	-	-
..-06	^{14}C			1_06		2_06		3_06		-		5_06: Cf. water/ Na OH		-	-	-
..-07	$^{90}Sr/^{90}Y$			1_07		2_07		3_07		4_07		-		-	-	-
..-08	Other pure beta emitters (Ni-63,...)			1_08		2_08 ^{99}Tc		3_08 ^{99}Tc		-		-		-	-	-
..-09	Isotopes U			1_09		2_09		3_09		4_09		-		-	-	-
..-10	Isotopes Th			1_10		2_10		3_10		4_10		-		-	-	-
..-11	^{226}Ra + daughters			1_11		2_11		3_11		-		Rn 222 : 5_11		-	-	-
..-12	^{228}Ra + daughters			1_12		2_12		3_12		-		Rn 220 : 5_12		-	-	-
..-13	Isotopes Pu, Am, (Cm, Np)			1_13		2_13		3_13		4_13		-		-	-	-
..-14	Halogenated gases			-		-		-		-		5_14		-	-	-
..-15	Rare gases			-		-		-		-		5_15 ^{85}Kr		-	-	-
..-16	Gamma dosimetry			-		-		-		-		-		6_16	-	-
..-17	Total uranium			1_17		2_17		3_17		4_17		-		-	-	-

1st semester 2016 · 2nd semester 2016 · 1st semester 2017 · 2nd semester 2017 · 1st semester 2018 · 2nd semester 2018 · 1st semester 2019 · 2nd semester 2019 · 1st semester 2020 · 2nd semester 2020

GRAPH 11: Breakdown of the number of approved laboratories for a given environmental matrix as at 1st January 2015



In 2015, ASN issued 248 approvals or approval renewals. As at 1st January 2016, the total number of approved laboratories stood at 61, representing 864 currently valid approvals of all types (in 2015, one laboratory requested the suspension of its previously held approvals).

The detailed list of approved laboratories and their scope of technical competence is available on *www.asn.fr*.

5. IDENTIFYING AND PENALISING DEVIATIONS

5.1 Ensuring that penalty decisions are fair and consistent

In certain situations in which the licensee fails to conform to the regulations or legislation, or when it is important that appropriate action be taken by it to remedy the most serious risks without delay, ASN may impose the penalties provided for by law. The principles of ASN's actions in this respect are:
- penalties that are impartial, justified and appropriate to the level of risk presented by the situation concerned. Their scale is proportionate to the health and environmental consequences associated with the deviation detected and also takes account of intrinsic factors relating to the behaviour of the party at fault and external factors relating to the context of the deviation.
- administrative action initiated on proposals from the inspectors and decided on by ASN in order to remedy risk situations and non-compliance with the legislative and regulatory requirements as observed during its inspections.

ASN has a range of tools at its disposal, in particular:
- remarks made by the inspector to the licensee;
- the official letter from the ASN departments to the licensee (inspection follow-up letter);
- formal notice from ASN to the licensee to regularise its administrative situation or meet certain specified conditions, within a given time-frame;
- administrative penalties applied after formal notice.

In addition to ASN's administrative actions, reports can be drafted by the inspector and sent to the Public Prosecutor's Office.

The decision to take enforcement measures is based on the observed risk for people or the environment and takes account of factors specific to the licensee (history, behaviour, repeated nature of the problem), contextual factors and the nature of the infringements observed (violation of regulations, standards, "rules of good practice", etc.).

THE ENERGY TRANSITION FOR GREEN GROWTH ACT

ASN is given increased powers of inspection and sanction

The 17th August 2015 Energy Transition for Green Growth Act provides for a reinforcement of ASN's oversight resources and powers of sanction.

Through the Ordinance of 10th February 2016, the following provisions were added to ASN's administrative sanctions, giving its inspectors more graduated power of inspection and sanction:
- payment of a maximum daily fine of €15,000;
- payment of a maximum administrative penalty of €10 million.

This same Ordinance created a sanctions committee responsible for ruling on the administrative penalties. It comprises four members who neither sit on the ASN Commission nor are part of its departments, in order to comply with the principle of separation between investigating and sentencing powers.

ASN's policing powers have been expanded to activities important for the protection of individuals and the environment performed outside BNIs by the licensee, its suppliers, contractors or subcontractors.

5.2 An appropriate policy of enforcement and sanctions

5.2.1 For the BNI licensees and entities responsible for the transport of radioactive substances

When ASN observes breaches of compliance with safety regulations, penalties can be imposed on the licensees, if necessary after formal notice has been served.

If an infringement is observed, the Environment Code comprises graduated administrative penalties that become applicable after formal notice, as defined in its Articles L. 596-14 to L. 596-22:
- deposit in the hands of a public accountant of a sum covering the total cost of the work to be performed;
- have the work or prescribed measures carried out without consulting the licensee and at its expense (any sums deposited beforehand can be used to pay for this work);
- suspension of the functioning of the installation or of performance of the operation (restart for example) until the licensee has brought it into conformity.

If the licensee has any observations concerning the penalties it shall present them to the ASN Commission before they are applied.

The Act also makes provision for interim measures to safeguard security and public health and safety or protect the environment. ASN can therefore:
- provisionally suspend operation of a BNI, immediately notifying the ministers responsible for nuclear safety, in the event of any serious and imminent risk;
- at all times require assessments and implementation of the necessary measures in the event of a threat to the abovementioned interests.

Infringements are written up in reports by the nuclear safety inspectors and transmitted to the Public Prosecutor's Office, which decides on what subsequent action, if any, is to be taken. The Environment Code makes provision for criminal penalties, detailed in Articles L. 596-10 to L. 596-12; these penalties include fines of €7,500 to €150,000 plus a possible prison term of 1 to 3 years, depending on the nature of the infringement. For legal persons found to be criminally liable, the amount of the fine is multiplied by ten. When the events mentioned have seriously affected the interests mentioned in Article L. 593-1, the prison sentences and the corresponding fines are doubled.

Decree 2007-1557 of 2nd November 2007 concerning BNIs and the regulation of the transport of radioactive substances with respect to nuclear safety, also imposes class 5 fines for infringements as detailed in its Article 56.

With regard to pressure equipment, the manufacturers and approved organisations are considered to be "licensees". Thus, pursuant to the provisions of Chapter VII of title V of book V of the Environment Code, which apply to high-risk products and equipment, including pressure equipment, ASN which is in charge of monitoring these items in BNIs, has powers of sanction against licensees. These provisions in particular enable it to order the payment of a fine, plus an additional daily payment applicable until such time as compliance with the formal notice is effective.

In addition to these provisions, which will be supplemented by implementing decrees, the Decree of 13th December 1999 concerning pressure equipment also comprises enforcement measures and sanctions against licensees and manufacturers of pressure equipment. These provisions aim to ban the marketing, commissioning or continued operation of an equipment item and to serve the licensee with formal notice to take all steps to ensure conformity.

5.2.2 For persons in charge of small-scale nuclear activities, approved organisations and laboratories

The Public Health Code makes provision for administrative and criminal sanctions in the event of breach of the radiation protection requirements.

Administrative decision-making powers lie with ASN and can entail:
- temporary or definitive license withdrawals after receiving formal notice;
- interim suspension of an activity (whether licensed or notified) if urgent measures are required to safeguard human health;
- revocation or suspension of any approvals it has issued.

The formal notice prior to revocation of a license (based on Article L.1333-5 of the Public Health Code) concerns implementation of all the requirements of the "ionising radiation" Chapter of the legislative part of the Public Health Code (Articles L.1333-1 to L.1333-20), regulatory requirements and the stipulations of the license. Temporary or final revocation of the license by ASN must be fully explained in a decision within one month following serving of formal notice.

The formal notices prior to criminal sanctions (based on Article L.1337-6 of the Public Health Code) are served by ASN. They concern the requirements of Articles L.1333-2, L.1333-8 (human exposure monitoring, protection and information measures), L.1333-10 (monitoring of exposure to enhanced natural radioactivity and in premises open to the public) and L.1333-20 (certain implementations of the chapter of the Public Health Code relating to ionising radiation, as determined by decrees).

Infringements are written up in reports by the radiation protection inspectors and transmitted to the Public Prosecutor's Office, which decides on what subsequent action, if any, is to be taken. The Public Health Code makes provision for criminal sanctions as detailed in Articles L.1337-5 to L.1337-9 and range from a fine of €3,750 to one year of imprisonment and a fine of €15,000.

5.2.3 For noncompliance with Labour Law

In the performance of their duties in NPPs, the ASN's labour inspectors have at their disposal all the inspection, decision-making and enforcement resources of ordinary law inspectors. Observation, formal notice, report, injunction (to obtain immediate cessation of the risks) or even shutdown of the worksite, offer a range of incentive and constraining measures for the ASN labour inspectors that is broader than that available to the nuclear safety or radiation protection inspectors.

The labour inspectors have special decision-making powers enabling them to check the employer's disciplinary capability, to protect the general interests from an economic standpoint and to act as arbitrator, if necessary by delegation from the Regional Directorate for Enterprises, Competition, Consumption, Labour and Employment (DIRECCTE).

5.2.4 2015 results concerning enforcement and sanctions

As a result of infringements observed, the ASN inspectors (nuclear safety inspectors, radioactive substances transport safety inspectors, labour inspectors and radiation protection

TABLE 10: Number of infringement reports transmitted by the ASN inspectors between 2010 and 2015

	2010	2011	2012	2013	2014	2015
Report excluding labour inspection in the nuclear power plants	14	27	12	26	15	14
Labour inspection report in the nuclear power plants	4	6	11	10	9	3

inspectors) transmitted 14 infringement reports to the public prosecutor's offices, three of which were related to labour inspections in the NPPs.

ASN took eight administrative actions (formal notice, deposit of sums, etc.) against licensees and managers of nuclear activities. In 2015, ASN continued with the process initiated for the first time in 2014, involving the sum deposited by the CIS bio international company, for the performance of fire risk management works (see chapter 14).

Table 10 shows the number of reports issued by the ASN inspectors since 2010.

6. OUTLOOK

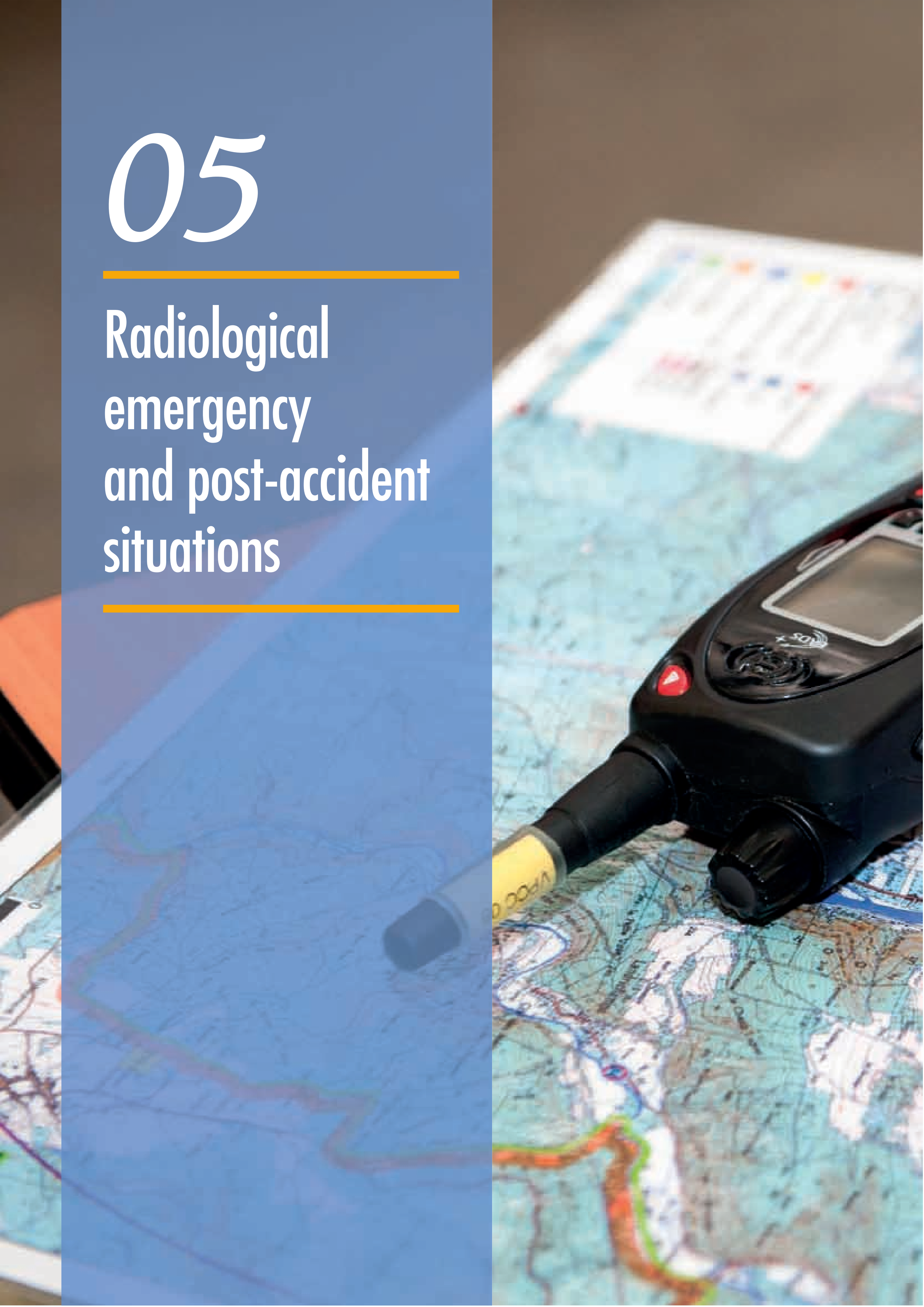
In 2016, ASN intends to perform about 1,800 inspections in BNIs, of radioactive substances transport activities, activities involving the use of ionising radiation, organisations and laboratories that it has approved for activities related to pressure equipment.

In 2016, ASN will as a priority inspect the activities with potentially high consequences, taking account of the experience feedback from 2015.

At the same time, ASN will continue to revise the procedures for notification of significant events, taking into account the experience feedback from the events notification guide in small-scale nuclear activities and the changes to the regulations in the BNI sector.

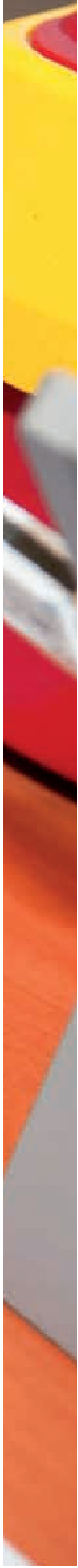
It will propose changes to the sanctions policy, pursuant to the provisions of the Energy Transition for Green Growth Act of 17th August 2015 and Ordinance 2016-128 of 10th February 2016.

In the environmental field, ASN will continue its regulatory work with a modification of the BNI Order, more particularly to take account of changes to the regulations, such as the entry into force on 1st June 2015 of Directive 2012/18/EU of 4th July 2012 concerning major accidents involving hazardous substances, known as "Seveso 3". It will also complete the revision of the ASN resolution of 16th July 2013, known as the "Environment resolution", which was started in 2015.



05

Radiological emergency and post-accident situations



Nuclear activities sare carried out with the two-fold aim of preventing accidents and mitigating any consequences should they occur. Despite all the precautions taken, an accident can never be completely ruled out and the necessary provisions for dealing with and managing a radiological emergency situation must be planned for, tested and regularly revised.

Radiological emergency situations, arising from an incident or accident, which risk leading to an emission of radioactive substances or to a level of radioactivity, liable to affect public health, include:
- emergency situations arising in a Basic Nuclear Installation (BNI);
- accidents involving Radioactive Substances Transports (RMT);
- emergency situations occurring in the field of small-scale nuclear activities.

Emergency situations affecting nuclear activities can also comprise non-radiological risks, such as fire, explosion or the release of toxic substances.

These emergency situations are covered by specific material and organisational arrangements, which include the emergency plans and involve both the licensee and or the party responsible for the activity and the public authorities.

The Nuclear Safety Authority (ASN) is involved in managing these situations, with regard to questions concerning the regulation of nuclear safety and radiation protection and, backed by the expertise of its technical support organisation, the Institute for Radiation Protection and Nuclear Safety (IRSN), it has the following four key duties:
- to ensure and verify the soundness of the steps taken by the licensee;
- to advise the Government and its local representatives;
- to contribute to the circulation of information;
- to act as competent authority within the framework of the international conventions.

In 2005, ASN also set up a Steering Committee to prepare for management of the post-accident Phase (Codirpa) following on from the management of a radiological emergency. The doctrine concerning the emergency phase exit, transition and long-term periods, was published in November 2012.

1. ANTICIPATING

Four main principles underpin the protection of the general public against BNI risks:
- risk reduction at source, wherein the licensee must take all steps to reduce the risks to a level that is as low as reasonably achievable in acceptable economic conditions;
- the emergency and contingency plans, designed to prevent and mitigate the consequences of an accident;
- controlling urban development around BNIs;
- informing the general public.

1.1 Looking ahead and planning

1.1.1 Emergency and contingency plans concerning BNIs

The emergency plans relative to accidents occurring in a BNI define the measures necessary to protect site personnel, the general public and the environment, and to control the accident.

The On-site Emergency Plan (PUI), prepared by the licensee, is designed to restore the plant to a safe condition and mitigate the consequences of an accident. It defines the organisational actions and the resources to be implemented on the site. It also comprises arrangements for informing the public authorities rapidly. Pursuant to Decree 2007-1557 of 2nd November 2007, the PUI is one of the items to be included in the file sent by the licensee to ASN prior to commissioning of its facility. The licensee's obligations in terms of preparedness and management of emergency situations are determined by the Order of 7th February 2012 setting the general rules for BNIs (Title VII). These obligations will be clarified by an ASN resolution currently under preparation.

The Off-site Emergency Plan (PPI) is established by the Prefect of the *département* concerned pursuant to Decree 2005-1158 of 13th September 2005, *"to protect the populations, property and the environment, and to cope with the specific risks associated with the existence of structures and facilities whose perimeter is localized and fixed. The PPI implements the orientations of civil protection policy in terms of mobilisation of resources, information, alert,* *exercises and training*". This Decree also stipulates the characteristics of the facilities or structures for which the Prefect is required to define a PPI.

The PPI specifies the initial actions to be taken to protect the general public, the roles of the various services concerned, the systems for giving the alert, and the human and material resources likely to be engaged in order to protect the general public.

The PPI falls within the framework of the ORSEC plan (Disaster and Emergency Response Organisation) that specifies the protective measures implemented in large-scale emergencies. Consequently, beyond the perimeter established by the PPI, the modular and progressive departmental or zone ORSEC plan applies in full.

More broadly, the Interministerial Directive of 7th April 2005 concerning the actions taken by the public authorities in response to an event leading to a radiological emergency situation sets the framework for the response by the public authorities and the steps they must take if an event could result in a radiological emergency situation leading to activation of the ORSEC or PPI-ORSEC plan, or one of the PIRATE plans[1].

1.1.2 The accident response plans for the transport of radioactive substances

Radioactive substances transport represents nearly a million packages carried in France every year. The dimensions, weight, radiological activity and corresponding safety implications can vary widely from one package to another.

Pursuant to the international regulations on dangerous goods, those involved in the transport of dangerous goods must take steps appropriate to the nature and scale of the foreseeable hazards, in order to avoid damage or, as applicable, to mitigate the effects. These steps are described in a management plan for events linked to RMT. The ideal content of these plans is defined in ASN Guide No. 17.

To deal with the eventuality of a radioactive substances transport accident in their *département*, each Prefect includes a part devoted to radioactive substances transport accidents in their version of the *"Major nuclear or radiological accident"* national response plan. Faced with the diversity of possible types of transport operations, this part of the plan defines the criteria and simple measures enabling the first respondents (Departmental Fire and Emergency Service (SDIS) and law enforcement services in particular) to initiate the first reflex response measures to protect the general public and sound the alert, based on their findings on the site of the accident.

1. Plans which are part of a larger system of vigilance, prevention, protection and counter-terrorism.

TO BE NOTED

The "Major nuclear or radiological accident" national response Plan

ASN took part in drafting the *"Major nuclear or radiological accident"* national response plan under the supervision of the General Secretariat for Defence and National Security (SGDSN), a department reporting to the Prime Minister. The plan was published in February 2014 and represents the Government's requirements regarding the safety of facilities and of nuclear transport operations, such as to address emergency situations of all types. It supplements the existing local planning arrangements (PUI – On-site Emergency Plan and PPI – Off-site Emergency Plan) and clarifies the organisation of the national response in the event of a nuclear accident.

This national response Plan takes account of changing modelling and measurement technology and is better able to anticipate the possible consequences of an accident, to mitigate them and measure their implications more rapidly. It also includes elements of post-accident doctrine established by the Codirpa, the international nature of emergencies and the mutual assistance possibilities in the case of an event.

In 2015, the local implementation of this plan began in the French *départements*, under the supervision of the defence and security zone Prefects. It must take account of the diversity of local situations and will first of all entail updating the existing planning measures in accordance with the method proposed by the guide issued by the Ministry of the Interior at the end of 2014.

1.1.3 The response to other radiological emergency situations

Apart from incidents affecting nuclear installations or a radioactive substances transport operation, radiological emergency situations can also occur:
- during performance of a nuclear activity, whether for medical, research or industrial purposes;
- in the event of intentional or inadvertent dispersal of radioactive substances into the environment;
- if radioactive sources are discovered in places where they are not supposed to be.

In such cases, intervention is necessary to put an end to any risk of human exposure to ionising radiation.

ASN, together with the Ministries and stakeholders concerned, drafted Government Circular DGSNR/DHOS/DDSC 2005/1390 of 23rd December 2005. This supplements the provisions of the Interministerial Directive of 7th April 2005 and defines the organisation of the State services for radiological emergency situations not covered by an Orsec, PPI-Orsec or Pirate-NRBC (nuclear, radiological, biological, chemical) plan.

Given the large numbers of those who could possibly issue an alert and the corresponding alert circuits, all the alerts are centralised in a single location, which then distributes them to the parties concerned: this is the fire brigade's centralised alert processing centre CODIS-CTA (Departmental Fire and Emergency Operations Centre – Alert Processing Centre), that can be reached by calling 18 or 112.

1.1.4 Role of ASN in the preparation and follow-up of emergency plans

Examination of emergency plans for nuclear facilities or activities

ASN reviews the On-site Emergency Plans as part of the procedure to authorise the commissioning of BNIs or the possession and utilisation of high-level sealed sources (Article R.1333-33 of the Public Health Code), as well as the management plans for events linked to radioactive substances transports.

Participation in drafting the Off-site Emergency Plans

Pursuant to the 13th September 2005 Decrees concerning the PPI and the Orsec plan, the Prefect is responsible for preparing and approving the PPI. ASN provides assistance by analysing the technical data to be provided by the licensees, in particular the nature and scope of the consequences of an accident, with the help of its technical support organisation, IRSN.

Contingency Plans, such as the PPI, identify the general public protection measures such as to mitigate the health and environmental consequences of any accident. The Prefect decides whether or not to deploy these measures on the basis of the predicted dose that would be received by a one year old child situated in the open air at the time of the accident.

The intervention levels associated with the implementation of general public protection measures in a radiological emergency situation, mentioned in Article R.1333-80 of the Public Health Code, are thus defined by ASN resolution 2009-DC-0153 of 18th August 2009:
- an effective dose of 10 millisieverts (mSv) for sheltering;
- an effective dose of 50 mSv for evacuation;
- an equivalent dose to the thyroid of 50 mSv for the administration of stable iodine.

The predicted doses are those that it is assumed will be received until releases into the environment are brought under control, generally calculated over a period of 24 hours. In the event of doubt concerning the duration of the releases, the time adopted for the calculation does not exceed one week.

The Fukushima Daiichi accident showed that a severe accident can have consequences that affect a radius of several tens of kilometres around an NPP. In France, PPI planning makes provision for civil protection of the population residing within a 10 km radius around the affected reactor in the initial hours of the accident. The effectiveness of this organisation thus requires the preparation and, as applicable, the implementation of measures beyond the PPI perimeter as part of the ORSEC planning process. ASN considers that it is today essential to continue with the harmonisation effort so that concrete results are achieved to ensure consistent population protection measures across Europe following an accident. Such an accident occurring in a European country would most probably affect several countries, thus strengthening the need for coordination between these countries (see points 2.2.1 and 2.2.2).

ASN also assists the Ministry of the Interior's General Directorate for Civil Security and Emergency Management (DGSCGC) with a view to supplementing the PPIs concerning aspects relating to post-accident management (see point 1.5).

1.2 Controlling urban development around nuclear sites

The aim of controlling urban development is to limit the consequences of a severe accident for the population and property. Since 1987, this type of approach has been implemented around non-nuclear industrial facilities and it has been reinforced since the AZF facility accident that occurred in Toulouse (South of France) in 2001. The TSN Act, now codified in Books I and V of the Environment Code, enables the public authorities to control urban development around BNIs, by implementing institutional controls limiting or prohibiting new constructions in the vicinity of these facilities.

The actions to control urban development entail a division of responsibilities between the licensee, the mayors and the State:
- The licensee is responsible for its activities and the related risks.
- The mayor is responsible for producing the town planning documents and issuing building permits.
- The Prefect informs the mayors of the existing risks, verifies the legality of the steps taken by the local authorities and may impose institutional controls as necessary.
- ASN supplies technical data in order to characterise the risk, and offers the Prefect its assistance in the urban development control process.

In recent years, urban development pressure in the vicinity of nuclear sites has increased. It is therefore important to incorporate the control of urban development into the management of the nuclear risk. ASN's current doctrine for controlling activities around nuclear facilities only concerns those facilities requiring a PPI and primarily aims to avoid compromising the feasibility of the sheltering and evacuation measures. It focuses on the “reflex” zones of the PPIs, or the rapid-development hazard zones, established in accordance with the Circular of 10th March 2000 and in which automatic measures to protect the general public are taken in the event of a rapidly developing accident.

A Circular from the Ministry for the Environment dated 17th February 2010 has asked the Prefects to exercise greater vigilance over urban development near nuclear installations. This Circular states that the greatest possible attention must be paid to projects that are sensitive owing to their size, their purpose, or the difficulties they could entail in terms of protection of the general public in the so-called «reflex» zone. A pluralistic working group jointly overseen by ASN and the General Directorate for Risk Prevention (DGPR), comprising elected officials and the National Association of Local Information Commissions and Committees (Anccli), drafted a guide in 2011 concerning the control of activities around BNIs, based on the following principles:
- to preserve the operability of the contingency plans;
- to favour urban development outside the rapid-development hazard zone;
- to allow controlled development that meets the needs of the resident population.

This draft guide was the subject of an extensive public consultation on the websites of the Ministry responsible for the Environment and of ASN, which led to the introduction of institutional controls, so that the principles of the control of activities are incorporated into land use planning documents. This guide is scheduled for publication in the first half of 2016, in order to make public the principles underpinning ASN’s opinions. ASN is consulted for all building projects within the PPI reflex response perimeters (zones in which predetermined population protection measures will be taken in the event of a rapidly developing accident). The opinions issued may be reserved or even unfavourable concerning projects considered to be sensitive with regard to implementation of the population protection measures included in the PPIs (sheltering, evacuation, distribution of stable iodine tablets): dense collective housing, shopping centres, schools, leisure parks, retirement homes, kindergartens, etc.

1.3 Organising a collective response

The response by the public authorities to an incident or accident is determined by a number of texts concerning nuclear safety, radiation protection, public order and civil protection, as well as by the emergency plans.

Act 2004-811 of 13th August 2004 on the modernisation of civil protection, makes provision for an updated inventory of risks, an overhaul of operational planning, performance of exercises involving the general public, information and training of the general public, an operational watching brief and alert procedures. Several Decrees implementing this Act, codified in Articles L 41-1 to L 741-32 of the Domestic Security Code, more specifically concerning the ORSEC plans and PPIs, clarified it in 2005.

The field of radiological emergency situations is clarified in the Interministerial Directive of 7th April 2005, which constitutes the basis for the organisations adopted by the public authorities and the licensee presented in diagram 1.

Following the Fukushima Daiichi accident, considerable thought was given nationally and internationally to consolidating and, as applicable, improving the response organisation of the public authorities. Indeed, this accident showed that it was necessary to improve preparation for the occurrence of a multi-faceted accident (natural disaster, accident affecting several facilities simultaneously). The response organisations thus put into place must be robust and capable of managing a large-scale emergency over a long period of time. There must be greater anticipation of and preparation for interventions in a degraded radiological situation along with better international relations to enable effective support to be provided to the country affected.

Thus, at the national level, ASN is actively involved in interministerial work on nuclear emergency management.

At the international level, ASN is taking part in the experience feedback work being done by international bodies such as the International Atomic Energy Agency (IAEA), the OECD’s Nuclear Energy Agency (NEA) and within regulatory authority networks such as the Western European Nuclear Regulators Association (WENRA) or the Heads of the European Radiological protection Competent Authorities (HERCA) (see point 2.2.2).

1.3.1 Local response organisation

In an emergency situation, several parties have the authority to take decisions
- The licensee of the affected nuclear facilities deploys the response organisation and the resources defined in its PUI (see point 1.1.1).
- One of ASN’s duties is to monitor the licensee’s actions in terms of nuclear safety and radiation protection. In an emergency situation, aided by IRSN’s assessments, it can at any time ask the licensee to perform assessments and take the necessary actions.
- The Prefect of the *département* in which the installation is located takes the necessary decisions to protect the population, the environment and the property threatened by the accident. He or she takes action according to the PPI and the ORSEC plans. The Prefect is thus responsible for coordinating the resources - both public and private, human and material - deployed in the plan. He keeps the population and the mayors informed of events. Through its regional division, ASN assists the Prefect in drafting the plans and managing the situation.

- Owing to his or her role in the local community, the mayor has an important part to play in anticipating and supporting the measures to protect the population. To this end, the mayor of a town included within the scope of application of an Off-site Emergency Plan (PPI) must draw up and implement a local safeguard plan to provide for, organise and structure the measures to accompany the Prefect's decisions. The mayor also plays a role in passing on information and heightening population awareness during iodine tablet distribution campaigns.

1.3.2 National response organisation

In the event of a severe accident, an Interministerial Crisis Committee (CIC) is set up. The relevant Ministries concerned, together with ASN, work together to advise both the Prefect at the local level and the Government, *via* the CIC, on the protective measures to be taken. They provide the information and advice necessary to assess the state of the facility, the seriousness of the incident or accident, its possible developments, and the measures required to protect the general public and the environment.

The Prime Minister, who is in charge of managing any major crisis, activates the CIC. The main participants liable to be convened within the CIC, are as follows:
- the Prime Minister, at the situation briefings, with the support of the SGDSN responsible for ensuring the interministerial consistency of the planned measures in the event of an accident, and for the planning and assessment of exercises. Its role is to coordinate governmental action in radiological or nuclear emergency situations;
- the Ministry for the Interior;
- the Ministry for Health;
- the Ministry for the Environment;
- the Ministry in charge of foreign affairs;
- the Ministry for Defence through the Defence Nuclear Safety Authority (ASND), which is the Competent Authority for regulating the safety of secret BNIs, Military Nuclear Systems (SNM) and defence-related transport operations. A protocol was signed by ASN and the ASND on 26th October 2009 to ensure coordination between these two entities in the event of an accident affecting an activity under the supervision of the ASND and to facilitate the transition from the emergency phase managed by the ASND to the post-accident phase for which ASN is competent (this protocol is currently being revised);
- ASN, for management of radiological emergency situations. Its duties are detailed in point 2.1.1.

Other Ministries and administrations or establishments involved (such as IRSN, *Météo-France*), and the heads of the national nuclear licensees concerned (for example EDF, CEA or Areva) may be summoned as applicable. IRSN and *Météo-France* act as public expert appraisal organisations in a nuclear emergency situation.

1.4 Preparing for public protection measures

The steps to protect the populations that can be taken during the emergency phase, as well as the initial actions as part of the post-accident phase, aim to protect the population from exposure to ionising radiation and to any chemical and toxic substances that may be present in the releases. These actions are included in the PPI.

1.4.1 General protective actions

In the event of a severe accident, liable to lead to releases, a number of preventive measures can be envisaged by the Prefect in order to protect the general public:
- sheltering and listening: the individuals concerned, alerted by a siren, take shelter at home or in a building, with all openings carefully closed, and wait for instructions from the Prefect broadcast by radio;
- administration of stable iodine tablets: when ordered by the Prefect, the individuals liable to be exposed to releases of radioactive iodine are urged to take the prescribed dose of potassium iodide tablets;
- evacuation: in the event of an imminent risk of large-scale radioactive releases, the Prefect may order evacuation. The populations concerned are asked to prepare a bag of essential personal effects, secure and leave their homes and go to the nearest assembly point.

If radioactive substances are actually released into the environment, steps to prepare for management of the post-accident phase are decided on: they are based on the definition of area zoning to be implemented on exiting the emergency phase and include:
- a Population Protection Zone (ZPP) within which action is required to reduce both the exposure of the populations to ambient radioactivity and the consumption of contaminated food, to a level that is as low as reasonably achievable;
- a Heightened Territorial Surveillance Zone (ZST), which is larger and which is more concerned with economic management, within which specific surveillance of foodstuffs and agricultural produce will be set up;
- if necessary, an evacuation perimeter is created within the ZPP, defined according to the ambient radioactivity (external exposure). The residents must be evacuated for a varying length of time depending on the level of exposure in their environment.

1.4.2 Iodine tablets

Administering stable iodine tablets is a means of saturating the thyroid gland and protecting against the carcinogenic effects of radioactive iodines.

The Circular of 27th May 2009 defines the principles governing the respective responsibilities of a BNI licensee and of the State with regard to the distribution of iodine tablets. The licensee is responsible for the safety of its facilities. This Circular requires that the licensee finance the public information campaigns within the perimeter of the PPI and carry out permanent preventive distribution of the stable iodine tablets, free of charge, through the network of pharmacies.

In 2016, a new national distribution campaign for iodine tablets, supervised by ASN, is being launched for the populations located within the zone covered by the PPIs around the NPPs operated by EDF (see chapter 6). The purpose of this distribution is to achieve overall population coverage that is as high as possible, but also to make the population and the local authorities (mayors) aware of the potential risks and the instructions to be followed as and when necessary, through specific communication media and local information meetings.

Other civil nuclear facilities are liable to release radioactive iodine in the event of a severe accident (Saclay and Cadarache nuclear facilities and the Institut Laue-Langevin – ILL – in Grenoble). The populations located in the zone covered by their PPI should subsequently benefit from a similar campaign.

Outside the zone covered by a PPI, tablets are stockpiled to cover the rest of the country. In this respect, the Ministries for Health and for the Interior decided to create stocks of iodine tablets, positioned and managed by the Health Emergency Preparedness and Response Organisation (EPRUS). In their *département*, each Prefect organises the procedures for distribution to the population, relying in particular on the mayors for this. This arrangement is described in a circular dated 11th July 2011. Pursuant to this Circular, the Prefects have drawn up plans to distribute iodine tablets in a radiological emergency situation, which can be included in exercises being held for the local implementation of the major nuclear or radiological accident national response plan.

1.4.3 Care and treatment of exposed persons

In the event of a radiological emergency situation, a significant number of people could be contaminated by radionuclides. This contamination could pose problems for specific care and treatment by the emergency response teams.

Circular 800/SGDN/PSE/PPS of 18th February 2011 specifies the national doctrine concerning the use of emergency and care resources in the event of a terrorist act involving radioactive substances. These provisions, which also apply to a nuclear or radiological accident, aim to implement a unified nationwide methodology for the use of resources, in order to optimise efficiency. They will need to be adapted to the situations encountered.

The *"Medical intervention following a nuclear or radiological event"* guide, the drafting of which was coordinated by ASN and which was published in 2008, accompanies Circular DHOS/HFD/DGSNR No. 2002/277 of 2nd May 2002 concerning the organisation of medical care in the event of a nuclear or radiological accident, giving all information of use for the medical response teams in charge of collecting and transporting the injured, as well as for the hospital staff admitting them to health care establishments. Under the supervision of the SGDSN, a working group comprising the authors of this guide was set up at the end of 2015 to begin its revision in order to take account of a number of changes to practices that have taken place since 2008.

1.5 Understanding the long-term consequences

The "post-accident" phase concerns the handling over a period of time of the consequences of long-term contamination of the environment by radioactive substances following a nuclear accident. It covers the handling of consequences that are varied (economic, health, social), by their nature complex and that need to be dealt with in the short, medium or even long term, with a view to returning to a situation considered to be acceptable.

The conditions for reimbursement for the damage resulting from a nuclear accident are currently covered by Act 68-943 of 30th October 1968, amended, concerning civil liability in the field of nuclear energy. France has also ratified the protocols signed on 12th February 2004, reinforcing the Paris Convention of 29th July 1960 and the Brussels Convention of 31st January 1963 concerning civil liability in the field of nuclear energy. These protocols and the measures necessary for their implementation are now codified in the Environment Code (Section I of Chapter VII of Title IX of Book V). The Green Growth Energy Transition Act (TECV) of 17th August 2015 makes provision for the entry into force in February 2016 of these provisions and of new liability thresholds set by the two protocols, without waiting for their ratification by all the Signatory States.

Pursuant to the Interministerial Directive of 7th April 2005, and in association with the ministerial departments involved, ASN was tasked with establishing the framework, and defining, preparing and taking part in implementing the necessary provisions for the response to post-accident situations following a nuclear accident. Post-accident management of a nuclear accident is a complex subject with many aspects and involving numerous players. This process should benefit from a pluralistic structure more specifically involving all the stakeholders concerned in post-accident management preparedness. In order to draw up the corresponding aspects of doctrine, ASN created the Steering Committee for the management of the Post-Accident Phase of a nuclear accident or radiological situation (Codirpa) in June 2005 and for which it acts as Chair and Technical Secretary.

In November 2012, ASN sent the Prime Minister elements of the doctrine drafted by the Codirpa, covering the emergency exit, transition and long-term phases, accompanied by an opinion from the ASN Commission. These elements were then posted on *www.asn.fr* and widely distributed at local, national and international levels.

In its opinion, the Commission considers that drafting and publishing the first elements of the doctrine is a first and important step in preparing for post-accident management and underlines the importance of continuing with and intensifying the implementation process.

The Codirpa carries out work to take account of the lessons learned from the post-accident management carried out in Japan in the wake of the Fukushima Daiichi disaster, but also to ensure support for the preparatory work to be organised at the regional level. Whereas thought has so far only been given to accidents with releases on a moderate scale and of short-duration, this has now been expanded to consider the management of the consequences of an accident with long-duration releases.

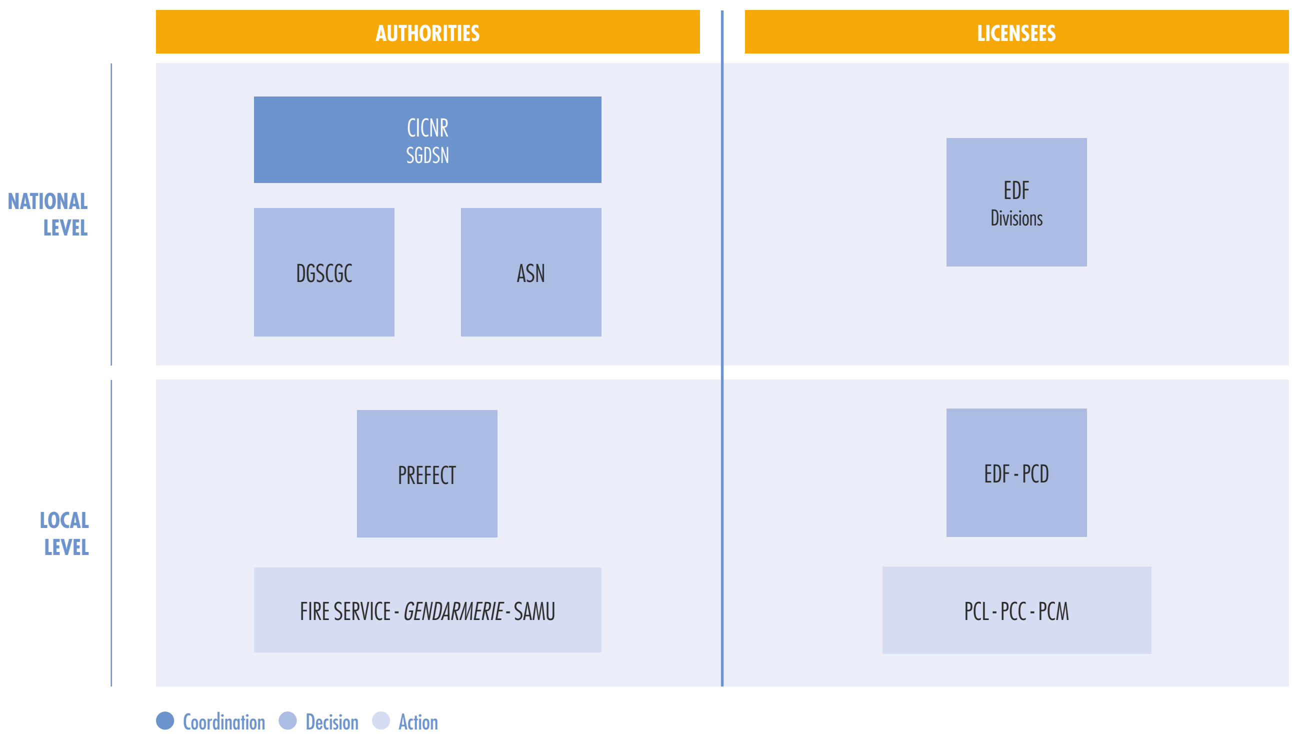
In this context, three areas for focus were chosen:

- test and supplement the policy elements with respect to the different accident situations;
- assist with regional implementation of the elements of post-accident management;
- take part in international work carried out on the post-accident theme, share and integrate its results.

In 2015, the new duties of the Codirpa, officially laid out in a letter from the Prime Minister on 29th October 2015, giving ASN a new five-year mandate, focused on watching over, supporting and analysing the various post-accident preparation processes with the aim of periodically proposing updates to the doctrine.

Three working groups were set up in 2014, one concerning long-duration releases doctrine, another concerning the involvement of the regional stakeholders in preparing for post-accident management and the third on the involvement of the health professionals. The working group for long-duration releases submitted its report in 2015.

DIAGRAM 1: Emergency response organisation in an accident situation affecting a nuclear reactor operated by EDF



CICNR: Inter-ministerial Committee for Nuclear or Radiological Emergencies
SGDSN: General Secretariat for Defence and National Security
DGSCGC: General Directorate for Civil Security and Emergency Management
PCD: Command and Decision Post
PCL: Local Command Post
PCC: Supervision Command Post
PCM: Resources Command Post

In conjunction with the experience feedback from the Fukushima Daiichi accident, a new working group was set up in 2015 on waste management in a post-accident situation, involving members of the Codirpa and of the National Radioactive Materials and Waste Management Plan (PNGMDR). Furthermore, subjects for which more detailed examination of doctrine is to be carried out in 2016 have already been identified. These mainly concern the management of manufactured products, management of water and marine environments, and radiological measurements in a post-accident situation.

The report from the pluralistic seminar on the economic assessment of a nuclear accident risk organised by ASN in October 2014 was released in 2015. ASN initiated the necessary steps to promote the development of research on this subject, nationally and internationally.

2. ACTING IN EMERGENCY AND POST-ACCIDENT SITUATIONS

The emergency plans require intervention by many players, whose respective roles and duties must be clearly identified, as must the way they interact, to ensure correct coordination of their actions. The organisation of each of the players involved in the State's response to a radiological emergency situation, and the way they interact, are essential to the correct management of this type of situation. The roles and organisation of ASN in an emergency situation are thus precisely defined. The coordination with the international authorities is also essential, both bilaterally and internationally.

2.1 Performing all duties in an emergency situation

Owing to their scale, major emergencies require the deployment of a global response by the State, which more specifically involves the departments of the Prime Minister (SGDSN) and the various ministries, in particular the Interior Ministry with responsibility for civil protection. At the local level, the Prefect thus acts as the director of emergency response operations. The *"Major nuclear or radiological accident"* national response Plan was published in February 2014 and addresses emergency situations of all types, covering the entire country, and describes the organisations to be put into place.

2.1.1 ASN roles and duties

In an emergency situation, the responsibilities of ASN, with the support of IRSN, are as follows:
- to check the steps taken by the licensee and ensure that they are pertinent;
- to advise the Government and its local representatives;
- to contribute to the dissemination of information;
- to act as Competent Authority within the framework of the international Conventions on Early Notification and Assistance.

Checking the measures taken by the licensee

As in a normal situation, ASN exercises its roles as the regulatory authority in an accident situation. In this particular context, ASN ensures that the licensee exercises in full its responsibility for keeping the accident under control, mitigating the consequences, and rapidly and regularly informing the public authorities. On the basis of IRSN's assessments, ASN can at any time ask the licensee to perform assessments and take the necessary actions, without substituting itself for the licensee in the technical operations.

Advising the Government and the Prefect

The decision by the Prefect concerning the general public protective measures to be taken in radiological emergency and post-accident situations depends on the actual or foreseeable consequences of the accident around the site. It is up to ASN to make recommendations to the Government and the Prefect, incorporating the analysis carried out by IRSN. This analysis covers a diagnosis of the situation (understanding of the situation of the installation affected, consequences for man and the environment) and a prognosis (assessment of possible developments, notably radioactive releases). This advice also concerns the steps to be taken to protect the health of the general public.

Circulation of information

ASN is involved in a number of ways in informing:
- the media and the public: ASN contributes to informing the media, the general public and the stakeholders in different ways (press releases, press conferences). It is important that this should be done in close collaboration with the other entities which are themselves involved in communication (Prefect, local and national licensee, etc.);
- institutional entities: ASN keeps the Government informed, along with the SGDSN, which is responsible for informing the President of the Republic and the Prime Minister;
- foreign nuclear safety Regulators.

Function of Competent Authority as defined by International Conventions

The Environment Code provides for ASN to fulfil the role of Competent Authority under the International Conventions on Early Notification and Assistance. As such it collates and summarises information for the purpose of sending or receiving notifications and for transmitting the information required by these Conventions to the International Organisations (IAEA and European Union) and to the countries possibly affected by radiological consequences on their own territory.

2.1.2 Organisation of ASN

Organising the response to accidents occurring in BNIs

The ASN emergency response organisation set up for an accident or incident in a BNI more specifically comprises:
- at the national level, an emergency centre in Montrouge, consisting of three Command Posts (PC):
  - a "Strategy" Command Post, consisting of the ASN Commission, which, in an emergency situation, could be called on to issue resolutions and impose prescriptions on the licensee of the installation concerned;
  - a Technical Command Post (PCT) in constant contact with its technical support organisation, IRSN, and with the ASN Commission. Its role is to adopt a stance for advising the Prefect, who acts as the director of contingency operations;
  - a Communication Command Post (PCC), located close to the Technical Command Post. The ASN Chairman or his representative acts as spokesperson, a role which is distinct from that of the head of the Technical Command Post.

This emergency centre is regularly tested during national emergency exercises and is activated for actual incidents or accidents.
- at the local level:
  - ASN representatives working with and advising the Prefect in his or her decisions and communications;
  - ASN inspectors present on the site affected by the accident.

In 2015, the national emergency centre was activated for six national exercises as well as on three occasions when the licensee triggered the on-site emergency plan for the Cattenom NPP on 28th May 2015, the Flamanville NPP in the night of 26th August 2015 and the decommissioning site for the former Brennilis NPP on 23rd September 2015. These three real situations led to no releases of radioactive substances. In all three cases, the licensees brought the situation under control within a few hours, which meant that ASN was able to authorise them to lift the PUI. The ASN emergency centre was also activated for several hours in standby mode, for an event in the Flamanville NPP in the evening of 9th October 2015.

ASN is supported by an analysis team working at the IRSN's Technical Emergency Centre (CTC).

Experience feedback from the Fukushima Daiichi accident also leads ASN to envisage sending one of its representatives, if necessary, to the French embassy of a country in which an accident occurred.

ASN's alert system allows mobilisation of its staff, for activation of its emergency response centre, as well as those of IRSN. This automatic system sends an alert signal to the staff equipped with appropriate reception devices, as soon as it is remotely triggered by the BNI licensee originating the alert. It also sends the alert to the staff of the DGSCGC, the Interministerial Emergency Management Operations Centre (Cogic), *Météo-France* and the ministerial operational monitoring and alert centre of the Ministry of the Environment, Energy and the Sea.

In order to improve these arrangements, ASN is working on creating a legal framework such as to allow the creation of an on-call duty system. Such an on-call duty system would improve robustness and efficiency such as to ensure rapid deployment of staff.

Diagram 2 summarises the role of ASN in a radiological emergency situation. This functional diagram illustrates the importance of the ASN representative to the Prefect, who relays and explains the recommendations being sent by the ASN emergency centre.

TABLE 1: Positions of the various players in a radiological emergency situation

		DECISION	EXPERT APPRAISAL	INTERVENTION	COMMUNICATION
Authorities		Government (CIC) COD Prefect	/	Prefect (PCO) Civil protection	COD Prefect
		ASN (PCT)	IRSN (CTC) *Météo-France*	IRSN (mobile units)	ASN IRSN
Licensees		National and local level	National and local level	Local level	National and local level

CIC: French Inter-ministerial Crisis Committee
COD: Departmental Operations Centre
PCO: Operational Command Post
CTC: Technical Emergency Centre

Table 1 shows the positions of the public authorities (Government, ASN and technical experts) and the licensees in a radiological emergency situation. These players each operate in their respective fields of competence with regard to assessment, decision-making, action and communication, for which regular audio-conferences are held. The exchanges lead to decisions and orientations concerning the safety of the facility and the protection of the general public. Similarly, relations between the communication units and the spokespersons of the emergency centres ensure that the public and media are given coherent information.

Organising a response to any other radiological emergency situation

A radiological emergency toll-free telephone number (0 800 804 135) enables ASN to receive calls notifying incidents involving sources of ionising radiation used outside BNIs or during the transport of radioactive substances. It is accessible 24 hours a day, 7 days a week. The information given during the call is transmitted to the locally competent division or to the ASN duty staff outside working hours. Depending on the seriousness of the accident, ASN may decide to activate its emergency centre in Montrouge. If not, only the ASN local level (regional division concerned) intervenes to perform its Prefect support and communication duties, if necessary calling on the expertise of the national departments. In order to enhance the graduated nature of the ASN response and organisation in the event of an emergency, for situations not warranting activation of the emergency centre, the system has been adapted for the creation of a national level support unit to assist the regional division concerned. The format and duties of this unit are tailored to each situation.

TO BE NOTED

FARN and FINA: the licensees' national intervention forces

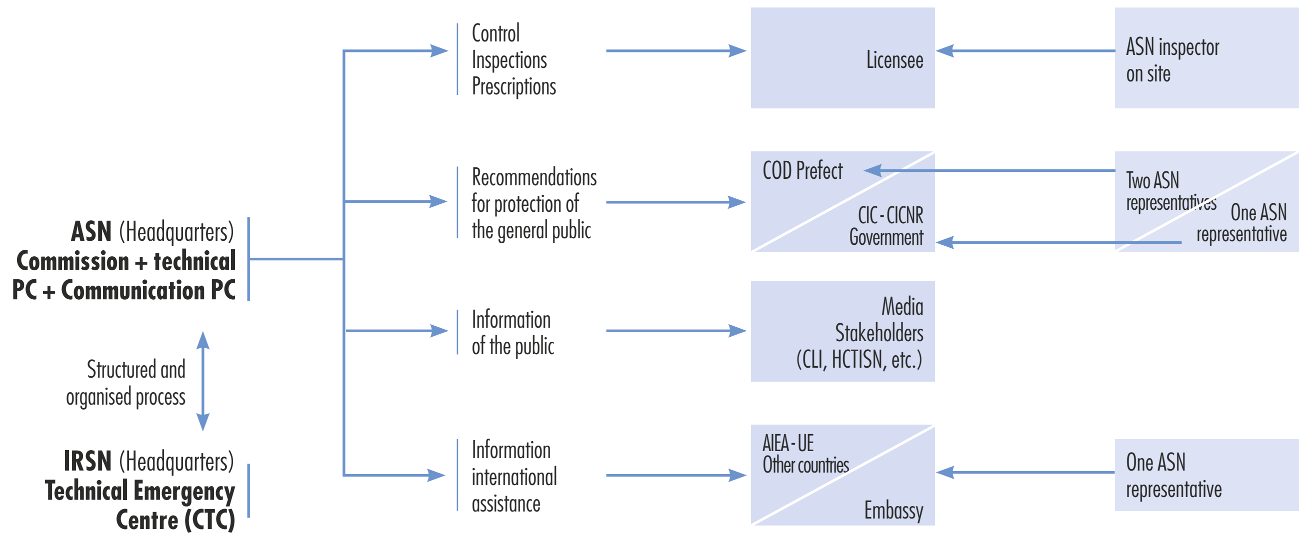
Following the stress tests, ASN in 2012 prescribed the deployment of the Nuclear Rapid Intervention Force (FARN) proposed by EDF. This national emergency system comprises specialised teams and equipment capable of Intervening on an accident site within 24 hours. ASN and IRSN were invited by EDF to take part as observers for a FARN deployment exercise on 30th June 2015, on the site of the Tricastin NPP. This was the first exercise of this scale, simultaneously involving four regional teams (columns) from the FARN for four days, on a site from which none of the columns originated*. The aim was to ensure satisfactory coordination of the intervention by the four columns. This exercise comprised four phases:
- the outward journey by each column to the Tricastin site;
- setting up the «support base»;
- interventions on the site: restoration of supplies of water,
- air and electricity to the plant;
- dismantling of the support base and return journey by the columns to their respective sites.

Areva also set up an intervention force called FINA (Areva national intervention force). CEA is currently examining this subject.

* The four columns came from the Bugey, Dampierre-en-Burly, Paluel and Civaux sites. Each column comprises a team of 14 members (specialists in logistics, maintenance and radiation protection) with its own equipment (lorries, lifting gear, electricity generating sets, etc.).

Technical Command Post in the ASN emergency centre during an emergency exercise, October 2015.

DIAGRAM 2: The role of ASN in a nuclear emergency situation



COD: Departmental Operations Centre
CIC: French Inter-ministerial Crisis Committee
CICNR: Inter-ministerial Committee for Nuclear or Radiological Emergencies
CLI: Local Information Committee
HCTISN: High Committee for Transparency and Information on Nuclear Security
PC: Command Post

Once the public authorities have been alerted, the response generally consists of four main phases: care for the individuals involved, confirmation of the radiological nature of the event, securing the zone and reducing the emission and, finally, clean-up.

The Prefect or the mayor coordinates the intervention response teams, taking account of their technical competence, and decides on the protective measures to be taken, on the basis of the plans they have drawn up (ORSEC and PPI for the Prefects, Local Safeguard Plans for the mayors). At the local level, the mayors can also call on the Mobile Radiological Intervention Units (CMIR) of the fire and emergency services.

In these situations, responsibility for the decision and for implementing protective measures lies with:
- the head of the establishment carrying out a nuclear activity (hospital, research laboratory, etc.) who implements the on-site emergency plan specified in Article L. 1333-6 of the Public Health Code (if the risks inherent to the installation so justify) or the owner of the site with regard to the safety of the persons on the site;
- the mayor or Prefect concerning public safety in the domain accessible to the public.

2.2 Ensuring efficient coordination with international authorities

Considering the potential repercussions that an accident may have in other countries, it is important that the information and intervention of the various countries concerned be as well-coordinated as possible. To this end, IAEA and the European Commission offer the Member States tools for notification and assistance in the event of a radiological emergency. ASN made an active contribution to the production of these tools, more specifically the new IAEA tool called USIE (Unified System for Information Exchange in Incidents and Emergencies), which is present in ASN's emergency centre and is tested on the occasion of each exercise.

Independently of any bilateral agreements on the exchange of information in the event of an incident or accident with possible radiological consequences, France is committed to applying the Convention on Early Notification of a Nuclear Accident adopted on 26th September 1986 by IAEA and the Euratom Decision of 14th December 1987 concerning community procedures for an early exchange of information in the event of a radiological emergency situation. On 26th September 1986, France also signed the convention adopted by IAEA concerning assistance in the event of a nuclear accident or a radiological emergency situation.

Two Interministerial Directives of 30th May 2005 and 30th November 2005 specify the procedures for

TO BE NOTED

The HERCA/WENRA approach

During their joint meeting in 2014, the HERCA and WENRA associations adopted a joint position aiming to improve cross-border coordination of protection measures during the first phase of a nuclear accident. The position of HERCA and WENRA aims, in the event of an accident, to promote the rapid transmission of information between the countries concerned and the consistency of the population protection recommendations issued by the nuclear safety and radiation protection authorities.

The approach thus recommends the following:
- outside emergency situations, exchanges between countries to promote Improved mutual familiarity with and understanding of their emergency organisations;
- in emergency situations
  - if the emergency organisations receive sufficient information to function normally: during the first hours of an emergency situation, attempts are made to ensure alignment of the population protection measures in neighbouring countries with those decided on by the country in which the accident occurred;
  - in the event of a highly improbable situation which would require urgent measures to protect the population but In which very little information is available, predetermined «reflex» measures are defined.

In order to implement these principles, a minimum harmonised level of preparation is necessary. HERCA and WENRA thus consider that in Europe:
- evacuation should be prepared up to 5 km around nuclear power plants, and sheltering and ingestion of Iodine Thyroid Blocking (ITB) tablets up to 20 km;
- a general strategy should be defined in order to be able to extend evacuation up to 20 km, and sheltering and ingestion of ITB tablets up to 100 km.

On this basis, the European safety and radiation protection Authorities have been asked to initiate national level discussions with the Authorities responsible for civil protection, with a view to implementing these recommendations. An evaluation of this approach by the Member States is to be presented to ENSREG (European Nuclear Safety Regulators Group) in 2016. In France, work is in progress concerning the organisation of public protection measures in an emergency situation and their scope of application. The HERCA-WENRA approach was presented in this context within a working group comprising in particular the authorities in charge of civil protection.

application of these texts in France and instate ASN as the competent national Authority. It is therefore up to ASN to notify the events without delay to the international institutions and to the Member States, to supply relevant information quickly in order to limit the radiological consequences abroad and finally to provide the Ministers concerned with a copy of the notifications and information transmitted or received.

2.2.1 Bilateral relations

Maintaining and strengthening bilateral relations with neighbouring and other European countries is one of ASN's major priorities.

In 2015, ASN thus continued regular exchanges with its European counterparts concerning the harmonisation of emergency management. Experience feedback from the Fukushima Daiichi accident and the steps taken since then in each country, were at the heart of the discussions. Finally, in 2015, protocols concerning cross-border alert mechanisms and information exchanges in an emergency situation were signed with Belgium and Luxembourg.

ASN is continuing to develop bilateral relations in emergency management with many countries, Spain, Luxembourg, Germany, Switzerland and Belgium in particular. Meetings specifically dedicated to emergency management were in particular held in 2015 with these five countries. Chinese and Japanese delegations visited ASN in 2015 to discuss emergency situations management and took this opportunity to visit the ASN emergency centre. A delegation from the United States also took part in an ASN national emergency exercise as an observer.

Finally, during the course of 2015, the emergency exercise at the Gravelines NPP was able to test cross-border information exchanges in the event of an accident.

2.2.2 Multilateral relations

The Fukushima Daiichi accident occupied a substantial amount of time of many of the ASN and IRSN staff, even though it was a remote accident for which the radiological consequences in France would appear to be limited. In addition, ASN's actions were also limited, because it is not its responsibility to monitor the actions of the Japanese licensee.

This accident highlighted the problems that would be encountered by ASN, IRSN, but also their European counterparts, in managing a large-scale accident in Europe. The nuclear safety regulators confirmed the need for mutual assistance mechanisms and have already undertaken international work to improve their response organisations.

ASN takes part in IAEA's work to improve notification and information exchanges in radiological emergency situations. It is helping to define international assistance

TO BE NOTED

Observation of the *"Southern Exposure 15"* nuclear emergency exercise at the Robinson NPP in July 2015

At the invitation of the United States Department of Energy (DOE) ASN observed the *"Southern Exposure 15"* national nuclear emergency exercise in July 2015, in Florence, South Carolina. This large-scale exercise mobilised some 700 people. About forty foreign observers from 11 countries (Canada, Japan, South Korea, France, Israel, Poland, Taiwan, etc.) and from two International Organisations (NEA and IAEA) were present. The emergency management roles of the Nuclear Regulatory Commission (NRC) and ASN are different: in the United States, it is up to the licensee to submit recommendations to the authorities for measures to protect the public and not the NRC, which carries out a counter-assessment of these recommendations. The decisions concerning the public protection measures are based on the actual situation of the installation rather than on modelling-based predictions. Responsibility for implementing them lies with the State, the county or the municipality, depending on the State. All those involved, including the licensee, work together to ensure optimum protection of the population.

strategy, requirements and resources and to develop the Response and Assistance Network (RANET).

In addition to the four traditional committees which draft its safety standards, IAEA created a new committee in 2015 called EPReSC (Emergency Preparedness and Response Standards Committee), to deal with emergency situations. The standards in this field had hitherto been monitored by the other existing committees. The document at the top of the standards hierarchy in this field is GSR Part 7, published in November 2015. The first meeting of the new committee was held in early December 2015 and ASN represented France on it.

ASN also collaborates with the NEA, under whose supervision it will organise the INEX 5 exercise in 2016 (with the participation of the various French emergency management players) and is taking part in the Working Party on Nuclear Emergency Matters (WPNEM).

At the European level, ASN is a participant in the "Emergencies" working group reporting to the Heads of European Radiological protection Competent Authorities Association (HERCA). It also acts as secretary. This group is tasked with proposing harmonised European actions to protect the general public, on the one hand in the event of an accident in Europe and, on the other, in the event of a more remote accident, in the light of the lessons learned from the Fukushima Daiichi accident. This group also comprises members appointed by the Western European Nuclear Regulators Association (WENRA).

2.2.3 International assistance

The Interministerial Directive of 30th November 2005 defines the procedures for international assistance when France is called on or when it requires assistance itself in the event of a radiological emergency situation. For each Ministry, it contains an obligation to keep an up-to-date inventory of its intervention capability in terms of experts, equipment, materials and medical resources, which must be forwarded to ASN. As coordinator of the national assistance resources (RANET database), ASN takes part in IAEA's work on the operational implementation of international assistance.

France has been called upon several times since 2008 to assist a foreign country in a radiological emergency situation. For example, ASN has been contacted regularly in recent years for assistance requests concerning persons accidentally exposed to high-level radioactive sources.

3. LEARNING FROM EXPERIENCE

3.1 Carrying out exercises

The main aim of these nuclear and radiological emergency exercises is to test the planned response in the event of a radiological emergency in order:
- to ensure that the plans are kept up to date, that they are well-known to those in charge and to the participants at all levels and that the corresponding alert and coordination procedures are effective;
- to train those who would be involved in such a situation;
- to implement the various organisational aspects and the procedures stipulated in the Interministerial Directives, the emergency response plans, the local safeguard plans and the various conventions;
- to develop a general public information approach so that everyone can, through their own individual behaviour, make a more effective contribution to civil protection.

These exercises, which are the subject of an annual Interministerial Circular, involve the licensee, the Ministries, the offices of the Prefect and services of the *départements*, ASN, ASND, IRSN and *Météo-France*. They aim to test the effectiveness of the provisions made for assessing the situation, bringing the installation or the package to a safe condition, taking appropriate measures to protect the general public and ensuring satisfactory communication with the media and the populations concerned. At the same time, the exercises are a means of testing the arrangements for alerting the national and international organisations.

3.1.1 National nuclear and radiological emergency exercises

In the same way as in previous years, and together with the SGDSN, the DGSCGC and the ASND, ASN has prepared a programme of national nuclear and radiological emergency exercises for 2015, concerning BNIs and RMT operations. This programme, announced to the Prefects in the Interministerial Circular of 15th December 2014, took account of the lessons learned from Fukushima Daiichi and the emergency exercises performed in 2014.

Generally speaking, these exercises enable the highest-level decision-making circles to be tested, along with the ability of the leading players to communicate, sometimes with simulated media pressure on them.

Table 2 describes the key characteristics of the national exercises conducted in 2015.

In addition to the national exercises, the Prefects are asked to conduct local exercises with the sites in their *département*, in order to improve preparedness for radiological emergency situations, more specifically testing the time needed to mobilise all the parties concerned.

The performance of a national nuclear and radiological emergency exercise, at maximum intervals of five years on the nuclear sites covered by a PPI, and at least one annual exercise concerning RMT, would seem to be a fair compromise between the training of individuals and the time needed to effect changes to organisations.

The exercises enable those involved to build on knowledge and experience in the management of emergency situations, in particular for the 300 or so persons mobilised in the field for each exercise.

For 2015, the objectives chosen in the annual Circular of 15th December 2014 concerning the national nuclear or radiological emergency exercises were:
- testing of international relations;
- setting up an organisation to simulate the Government level;
- carrying out exercises in real meteorological conditions whenever possible;
- carrying out exercise scenarios for which the writers are given as few restrictions as possible;
- testing the response plan for a major nuclear or radiological accident and implementing it if effective.

With regard to nuclear safety aspects:
- continue to train experts with focus on technical aspects;
- carry out a safety exercise with a malicious initiating event;
- carry out an exercise involving several installations on the same site;
- carry out an exercise requiring ASN to issue an official resolution;
- bring in the licensees' national intervention forces as stipulated by the statutory resolutions.

Check on contamination during a seismic exercise on the CEA site in Cadarache.

With regard to civil security aspects:
- on the occasion of the exercises, develop the ties between the authorities of the Prefect and the local authorities;
- promote greater anticipation of civil protection measures to ensure protection of the population;
- implement and coordinate thematic workshops separated from the technical scenario.

ASN is also heavily involved in the preparation and performance of other emergency exercises that have a nuclear safety component and are organised by other players such as:
- its counterparts for nuclear security (HFDS – Defence and Security High Official reporting to the Minister for the Environment) or for defence-related facilities (ASND);
- international bodies (IAEA, European Commission, NEA);
- the Ministries (Health, Interior, etc.).

With regard to defence-related facilities, two exercises run by the ASND were organised during the course of 2015, in accordance with the Interministerial Circular on nuclear and radiological emergency exercises. One of them was carried out jointly with ASN, as it concerned several installations, both civil and defence-related, on the same site.

Pursuant to the ASN/ASND protocol of 26th October 2009, ASN takes part in some of these exercises:
- at the ASND national emergency centre: an ASN representative goes to the ASND's emergency centre to act as the interface between ASN and the ASND, to advise the ASND on aspects relating to the environmental impact of releases, and to prepare for post-accident management of the emergency by ASN;
- at the office of the Prefect: a representative of the ASN division concerned goes to the office of the Prefect to advise the Prefect pending the arrival of the ASND's representative.

The ASN personnel draw on the experience acquired during these numerous exercises in order to respond more effectively in real-life emergency situations. Thus, during the real situations in 2015 concerning the NPPs of Flamanville and Cattenom, the organisation set up among all the stakeholders, who had become used to cooperating with each other during the exercises, was found to be efficient and effective.

3.2 Assessing with a view to improvement

Evaluation meetings are organised immediately after each exercise in each emergency centre and at ASN a few weeks after the exercise. ASN, along with the other players, endeavours to identify best practices and the areas for improvement brought to light during these exercises. Feedback meetings are also organised in order to learn the lessons from any real-life situations that have occurred. On a six-monthly basis, ASN also brings all the players together to review best practices to improve the response organisation as a whole. These meetings enable the players to share their experience through a participative approach. They more specifically revealed the importance of having scenarios that were as realistic as possible, in real meteorological conditions and that were technically complex enough to be able to provide useful experience feedback.

Of the objectives identified, some will be mentioned in the 2016 interministerial instruction on exercises:
- test the regional implementation of the national plan for response to a major nuclear or radiological accident, in particular in all the *départements* which do not contain a nuclear facility (half-day "transport" exercises);

TABLE 2: National civil nuclear and radiological emergency exercises conducted in 2015

NUCLEAR SITE	DATE OF EXERCISE	MAIN CHARACTERISTICS
Gravelines NPP	10th February	Health aspect, post-accident aspect Involvement of Seveso industrial firms Inter-*département* and inter-region aspect (exchanges with Belgium, etc.)
Chinon NPP	28th May	Alert aspect Protection of populations aspect
Cadarache site	23rd June	Events simultaneously affecting several BNIs and SBNIs on the same site Deployment of means from another CEA site Definition of an environment measurements strategy and output of results
Civaux NPP	22th September	Tests to check understanding of instructions by the public Activation of the general public information unit Communication aspect
Transport of radioactive substances (Doubs *département*)	1st October	Organisation of radiological emergency management in a *département* without a nuclear facility Communication aspect
Penly NPP	13th October	Activation of the PPI reflex phase Inter-communes dimension

- prepare the offices of the Prefects for implementing public protection measures or post-accident actions, by following up slow-development accident exercises with a phase focusing on civil security;
- test the capacity of the entities involved to provide the interministerial level with information linked to the national plan for response to a major nuclear or radiological accident, on the occasion of the Secnuc (Nuclear Security) major exercise;
- involve the Prefects of the defence and security zones in certain exercises.

The exercises, as well as the real situations that occurred, demonstrated the importance of communication in an emergency situation, in particular to inform the public and the foreign regulators sufficiently early and avoid the spread of rumours that could lead to panic among the population, whether in France or abroad.

Finally, for several years, IRSN has been using a system giving a geographical representation of the environmental radioactivity measurements during exercises and actual situations. This tool, called CRITER, gives a rapid display summarising all the environmental radiological measurements taken, providing decision-makers with a clear view of any radiological impacts. Work is currently under way to improve the cartographic representations and to facilitate the decision-making process.

4. OUTLOOK

In accordance with the important nuclear emergency duties entrusted to it by the Environment Code, ASN makes an active contribution to the review process currently being carried out by the public authorities following the Fukushima Daiichi accident, with the aim of improving the national radiological emergency organisation.

ASN thus participates in the work to implement the major nuclear or radiological accident national response plan and in particular calls on the assistance of the Ministry of the Interior and the offices of the Prefects following the publication of the regional implementation guide. This regional implementation will be tested in 2016 and 2017, more particularly in the *départements* in which there are no BNIs, during half-day exercises based on a radioactive substances transport accident scenario. In 2016, ASN will also take part in a major exercise involving the Government level.

Exchanges with the Ministry for the Environment, Energy and the Sea will continue in 2016 to set up the legal framework enabling an on-call duty system to be created at ASN.

The nuclear safety regulators confirmed the need for continued work internationally to improve the coordination of the respective approaches of each country in an emergency situation. In 2016, ASN will thus continue with the European initiatives taken with a view to transboundary harmonisation of actions to protect populations in an emergency situation and to develop a coordinated response by the safety and radiation protection authorities in the event of a near or remote accident, more specifically as part of the follow-up to the HERCA/WENRA approach. In 2016, ASN will take part in organising a seminar on this approach, involving the European Authorities responsible for civil protection.

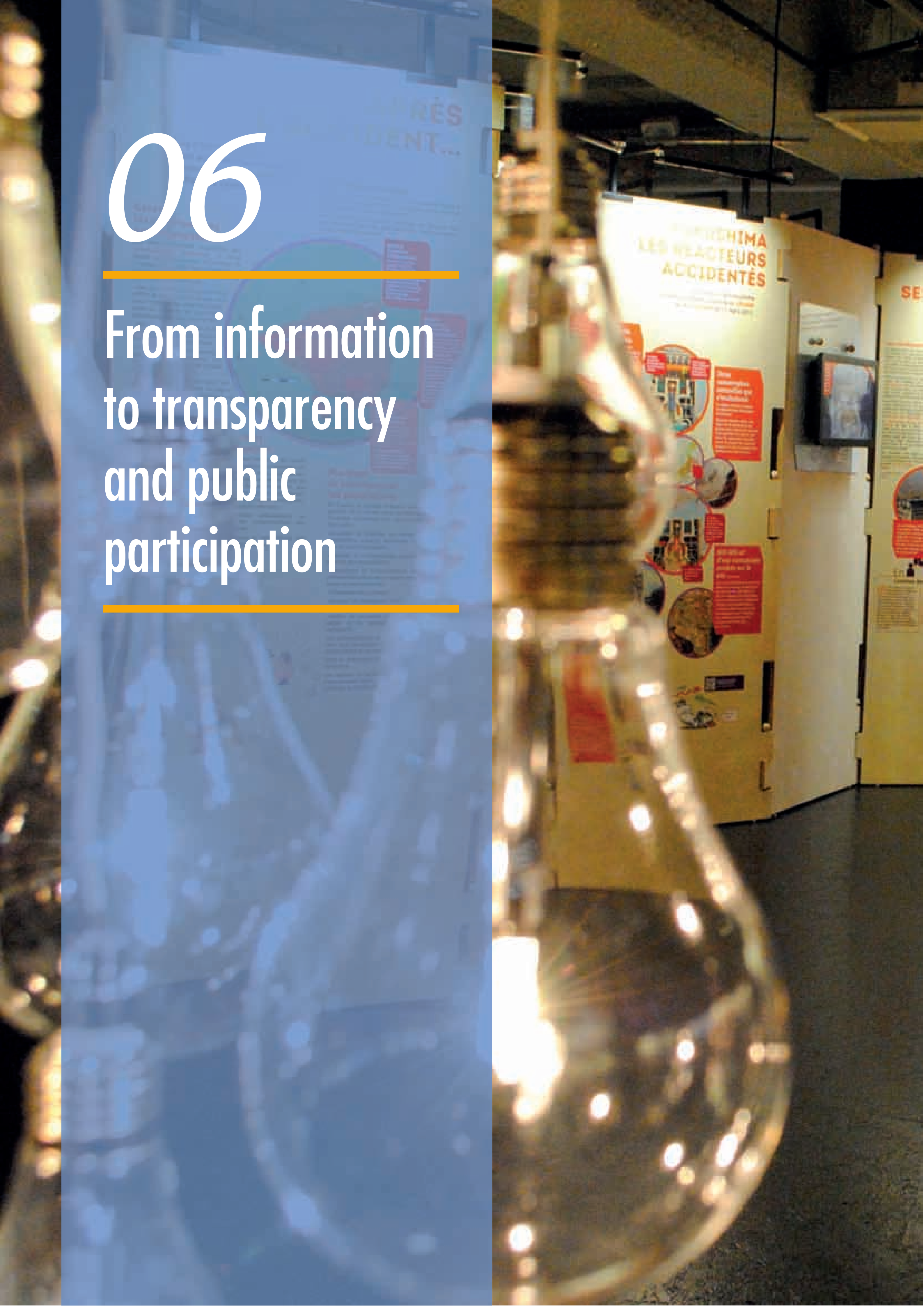
The Fukushima Daiichi accident also showed that it is important for the emergency exercises to be able to test the organisation specified in the emergency plans, notably the interfacing between the ORSEC and PPI systems, to ensure that the skills of the stakeholders required in an emergency remain current and showed that it was necessary to improve transboundary coordination. ASN will ensure that these exercises also have an educational and informative dimension by extensively involving the populations in their preparation and by implementing the post-accident aspect, by means of specific workshops, along with international relations aspects.

In 2016, in order to prepare the offices of the Prefects for the performance of public protection measures or post-accident actions, certain exercises will be followed up by a phase focusing on civil security objectives.

Finally, in 2016, ASN will continue its work to draft a resolution concerning the obligations of the BNI licensees with respect to preparedness for and management of emergency situations and the content of the on-site emergency plan, in order to clarify the provisions of Title VII of the Order of 7th February 2012 setting the general rules applicable to Basic Nuclear Installations.

06

From information to transparency and public participation




TCHERNOBYL ET
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The Act of 13th june 2006 ("TSN Act") relative to transparency and security in the nuclear field considerably tightened the requirement for transparency and the right to information regarding nuclear matters. It defines transparency in the nuclear field as *"the set of provisions adopted to ensure the public's right to reliable and accessible information on nuclear security"* (Article L.125-12 of the Environment Code, formerly Article 1 of the TSN Act).

The Energy Transition for Green Growth Act (TECV) of 17th August 2015 takes even further the provisions regarding transparency. This act explicitly sets out the role of ASN in producing its annual Report on the state of nuclear safety and radiation protection in France.

The Act also includes a set of provisions relating to the Local Information Committees (CLI) of the Basic Nuclear Installations (BNI). It provides for the CLIs to organise at least one meeting each year that is open to the public and that those CLIs situated in *départements* located on national borders include representatives of the neighbouring countries.

For many years now ASN has been developing the culture of risk in the areas of activity it regulates. This is witnessed for example by the post-accident procedure developed under the Codirpa (Steering Committee for Managing the Post-accident Phase of a nuclear accident or radiological emergency situation), heightening awareness on the control of doses in the medical field or managing the risks associated with gamma radiography, which involve the stakeholders at different levels.

ASN will continue this effort, more specifically through the 2016 campaign for distributing iodine tablets to the populations living in the vicinity of nuclear power plants, through the ASN/IRSN road show and through the initiatives of openness to civil society in collaboration with the CLIs.

This is a citizen-centric approach, because ultimately the individual citizens are responsible for taking measures to protect themselves against the risks according to their analysis of the situation, the information received, the credibility they assign to the prescribers and their (the citizens) level of preparedness.

To improve its actions, ASN uses the results of its annual barometer which enables it to adapt its information policy to its various audiences. In 2015, 85% of the professionals questioned knew of ASN – a figure very similar to that for 2014 – and 59% of them said they were satisfied with the way in which ASN informs them.

ASN maintains regular relations with the nuclear licensees, develops relations with the users of ionising radiation in the industrial and health sectors and contributes to keeping them well informed.

In 2015 ASN implemented proactive communication efforts targeting the media and the institutional audiences, particularly the local elected officials.

Each year at national level ASN presents its Report on the state of nuclear safety and radiation protection in France to Parliament and develops its relations with the members of parliament.

1. DEVELOPING RELATIONS BETWEEN ASN AND THE PUBLIC

1.1 Opening to the public at large and development of a risk culture among citizens

ASN wishes to develop a nuclear risk culture by fostering the involvement of the citizens in the subjects relating to nuclear safety and radiation protection. To this end, ASN uses several means of communication and delivers transparent information in these areas.

1.1.1 The ASN Information Centre

The role of the ASN Information Centre is to inform the public on nuclear safety and radiation protection: it coordinates the processing of the demands addressed to ASN (technical questions, requests for administrative documents, environmental information, dispatching of publications, document searches). It responded to nearly 2,000 requests from varied audiences in 2015.

The centre also has more than 3,000 documents relating to nuclear safety and radiation protection, particularly administrative documents (public inquiry files, impact studies and annual reports from the licensees), which are available for consultation. The public has access to all the ASN publications and can consult the French and international publications produced by various stakeholders (CLIs, nuclear licensees, IRSN – Institute of Radiation Protection and Nuclear Safety – and other technical experts, learned societies, professionals, non-governmental organisations).

Information sheets provide syntheses and educational information on the broad subjects of nuclear safety and radiation protection for the general public: *"The French nuclear fuel cycle"*; *"Transport of radioactive substances"*, *"The taking of stable iodine in the event of a nuclear accident"*; *"The principles of radiation protection"*; *"Nuclear emergency situations"*.

The Information Centre also hosts temporary exhibitions on nuclear safety and radiation protection which are free of charge and open to everyone. In 2015 the centre hosted an exhibition created by ASN and IRSN entitled *"Nuclear Safety? A key issue!"*

1.1.2 The ASN/IRSN exhibition

ASN and IRSN jointly created a road show with the aim of developing the nuclear risk culture of the citizens. The exhibition comprises 10 modules and features explanatory display panels, documentary films and an animated reactor model to enable visitors to discover the principles and effects of radioactivity, to learn how nuclear power plants function and the way in which they are regulated and overseen. During the year it was presented to the public in schools and in the municipalities located near nuclear power plants.

TO BE NOTED

"MORE risk culture in Dunkerque!"

ASN's Lille division and IRSN deployed the exhibition *"Nuclear safety? A key issue!"* (see point 1.1.2) jointly with their partners of the urban community of Dunkerque, the Gravelines CLI and the National Association of Local Information Committees (Anccli).

The exhibition was housed in the PLUS *(Palais de l'Univers et des Sciences* – Palace of Science and the Universe) in Cappelle-la-Grande from 17th September to 21st December 2015. It proposed an educational circuit comprising nearly 80 information boards, along with multimedia presentations and personalised visits revolving around ten major themes.

A cycle of four conferences was also organised to discuss with the public subjects such as the operating life of the nuclear power plants, the lessons learned from Chernobyl and Fukushima Daiichi, nuclear emergency situations and medical uses of radiation.

ASN/IRSN exhibition at the PLUS (Palace of Science and the Universe) in Cappelle-la-Grande, near Dunkerque.

1.1.3 Relations with the French National Education Authority

In 2015, ASN continued to strengthen its interchanges with the school environment with the aim of developing the nuclear risk culture with teachers and pupils. Several operations were deployed at both local and national level.

ASN renewed its support of the *"Radiation protection workshops"* organised by the Nuclear Protection Evaluation Centre (CEPN) and the Franche-Comté *département*'s *"Pavillon des sciences"* science centre which brings together French and European high schools to work on educational projects relating to radiation protection. ASN's Dijon and Lille divisions accompanied two schools in their project work on radiation protection in the hospital environment. The Marseille division took part in the international radiation protection meetings in Cadarache in March 2015 on the theme *"Decommissioning and radiation protection issues"*.

TO BE NOTED

In 2015, ASN supported the public meeting of the Belleville-sur-Loire CLI on the theme of the nuclear accident

The Belleville-sur-Loire CLI and the municipality of Boulleret (Cher *département*) organised a public information and discussion meeting on 22nd January 2015 on the theme: *"If an accident were to occur in the nuclear power plant"*.

The 170 citizens who attended were thus able to ask their questions to representatives of the State services – the Cher Prefecture and the Regional Health Agency (ARS) –, of IRSN, EDF and ASN who took part in the meeting.

The participants were also able to see the exhibition *"Nuclear safety? A key issue!"* (see point 1.1.2) presented in Boulleret on this occasion.

ASN also renewed its partnership with the French Institute for Major Risks and Environmental Protection Instructors (IFFO-RME), a network of risk specialists with experience of working in the school environment. Together they prepared actions relative to the next nuclear risk awareness-raising and iodine tablet distribution campaign which will take place in 2016.

1.1.4 The website - *www.asn.fr*

The principal vector for informing the public is the ASN website at *www.asn.fr,* which gives the various audiences access to information. Links to oversight documents (incident opinions, inspection follow-up letters, position statement letters, reactor shutdown notices) are available from the site homepage, alongside the ASN opinions and resolutions, information notices and publications, educational content (films, dossiers, etc.), as well as public consultations on draft resolutions, etc. The site has dedicated sections for the professionals (see point 1.2).

Most of the content published on *www.asn.fr* is accompanied by computer graphics and videos, accessible from the home page. In 2015 ASN inaugurated a series of educational videos entitled *"Let's talk about nuclear safety and radiation protection"* designed to convey information to a wide audience in simple terms using a question-and-answer approach. Videos were produced on five subjects in 2015, namely radon, the operating life of the NPPs, emergency situation management, decommissioning of nuclear installations and iodine tablets.

A film explaining the implications of the ASN resolution on legacy Waste Retrieval and Packaging (RCD) on the La Hague site was broadcast in early 2015 on *http://tv.asn.fr* and on the social networks.

Public meeting on the theme *"Accident in the power plant, impacts and implications for the population and the environment"*, Thursday 22nd January 2015 In Boulleret (Cher).

TO BE NOTED

Information and iodine tablet distribution campaign

A campaign for distributing iodine tablets to populations living near nuclear power plants was launched publicly in January 2016. It is the fifth campaign of this type, the last one having taken place in 2009-2010. It serves to replace the iodine tablets whose shelf life expires in February 2016. The shelf life of the new tablets is seven years.

This is a large-scale operation which concerns some 400,000 households and will involve an information campaign and the mobilising of the populations concerned in the spirit of the act of 13th August 2004 concerning the modernisation of civil protection.

This opportunity must be used to raise citizens' awareness of the nuclear risks and of all the appropriate protection measures. Achieving this objective requires increased involvement on the part of the licensee, the public authorities and the stakeholders (regional authorities, health professionals, etc.), and sustained communication efforts.

In order to organise this campaign, a pluralistic steering committee led by ASN brought together representatives of the Ministries of National Education, of the Interior and of Health, IRSN, the Regional Health Agencies, the National Order of Pharmacists, the National Order of Medical Physicians, ANCCLI, the ARCICEN (Association of representatives of the municipalities and urban communities in which nuclear power plants are installed) and EDF.

The neighbouring residents are informed through public meetings, press articles, a website *(www.distribution-iode.com)*, information leaflets and posters.

This information mechanism is passed on by the campaign stakeholders: the prefectures, the ASN regional divisions, the pharmacies, the NPPs, the CLIs, the town councils and the health professionals.

In 2015, ASN continued to involve the public widely in the decision-making process (see point 2.2).

In order to also inform the international audience, ASN publishes on the English version of its website – *www.french-nuclear-safety.fr* – information notices, press releases and a variety of specific editorial content, in particular concerning the stress tests, the international working groups and the French National Radioactive Material and Waste Management Plan (PNGMDR).

1.1.5 The social networks

The content of the ASN website is available on mobile equipment (digital tablets, smartphones, etc.) and on the main social media. In 2015, ASN used Twitter to foster the widest possible dissemination of its news. Its numerous subscribers are informed of the events in which the Commission and Director General's Office participate. Content from other nuclear safety and radiation protection actors and ASN's foreign counterparts have enriched the ASN pages in Facebook. Lastly, ASN continued to develop its network of users on Dailymotion, YouTube, Viadeo and LinkedIn in 2015.

Using the social networks in emergency exercises has moreover enabled ASN to fulfil its duty to inform, alongside the other institutional actors called upon in nuclear and radiological emergency situations (prefecture, Ministries, etc.).

1.2 ASN and the professionals

ASN wishes to improve knowledge of the regulations and the technical, organisational and human aspects of the culture of nuclear safety and radiation protection with professional audiences, namely nuclear licensees and users of ionising radiation in industry and the health sectors.

On this account, ASN produces specific publications, organises and takes part in numerous symposia, seminars and meetings to raise the awareness of professionals to the responsibilities and the implications of radiation protection, to make known the regulations and to encourage the notification of significant events and experience feedback.

1.2.1 Advancing the safety culture

The website *http://professionnels.asn.fr* gives professionals access to the regulatory texts and ASN forms concerning their area of activity, along with the possibility of creating a personal account. It highlights the experience feedback from the inspections and the analysis of significant event notifications by giving access to various ASN publications and presentations given at the professional seminars.

Issued to more than 10,000 subscribers in France and abroad, the review *Contrôle* provides in-depth examinations of major subjects relating to nuclear safety and radiation protection. In its three sections – *"Analysis"*, *"Experience feedback"* and *"In question"* – *Contrôle* explains the major issues subtended by the changes in legislation, compares the viewpoints of experts who are asked to express themselves in complete transparency, and draws lessons from experience.

Issue No. 199 published in 2015 devoted a large feature article to the safety issues associated with the decommissioning of nuclear installations. Promulgation of the TECV Act in August 2015 effectively introduced new provisions to bolster the tools at ASN's disposal to address the major challenges associated with the decommissioning of the BNIs in the years to come. The transposition into the French legislative framework of the European directive on the basic standards relative to protection against the dangers of exposure to ionising radiation is covered in the *"In question"* section.

1.2.2 Disseminate the regulations and promote their implementation

ASN considers that having clear regulations based on the best safety standards is an important factor for improving the safety of BNIs. Over the last few years it has thus undertaken a major overhaul of the technical and general regulations applicable to BNIs.

The BNI Order of 7th February 2012 constitutes the cornerstone of a regulatory framework applicable to all BNIs and which has been substantially reinforced and is in conformity with the best international practices.

ASN guides for concrete application of resolutions

The ASN guides give recommendations, suggest the means ASN considers appropriate for achieving the objectives set by the regulations, and share methods and good practices resulting from experience feedback from significant events.

Some guides are designed to assist with implementation of the BNI Order and its resolutions and concern the annual public information report, the protection of BNIs against external flooding, nuclear pressure equipment, the management of sites potentially polluted by radioactive substances and the determining of the perimeter of a BNI. The integrated management system guide was subject to a public consultation process in 2015. The ongoing drafting of other ASN guides is part of an impact analysis initiative involving the nuclear licensees. The ASN guides also contribute to the harmonising of European regulations by applying the WENRA (Western European Nuclear Regulators Association) safety reference levels in France.

Seminars to explain and discuss application of the Order

Further to the 2014 seminar on the regulations applicable to BNIs, regional discussion days were held in Caen (in 2014) and in Marseilles (in 2015). The licensees made a first assessment of the implementation of the BNI Order, focusing in particular on the lines for improvement and the difficulties encountered. The ASN regional divisions answered the operational questions of the licensees and put the regulatory objectives into perspective.

1.2.3 Encourage the notification of significant events and experience feedback

The notification of significant events is a key factor in strengthening the safety and radiation protection culture.

Since July 2015, the on-line notification portal *www.vigie-radiotherapie.fr,* launched jointly by ASN and the ANSM (French National Agency for Medicines and Health Products Safety), can be used to transmit notifications concerning radiation protection and equipment incidents radiotherapy).

ASN publishes the twice-yearly bulletin *"Healthcare safety – Building momentum for progress",* co-signed by the SFRO (French Society for Radiation Oncology), the SFPM (French Society for Medical Physics), the AFPPE (the French Association of Radiographers), and the AFQSR (French Association for Quality and Safety in Radiotherapy). Sent to 180 radiotherapy centres in France, the bulletin highlights the progress and experience sharing approach initiated by the radiotherapy centres to enhance health care safety. Two new issues were published in 2015 focusing on the recording errors in the Record and Verify system and pulsed high-dose rate brachytherapy.

Since 2014, a complementary information sheet entitled *"Experience feedback"* alerts professionals about significant events notified to ASN to prevent them from recurring in other radiotherapy centres. The aim of this sheet is to inform the centres rapidly and to incite reflection as part of their risk analysis actions.

1.2.4 The professional events

The symposia and events organised by the professionals provide opportunities for ASN to develop its relations with the professionals.

The ASN regional divisions reaching out to professionals in the small-scale nuclear sector

In 2015 the ASN regional divisions took action to promote the principles of radiation protection and dose optimisation with the nuclear medicine professionals in Nantes (11th June) and in Paris (29th September) and with the research actors of the Nord – Pas-de-Calais region in Lille (1st October).

On 13th October, the Nantes division organised the second regional meeting of external Persons Competent in Radiation protection (PCR) working in the Pays de la Loire and Bretagne (Brittany) regions with the *Réseau Grand Ouest* (Greater Western France Network).

Conferences in the medical and radiation protection sector

ASN met paramedical electroradiology personnel on its stand at the AFPPE congress (20th-22nd March 2015) and medical imaging professionals at the French Radiology Days (JFR, 16th-19th October). The ongoing work concerning the extension of the INES scale to patient radiation protection events was presented at the congress of the French Society of Nuclear Medicine and Molecular Imaging (SFMN, 28th-31st May).

The interchanges with the professionals aim primarily at improving their knowledge of the regulations that apply to them by distributing regulatory sheets and the guide to the regulatory provisions relative to the medical and dental radiology, which is updated each year. The professional trade fairs also provide the opportunity to assess the situation of the inspections (interventional radiology, computed tomography) and to disseminate the lessons learned from the analysis of the significant radiation protection events.

In June 2015, ASN presented an historical retrospective at the 50th anniversary of the French Society of Radiation Protection (SFRP) to highlight the development of the oversight of nuclear safety and radiation protection in France.

Raising awareness in the control and optimisation of doses in medical imaging

The SFRP's 50th anniversary congress also provided the occasion to inform the radiation protection professionals of the efforts still to be made to optimise the control of ionising radiation doses delivered to patients during medical imaging examinations. Distributed on the stand, ASN's review of the 32-action programme involving the health authorities and learned societies reveals the positive development of good professional practices, but shortages of human resources and procedural shortcomings.

Another high point was the meeting entitled *"Radiation protection: everyone's concern"*, held on 29th September 2015 in Lille and attended by 160 medical professionals and association representatives who discussed dose optimisation in medical imaging and individual radiosensitivity. This second regional event was co-organised by the Lille division of ASN, a citizens association for Alternative Environmental Development (EDA), and Pégase, a patients' association.

1.3 ASN and the media

ASN maintains regular relations with the regional, national and foreign media throughout the year.

ASN supervisors had regular meetings and contacts with the media during 2015 to keep the journalists informed of the latest news concerning nuclear safety and radiation protection in France.

In the area of nuclear safety, journalists focused their attention primarily on the Energy Transition for Green Growth Act (TECV), the continuation of operation of the nuclear reactors, the EPR reactor construction project, the decommissioning of nuclear installations, the situation regarding the safety of the Fessenheim NPP, and the Cigéo project.

ASN's Chairman Pierre-Franck Chevet, was interviewed several times on the ASN positions and on the issues of nuclear safety in the context of the debate on the energy transition for green growth. Pierre-Franck Chevet also spoke on subjects concerning ASN, namely its status, its means of operation, its power to impose sanctions and its independence.

The functioning of the radiotherapy centres, ASN's recommendations in terms of improvement of treatment safety, the optimisation of doses received by patients and practitioners in medical imaging, and the controls in nuclear medicine were the subjects broached most frequently with regard to the radiation protection of patients.

During the year ASN also received media organisations from many countries seeking information on its functioning, its current news and the events occurring in France, or to discuss various subjects relating to nuclear safety and radiation protection with ASN supervisors.

Lastly, in 2015 the ASN press service managed the media attention raised by incidents that occurred in the nuclear facilities. The press service was mobilised in particular following the events that occurred on reactor 1 of the Cattenom NPP on 28th May (untimely opening of a valve on the secondary system), in the reactor building of the Brennilis NPP undergoing decommissioning on 23rd September (fire on the heat exchanger decommissioning work site) and on reactor 2 of the Flamanville NPP on 26th August (emission of smoke in the nuclear auxiliary building) and on 10th October (shutdown of one of the electrical transformers).

Numerous interviews and coverage in the field with the regional divisions enabled the media to understand the different steps involved in ASN's regulatory work and to inform their audience about the steps taken to ensure the safety of nuclear facilities and the safety of medical treatments.

Interview with Pierre-Franck Chevet at the ASN head office on 17th April 2015.

TO BE NOTED

Press conferences

In 2015 ASN organised twenty national and regional press conferences.

On 20th January 2015, ASN presented its wishes for the New Year to some thirty journalists from the national and international press. During this event, Pierre-Franck Chevet and Jean-Christophe Niel presented a review of ASN, its development, its relations with its international counterparts and its strategic priorities for the coming year.

On 16th April, ASN organised a press conference attended by some forty journalists to present its *Report on the state of nuclear safety and radiation protection in France in 2014.*

The regional divisions of ASN subsequently organised regional conferences to present the results of their activity during the year to their region and inform the regional media of the forthcoming issues at stake for ASN. The local press focused essentially on the regional situation assessments of each division, asking questions concerning the operation and oversight of the nuclear facilities, the incidents that occurred during the year and the environmental impact of the activities overseen.

1.4 ASN's relations with elected officials and institutional bodies

In 2015, ASN was regularly summoned to hearings before Parliament concerning its activity on subjects relating to nuclear safety and radiation protection, and the Energy Transition for Green Growth Bill.

- In May 2015 the Commission of Economic Affairs of the Senate questioned the ASN Chairman on Article 54 of the "Macron" Bill relative to the export of French reactors, the Cigéo project and the notion of reversibility, and on the Energy Transition Bill. Several questions also focused on the forthcoming major issues for ASN, and in particular on the possible continuation of operation of the NPPs beyond 40 years, the implementation of the post-Fukushima safety measures, the examination of the Cigéo authorisation request, and the future commissioning of the Flamanville EPR reactor.
- In May, the Finance Commission of the National Assembly heard ASN as part of its examination of the situation of the Areva Group.
- In June the OPECST (Parliamentary Office for the Evaluation of Scientific and Technological Choices) heard ASN on the oversight of nuclear pressure equipment and the EPR reactor vessel.
- ASN was also heard on several occasions by the National Assembly and the Senate concerning its financial and human resources and the future issues regarding nuclear regulation in France, in the context of the 2016 Budget Bill.

ASN presented its *Report on the State of Nuclear Safety and Radiation Protection in France* to the OPECST on 15th April. This report, which constitutes the reference document on the state of the activities regulated by ASN in France, is submitted each year to the President of the Republic, to the Government and to the Parliament. It is also sent out to nearly 2,000 addressees, including heads of administrations, local elected officials, licensees and heads of regulated activities or facilities, associations, professional trades unions, and learned societies.

Alongside these hearings, and to be more effective in the exercise of its duties, ASN maintains regular contact with the elected officials and interchanges with its institutional contacts on subjects relating to nuclear safety and radiation protection.

Underpinning this regular contact with the local elected officials, ASN and IRSN will be present at the Mayors and Local Authorities Exhibition, to be held at Paris Expo, Porte de Versailles, from 31st May to 2nd June 2016. Initially planned for November 2015, the exhibition was postponed following the terrorist attacks of 13th November 2015.

In order to inform its institutional contacts more regularly, ASN publishes the *"Lettre de l'Autorité de sûreté nucléaire"* every two months. This letter provides a summary of the important topical issues and information relative to ASN resolutions and actions, including on the international front. It can be consulted and downloaded from *www.asn.fr* and sent by electronic mail on subscription.

1.5 International cooperation in the field of communication

ASN invests itself on the international scene to promote experience feedback and the sharing of best practices for informing the public.

In 2015, ASN continued its participation in the communication working group coordinated by Nuclear Energy Agency (NEA). It participated with various stakeholders (media, NGOs, etc.) in an international workshop organised by its American counterpart, the NRC, from 21st March to 2nd April 2015 to discuss the quality of the information issued by the Nuclear Safety Authorities.

ASN took part in two cooperation missions financed by the European Commission for the Moroccan and Vietnamese Authorities to help them establish an information policy that complies with the best standards (see chapter 7).

1.6 The ASN staff and information

The main internal information vector available to the ASN staff is OASIS, the intranet that gives them access to the documents concerning the life of ASN and the exercise of its activities. OASIS is also the interface for the ASN information system which organises the documentary base covering the main professional processes within ASN.

The magazine *Transparence*, created in 2010, is issued three times per year to all ASN staff and to targeted external audiences such as the operational partners, the CLIs, members of parliament, and engineering school students. As of 2016, this magazine will be completely dematerialised.

ASN publishes an activity report for its staff, highlighting information on subjects ranging from training or social dialogue to the quality management system and financial resources.

Training in communication and media relations

With the aim of issuing high-quality, clear and understandable information, ASN offers its staff training in spoken and written communication and emergency management, tailored to their various responsibilities.

ASN spokespersons prepare themselves for public speaking and communication with the media, notably during emergency exercises with simulated media pressure (see chapter 5).

Training in written communication is provided for all the ASN inspectors.

Emergency situation preparedness

ASN has a duty to inform the public in the event of an emergency situation (Article L. 592-32 of the Environment Code). In order to prepare for this, ASN staff receive specific training and take part in emergency exercises. In 2015, four emergency exercises included simulated media pressure from journalists, designed to assess and strengthen ASN's reactivity to the media, as well as the consistency and quality of the messages put across by the various stakeholders, licensees and public authorities, both nationally and locally (see chapter 5).

2. REINFORCING THE RIGHT TO INFORMATION AND PARTICIPATION OF THE PUBLIC

The legislative and regulatory provisions relative to nuclear activities, which have been progressively reinforced over the last few years, and recently more particularly by the Energy Transition for Green Growth Act, give the general public wide access to information.

ASN applies these measures within its organisation and ensures that they are also applied by the licensees subject to its oversight; it endeavours to facilitate interchanges between all the stakeholders.

2.1 Information provided by the licensees

The main licensees of nuclear activities operate a proactive public information policy.

They are also subject to a number of legal obligations, either general, such as the environmental report required by the Commercial Code for joint stock companies, or specific to the nuclear sector. The latter are presented below.

2.1.1 The annual report for informing the public drawn up by the BNI licensees

All BNI licensees must establish an annual report concerning more specifically their situation and the steps they take with respect to nuclear safety and radiation protection (Article L. 121-15 of the Environment Code). The writing of these reports is covered by ASN recommendations provided in a guide published in 2010.

The reports are generally available on the licensees' websites and are often presented to the CLIs.

2.1.2 Access to information in the possession of the licensees

Since the TSN Act came into force, the nuclear field has a unique system governing public access to information.

Pursuant to Articles L. 125-10 and L. 125-11 of the Environment Code, the licensees are required to communicate to anyone who so requests, the information in their possession concerning risks linked to exposure to ionising radiation that could result from this activity and the safety and radiation protection measures taken to prevent or mitigate these risks or this exposure.

There are provisions for protecting public safety and commercial and industrial secrecy.

The right to information concerning nuclear safety and radiation protection is today in force with regard to BNI licensees and to those in charge of radioactive substances transport operations, provided that the quantities are higher than the thresholds set in the Act. The conditions under which this right will be extended to other nuclear activities that so warrant remain to be defined.

The Commission for Access to Administrative Documents (CADA)

The procedures governing disputes following a refusal to communicate information are similar to those of the general regime for access to information concerning the environment: in the event of refusal by a licensee to communicate information, the applicant can refer the matter to the Commission for Access to Administrative Documents (CADA), an independent administrative Authority, which gives its opinion on whether the refusal is justified. Should the interested parties not follow the opinion of the CADA, the dispute could be taken before the administrative jurisdiction which would rule on whether or not the information in question should be communicated. ASN is heavily committed to the implementation of this right.

The number of referrals to CADA still remains extremely limited. ASN therefore continues to regularly encourage the public to make use of this right to information.

ENERGY TRANSITION FOR GREEN GROWTH ACT

This Act reinforces the licensees' obligations regarding the provision of information:
- People living near BNIs must now be regularly informed at the licensee's expense of the nature of accident risks, the possible consequences, the safety measures and the action to take (an equivalent system is already applicable around hazardous industrial facilities that are subject to the "Seveso" European Directive).
- The BNI licensees' obligations to provide information shall be extended to all aspects concerning public security, health and safety and protection of nature and the environment.

2.2 Public consultation about projected resolutions

Article 7 of the Environment Charter embodies the right of participation of any citizen in the framing of public decisions having an impact on the environment (see chapter 3).

This provision is applicable to a large proportion of the resolutions taken by ASN or in which it is involved.

2.2.1 Consultation of the general public on draft statutory resolutions having an impact on the environment

Article L. 120-1 of the Environment Code provides for a procedure of public consultation via the Internet on draft regulatory texts having an impact on the environment.

ASN has decided to apply this widely. Consequently, all ASN draft statutory resolutions concerning BNIs, including those relating to nuclear pressure equipment, are considered as having an impact on the environment and are therefore subject to public participation. The same approach is applied for the statutory resolutions relative to the transport of radioactive substances that ASN adopts. ASN's statutory resolutions relating to radiation protection are also submitted to public participation if they concern activities involving significant discharges into the environment, producing a significant quantity of waste, causing significant nuisance for the neighbourhood or representing a significant hazard for the nearby residents and the surrounding environments in the event of an accident.

Lastly, although they are not of a statutory nature, ASN applies this same procedure to certain guides.

An indicative list of the scheduled consultations on draft statutory resolutions and guides having an impact on the environment is updated every three months on the *www.asn.fr* website.

The public participation procedure consists in posting the draft statutory resolution on *www.asn.fr* for at least 21 days in order to give people time to make their comments .

A synthesis of the remarks made, indicating those taken into account and a document setting out the reasons for the resolution are published on *www.asn.fr* at the latest on the date of publication of the resolution. During the year 2015, three draft statutory resolutions and three draft guides thus underwent public consultation.

2.2.2 Consultation of the general public on draft individual resolutions having an impact on the environment

The individual resolutions on nuclear safety and radiation protection can form the subject of several public consultation procedures which are presented below.

The public inquiry

In application of the Environment Code (TSN Act) and Decree 2007-1557 of 2nd November 2007, the BNI creation authorisation and final shutdown and decommissioning authorisation procedures form the subject of a public inquiry. Since 1st June 2012, an experiment instituted by Decree 2011-2021 of 29th December 2011, the results of which will be assessed in 2017, involves making available by electronic means the files of projects that are subject to a public inquiry and which could affect the environment. The BNIs, whether for their creation or their decommissioning, are included in this experiment.

Two public inquiries were conducted in 2015, one concerning a projected significant modification of a BNI (EEVLH2), the other concerning the introduction of active institutional controls on the site of a former BNI (LURE).

The posting of projects on the ASN website

The individual resolutions which are not subject to public inquiry and which could have a significant effect on the environment are made available for consultation on the Internet. For the ASN resolutions, these are notably individual prescriptions applicable to BNIs, the authorisation to commission a BNI or the delicensing of a decommissioned BNI, as well as authorisations for small-scale nuclear activities that could produce effluents or waste.

The consultation concerns the draft resolution and, for resolutions adopted on request, the application file. The consultation is open for at least fifteen days on *www.asn.fr.*

During the year 2015, 112 draft individual resolutions were thus posted for public consultation on *www.asn.fr.*

Disclosure of the files by the licensee

Before setting up the general procedure for consultation via the Internet, a procedure for file disclosure by the licensee was instituted for any project to modify a BNI or its operating conditions that could lead to a significant increase in its water intakes or environmental discharges (while being of insufficient scale to warrant a public inquiry procedure). This procedure is governed by II of Article 26 of the Decree of 2nd November 2007 and by ASN resolution 2013-DC-0352 of 18th June 2013. It now supplements the general consultation procedure via the ASN website.

This procedure was applied three times in 2015.

ENERGY TRANSITION FOR GREEN GROWTH ACT

For nuclear power reactors undergoing a periodic safety review after their thirty-fifth year of operation, the Act stipulates that the measures proposed by the licensee to increase the safety of its facility and to correct any observed anomalies shall be subject to a public inquiry before ASN finally decides on its prescriptions.

2.2.3 Consultation of particular bodies

The BNI authorisation procedures also provide for the opinion of the departmental council, the municipal councils and the CLIs to be obtained (see point 2.3.1). The CLIs also have the possibility of being heard by the ASN Commission before it issues its opinion on the draft authorisation decree submitted to ASN by the Minister responsible for Nuclear Safety.

The CLI and the CODERST (Departmental Council for the Environment and for Health and Technological Risks) are consulted on the draft ASN prescriptions concerning water intakes, effluent discharges into the surrounding environment and the prevention or mitigation of detrimental effects of the installation for the public and the environment.

2.2.4 Progress to be consolidated

ASN ensures that these consultations enable the public and the associations concerned to express their views, in particular by verifying the quality of the licensee's files and by developing the CLI's resources so that they can express an independent opinion on the files (in particular thanks to the possibility of consulting experts other than those of the licensee and ASN).

ASN also endeavours to ensure that the public has information that is as extensive as possible in compliance with the limits on the communication of environmental information provided for in Articles L. 124-1 to L. 124-6 of the Environment Code, in particular to protect public safety or commercial and industrial confidentiality.

The framework of the public consultation has greatly evolved over the last few years. The first efforts consisted in applying the new rules. It is now necessary to examine how to improve the practical conditions of these consultations to make them more effective aids to public participation.

2.3 The other actors in the area of information

2.3.1 The BNI Local Information Committees (CLI)

Operating framework

The CLIs have a general duty of monitoring, information and consultation concerning nuclear safety, radiation protection and the impact of nuclear activities on humans and the environment with regard to the installations of the site(s) that concern them.

The operating framework of the CLIs is defined by Articles L. 125-17 to L. 125-33 of the Environment Code and by Decree 2008-251 of 12th March 2008 relative to the CLIs for the BNIs.

The CLIs, whose creation is incumbent upon the President of the *conseil départemental* (departmental council), comprise various categories of members: representatives of departmental councils, of the municipal councils or representative bodies of the groups of municipalities and conseils régionaux (regional councils) concerned, members of Parliament elected in the *département*, representatives of environmental or economic interest protection associations, employee and medical profession union organisations, and qualified personalities. The representatives of Government departments, including ASN, and of the licensee have an automatic right to participate in the work of a CLI, in an advisory capacity.

The CLIs are chaired by the President of the departmental council or by an elected official from the *département* designated by him for this purpose.

The CLIs receive the information they need to function from the licensee, from ASN and from the other Government departments. They may request expert assessments or have measurements taken on the installation's discharges into the environment.

The CLIs are financed by the regional authorities and by ASN. ASN devotes about one million euros per year to the financial support of the CLIs and their federation. Within the framework of its reflection on the financing of the oversight of nuclear safety and radiation protection, ASN has again suggested to the Government the application of the provision of the TSN Act to add to the budget of the CLIs with association status (there are about ten of them) with a matching contribution of funds from the BNI Tax; however, this provision has not yet been implemented.

ASN support is not restricted simply to financial aspects. ASN considers that the good functioning of the CLIs contributes to safety. ASN also aims to ensure that the CLIs receive information that is as complete as possible. It also invites CLI representatives to take part in inspections.

ENERGY TRANSITION FOR GREEN GROWTH ACT

This Act provides for diverse provisions concerning the CLIs:

- Their right to address all questions within their competence without referral to a higher authority will now be explicitly written in the Act.
- The CLIs will also be able to visit the installations, either for a general presentation of their functioning or following an incident or accident to obtain an explanation of the causes and effects of the event.
- All the CLIs must also hold at least one public meeting per year.
- Lastly, the composition of the CLIs in *départements* situated on a national border shall be supplemented to ensure better representation of the neighbouring countries concerned.

Within the present framework, only the access right to facilities by ASN inspectors can be enforced upon the licensees, therefore the participation of observers from CLIs is subject to the agreement of the licensees.

ASN encourages BNI licensees to facilitate CLI access – as early as possible – to the procedure files for which the opinion of the CLIs will be required, so that they have sufficient time to develop a well-founded opinion. Similarly, ASN considers that the development of a diversified range of expertise in the nuclear field is essential if the CLIs are to be able to base their opinions, when needed, on the work of experts other than those called on by the licensee or ASN itself.

All BNI sites have a CLI, except for the Ionisos facility in Dagneux in the Ain *département*.

This means that there are 35 CLIs coming under the Environment Code. To this total we must add the Bure underground laboratory CLIS (Local Information and Monitoring Committee), created in application of Article L. 542-13 of the Environment Code and whose composition and role are similar to those of a CLI.

For the nuclear sites concerning defence, which are regulated by the DSND, Articles R. 1333-38 and R. 1333-39 of the Defence Code provide for the creation of information committees quite similar to the CLIs but whose members are appointed by the State and not by the President of the departmental council. There are about fifteen such committees. For the Valduc site, in addition to the information committee there is also an associative consultation structure called the Seiva (Structure for exchanges and information on Valduc).

The CLI activities

The activities of the CLIs take the form of plenary meetings, some of which are open to the public (about a third of the CLIs hold public meetings), and work involving specialised commissions.

The annual public information report drawn up by the licensee is presented to the CLI. Any significant events are also usually presented to the CLI.

About thirty CLIs have a website or have pages on the website of the local authority that supports them. Nearly half the CLIs publish a newsletter (sometimes an insert in the newsletter of the municipality).

The CLIs can have special advisers, generally on a part-time basis. They are members of staff of the local authorities or, for those CLIs with association status, employees of the association itself. If these special advisers are in place, this clearly helps the CLIs adopt a more proactive attitude.

In 2015, ASN informed the CLIs regularly about the files concerning the nuclear facilities. More than ten CLIs were consulted about licensees' projects in 2015. The CLIs are moreover always informed of the launching of public consultation procedures by ASN. Some ten CLIs have also had appraisals carried out, as allowed by the TSN Act, for example during the reactor ten-yearly outage inspections or in the form of environmental analysis campaigns.

More detailed information on the action of some of the CLIs is given in chapter 8.

TO BE NOTED

27th Conference of Local Information Committees

The 27th Conference of Local Information Committees brought together 236 participants on 4th November 2015 in Paris at the initiative of ASN and in partnership with ANCCLI.

As in the previous years, the conference also brought together around the CLI representatives, representatives of the departmental councils and the prefectures of *départements* with CLIs, the Government departments concerned, associations and nuclear installation licensees.

The morning was devoted to "topical questions" with presentations by ASN, HCTISN (French High Committee for Transparency and Information on Nuclear Security) and ANCCLI, and lively exchanges with the floor.

Jean-Yves Le Déaut, President of the OPECST, took the floor in front of the participants to talk about the need for a debate on the reversibility and retrievability of waste, in relation with his proposed bill on the conditions of underground disposal of the most hazardous radioactive wastes.

Ségolène Royal, Minister of Ecology, Sustainable Development and Energy, sent a video message to the CLI members on the new responsibilities conferred upon these committees by the Energy Transition for Green Growth Act.

Two successive round tables were held in the afternoon on the topics of *"Decommissioning nuclear installations and the future of the country"* and *"What form of participative democracy is appropriate for nuclear issues?"*. Alain Richard, former Minister and member of the Senate for Val-d'Oise, spoke to the participants about the recommendations of the specialised "Environmental dialogue" commission of the French National Council for Ecological Transition (CNTE), which he chaired in 2015.

The 28th CLI Conference is scheduled for 16th November 2016.

2.3.2 National Association of Local Information Commissions and Committees (Anccli)

The TSN Act provides for the constitution of a federation of CLIs, and the Decree of 12th March 2008 sets forth certain provisions that this federation must adhere to. This federation is the National Association of Local Information Commissions and Committees (Anccli), chaired by Jean-Claude Delalonde.

The activity of Anccli in 2015

In 2015, Anccli federated all the existing CLIs (or equivalent structures); these 37 bodies bring together more than 3,000 representatives of civil society, including 1,500 elected officials.

In 2015, Anccli organised more than 50 meetings of its various bodies (administrative council, annual general meeting, Scientific Committee, Advisory Committees, special advisors club, Consultative Committee) and took part in more than 80 events organised by its partners (ASN, IRSN, European Union, etc.), which bears witness to the continuing strong commitment of the volunteer members of the CLIs and Anccli.

The Anccli bodies

Anccli comprises a number of bodies, which continued their work in 2015.

The Anccli Scientific Committee

Comprising independent, volunteer experts from various backgrounds, the Scientific Committee met three times during the course of 2015. It pursued its work with the Fessenheim CLIS on the issue of water intakes and the discharges, by examining the integration of its recommendations in the ASN draft resolutions.

The guide listing the right questions to ask during the ten-year outages was finalised by integrating more specifically the feedback from the CLIs that were involved in this process.

The Scientific Committee made an in-depth analysis of the Off-site Emergency Plans (PPI) and the measures to protect the populations concerned. The recommendations and proposals resulting from this work will be presented to the members of the CLIs, the institutional bodies and the partners before the end of the year.

The Scientific Committee also invested itself in the "Health-Environment" seminar organised by Anccli and IRSN for the CLIs in November 2015.

Lastly, the Scientific Committee is currently undertaking a reflection on climate change and its consequences for the nuclear power plants.

The Anccli Advisory Committees

Anccli has set up various "advisory committees" comprising members of CLIs or Anccli. The aim of these advisory committees is to discuss the technical implications of nuclear issues with the CLIs, to incite reflection and encourage the development of citizens special interest groups.

The "Post-accident and Regions Advisory Committee" (GPPA)

The GPPA met twice in 2015. It is currently drafting a white paper on the questions of "planning emergency management and post-accident management".

It is also involved in the Codirpa initiative. On this account, some members will participate, in partnership with ASN and IRSN, in the drafting of a document to raise the awareness of regional actors to the post-accident approaches following a nuclear accident and to assist with the local application of the Codirpa doctrine.

Anccli and IRSN continue to promote Opal (a tool for raising awareness on the post-accident consequences associated with emergency situations that could concern nuclear installations) with the CLIs (presentation to the CLIs of Blayais and Gravelines in 2015). Furthermore, Opal has been "nominated" to take part in IRISES, an information and awareness-raising forum on major risks, in the "preventive information" category.

Alongside the work of the GPPA, Anccli has commissioned ACRO (Association for the Radioactivity Oversight in the West) to conduct an appraisal of the strengths and weaknesses of the French Off-site Emergency Plans (PPI). The aim is to provide a constructive critical analysis and to issue recommendations.

The Advisory Committee on Radioactive Materials and Waste (GPMDR)

The GPMDR met three times in 2015. In partnership with IRSN and the CLIS of Bure, it pursued the discussion on the ILW-HLW-LL (Intermediate and High Level, Long Lived Waste – Seminar of 9th and 10th April on *"Risks and concomitant activities"*).

Furthermore, the committee is currently drafting a white paper entitled *"Reversibility and retrievability"* in order to issue recommendations prior to the future Reversibility Act.

Lastly, the GPMDR organised a reflection workshop on 23rd September 2015 on the subject of *"How can we live with radioactive waste ?"*

The Advisory Committee on Safety

The Advisory Committee on Safety met twice in 2015. It worked on the problem of the electrical circuit breakers, on the corrosion of fuel cladding and on the major issues at stake associated with the extension of operation. In 2016, the group plans to draft a "white paper" on the *"Vulnerability of fuel pools"*.

The Advisory Committee on Decommissioning

The Advisory Committee on Decommissioning met three times in 2015. It draws up technical data sheets for the CLI members to familiarise them with the final shutdown and decommissioning procedures. This Advisory Committee has also started drafting a white paper that will issue recommendations on all the questions relating to decommissioning, that is to say informing the public, the impact on safety in all its forms (immediate / deferred dismantling, etc.), what is to become of the site, the economic impacts on the region and any transitions that might be entailed by these impacts, etc.

Relations with the CLIs

The Anccli Officers' club

The CLI Officers meet regularly (twice in 2015) to discuss their activities and the difficulties encountered, and to reflect jointly on the sharing of their work. ASN, IRSN and the licensees are invited from time to time.

Anccli proposes national actions to the CLIs (ILW-HLW-LL, Health-Environment seminars) or actions by geographical location (project for action with the CLIs of the Loire, presentation of IRSN's environmental monitoring strategy in Dunkerque).

Lastly, in the context of this group some CLIs wanted Anccli to come and visit them in their region. In this context, Anccli attended the meetings of the CLIs of Cattenom, Somanu, Cadarache, Marcoule-Gard, Fontenay-aux-Roses and Gravelines.

The "Cross-border CLI" working group

The CLIs of Manche, Cattenom, Chooz, Gravelines and Fessenheim met within the framework of the "Cross-border CLI" Working Group (WG) to share best practices and discuss their experience regarding relations between CLIs and neighbouring countries. This WG met once in 2015 and plans organising a seminar in 2016 on the cross-border approach to nuclear questions in Cattenom.

The institutional partners of Anccli

Partnership with ASN

Anccli has regular interchanges with ASN and participates in several of its working groups (PNGMDR, Codirpa, RNM - National network of environmental radioactivity monitoring, COFSOH - Steering Committee for Social, Organisational and Human Factors, child leukemias, GEP – pluralistic expert group).

In 2015, at the request of ASN, Anccli designated experts to participate in the Advisory Group of Experts on "Nuclear Pressure Equipment" (NPE) which is responsible for keeping track of the problems encountered by the Flamanville EPR reactor vessel.

Anccli was also associated with the steering committee tasked with preparing the new iodine tablet distribution campaign.

Lastly, Anccli and ASN work together each year on the preparation of the annual CLI conference.

Partnership with IRSN

Anccli and IRSN have been cooperating very closely for more than ten years. The members of the CLIs participate in many working groups (Steering and Research Committee - COR, board of directors, HLW-LL dialogue, action baptised "permanent IRSN representative in the CLIs", "periodic safety review" WG, Opal, etc.). Three meetings of the monitoring committee were held in 2015. The interchange and discussion process on the periodic safety reviews and reactor lifetime extension should lead to the organisation of an ad hoc seminar in autumn 2016.

Partnership with the High Committee for Transparency and Information on Nuclear Security (HCTISN)

Anccli was very pleased to see the reactivation of the HCTISN in 2015, enabling the work on ACN (Aarhus Convention and Nuclear) France to be resumed.

Anccli, a source of proposals in the parliamentary debates on nuclear issues

During 2015, Anccli continued to play a driving role in the contribution of civil society to the public consultations in the nuclear field.

In 2104 Anccli was convened to a hearing by Senator Berson, and was effectively heard. The Berson Report published in 2015 describes the CLIs as *"privileged places for the expression of citizens special interest groups"* and the *"common sense of the non-experts"* with regard to nuclear safety. This same report considers that the *"Local Information Committees play a vital role in informing the audiences and can therefore foster the emergence of a constructive public debate…"* and propose the creation of a nuclear safety and transparency contribution which would serve to *"clarify the financing of the nuclear structure, of radiation protection and of nuclear transparency"*.

Furthermore, in 2015 Anccli made recommendations and proposals to the "Richard Commission", a commission specialised in the democratisation of the environmental dialogue, set up by Ségolène Royal, Minister of the Environment, Energy and the Sea. The objective of this commission was to *"increase the transparency and effectiveness of the public debate and to involve the citizens in the decisions that concern them"*. The report of Senator Richard, published in June 2015, takes up the proposals put forward by Anccli, particularly concerning consultation of the public on the plans and programmes, etc., and encourages reporting back to the public on the follow-up to their participation.

Anccli also transmitted amendment proposals to the various members of Parliament on the Bill to reinforce the protection of the civil facilities accommodating nuclear materials (De Ganay Act).

Anccli expressed the wish that the licensees inform the CLIs of any intrusion attempts. Likewise, it would like the CLIs to be able to refer any question relating not only to safety and radiation protection but also to protection against malicious acts, to ASN or the Ministry.

Lastly, with regard to the TECV Bill, Anccli transmitted its amendment proposals to the Parliament members concerned. Continuing in the spirit of this work, Anccli also responded to the public consultation concerning the draft ordinance concerning diverse nuclear provisions in September 2015.

Symposia, seminars and training

In 2015, Anccli organised two training seminars in partnership with IRSN for the members of the CLIs (waste, environment and health).

Anccli also participated in a seminar on child leukemia organised by ASN.

Lastly, the members of the Anccli board took part in a discussion with the representatives of the INSTN (French National Institute for Nuclear Science and Technology) as part of the testing of a training course on nuclear issues intended for elected officials and the media (European programme Nushare).

Communication at Anccli

The new communication strategy initiated in 2014 (new logo, new website, new newsletter, strengthening of ties with the media, etc.) continued in 2015.

Anccli issued press releases expressing its opinions on subjects such as the Off-site Emergency Plans (PPI) and their scope, drones, and the links between safety and security.

Anccli now has an institutional brochure which it sends to all its partners and which represents its "identity card" (presentation of the organisation, its locations, its origins, its duties, its work, its added value, etc.).

Lastly, Anccli distributes three newsletters by e-mail to more than 1,400 addressees.

A new episode in the *"Chronicles of Julie and Martin"* will be prepared in 2016 and will be devoted to the culture of risk, including the distribution of iodine tablets.

European cooperation

Anccli participates in European programmes (PREPARE, BEPPER, etc.).

The ACN initiative launched by Anccli

The Aarhus Convention and Nuclear (ACN) is an initiative launched in 2008 by Anccli and the European Commission with the aim of progressing with the practical implementation of the Aarhus Convention in the nuclear field. Some fifteen Member States participate in it. This initiative ended in March 2013. The ACN process is continuing and the steering committee has decided to organise a round table on 22nd and 23rd March 2016 in Luxembourg on the theme *"Emergency Preparedness and Response to nuclear accident and post-accident situations (EP&R)"*. Anccli remains a partner in this initiative, but in 2016 it will transfer tasks to NTW (Nuclear Transparency Watch) which will take care of the logistics.

The NTW initiative launched by Anccli

NTW (Nuclear Transparency Watch) is a European network created in 2013 to promote transparency in nuclear activities and the effective participation of the public in the nuclear sector in order to improve the decisions concerning nuclear safety and the protection of health and the environment. It is chaired by Michèle Rivasi, Member of European Parliament, while Jean-Claude Delalonde is vice-chairman. NTW supports national and local initiatives and the civil society organisations that share these objectives. Two working groups were set up in 2014, one on Civil Protection and Disaster and Emergency Services (EP&R WG), the other on the ageing of nuclear power plants in Europe.

In 2015, the members of the board wanted to put in place a commitment charter for its members in order to ensure that everyone was striving to achieve a common goal, namely transparency and safety in the nuclear field, without adopting a pro- or anti-nuclear position.

2.3.3 High Committee for Transparency and Information on Nuclear Security

The High Committee for Transparency and Information on Nuclear Security (HCTISN) created by the TSN Act is a body that informs, discusses and debates on nuclear activities, their safety and their impact on health and the environment.

The HCTISN comprises 40 members appointed by decree for six years. They include:
- 2 members of the National Assembly appointed by the National Assembly and two members of the Senate appointed by the Senate;
- 6 representatives of the CLIs;
- 6 representatives of environmental protection associations and approved health system users associations;
- 6 representatives of persons in charge of nuclear activities;
- 6 representatives of representative employee labour organisations;
- 6 "qualified personalities" chosen for their scientific, technical, economic or social competence, or for their information and communication expertise, including one appointed by the Government, three appointed by OPECST, one by the Academy of Science and one by the Academy of Moral and Political Sciences;
- the ASN Chairman, an IRSN representative and 4 representatives of the ministries concerned.

The Chairman of the HCTISN is appointed by the Prime Minister from among Members of Parliament, members of the CLIs or qualified public figures.

The members of the second mandate of the High Committee were appointed by the Decree of 24th February 2015. Marie-Pierre Comets was appointed Chairwoman.

After a break of about one year, the HCTISN resumed its work in 2015. This consisted primarily in:
- establishing a resolutely ambitious work programme for the HCTISN, which will continue in line with the action of the first mandate;
- holding four plenary meetings during which the major currently topical subjects concerning nuclear activities were detailed and discussed ("nuclear" section of the Energy Transition for Green Growth Act and the draft "nuclear" Ordinance called out by this act, manufacturing anomalies of the Flamanville EPR reactor vessel domes, emergency situation management, disposal facility project for low-level long-lived waste, ageing and extension of the service life of the nuclear power plants, etc.);

- setting up a group for monitoring the process of complementary appraisals and analyses that will be implemented to enable ASN to rule on the mechanical strength of the Flamanville EPR reactor vessel and responding to Minister Ségolène Royal's referral of this matter to the High Committee.

The issues presented and discussed at the High Committee meetings can be consulted on *www.hctisn.fr.* ASN considers that the HCTISN plays an important consultative role at national level and is very pleased that it resumed its activities in 2015.

2.3.4 IRSN

IRSN reports on its activities in its bilingual (French-English) annual report. This document is officially communicated to IRSN's supervisory Ministers, as well as to the HCTISN, the French High Public Health Council (HCSP) and the Working Conditions Guidance Council (COCT). It is also available to the general public *via* the IRSN's website.

IRSN also implements a policy of information and communication that is consistent with the objectives agreement signed with the Government. As in the previous years, in 2015 IRSN made public all the results of its research and development programs, with the exception of those concerning national defence. In accordance with the transparency approach initiated jointly with ASN in 2010, IRSN published on its website at *www.irsn.fr* more than 50 technical opinions produced and some ten reports produced at the request of ASN.

The new exhibition for the general public on nuclear and radiological risks has been completed. It was presented at the Palace of Science and the Universe in Cappelle-la-Grande near Dunkerque (see point 1.1.2). Furthermore, exhibition modules in a lighter and more readily transportable format were deployed in 12 high schools with presentations to the pupils, to the Lille DREAL (Regional Directorate for the Environment, Planning and Housing) and in major events such as the Nantes University Scientific Days devoted to "Risks". Lastly, this new exhibition has also been presented to the major risks instructors of the IFFO-RME and at the Festival of Science in Saint-Tropez and Marseille. Although it is impossible to give an exact figure, it is estimated that more than 4,500 people have seen this exhibition.

Furthermore, throughout the year 2015, IRSN maintained its readiness to answer questions from the media and the public, an area were the demand is growing strongly given the wealth of news concerning the nuclear field.

Lastly, IRSN has integrated the rapid development of the social networks and a multi-channel approach in its information policy.

3. OUTLOOK

In 2016, ASN will actively contribute to implementing steps to reinforce nuclear transparency in accordance with the requirements of the Energy Transition for Green Growth Act.

ASN will further develop its information actions targeting the general public in order to make the technical subjects it presents clearer and more accessible. It will thus continue its approach to popularise and facilitate the understanding of the information in its publications, with the aim of playing a more educational role with its various audiences, in particular by increasing the number of videos available on *www.asn.fr.*

It will reinforce transparency on the subjects under its responsibility, together with the other players and stakeholders. ASN will also improve the conditions in which members of the public can express their opinions on the draft regulatory texts on *www.asn.fr.* The setting up of new exhibitions on nuclear safety and radiation protection in its public information centre, the strengthening of ties with schools and the National Education Authority, the creation of new information media for the populations situated in Off-site Emergency Plan (PPI) zones around the nuclear installations are all actions designed to make the various audiences more aware of the culture of risk and questions concerning nuclear safety and radiation protection.

The campaign for informing and distributing iodine tablets to the populations living near the EDF nuclear power plants will run in 2016. Coordinated by ASN, the aim of the campaign is to inform the citizens of the nuclear risk, of all the appropriate protection measures and, in particular, the taking of iodine tablets.

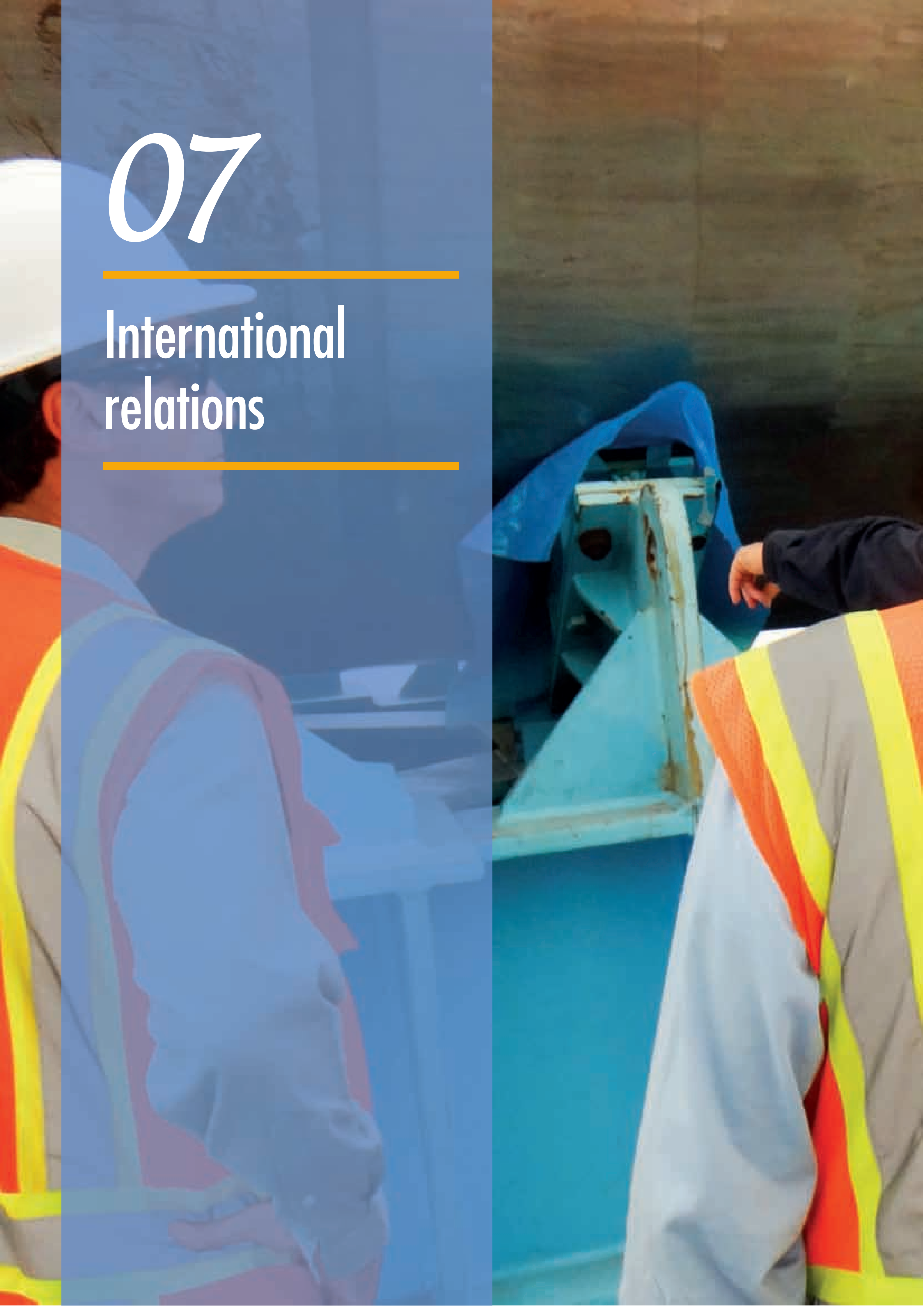
ASN will continue its interchanges with elected officials and stakeholders. It will continue its participation in the debates on nuclear safety and radiation protection.

ASN will also organise a consultation with stakeholders on the first results of the procedures enabling the public to participate in the development of its resolutions.

ASN will continue to support CLI activities. It will also continue its actions with respect to the Government and Parliament, to ensure that the CLIs are given the resources they need.

07

International relations



USNRC

ASN's international role was recognised and legitimised by the legislative provisions contained in the Environment Code[1]. ASN considers that the development of its international relations is essential to promoting a high level of safety worldwide, while consolidating its competence and its independence.

Even if nuclear safety and radiation protection remain a national prerogative, they are increasingly a part of an international move towards sharing and harmonisation of knowledge and practices. A country will therefore seek to benefit from the experience of other countries in order to improve its expertise. Moreover, a significant nuclear accident or event occurring in one country can affect other, sometimes remote countries, as was the case with the Chernobyl and Fukushima Daiichi accidents.

ASN's international action concerns two key issues: on the one hand, identifying and promoting best practices in terms of nuclear safety and radiation protection and, on the other – should an accident occur – informing, being informed and being able to react rapidly.

1. ASN OBJECTIVES IN EUROPE AND WORLDWIDE

The regulatory context has changed in Europe in recent years with the adoption of European Directives in the fields of nuclear safety and radiation protection.

These directives set the requirements and standards to be applied by the Member States of the European Union, with transposition into their legislative and regulatory frameworks. In coordination with the French administrations concerned, ASN thus actively participates in drafting and revising directives concerning its fields of activity.

In the construction of this legal corpus, the European Commission is assisted by ENSREG (European Nuclear Safety Regulators Group), a group comprising experts from the European Commission and from the Member States of the European Union (the national delegations are made up of heads of safety regulators and representatives from the Ministries for the Environment and Energy, each group representing half the members).

The safety regulators have also set up associations in which their heads are represented, such as WENRA (Western European Nuclear Regulators Association) and HERCA (Heads of the European Radiological protection Competent Authorities).

For several decades now, outside Europe, international cooperation has been intensified under the supervision of organisations such as the International Atomic Energy Agency (IAEA), a UN agency founded in 1957, and the OECD's Nuclear Energy Agency, created in 1958. IAEA and NEA are the most important inter-governmental organisations in the field of nuclear safety and radiation protection. One of the key activities of IAEA is to draft international nuclear safety and radiation protection standards. NEA is an ideal forum for the exchange of information and experience, leading to identification of the best practices that the Agency wishes to promote. ASN participates actively in the work being carried out within these international organisations.

In the aftermath of the Chernobyl accident (26th April 1986), the international community negotiated a number of conventions for preventing accidents linked to the use

1. *Article L.592-28 of the of Environment Code states that* "ASN sends the Government its proposals to define the French position in international negotiations in the fields of its competence" *and that* "it participates, on request by the Government, in the French representation in the bodies of international organisations and of the European Communities competent in these fields". *Article L.592-33 also states that* "To implement international agreements or European Union regulations relative to radiological emergency situations, ASN is empowered to warn and inform the Authorities of third States or to receive their warnings and information". *These legislative arrangements underpin the legitimacy of ASN's international actions.*

of nuclear power and mitigating their consequences[2] should they occur. These conventions are based on the principle of a voluntary undertaking on the part of the States (who alone remain responsible for the facilities situated on their territory) and entail no sanctions in the event of any failure to meet their obligations. France is a contracting party to these conventions, with IAEA being the depository and acting as secretary.

Finally, ASN collaborates with numerous countries under bilateral agreements, which can be governmental agreements (more particularly with neighbouring countries) or administrative arrangements. Bilateral relations allow direct exchanges on topical subjects and the rapid implementation of cooperation measures. They also prove to be extremely useful in the event of emergency situations, hence the aim of increased interactions with our European neighbours.

In short, ASN's international actions can be divided into four parts, as presented in the diagram below.

1.1 Giving priority to Europe

Europe is the priority of international action by ASN, which thus aims to contribute to building two hubs, one for nuclear safety and the safe management of waste and spent fuel and the other for radiation protection.

With regard to nuclear safety, ASN contributes to two major institutions for European harmonisation: ENSREG and WENRA.

ENSREG was created in 2008 and has led to a political consensus on European Directives concerning nuclear safety in June 2009, followed by spent fuel management and waste in July 2011. This institution also took part in a process to revise the Nuclear Safety Directive proposed by the European Commission in 2013, following on from the review further to the Fukushima Daiichi accident. Each safety regulator then provided technical advice to its government responsible for the negotiations in Brussels, until its revision on 8th July 2014.

ENSREG also played a key role in initiating, performing and defining the conclusions of the stress tests. It is now responsible for the follow-up to this unique exercise, in particular for the implementation of the national action plans with a view to application of the recommendations defined in 2012. For performance of the stress tests, ENSREG relied on the specifications drafted by WENRA.

WENRA was created in 1999 to act as the technical support organisation for ENSREG. It is an association specifically for the heads of the safety regulators, basing its work on experience sharing by safety regulators with a view to harmonising safety rules for reactors and waste management facilities.

In the field of radiation protection, the HERCA association has been a part of the European scene since 2007 and benefits from a number of advantages: regular meetings between the heads of radiation protection authorities outside any formal institutional framework, the desire to harmonise national practices and to increase European cooperation in the field of radiation protection.

ASN ACTION on the international stage

European Community part
EURATOM
ENSREG, WENRA, HERCA

Multilateral part
IAEA, NEA, MDEP, INRA,
UNSCEAR, ICRP

ASN action
on the international stage

Conventions
Nuclear safety, safety of spent fuel and radioactive waste,
early notification of a nuclear accident, assistance

Bilateral part
Cooperation and exchange of information,
assistance, personnel exchanges

2. . The Convention on Early Notification of a Nuclear Accident (signed in 1986), the Convention on Assistance in the Case of a Nuclear Accident or Radiological Emergency (signed in 1987), the Convention on Nuclear Safety (signed in 1994) and the Joint Convention on the Safety of Spent Fuel management and the Safety of Radioactive Waste Management (signed in 1997).

After eight years, the HERCA association has become a key radiation protection player in Europe, and can already claim tangible progress in the harmonisation of regulations and practices. HERCA thus worked on optimisation and justification of medical imaging procedures for patients, as well as the management of transboundary emergency situations in the event of a nuclear accident.

1.2 Cooperation in the fields of nuclear safety and radiation protection worldwide

ASN multiplies its initiatives to share nuclear safety and radiation protection best practices and regulations outside Europe.

Within IAEA, ASN thus actively participates in the work of the Commission on Safety Standards (CSS) which drafts international standards for the safety of nuclear installations, waste management, the transport of radioactive substances and radiation protection. Although not legally binding, these standards do constitute an international reference, including in Europe. They are also the documentary reference standards for the international audits overseen by the Agency. They in particular include the Safety Regulator Audit Missions (IRRS, Integrated Regulatory Review Service) the development of which is being supported by ASN, along with OSART (Operational Safety Review Team) audits of nuclear power plants in operation.

Meeting between Philippe Jamet, ASN Commissioner, and Gerassimos Thomas, Deputy Director General DG ENER, European Commission, ASN, 27th March 2015.

ASN also contributes to safety harmonisation work by actively participating in the Multinational Design Evaluation Programme (MDEP) the aim of which is joint evaluation by safety regulators of the design of new reactors, including the EPR. This programme was initiated in 2006 by ASN and the United States Nuclear Regulatory Commission (US-NRC) and currently comprises 14 regulatory bodies. Its aim is harmonisation of the safety objectives, codes and standards associated with the safety evaluation of new reactors.

In the field of radiation protection, ASN is a stakeholder in various international review forums such as UNSCEAR (United Nations Scientific Committee on the Effects of Atomic Radiation) or ICRP (International Commission on Radiological Protection). ASN considers that through their publications, these entities contribute to improved understanding of exposure to ionising radiation and of health effects. They issue recommendations helping to improve the protection of exposed persons, whether patients in the medical sector or specific categories of workers.

2. RELATIONS WITH THE EUROPEAN UNION

2.1 European Union

ASN has always considered that a move towards European harmonisation of nuclear safety principles and standards was necessary, provided that this is the result of fundamental work by the regulatory bodies and between regulatory bodies and licensees. European harmonisation and the adoption of community directives depend on upstream technical exchanges between the main stakeholders.

2.2 The EURATOM Treaty

The Treaty creating the European Atomic Energy Community (EURATOM) was signed in 1957 and has led to the harmonised development of a strict oversight system for nuclear safety (see Chapter 7 of the Treaty) and radiation protection (see Chapter 3 of the Treaty). In an Order of 10th December 2002 (Case C-29/99 Commission of European Communities *versus* EU Council), the EU Court of Justice, ruling that no artificial boundary could be created between radiation protection and nuclear safety, recognised the principle of the existence of Community competence in the field of safety, as in the field of management of radioactive waste and spent fuel.

2.3 European Nuclear Safety Regulators Group (ENSREG)

ASN plays an active part in the work of ENSREG, which supports the European Commission's European legislation initiatives. Four working groups were created, devoted to the safety of installations, to the safe management of radioactive waste and of spent fuel, to transparency in the nuclear sector and to international cooperation (outside the European Union).

On 26th April 2012, one year after the Fukushima Daiichi accident, a joint statement by ENSREG and the European Commission marked the end of the stress tests conducted on the European Nuclear Power Plants (NPP). This statement emphasised the need to implement an overall action plan to make sure that these stress tests are followed by improvements to safety measures, at the national level, and that these measures are implemented in a consistent manner.

This ENSREG overall action plan more specifically required that the nuclear safety regulator of each member country publish a national action plan by the end of 2012, with each of them being assessed during a seminar bringing together the safety regulators concerned. This seminar took place in April 2013. A further exercise to follow up the recommendations of the stress tests was carried out in 2015.

The safety regulators were thus urged to update their action plans by the end of 2014 in preparation for a European peer review, which ended with a seminar organised by ENSREG in the spring of 2015.

ENSREG also organised the third edition of the Conference on Nuclear Safety in Europe in Brussels, on 29th and 30th June 2015. This conference reviewed the current state of safety in Europe.

2.4 The European Directive on the Safety of nuclear installations

The Council 2009/71/Euratom Directive of 25th June 2009 aims to establish a Community framework to ensure nuclear safety within the European Atomic Energy Community and to encourage the Member States to guarantee a high level of nuclear safety.

The European Union has thus remedied the absence of European nuclear safety legislation. This has the advantage of making its provisions binding through their transposition into the legislation of the 28 Member States.

On 22nd July 2011, France complied with its directive transposition obligations.

As required by the 2009 Directive, France sent the European Commission a first national report on the implementation of the directive in late July 2014. The preparation of this national report was entrusted to ASN. In addition to ASN, this involved the main French administrations concerned, as well as the licensees of the nuclear facilities targeted by the Directive (in particular NPP reactors, fuel cycle facilities and research reactors).

Under the mandate given by the heads of State and Governments in March 2011, asking the European Commission to look at the necessary changes to the European safety legal framework following the Fukushima Daiichi accident, it stated that it intended to propose a revision of the 2009 directive and to involve ENSREG in this process in early 2013.

During the negotiations in Brussels, ASN issued an opinion expressing its satisfaction with the clear progress with respect to the existing Directive of 25th June 2009.

ASN stressed the following points:
- strengthening the provisions concerning transparency and involvement of the public;
- definition of safety objectives for nuclear facilities, covering all steps in their operation and taking account of the conclusions of the last meeting of the contracting parties to the Nuclear Safety Convention;
- obligation to conduct ten-yearly periodic safety reviews of the facilities, which is one of the recommendations to come out of the European stress tests conducted following the Fukushima Daiichi accident.

ASN however underlined the fact that the new European nuclear safety framework, which the European Council and Parliament wanted to see implemented, could only be truly successful in the long run if this framework:
- avoids creating any ambiguity concerning responsibility for the oversight of nuclear safety;
- further reinforces the institutional independence of the safety regulators, over and above the functional separation, with these regulators more specifically being legally independent from the authorities in charge of energy policy;
- were to make provision for a joint mechanism in Europe for reviewing safety problems, under the responsibility of the safety regulators, with peer review and monitoring and with the results being made public;
- were to ensure the consistency of the measures taken by the Member States for managing a radiological emergency situation in Europe.

The revised European Union Directive was adopted on 8th July 2014 and took account of the vast majority of the text improvements pointed out by ASN. It makes provision for increased powers and independence of the national safety regulators, sets an ambitious safety objective for the entire Union (based on the baseline safety requirements used by WENRA) and establishes a European system of peer reviews on safety topics (fire risk and flooding for example). It also establishes national periodic safety assessments and provisions concerning preparedness for interventions in an emergency situation. It also reinforces the transparency requirements and provisions concerning education and training. During the negotiations, ASN endeavoured to promote France's position in favour of these measures, which significantly strengthen the Community's nuclear facilities safety oversight framework. However, European legislation does not yet enshrine in law the institutional independence of the safety regulators.

2.5 The European Directive on the Management of spent fuel and radioactive waste

On 19th July 2011, the Council of the European Union adopted a directive *"establishing a community framework for the responsible and safe management of spent fuel and radioactive waste"* (Directive 2011/70/Euratom). The adoption of this Directive is a major event and one that helps strengthen nuclear safety within the European Union, by making the Member States more accountable for the management of their spent fuel and radioactive wastes.

This Directive is legally binding and covers all aspects of the management of spent fuel and radioactive waste, from production up to long-term disposal. It recalls the prime responsibility of the producers and the ultimate responsibility of each Member State for ensuring the management of the waste produced on its territory, ensuring that the necessary steps are taken to guarantee a high level of safety and to protect the workers and the public from the dangers of ionising radiation.

It clearly defines obligations concerning the safe management of spent fuel and radioactive waste and requires that each Member State adopt a legal framework covering safety issues, stipulating:
- the creation of a competent regulatory authority with a status such as to guarantee its independence from the producers of waste;
- the definition of authorisation procedures involving authorisation requests examined on the basis of the safety cases required from the licensees.

The Directive regulates the drafting of the national spent fuel and radioactive waste management policies to be implemented by each Member State. It in particular specifies that each Member State has to adopt a legislative and regulatory framework designed to implement national radioactive waste and spent fuel management programmes. The Directive also contains provisions concerning transparency and participation of the public, the financial resources for management of spent fuel and radioactive waste, training, self-assessment obligations and regular peer reviews. It officially determines the ultimate responsibility of each Member State for the management of its radioactive waste and specifies the possibilities with regard to export for disposal of this waste. These aspects constitute major advances in reinforcing the safety and accountability of spent fuel and radioactive waste management in the European Union.

2.6 The European "Basic Safety Standards" Directive

The new Directive 2013/59/Euratom of 5th December 2013 updates the basic standards for health protection against the hazards arising from the exposure of individuals to ionising radiation. It repeals the five previous Euratom Directives (Directives 89/618, 90/641, 96/29, 97/43 and 2003/122) and also takes account of the latest recommendations in ICRP 103 and the basic standards published by IAEA.

The new provisions include the following which are of particular note:
- the introduction of the three exposure situations defined by ICRP: exposure situations linked to the performance of a nuclear activity, emergency exposure situations and exposure situations resulting from radioactive contamination of the environment or of products, or exposure to naturally occurring radiation, including radon;
- the obligation to set up a national radon risks management plan;
- a framework for regulating natural radioactivity in building materials;
- the creation of the position of "radiation protection expert" responsible for advising employers or managers with regard to the protection of workers and the public;
- lowering the dose limit for the lens of the eye from 150 mSv to 20 mSv/year.

The Member States have a period of 4 years in which to transpose this new Directive following its publication.

In November 2013, with the agreement of the Government, ASN took the initiative of setting up the transposition committee for this new Directive, for which it now acts as coordinator and technical secretary. The committee decided that its first working priority would be the legislative changes to be made to the Public Health Code (see chapter 3).

2.7 The EURATOM Treaty European working groups

ASN also participates in the work of the EURATOM Treaty committees and working groups:
- Article 31 experts group (basic radiation protection standards);
- Article 35 experts group (checking and monitoring radioactivity in the environment);
- Article 36 experts group (information concerning regulation of radioactivity in the environment);
- Article 37 experts group (notifications concerning radioactive effluent discharges).

The Article 31 experts group also discussed useful measures for supporting the transposition and implementation of the new radiation protection Basic Safety Standards Directive (BSS Directive).

2.8 The Western European Nuclear Regulators Association (WENRA)

WENRA has since its creation followed clearly defined objectives:
- to provide the European Union with independent expertise for examining nuclear safety and regulatory issues in the countries applying for membership of the European Union. This first objective was successfully achieved on the occasion of the EU expansions of 2004 and 2007.
- to develop a common approach to nuclear safety and regulation, in particular within the European Union. Then to commit to transposing the jointly decided reference levels into the national regulations.
- For this second objective, WENRA set up two working groups to harmonise the safety approaches, with a view to ensuring continuous improvement in the fields of:
  - reactor safety (Reactor Harmonisation Working Group – RHWG).
  - radioactive waste, the disposal of spent fuel, decommissioning (WGWD – Working Group on Radioactive Waste and Decommissioning).

In each of these fields, the groups defined the reference levels for each technical topic, based on IAEA's most recent standards and on the most demanding approaches adopted within the European Union. In 2008, in addition to continuing the work already under way, WENRA initiated new work concerning safety objectives for new reactors (adopted in November 2010).

In 2014, after making a technical contribution to the specifications of the stress tests, WENRA reinforced the baseline safety requirements for new reactors and existing reactors, in order to take account of the lessons learned from the Fukushima Daiichi accident.

In 2015, WENRA organised two plenary meetings in Geneva (26th and 27th March) then Madrid (27th to 28th October). These meetings resulted more particularly in the following:
- WENRA initiated two main avenues for work: preparation of the first peer review on a safety topic identified with respect to the European Nuclear Safety Directive revised in 2014. This peer review will take place in 2017. In 2016, WENRA also decided to have the RHWG check satisfactory application of the WENRA safety baselines in the respective national regulations of its members. This work will continue in 2016.
- WENRA decided to open up cooperation to other entities outside Europe, by establishing bilateral relations with various organisations, both global (IAEA) and regional (ANSN – Asian Nuclear Safety Network) and major safety regulators (CNSC – Canadian Nuclear Safety Commission; Japan's Nuclear Regulation Authority (NRA), etc.).

Throughout the year, the European regulators examined the anomalies detected on the vessels of various types of reactors in Belgium (Doel and Tihange NPPs), Switzerland (Beznau NPP) and France (Flamanville NPP).

Ukraine joined WENRA as a fully-fledged member and Belarus as an observer in 2015.

2.9 Association of the Heads of the European Radiological Protection Competent Authorities (HERCA)

The existence of a common European regulatory basis for radiation protection nonetheless leaves each country with a certain degree of freedom concerning the integration of European rules into national law.

ASN is convinced that if progress is to be made on harmonisation in Europe on the topic of radiation protection, close collaboration must be organised between the heads of European Authorities with competence for radiation protection. HERCA, the association of the Heads of European Radiological Protection Competent Authorities, was created in 2007 for this purpose at the initiative of ASN.

Five working groups are currently studying the following topics:
- justification and optimisation of the use of sources in the non-medical field;
- medical applications of ionising radiation;
- emergency preparedness and management;
- veterinary applications;
- education and training.

In 2014, HERCA approved an action plan to facilitate the transposition of the Euratom Directive on radiation protection basic standards 2013/59 (see point 2.6). Actions were identified, most of which are handled by the various HERCA working groups (see box opposite).

For transposition of the Euratom Directive on the Basic Standards (see box on page 207), HERCA organised three workshops in 2015.

International organisations such as the European Commission, IAEA, IRPA (International Radiation Protection Association) or ICRP took part in these workshops.

On 4th and 5th May 2015, the 15th meeting of the board of the HERCA association was held in Lisbon.

During this meeting, the following documents were approved:
- a new action plan for the period 2015-2017 from the emergencies group. Following the October 2014 approval of the *"HERCA-WENRA emergencies"* approach, the working plan for this group is now focused on the development of tools for improved implementation of this approach and on the transposition of the new BSS Directive.
- a document laying down the foundations for the development of a European electronic data exchange system for radiological monitoring of transboundary workers. This document was sent to the European Commission for possible financing.

On 9th and 10th November 2015, the Greek safety and radiation protection regulator (EEAE, *Elliniki Epitropi Atomikis Energeias*) hosted the 16th meeting of the HERCA board. During this meeting, a new working group was created to deal with education and training. Numerous documents, in particular those relating to the transposition of the Euratom Directive on Basic Standards, were approved (documents available for consultation on *www.herca.org*).

UNDERSTAND

Actions to improve coordination of protection measures in the event of a nuclear accident

The Fukushima Daiichi accident had a major impact on the work being done by the various multilateral forums looking at the prevention and management of a nuclear emergency. HERCA thus developed an approach aiming to implement more coherent measures to protect the populations living in the vicinity of a nuclear facility if an accident were to occur in Europe, but also outside the European continent.

This approach was tested during an exercise in 2013 and was presented to the main forums, both European (2nd ENSREG conference, the EURATOM Treaty Article 31 committee, etc.) and international (NEA, IAEA). This was then joined by WENRA in 2014 and is now known as the HERCA-WENRA approach.

It should also act as the basis for application of Article 99 of the new Euratom 2013/59 - BSS Directive on international cooperation in the preparedness for and management of emergency situations outside the damaged site.

In addition, HERCA and WENRA joined forces in January 2014 to create a joint working group which proposed "reflex" measures to be taken in the event of a severe accident in which the authorities would have very little information about the status of the facility affected (scenario similar to that of the accident which struck the Fukushima Daiichi NPP).

This group brought together 21 experts from the safety and radiation protection authorities of 14 different countries, under the chairmanship of ASN Commissioner Philippe Jamet. They reached a consensus on the positions presented to HERCA and WENRA on 22nd October 2014 at an extraordinary meeting held in Stockholm. The conclusions of this group are presented in chapter 5 point 1.1.2 concerning radiological and post-accident situations.

Collaboration between HERCA and WENRA continued in this field in 2015 in order to disseminate this approach internationally and will be carried on by means of a dedicated workshop in 2016.

2.10 ASN participation in the European Horizon 2020 programme

In 2015, ASN continued its involvement in the research sector, with participation in consortiums financed from European funds. ASN is thus one of the partners in the consortium for the European SITEX (Sustainable network of Independent Technical EXpertise for radioactive waste disposal) project, carried out under the European Horizon 2020 Programme.

The SITEX project was carried out from 1st January 2012 to 31st December 2013 under the European atomic energy community's (Euratom) seventh framework programme for nuclear research and training. Its aim was to identify the conditions and means necessary for creating an international public expertise network to address the safety and radiological protection issues entailed by the geological disposal of radioactive waste. This work led to the identification of priority topics in terms of R&D, development or harmonisation of technical guides.

A follow-up to this project was launched in June 2015 for a period of 30 months, under the European Commission's Horizon 2020 Programme, which aims primarily to create a platform of technical experts for studies into geological disposal facilities.

UNDERSTAND

The HERCA action plan for transposition and application of the new BSS Directive

Even if HERCA has no official role in the BSS Directive transposition process, it can nonetheless make an effective contribution to it. Its aim is not to achieve uniform transposition or application in national legislations, because the Member States remain free to decide on the extent to which they use the association's work.

In this respect, during its 14th meeting (21st and 22nd October 2014), the HERCA board approved an action plan on transposition and application of the new BSS Directive (Council Directive 2013/59/Euratom, available on the *www.herca.org* website).

This action plan covers the following points:
- definition of the role of HERCA In the transposition of the BSS Directive into specific national regulations;
- choice of steps to be taken for transposition of the BSS Directive;
- coordination between HERCA and the European Commission with regard to the actions considered.

The role of HERCA in the transposition of the BSS Directive, as defined, consists more specifically in:
- acting as a collaborative platform for identifying and analysing the technical and practical problems relating to regulations, discussing national approaches and presenting the planned studies concerning the application of the BSS Directive and its results;
- looking for a consensus on the new requirements and the common approaches and defining guidelines whenever possible and appropriate;
- providing information on the transposition processes, sharing the experiences of the safety regulators;
- playing an active role with the European Commission so that the European Authorities responsible for radiation protection make their voices heard in the drafting of radiation protection policies and BSS guidelines;
- contributing to the transposition and application of the BSS Directive paying particular attention to the fields in which transboundary processes are implemented.

The actions to be carried out concern the following areas:
- preparedness for and response to emergency situations (international cooperation, respondents in an emergency situation, reference values for public exposure levels in the event of an emergency situation);
- medical exposure (medical equipment, justification – level 2 –, education and training, notification of significant events);
- radon;
- exposure for non-medical imaging purposes;
- education and training: RPE/RPO (Radiation Protection Expert/ Radiation Protection Officer).

HERCA organised workshops:
- on implementation of the Council directive, Directive 13/59/ Euratom concerning preparedness and management of emergency situations (Berlin, 13th-14th April 2015);
- on the respective roles of the Radiation Protection Expert (RPE) and the Radiation Protection Officer (RPO) (Montrouge, 6th-8th July 2015);
- on the action plan concerning exposure to radon in the workplace (Geneva, 12th-14th October 2015).

2.11 Assistance programmes under the Instrument for Nuclear Safety Cooperation (INSC)

Following the collapse of the Soviet bloc, three priority areas for assistance to the countries of Eastern Europe were defined in the field of nuclear safety:
- contribution to improving the operating safety of existing reactors;
- provision of funding for short-term improvements to the least safe reactors;
- improvement in the organisation of safety regulation, making a clear distinction between the responsibilities of the different entities concerned and reinforcing the role and competence of national nuclear regulatory bodies.

In this context, Europe rapidly set up nuclear safety cooperation instruments to ensure that the nuclear facilities in the eastern part of Europe met IAEA safety standards. There then followed a succession of instruments as the geographical coverage of this cooperation expanded.

Since 2007, the Instrument for Nuclear Safety Cooperation (INSC) has been the tool used for all countries outside the European Union, even if geographical priority is given to the countries bordering the European Union.

The concrete assistance provided by ASN via the INSC primarily took the form of help to nuclear safety regulatory bodies. In 2015, ASN thus took part in regulatory assistance projects on behalf of the safety regulators of China, Ukraine, Vietnam and Morocco.

Regulation (Euratom) 237/2014 of the European Parliament and the Council, dated 13th December 2013, revised the instrument for nuclear safety cooperation for the period from 1st January 2014 to 31st December 2020 with a budget envelope of € 225.3 million, owing to European budget restrictions.

Moreover, regulation (EU) 236/2014 of the European Parliament and of the Council, dated 11th March 2014, laid out common rules and procedures for the implementation of the Union's instruments for financing external actions. The objectives of the new instrument include the goals of:
- supporting the promotion and implementation of stricter nuclear safety and radiation protection standards in nuclear facilities and of radiological practices in third-party countries;
- supporting the drafting and implementation of responsible strategies for ultimate disposal of spent fuel, for waste management, for decommissioning of facilities and for cleanout of former nuclear sites;
- improving the implementation of the INSC for the new period with the European Commission now consulting ENSREG for the definition of the strategy to be adopted to support the third-party countries.

These actions are supplemented by other international technical assistance programmes, in accordance with resolutions adopted by the G8, or by IAEA, to improve nuclear safety in third party countries, and which are funded by contributions from donor States and the European Union.

3. MULTILATERAL INTERNATIONAL RELATIONS

3.1 International Atomic Energy Agency (IAEA)

The International Atomic Energy Agency (IAEA) is a United Nations organisation based in Vienna. It comprises 165 Member States (September 2015 data). IAEA's activities are focused on two main areas: on the one hand, the control of nuclear materials and non-proliferation and, on the other, all activities related to the peaceful uses of nuclear energy. In this latter field, two IAEA departments are tasked on the one hand with developing and promoting applications of radioactivity, nuclear energy in particular, and on the other with the safety and security of nuclear facilities and activities.

In September 2011, the IAEA Board of Governors approved an action plan prepared by the Agency's secretariat. The main aim of this plan is to reinforce safety worldwide, taking account of the first lessons learned from the Fukushima Daiichi accident. This plan identified 12 main actions, themselves comprising targeted measures implemented by the Agency's secretariat and by the Member States.

These include reinforcing IAEA's activities to maintain a high level of nuclear safety (definition of safety standards, use of peer review instruments such as IRRS, OSART, revision of international conventions on nuclear safety, accident notification and assistance to countries affected by an accident, etc.).

IAEA is focusing its work on the following fields:

- **Revision and consolidation of the safety standards,** describing the safety principles and practices that the vast majority of Member States use as the basis for their national regulations.

This activity is supervised by the Commission on Safety Standards (CSS) set up in 1996. The CSS consists of 24 highest level safety regulator representatives, appointed for four years and has been chaired since early 2012 by the Director General of the Czech regulatory body, Dana Drabova. In 2014, the CSS held its 35th and 36th meetings. ASN's deputy Director General, Jean-Luc Lachaume, was the French representative on this Commission.

The CSS coordinates the activities of four committees tasked with supervising the drafting of documents in four areas: NUSSC (Nuclear Safety Standards Committee) for installations safety, RASSC (Radiation Safety Standards Committee) for radiation protection, TRANSSC (Transport Safety Standards Committee) for the safe transport of radioactive materials and WASSC (Waste Safety Standards Committee) for safe radioactive waste management. France, represented by ASN, is present on each of these committees, which meet twice a year. It should be noted that the ASN representative on the NUSSC, Fabien Féron, was appointed chairman of this committee in 2011 and that his three-year mandate was renewed in 2014. Representatives of the relevant French organisations also participate in the work of the technical groups drafting the documents.

The creation of a new committee dealing with emergency preparedness and response was approved in June 2015 by the Deputy Director General of IAEA in charge of the safety and security of nuclear facilities. Ann Heinrich of the NNSA (National Nuclear Security Administration), an agency of the US DOE (United States Department of Energy) was appointed Chair of this 5th committee, which held its first meeting from 30th November to 2nd December 2015.

The French representative is ASN, with the participation of an IRSN expert to provide technical support.

In order to improve the incorporation of aspects relative to nuclear safety and security, a specific Nuclear Security Guidance Committee (NSGC) was created, similar to those which already exist for safety, with an official interface being set up between the "safety" and "security" committees. In the longer term, expansion of the scope of the CSS to "security" subjects which overlap the field of safety, is being envisaged.

- **The rise in the number of audit missions** requested from IAEA by the Member States and their increased effectiveness.

The IRRS and OSART missions belong to this category. These missions are performed using the IAEA safety standards as the reference, which confirms the international benchmark status of these standards.

ASN is in favour of holding these peer reviews on a regular basis, with widespread dissemination of their results. It is worth noting that through the provisions of the 2009 European directive on the safety of nuclear facilities, revised in 2014, the member countries of the European Union are already subject to periodic and mandatory peer reviews of their general nuclear safety arrangements.

The IRRS missions are devoted to analysing all safety aspects of the activities of a regulatory authority. In 2014, ASN took part in several IRRS missions, in Hungary, Croatia and Ireland respectively, as well as in follow-up missions to Switzerland and Finland.

The ASN Commissioner, Margot Tirmarche, thus ran the IAEA IRRS mission in Dublin, Ireland from 30th August to 9th September 2015. This peer audit concerned all the activities regulated by the Environmental Protection Agency (EPA), the authority in charge of radiation protection in Ireland, and by the Health Safety Executive (HSE), the authority in charge of radiation protection of patients. In the same way as the "IRRS" mission, which audited ASN operations in France in 2014, the strengths and weaknesses of the Irish nuclear safety and radiation protection oversight system were benchmarked against IAEA standards.

ASN, which had received an IRRS mission in 2006 (plus a mission to follow-up the recommendations of this assessment) hosted another one from 17th to 28th November 2014. On this occasion, 29 foreign auditors examined the French nuclear safety regulation and monitoring system.

ASN has developed an action plan to address the recommendations and suggestions received during the IRRS mission. The follow-up mission should take place in 2017.

The OSART missions are carried out by a team of experts from third party countries who, for two to three weeks, assess the safety organisation of the nuclear power plants in operation. The actual implementation of the recommendations and suggestions put forward by the team of experts is verified during a follow-up mission, 18 months after the visit by the experts. The 29th OSART mission carried out in France (in other words one OSART mission per year) was held at the Dampierre NPP in September 2015. As for the previous missions, the report drafted afterwards is published on *www.asn.fr* after validation by the parties. An OSART follow-up mission was also held in June 2015 on the Chooz site. Finally, an OSART Corporate EDF follow-up mission (carried out in the head office departments of the industrial licensee) is scheduled for October 2016 (the OSART Corporate mission took place in 2014).

- **Regional training and assistance missions:** ASN responds to other requests from the IAEA secretariat, in particular to take part in regional radiation protection training and assistance missions. The beneficiaries are generally countries of the French-speaking community. Thus, in 2015, ASN representatives went to Algeria, Benin and Madagascar in turn.

- **Harmonisation of communication tools.** ASN remains closely involved in the work on the INES (International Nuclear and radiological Event Scale).

In order to contribute to the harmonisation of the use of the INES scale when communicating about an event, IAEA published guidelines in October 2014. These guidelines, which include lessons learned from the Fukushima Daiichi accident, also comprise an appendix which gives advice on how to use the INES scale in the event of an evolving severe accident.

In 2006, at France's request, a working group on the rating of radiation protection events involving patients was set up. This field is one that is not covered by the existing INES scale and in which France, thanks to the experience it has acquired with the ASN-SFRO scale, is closely involved.

In July 2012, a draft technical document was produced, proposing a method for rating radiation protection events involving patients that is consistent with the INES rating methodology. Starting in February 2013, this method was tested for eighteen months by a small group of countries. In October 2014, the consolidated methodology was presented to all the countries using the INES scale. The documents explaining the proposed methodology were completed in 2015 and submitted to the INES Advisory Committee. They were distributed to all INES correspondents at the end of 2015.

Generally speaking, ASN is closely involved in the various actions carried out by IAEA, providing significant support for certain initiatives, notably those which were developed following the Fukushima Daiichi accident. ASN will thus have taken part in three of the five working groups which drew up the full report on the Japanese accident, coordinated by the Agency's secretariat and which was presented in September 2015 at the IAEA General Conference. Furthermore, ASN Commissioner Philippe Jamet took part in the advisory group for the drafting of said report.

Finally and still under the supervision of IAEA, ASN also participated in the RCF (Regulatory Cooperation Forum) chaired by Jean-Luc Lachaume. This forum aims to bring those safety regulators in countries adopting

Meeting between Pierre-Franck Chevet and Yukiya Amano, IAEA Director General, ASN, 27th May 2015.

nuclear energy for the first time into contact with the safety regulators of the major nuclear countries, so that their needs can be identified and the required support can be coordinated, to ensure that fundamental nuclear safety objectives can be met (independence of the regulator, appropriate legal and regulatory framework, etc.). The RCF tries to coordinate with the European Commission in order to target the steps to be taken and avoid duplicating the efforts of the safety regulators (for example a seminar was held in May 2015).

3.2 OECD's Nuclear Energy Agency (NEA)

NEA, created in 1958, now counts 31 member countries from Europe, North America and the Asia-Pacific region. Its main role is to assist the member countries in maintaining and developing the scientific, technological and legal bases essential for safe, environmentally-friendly and economic utilisation of nuclear energy.

During the course of 2015, NEA continued its analysis of experience feedback from the Fukushima Daiichi accident, both through its working groups and at specific seminars. ASN thus contributes to the work initiated by NEA to update the report entitled *"The Fukushima Daiichi Nuclear Power Plant Accident: OECD/NEA Nuclear Safety Response and Lessons Learnt"*, published in September 2013, which presented the summary of the steps taken by the NEA member countries and defined working priorities on various subjects identified following the accident. Pierre-Franck Chevet and Jean-Christophe Niel, ASN Chairman and Director General respectively, spoke at the seminar organised by the NEA on 3rd June 2015, concerning the safety culture in place in the regulators' organisations.

Within NEA, ASN takes part in the work of the Committee on Nuclear Regulatory Activities (CNRA), chaired since December 2012 by Jean-Christophe Niel, the Committee on Radiation Protection and Public Health (CRPPH), the Radioactive Waste Management Committee (RWMC), and several working groups of the Committee on the Safety of Nuclear Installations (CSNI).

ASN also contributed to France's answers to the questionnaire sent out by the NEA to prepare for the new strategic action plan covering the period 2017-2022 and which will in particular define the main objectives to be reached for the work of the CNRA and the CSNI.

In 2015, the CNRA supervised the work of these four working groups covering a variety of fields (Working Group on Operating Experience, Working Group on Inspection Practises, Working Group on Public Communication and Working Group on the Regulation of New Reactors).

It also set up working groups specifically for the following topics:
- *"Defence in depth"*: chaired by Jean-Luc Lachaume. This group drafted a specific green paper which was published at the end of 2015;
- *"Safety culture"*: this group looked at the safety culture characteristics within the safety regulator organisations and published a specific green paper in January 2016.

ASN also chairs a technical group devoted to inspection practices (WGIP – Working Group on Inspection Practices), which is in particular developing a programme of observation of inspections conducted in the various member countries. Representatives from the working group thus observed an inspection on the Bugey NPP organised in the autumn of 2015.

Additional information on the AEN/CNRA activities are avalaible on the folowing website: *www.oecd-nea.org/nsd/cnra/*

3.3 The Multinational Reactor Design Evaluation Program (MDEP)

The MDEP (Multinational Design Evaluation Programme), created in 2006, is an international cooperative initiative to develop innovative approaches for pooling the resources and know-how of the regulatory bodies which have responsibility for regulatory assessment of new reactors. The key goal of this programme is to contribute to the harmonisation and implementation of safety standards.

At the request of the regulatory bodies which are members of the MDEP, NEA is responsible for the technical secretariat of this programme. An ASN staff member is seconded to NEA to help with this task.

INRA meeting at ASN (France), 7th-8th May 2015. Left to right: Stephen G. Burns, Chairman, NRC (United States); Pierre-Franck Chevet, Chairman, ASN (France); Fernando Marti Scharfhausen, Chairman, CSN (Spain); Shunichi Tanaka, Chairman, NRA (Japan); Michael Binder, President and CEO, CCSN (Canada); Wolfgang Cloosters, Head of safety for nuclear facilities, radiation protection and the nuclear fuel cycle, BMUB (Germany); Mats Persson, President, SSM (Sweden); Andy Hall, Chief nuclear inspector, ONR (United Kingdom); Un Chul Lee, Chairman and head of regulatory affairs, NSSC (South Korea).

Members of the programme

Since 2015, the MDEP has comprised 15 national regulatory bodies (AERB – India, ASN – France, CCSN – Canada, FANR – United Arab Emirates, HAEA – Hungary, NNR – South Africa, NNSA – China, NRA – Japan, NRC – United States, NSSC – South Korea, ONR – United Kingdom, RTN – Russian Federation, SSM – Sweden, STUK – Finland, TAEK – Turkey).

Organisation

The broad outlines of the work achieved within the MDEP are defined by its Strategy Committee and implemented by the Steering Technical Committee. The Steering Technical Committee has been chaired since February 2015 by Julien Collet, ASN Deputy Director General. This work is performed by working groups which meet periodically to deal with specific projects for nuclear reactors – the Design Specific Working Groups (DSWG) and specific technical subjects – the Issue Specific Working Group (ISWG).

The DSWG groups devoted to the EPR reactor (comprising the safety regulators of China, the United States, France, Finland, India, the United Kingdom and Sweden), to the AP1000 reactor (comprising the safety regulators of Canada, China, the United States, the United Kingdom and Sweden) and the APR1400 reactor (comprising the safety regulators of South Korea, the United Arab Emirates, United States and Finland), were supplemented in 2014 by a group devoted to the VVER reactor (in which the safety regulators of Finland, India, Russia and Turkey in particular take part) and a group devoted to the ABWR reactor (safety regulators of the United States, Finland, Japan, the United Kingdom and Sweden).

Three ISWG groups are working on harmonising the multinational inspection of nuclear component manufacturers (Vendor Inspection Cooperation Working Group – VICWG), on standards and codes for pressure vessel components (Codes and Standards Working Group – CSWG), and on design standards for digital I&C (Digital Instrumentation and Control Working Group – DICWG).

Activities

In addition to the periodic meetings by the various working groups, the MDEP began a review of its activities in 2015 in order to reinforce the effectiveness of its actions and optimise its preparations for meeting the forthcoming challenges it will have to face (activities linked to monitoring the start-up process for the EPR and AP1000 reactors, organisation of the working groups, etc.). The results of this review were debated by the heads of the member authorities of the programme during the annual Policy Group meeting in Paris on 4th June 2015.

The MDEP's 2014-2015 activity report was published in June 2015, providing information about the MDEP's work to the stakeholders, i.e. the regulatory authorities not participating in the MDEP, the nuclear sector industry and the general public. This report can be found at the following address: *https://www.oecd-nea.org/mdep/annual-reports/mdep-annual-report-2014.pdf*.

The MDEP made sure to maintain its interaction with the nuclear industry by organising specific meetings with the designers and the CORDEL group – Cooperation in Reactor Design Evaluation and Licensing – of the World Nuclear Association (WNA).

3.4 International Nuclear Regulators' Association (INRA)

The International Nuclear Regulators' Association (INRA) comprises the regulatory bodies from Germany, Canada, South Korea, Spain, the United States, France, Japan, the United Kingdom and Sweden. This association is a forum for regular and informal discussions concerning nuclear safety issues (each member presents its latest national news and its positions on international issues). It meets twice a year in the country holding the presidency, with each country acting as president for one year in turn (France in 2015 and Spain in 2016).

In 2015, the association's work was marked in particular by a number of subjects:
- the use of international instruments (in particular the IRRS and OSART audits) made available by IAEA;
- cooperation between the World Association of Nuclear Operators (WANO) and IAEA;
- the manufacturing anomaly on the Flamanville EPR reactor vessel.

3.5 The Association of nuclear regulators of countries operating French designed nuclear power plants (FRAREG)

The FRAREG (Framatome Regulators) association was created in May 2000 at the inaugural meeting held in Cape Town at the invitation of the South African nuclear regulator. It comprises the nuclear safety regulators of South Africa, Belgium, China, South Korea and France.

Its goal is to facilitate the exchange of operating experience feedback from regulation of the reactors designed or built by the same supplier and to enable the nuclear regulators to compare the methods they use to handle generic problems and evaluate the level of safety of the Framatome type reactors they regulate.

Visit by the CSN (Spanish nuclear safety regulatory) to the EPR construction site in Flamanville, 4th March 2015.

The 8th meeting of the FRAREG association was held in Belgium in November 2015. Each member presented the regulatory changes concerning the nuclear reactors in its country. Each member also reviewed the measures adopted following the Fukushima Daiichi accident. Several countries, including France, presented their experience of steam generator replacement operations. Other subjects, such as the issues involved in extending the operating life of the NPPs, or the anomalies discovered on the reactor vessels in Belgium, were also discussed.

The 9th meeting is to be held in South Korea in 2017.

3.6 The United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR)

The United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) was created in 1955. It examines all scientific data on radiation sources and the risks this radiation represents for the environment and for health. This activity is supervised by the annual meeting of the national representations of the Member States, comprising high-level experts, including an ASN Commissioner, Margot Tirmarche.

The last UNSCEAR reports cover a variety of topics such as risks other than cancers, the attributable risk and its interpretation, taking account of the uncertainty of the dose received and its impact on the incidence of cancers. An advisory committee was thus set up to study the exposure levels and the foreseeable effects for the general population and the workers exposed during the accident in the Fukushima Daiichi NPP. Following the 2013 Fukushima Daiichi report, published in 2014, a supplementary document was published in 2015, summarising the publications which have appeared since 2013 and providing a guide for the future programme that the scientific committee will need to consider when assessing post-Fukushima risks.

3.7 The Committee on Radiation Protection and Public Health (CRPPH)

In April 2015, ASN took part in the 73rd meeting of the NEA's CRPPH. This committee, which consists of radiation protection experts, is recognised worldwide and works in close cooperation with the other international organisations active in the field of radiation protection (ICRP, IAEA, European Commission, World Health Organisation (WHO), UNSCEAR).

More information about NEA/CRPPH activities can be found at the following address: *www.oecd-nea.org/rp/crpph.html*

3.8 The International Commission on Radiological Protection (ICRP)

The ICRP is a Non-Governmental Organisation (NGO) created in 1928 for the purpose of assessing the state of knowledge on the effects of radiation in order to identify their implications with regard to the radiological protection rules to be adopted. The ICRP analyses the results of the research work carried out around the world and examines the work of other international organisations, such as in particular that of UNSCEAR. It issues general recommendations on the protection rules and exposure levels not to be exceeded, intended more particularly for the regulatory bodies.

Margot Tirmarche is a member of the "Health effects of radiation" C1 committee of the International Commission on Radiological Protection and chairs a working group evaluating cancer risks linked to alpha emitters. In 2015, this group met for a week from 28th September to 2nd October, at ASN headquarters in Montrouge, and worked on finalising a report concerning uranium and plutonium.

4. INTERNATIONAL AGREEMENTS

ASN acts as the national point of contact for the two conventions dealing specifically with nuclear safety (the Convention on Nuclear Safety and the Joint Convention on the Safety of Spent fuel Management and on the Safety of Radioactive Waste Management). ASN is also the competent authority for the two conventions dedicated to the operational management of the possible consequences of accidents (the Convention on the Early Notification of a Nuclear Accident and the Convention on Assistance in the case of a Nuclear Accident or Radiological Emergency).

4.1 The Convention on Nuclear Safety

The Convention on Nuclear Safety is one of the results of international discussions initiated in 1992 in order to contribute to maintaining a high level of nuclear safety worldwide. This convention sets a certain number of safety objectives and defines appropriate measures for achieving them. France signed it on 20th September 1994, the date on which it was opened for signature at the IAEA General Conference, and approved it on 13th September 1995. The Convention on Nuclear Safety came into force on 24th October 1996. As of July 2015, it had been ratified by 78 States.

ASN considers this Convention to be a major tool in reinforcing nuclear safety. The areas covered by the Convention have long been part of the French approach to nuclear safety.

The Convention makes provision for review meetings by the contracting parties every three years, to develop cooperation and the exchange of experience. Several months before the review meeting is held, each contracting party is required to submit a national report describing how it intends to meet the obligations of the Convention. This report is then subjected to a peer review ahead of the review meeting, which involves the contracting parties asking questions about foreign national reports and answering questions about their own. During the meeting, the contracting parties present their national reports and take part in discussions, which can then raise additional questions. A summary report, drawn up by the meeting chairman and made public, presents the progress achieved and any difficulties that subsist.

In France, ASN acts as the competent authority for the Convention on Nuclear Safety. It coordinates all the preparatory phases prior to the review meetings, in close collaboration with the entities concerned. ASN also devotes considerable resources so that it can participate in the review meetings and be present at the various presentations and discussions.

Since 1999, six review meetings of the Convention on Nuclear Safety have been held. The sixth review meeting was held from 24th March to 4th April 2014 at IAEA headquarters in Vienna. André-Claude Lacoste, ASN Chairman until 2012, chaired this three-yearly meeting, attended by 69 of the 77 "contracting parties" to the Convention.

During this review meeting, the contracting parties voted in favour of organising a diplomatic conference, with the unanimous support of the Member States of the European Union, to review a proposal by the Swiss Confederation to amend the text of the Convention. This amendment aims to strengthen the Convention by incorporating more ambitious safety objectives for the future reactors and using these same objectives as the benchmark for improving the safety of existing reactors as far as is reasonably achievable.

ASN observes that the conclusions of the diplomatic conference, held in Vienna on 9th February 2015, went no further than a political declaration which does not reinforce the legal obligations of the signatory States. The general safety objectives of the Convention remain below the legally binding requirements of the European Nuclear Safety Directive, revised in 2014. In any case, this result is not sufficient to address the issues highlighted by the Fukushima Daiichi accident. ASN will continue to promote the highest standards of nuclear safety on the international stage. The organisation meeting for the 7th review meeting (scheduled from 27th March to 17th April 2017), held in Vienna on 15th October 2015 elected the officers for the next review meeting. They are Ramzi Jamal (CNSC, Canada), who followed André-Claude Lacoste as President of the CSN, and Fabien Féron (ASN, France) as Chairman of a country group. This meeting was also an opportunity for André-Claude Lacoste to submit his recommendations for drafting the future national reports, in particular to ensure that the principles of the Vienna declaration are included in these reports.

4.2 The Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management

The "Joint Convention" as it is often called, is the equivalent of the Convention on Nuclear Safety (CNS) for management of the spent fuel and radioactive waste produced by civil nuclear activities. France signed it on 29th September 1997 and it entered into force on 18th June 2001. As at 31st December 2014, there were 69 contracting parties.

The French proposal to set up a mechanism for comparing the review rules for the Joint Convention and those for the Convention on Nuclear Safety to ensure that they are consistent, was adopted and put into practice. Furthermore, at the proposal of the United States, additional meetings designed to ensure follow-up between the review meetings will be organised.

The 5th review meeting of the Joint Convention was held from 11th to 22nd May 2015 and the ASN Commissioner Philippe Jamet, acted as Vice-Chairman.

This review meeting comprised two parts. During the first week, each contracting party presented its national report. That of France was presented on 13th May 2015 by Jean-Christophe Niel. A presentation by Andra's CEO, Pierre-Marie Abadie, gave the licensee's viewpoint on a certain number of subjects. The maint points and issues for spent fuel and radioactive waste management in France were identified and validated by the participants after a question-and-answer session. These primarily concerned the planned deep disposal project called Cigeo (geological characteristics, concept of reversibility and acceptance by the public), management of nuclear facility decommissioning waste, management of legacy waste and used sealed sources, or the financial provisions made for the decommissioning of nuclear facilities. The second week was devoted to plenary session exchanges and to the publication of the Chairman's report approved by the contracting parties at the end of the review meeting.

These discussions identified the fact that promoting membership by new States is once again a priority. In this respect, a consultation meeting of the contracting parties is scheduled for 2016 in order to propose appropriate actions and measures to increase the number of members.

Discussions also repeatedly questioned whether the creation of a multinational nuclear waste disposal facility was both appropriate and feasible. The debate on this subject is ongoing and it should be examined during a thematic meeting which could be held in 2016 or 2017 on safety problems and questions of liability with regard to the final disposal of spent fuel or radioactive waste in a country other than that in which it was generated.

ASN will continue to act as a driving force in the above-mentioned fields, but also in those dealt with as a whole by the Joint Convention.

4.3 The Convention on Early Notification of a Nuclear Accident

The Convention on Early Notification of a Nuclear Accident came into force on 27th October 1986, six months after the Chernobyl accident. It had 119 contracting parties as at 31st December 2015.

The contracting parties agree to inform the international community as rapidly as possible of any accident leading to uncontrolled release into the environment of radioactive material likely to affect a neighbouring State. A system of communication between the States is thus coordinated by IAEA. Exercises are periodically organised between the contracting parties.

4.4 The Convention on Assistance in the Case of a Nuclear Accident or Radiological Emergency

The Convention on Assistance in the Case of a Nuclear Accident or Radiological Emergency came into force on 26th February 1987. As at 31st December 2015, there were 112 contracting parties.

Its purpose is to facilitate cooperation between countries if one of them were to be affected by an accident with radiological consequences. This Convention has already been used on several occasions for irradiation accidents due to abandoned radioactive sources. Within this context, France's specialised services have notably already taken charge of treating victims of such accidents

4.5 Other conventions linked to nuclear safety and radiation protection

Other international conventions, the scope of which does not fall within the remit of ASN, may be linked to nuclear safety.

Of particular relevance is the Convention on the Physical Protection of Nuclear Material, the purpose of which is to reinforce protection against malicious acts and against misappropriation of nuclear materials. The Convention came into force on 8th February 1987. It had 145 contracting parties in 2014.

Additional information on these conventions may be obtained from the IAEA website: *www-ns.iaea.org/conventions/*

5. BILATERAL RELATIONS

ASN collaborates with numerous countries through bilateral agreements, which can take the form of governmental agreements (such as with Germany, Belgium, Luxembourg and Switzerland) or administrative arrangements between ASN and its counterparts (about twenty). ASN intends to share its best practices and conversely to understand the methods used elsewhere in the approach to safety. The activities of ASN and its counterparts vary according to the safety and radiation protection topics which emerge nationally (legislation, safety topics, incidents, inspection approach, etc.).

5.1 Staff exchanges between ASN and its foreign counterparts

Better understanding how foreign nuclear safety and radiation protection regulators actually function is a way to learn pertinent lessons for the working of ASN itself and enhance staff training. One way to achieve this goal is to develop the staff exchange system.

Provision is made for several types of exchange:
- very short term actions (a few days) are a means of offering our counterparts a chance to take part in peer-observation of inspections and nuclear and radiological emergency exercises. In 2015, just under 40 peer observations were organised in the field of nuclear safety and radiation protection with Germany, Belgium, Brazil, Bulgaria, China, South Korea, Spain, Finland, Ireland, Japan, Luxembourg, Netherlands, Poland, Russia and Switzerland;
- short-term assignments (2 weeks to 6 months) aimed at studying a specific technical topic;

• long-term exchanges (about one to three years) for immersion in the working of foreign nuclear safety and radiation protection regulators. Whenever possible, this type of exchange should be reciprocal.

For many years, ASN and the ONR (Office for Nuclear Regulation – United Kingdom) have engaged in long-term staff exchanges. Since June 2014, an ASN staff member has been seconded to ONR, to join the Sellafield programme for a three-year period. This programme is one with major implications for the ONR in the coming years, in some respects very similar to those being encountered in France with the fuel reprocessing facilities (for example La Hague).

An ASN engineer has been seconded to the Spanish safety regulator (CSN – *Consejo de Seguridad Nuclear)* since February 2014, working in the division responsible for radiological emergencies.

In August 2013, the secondment of an ASN staff member to the American safety regulator began for a period of three years. He is more specifically working in the field of Social, Human and Organisational Factors (SOHF). Since the beginning of March 2015, ASN has also hosted a member of the NRC for a period of one year. This NRC representative is working in the Nuclear Power plant Department (DCN) on drafting inspection guides, more specifically with regard to the flooding risk. At the beginning of 2016, another NRC representative joined the DCN in place of his colleague.

Staff exchanges are also organised with international organisations. For instance, a member of ASN has been working at IAEA since autumn 2010, in the team tasked with organising Integrated Regulatory Review Service (IRRS) assignments. Finally, ASN is seconding two of its staff to NEA, on the one hand to contribute to the work of the MDEP technical secretariat and, on the other, to assist the Safety Department.

These staff exchanges or secondments are a means of enhancing ASN practices. Experience acquired over more than ten years now indicates that inspector exchange programmes make a significant contribution to stimulating bilateral relations between nuclear safety and radiation protection regulators.

It is also worth underlining the appointment of representatives of foreign safety regulatory bodies to the Advisory Committees of Experts. ASN has adopted this practice, which enables experts from other countries not only to take part in these advisory committees, but also occasionally to act as Chair or Deputy Chair.

5.2 Bilateral cooperation between ASN and its foreign counterparts

Bilateral relations between ASN and its foreign counterparts are built around an approach that integrates nuclear safety and radiation protection for each of the countries with which ASN maintains relations. The following can be offered as examples:

South Africa

In 2015, active technical exchanges continued between ASN and its South African counterpart, the National Nuclear Regulator (NNR). The main exchanges covered the question of steam generator renewal. The NNR is preparing to examine the replacement file for the steam generators in the Koeberg NPP and wishes to draw on ASN's experience in this field. Two technical meetings were therefore held in France in 2015. The first was in Lyon, to discuss the inspection process and its implementation. The second took place in Dijon in October, to examine the more technical aspects of regulation.

Germany

The 41st French-German Commission for nuclear facility safety issues *(Die Deutsche-Französische Kommission für Fragen der Sicherheit kerntechnischer Einrichtungen* – DFK) was held in June 2015 in Cherbourg. This annual meeting enabled the two delegations to present topical matters related to nuclear safety and radiation protection, as well as the annual reviews concerning the safety of the Fessenheim and Cattenom NPPs in France and Neckarwestheim and Philippsburg in Germany. The representatives of the four thematic working groups set up by the DFK also presented their work. The decision was taken to terminate the 4th Working Group (WG) on small-scale nuclear activities as its work was considered to duplicate that carried out in multilateral forums such as HERCA. The two delegations had the opportunity to visit the EPR construction site at Flamanville.

Belgium

ASN enjoys long-standing and regular relations with its Belgian counterpart, AFCN (Federal Agency for Nuclear Regulation), and Bel V, its technical support organisation, on a variety of subjects (power and research reactors, cyclotrons, radiation protection in particular in the medical field, radon, transport, etc.).

In addition to the periodic meetings on the safety of nuclear facilities (two meetings per year) and transport (one meeting per year), AFCN and ASN are also continuing their exchange of experience of the regulation of facilities such as the *Institut national des Radioéléments (IRE)* in Belgium or CIS bio international in France.

As in previous years, several peer observations of inspections were organised with ASN's Belgian counterparts, whether in the NPPs or in the field of small-scale nuclear activities.

Worth noting is the signature in March 2015 of a convention on the rapid exchange of information between ASN's Châlons-en-Champagne, Lille and Strasbourg divisions on the one hand, and AFCN on the other. This convention concerns situations in sites holding nuclear or radiological materials close to the Franco-Belgian border. This convention came into effect on 1st March 2015.

The annual meeting of the Franco-Belgian steering committee, co-chaired by Pierre-Franck Chevet and Jan Bens, Director General of AFCN, was held on 28th May 2015 at the AFCN headquarters in Belgium. On the sidelines of this meeting, the ASN delegation visited the Tihange NPP site and looked at the reinforcement work currently in progress as part of the post-Fukushima measures.

Since 2015, internal training has been organised by ASN for AFCN and Bel V personnel. About ten staff members from these entities were able to benefit from this training. Conversely, two ASN staff members followed training proposed by AFCN concerning the Belgian guides published on the safety levels of the new reactors.

China

ASN and its Chinese counterpart, NNSA (National Nuclear Safety Administration), renewed their overall nuclear safety and radiation protection cooperation agreement in 2014, expanding the scope of this agreement to include radioactive waste management and fuel cycle facilities. The specific cooperation agreement on the EPR was also extended by five years.

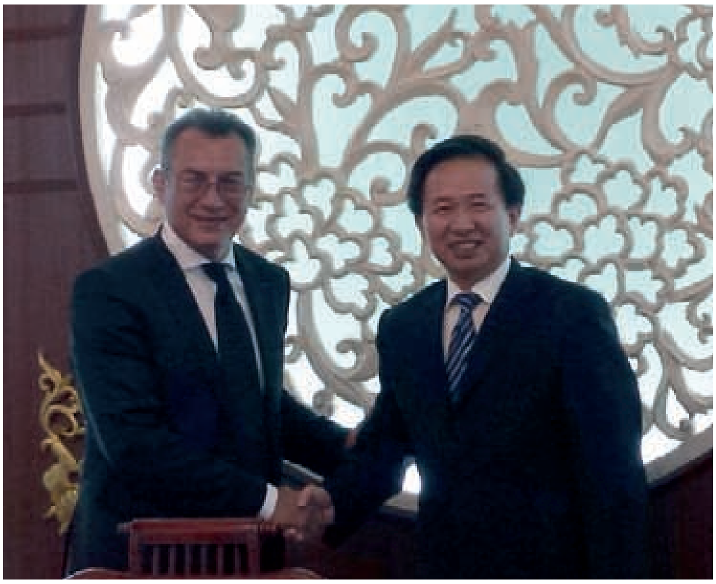
A steering committee combining the French and Chinese safety regulators thus met in Beijing on 20th and 21st July 2015. The ASN Chairman, Pierre-Franck Chevet, and the Deputy Minister in charge of environmental protection and nuclear safety, Li Ganjie, the Administrator of the NNSA, presented the activity of the two safety regulators and the corresponding issues and challenges. To conclude the exchanges between the two delegations, a cooperation action plan between ASN and NNSA was drafted. It comprises six topics, including greater cooperation on the EPR, the safety of existing reactors, personnel exchanges between the two regulators and information of the public.

Following this meeting, the delegation headed by Pierre-Franck Chevet went to the Taishan site where two EPR reactors are being built. Some members of the delegation also visited the Daya Bay NPP in Shenzhen, north of Hong Kong.

The ASN Lyon division has also enjoyed close relations with the NNSA's Guangdong division for several years. In January 2015, three inspectors from the Lyon division thus took part in an in-depth inspection of the NNSA concerning preparations for the first outage of reactor 1 on the Yang Jiang nuclear site. In return, in November 2015, three NNSA inspectors observed an ASN worksite inspection on reactor 2 in the Cruas NPP. They also visited the Areva nuclear fuels fabrication site in Romans-sur-Isère (see chapter 8).

Within the framework of the Instrument for Nuclear Safety Cooperation (INSC), the consortium set up by ASN, comprising the nuclear safety regulators from Spain (CSN, Consejo de Seguridad Nuclear) and Finland (STUK, Säteilyturvakeskus), along with the technical support organisations from France (IRSN), Germany (GRS, Gesellschaft für Anlagen und Reaktorsicherheit) and Belgium (Bel V), in response to the call for proposals from the European Commission, assisted China with its process to improve the regulatory framework applicable to nuclear safety. This assistance project, which began in December 2013, will end in 2016.

This programme comprises six areas for work: firstly, the aim is to support NNSA and its technical support organisation the NSC (Nuclear Safety Center) in their NPP reactor authorisation assessment procedures. The second goal is to help them perform these assessments in complete independence from the operator. The other areas for work are: improving the evaluation procedures for new technologies (of particular importance because China is currently building new reactors), flood protection in the NPPs and the development of operating experience feedback analysis. Finally, the aim is to reinforce the safety culture of our counterparts.



ASN-NNSA bilateral meeting In Beijing (China), 19th-23rd July 2015. Pierre-Franck Chevet and Ganjie Li, Deputy Minister responsible for environmental protection and nuclear safety, Administrator of the NNSA.

Visit to the Taishan NPP (China) on the occasion of the ASN-NNSA bilateral meeting, 19th-23rd July 2015.

South Korea

As part of the process of exchanges between inspectors initiated in 2013, a South Korean delegation comprising inspectors from the NSSC (Nuclear Safety and Security Commission) and the KINS (Korean Institute of Nuclear Safety) met the ASN Bordeaux division. A first bilateral meeting compared French and Korean safety requirements concerning protection against flooding and managing the ageing of components. This meeting was followed by an inspection in the Le Blayais NPP. The Korean inspectors were able to observe an inspection. They then described the differences with respect to their own practices at a meeting held following the inspection (see chapter 8 concerning the regional overview of nuclear safety and radiation protection).

Spain

The meeting by the steering committee of the two regulators was held on 5th March 2015. The Spanish delegation, led by the CSN Chairman, Fernando Marti Scharfhausen, met the ASN Chairman and a number of its Commissioners. The two entities discussed a number of topics, including:
- taking part in emergency exercises;
- participating in peer inspections;
- discussing best practices in the field of radiotherapy in France and Spain.

The ASN Bordeaux division also took part in a medical peer inspection in Madrid, in October 2015.

In the same spirit of cooperation between the two entities, ASN received a CSN delegation to observe the emergency exercise in the Civaux NPP on 22nd September 2015. The next meeting of the steering committee of the safety regulators is scheduled for May 2016 in Madrid.

United States

ASN and NRC, its American counterpart, maintained a high level of cooperation in 2014 on a variety of topics (action carried out with regard to the lessons learned from the Fukushima Daiichi accident, operating life extension of reactors in service, etc.).

The two regulators restated their joint desire to continue with personnel exchanges and are already preparing the secondments planned as of 2016.

The following exchanges should in particular be mentioned:
- April 2015: organisation of an audio-conference between ASN, the NRC and the Canadian Nuclear Safety Commission (CNSC);
- June 2015: technical meeting with an NRC delegation followed by a visit to the La Hague facilities to look at the regulation of fuel cycle facilities;
- June 2015: presentation by an ASN expert at the annual FCIX (Fuel Cycle Information Exchange) conference;
- July 2015: observation by Jean-Luc Lachaume of a national emergency exercise organised at the Robinson NPP (South Carolina) and meetings with NRC experts from head office and from a regional office (equivalent to an ASN regional division).

These actions are coordinated by the steering committee, co-chaired by Jean-Christophe Niel and Marc Satorius, his American counterpart. The last meeting was held at NRC headquarters in March 2015.

The Russian Federation

Under the terms of the bilateral cooperation between the Russian safety regulator *Rostekhnadzor* (RTN) and ASN, an action protocol was decided on in 2011. The following measures were taken in 2015:
- A delegation of staff from RTN took part in a peer-inspection on 25th February 2015 at the Val-de-Grâce hospital in Paris.

- A delegation of ASN staff took part in a medical peer-inspection on 27th May 2015 on the site of the Berezin International Institute of biological systems in Saint-Petersburg.
- A delegation of staff from ASN went to Moscow on 7th and 8th July 2015 to continue to share the lessons learned from the stress tests performed on the NPPs in France and Russia. The aim was to discuss the hypotheses adopted in the assessment of safety margins.

In parallel with the IAEA general conference, on 15th September 2015, Pierre-Franck Chevet and Alexey Ferapontov, Deputy Director of RTN, met to review the progress of the cooperation between the two entities. The subjects covered included the organisation of peer inspections on research reactors and they discussed the benefits to be gained from exchanges concerning Periodic Safety Reviews in the stress tests follow-up context.

Finland

There has been longstanding cooperation between ASN and its Finnish counterpart STUK, especially in the area of the management of waste and of spent fuel. But cooperation has been significantly enhanced in recent years owing to the construction of an EPR type reactor at the Finnish site of Olkiluoto (see chapter 12 point 2.10.3).

Ireland

In 2015, ASN continued its collaboration with its Irish counterparts. A bilateral meeting held in January in Dublin, enabled ASN to make contact with its new interlocutor, the Environmental Protection Agency (EPA). EPA has been in charge of radiation protection issues since its 2014 merger with the Radiological Protection Institute of Ireland (RPII), with which ASN has always maintained close cooperative relations. This cooperation in particular concerns management of the radon risk, which is a common concern and a subject of past and future collaboration, as is harmonisation of emergency management. Medical peer inspections are thus planned. Finally, as mentioned in point 3 of this chapter, Margot Tirmarche led an IRRS mission to Ireland in August-September 2015.

Israel

Even if regular exchanges were held in the past between ASN and its Israeli counterpart, the NLSO (Nuclear Licensing and Safety Office), linked to the IAEC (Israel Atomic Energy Commission), 2015 provided an opportunity to consolidate the relations between the two entities, with the aim of signing a bilateral ASN-NLSO agreement at the end of the year. This cooperation would primarily concern the safety of research reactors, nuclear waste management and radiation protection; it would also promote personnel exchanges.

An NLSO delegation, led by its Director, Meir Markovits, was therefore received in Montrouge in July 2015 by Jean-Luc Lachaume. A bilateral meeting was held on this occasion, followed by a visit organised by the Caen division to the Ganil accelerator, in particular the Spiral 2 facility currently under construction.

Meeting with NRC Commissioner Stephen G. Burns, Washington (United States), 15th March 2015 (from left to right: Philippe Jamet, ASN Commissioner, Stephen G. NRC Chairman and Jean-Christophe Niel, ASN Director General).

Furthermore, on the sidelines of the IAEA General Conference, on 16th September 2015, an ASN delegation led by Commissioner Philippe Jamet met the Director of the NLSO, to review cooperation between the two entities and confirm the planned bilateral agreement.

Japan

Under the arrangements between ASN and its Japanese counterpart, the NRA (Japan's Nuclear Regulation Authority), a bilateral steering committee meeting was held in France on 9th and 10th September 2015. The particularly warm exchanges notably concerned the measures linked to the restart of reactors and the situation on the site of the Fukushima Daiichi NPP, the monitoring of implementation of "post-Fukushima" measures in France and the management of radioactive waste. This meeting was followed by a visit to the Aube repository and Andra's Bure underground laboratory.

Since 2010, the ASN Lyon division has maintained regular relations with the Japanese safety regulator, NRA, and its technical support organisation, JNES (Japan Nuclear energy Safety Organisation, now integrated into the NRA) and in 2015 it received a delegation of Japanese inspectors. The discussions concerned safety culture and the integration of SOHF. A visit to the EPR construction site at Flamanville was also organised (see chapter 8).

Norway

The annual bilateral meeting between the NRPA (Norwegian Radiation Protection Authority) and ASN was held in November 2015 in Oslo, as part of the follow-up to the cooperation agreement signed in December 2011.

This meeting was an opportunity to review the cooperation measures initiated in a number of fields. On the topic of radon, ASN and the NRPA concluded that the two workshops held in 2014 and 2015 had been extremely fruitful. With regard to the security of radioactive sources, the two regulators will continue their collaboration, in particular under an international initiative which aims to promote the search for alternatives to the use of high-level sources. In the field of emergency management, ASN, which received a Norwegian observer during a French emergency exercise in October 2015, will be invited to observe an exercise scheduled in Andreev Bay in May 2016. It was also agreed that NRPA inspectors will be able to follow a research reactor inspection carried out in France by ASN in 2016.

Netherlands

In 2015, the Netherlands decided to group all the departments in charge of nuclear safety and radiation protection currently spread around the various ministries within a single independent regulator called the ANVS (Authority for Nuclear Safety and Radiation Protection). ASN will continue to develop and strengthen its cooperation with the ANVS in the future.

United Kingdom

Cooperation between ASN and the British safety regulator (ONR – Office for Nuclear Regulation) has been expanded over the years. In September 2013, a new cooperation and information exchange agreement was signed by ASN and the ONR. This agreement was supplemented in September 2014 by a cooperation protocol to more precisely define the nature of the cooperative work between the two entities and to define a certain number of working groups for improved oversight of the work performed jointly (see chapter 12 point 2.10.3).

Sweden

Under the cooperation and information exchange agreement signed by ASN and its Swedish counterpart, the SSM *(Strål Säkerhets Myndigheten)* in September 2013, a delegation from the ASN Orleans division went to Sweden in June 2015 to take part in an inspection to verify the licensee's adoption of post-Fukushima measures on the Ringhals site.

Switzerland

ASN enjoys long-standing and regular relations with its Swiss counterpart, the IFSN (Federal Nuclear Safety Inspectorate) on a variety of subjects (safety of nuclear facilities, radiation protection in the medical field, preparedness for and management of emergency situations, transport, etc.).

Working groups meet periodically to discuss subjects related to transport and to preparedness for emergency situations (experience feedback and exchanges of best practices).

The 26th annual meeting of the Franco-Swiss nuclear safety and radiation protection committee, co-chaired by Pierre-Franck Chevet and Hans Wanner, Director General of the IFSN, took place from 31st August to 1st September 2015 in Spiez, Switzerland. One notable decision was to initiate exchanges on the reactor vessels problem on each side of the border and to continue the discussions on the regulation of geological disposal sites. The organisation of personnel exchanges was also discussed.

The meeting was preceded by a visit to the NRBC LaborSpiez centre which works closely with IAEA, in particular on the topic of non-proliferation.

5.3 ASN bilateral assistance

In 2015, at their request, ASN had contacts with several safety regulators in countries looking to find out about the safety measures to be implemented (creation of a nuclear safety regulatory and oversight infrastructure).

In line with its policy, ASN responds to these requests as part of its bilateral actions with the safety regulator of the country concerned, in addition to instruments that are either European (EU Instrument for Nuclear Safety Cooperation – INSC) or international (IAEA's Regulatory Cooperation Forum – RCF). The purpose of this cooperation is to enable the beneficiary countries to acquire the safety and transparency culture that is essential for a national system of nuclear safety and radiation protection oversight. Nuclear safety oversight must be based on national competence and ASN consequently only provides support for the establishment of an adequate national framework and advises the national safety regulator, which must retain full responsibility for its oversight of the nuclear facilities. It pays particular attention to countries acquiring technologies of which it has experience in France.

ASN considers that developing an appropriate safety infrastructure takes at least fifteen years before operation of a nuclear power reactor can begin in good conditions. For these countries, the goal is to set up a legislative framework and an independent and competent safety regulator with the financial and human resources it needs to perform its duties and to develop capacity in terms of safety, safety and regulatory culture and oversight of radiological emergency management.

In 2015, ASN had contacts with the following safety regulators:

Poland

A bilateral meeting was held in Paris between ASN and its Polish counterpart, the PAA *(Panstwowa Agencja Atomistyki* or National Atomic Energy Agency) in July 2014. On the occasion of this meeting, various safety topics were discussed: the steps in the power reactor operations licensing process, cooperation policy with the safety regulator technical support organisations, the policy of public communication and transparency.

One of the main concrete decisions of this first ASN-PAA bilateral meeting was the proposed training of PAA staff by ASN teams, in particular concerning the process to issue operating licenses for power reactors as mentioned above. Four trainees thus spent a month at ASN in June 2015, firstly at the headquarters in Montrouge and then in the Caen, Dijon and Marseille divisions.

To maintain the momentum of these exchanges between France and Poland, a seminar – once again on the process for the issue of operating licenses for power reactors – was organised in December 2015 in Warsaw. ASN and IRSN gave presentations, as did the PAA.

Turkey

Pierre-Franck Chevet met his counterpart during the IAEA General Conference on 15th September 2015, in order to continue with the exchanges between the two authorities and establish a cooperation programme for 2016.

Vietnam

In 2015, ASN ran an assistance programme in Vietnam through the Instrument for Nuclear Safety Cooperation (INSC), in order to develop its safety, safety culture and monitoring capacity. This assistance project, which started in 2012, was scheduled to last for three years and ended in May 2015.

ASN is also involved in assistance to Vietnam via the RCF, the forum for exchanges between safety regulators, created under the aegis of IAEA. In this context, a meeting was held on 20th and 21st May 2015 in Brussels, with a view to facilitating the sharing of experience between regulators and rationalising the assistance given to those countries looking to develop nuclear energy.

RCF-INSC meeting at the European Commission, Brussels,19th-20th May 2015.
Left to right Jean-Luc Lachaume, ASN Deputy Director General, Adriana Nicic, head of Regulatory activities section, IAEA.

TABLE OF AREAS OF COMPETENCE of the main civil nuclear activity regulating authorities*

COUNTRY/ SAFETY AUTHORITY	STATUS			ACTIVITIES						
	ADMINIS-TRATION	GOVERNMENT AGENCY	INDEPENDENT AGENCY	SAFETY OF CIVIL INSTALLATIONS	RADIATION PROTECTION			SECURITY (PROTECTION AGAINST VANDALISM AND MALICIOUS ACTS)		TRANSPORT SAFETY
					BNI	OTHER INSTALLATIONS	PATIENTS	SOURCES	NUCLEAR MATERIALS	
EUROPE										
Germany/ BMUB + Länder	•			•	•	•	•	•	•	•
Belgium/ AFCN		•		•	•	•	•	•	•	•
Spain/CSN			•	•	•	•	•	•	•	•
Finland/ STUK		•		•	•	•	•	•	•	•
France/ASN			•	•	•	•	•	•***		•
United Kingdom/ ONR		•		•	•			•	•	•
Sweden/SSM		•		•	•	•	•	•	•	•
Switzerland/ENSI			•	•	•				•	•
OTHER COUNTRIES										
Canada/CCSN			•	•	•	•	•	•	•	•
China/NNSA	•			•	•	•		•	•	•
South Korea/NSSC		•		•	•	•			•	•
United States/ NRC			•	•	•	•	•	•	•	•**
India/AERB		•		•	•	•	•	•	•	•
Japan/NRA	•		•	•	•	•	•	•	•	
Russia/ *Rostekhnadzor*	•	•		•	•			•	•	•
Ukraine/ SNRIU	•	•		•	•	•		•	•	•

** Schematic, simplified representation of the main areas of competence of the entities (administration, independent agencies within government or independent agencies outside government) responsible for regulating nuclear activities in the world's nuclear countries.*
***National transports only.*
**** Responsibility for source security was given to ASN by the Ordinance of 10th February 2016. This provision will come into force no later than 1st July 2017.*

6. OUTLOOK

In 2016, ASN will continue its work to develop the European approach to nuclear safety and radiation protection.

Following on from the lessons to be learned from the Fukushima Daiichi accident, a review has in particular been initiated on the European approach to the prevention and management of a nuclear accident. The approach proposed by HERCA and WENRA is promising and will be taken further with a programme to raise the awareness of national departments in charge of civil protection of the general population. WENRA and HERCA succeeded in defining a number of joint key principles which should enable decisions to be harmonised and resources to be shared in the case of a nuclear accident on a scale such as that at Fukushima Daiichi. This approach constitutes a basis for a European approach to preparedness for emergency situations and this work will need to be continued. Over and above considerations regarding the technical specifications linked to the Fukushima Daiichi accident (protection against external hazards, reinforced reactor containment integrity, consideration of Social, Organisational and Human Factors – SOHF, etc.), on an international level ASN will continue to disseminate the following messages:

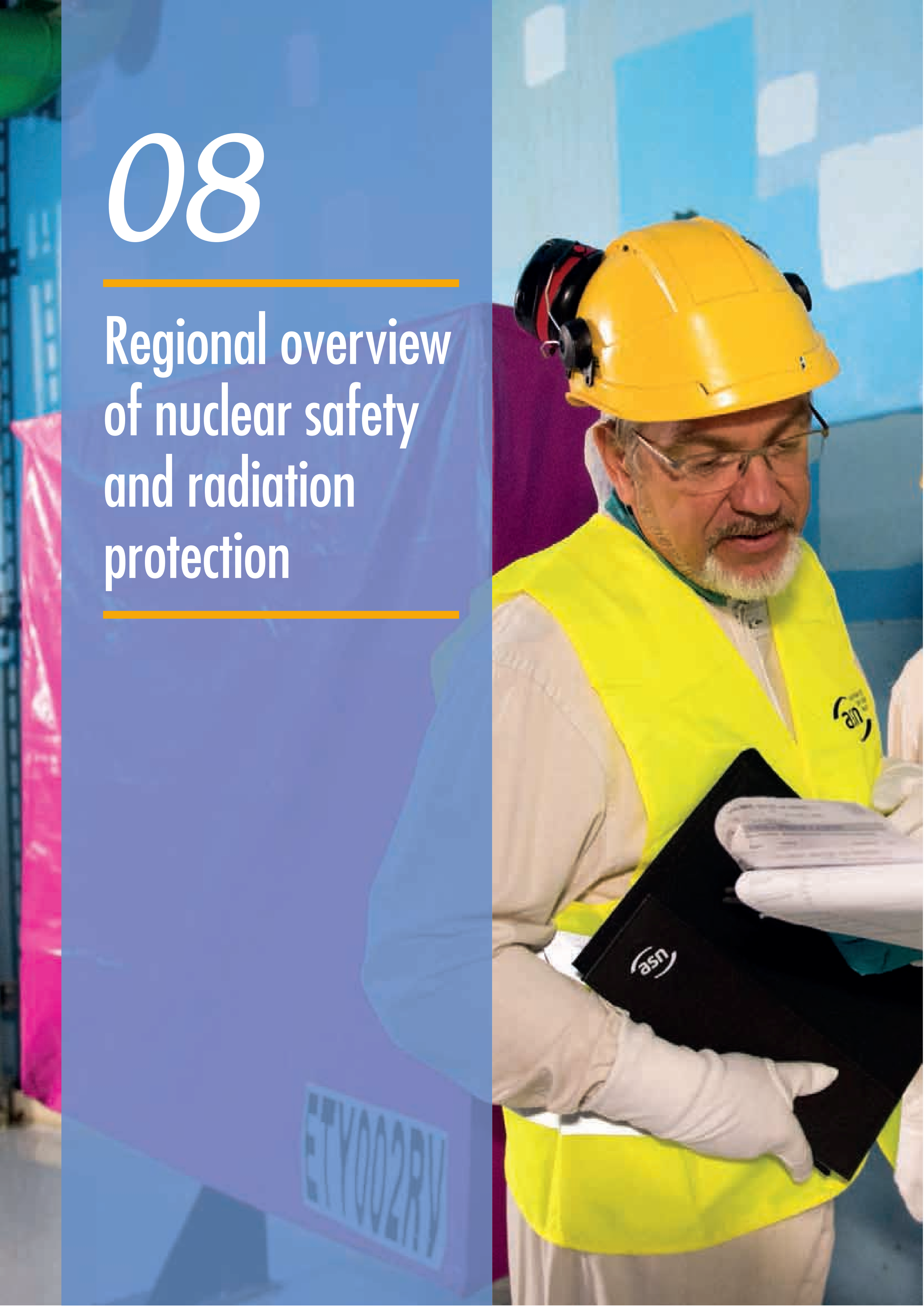
- There is a before and after Fukushima Daiichi. At least ten years will be needed before we have learned all the lessons from the Fukushima Daiichi accident and understood all the technical and SOHF implications.
- Questions must be asked regarding the international actions that could have helped to avoid the Fukushima Daiichi accident.

In 2016, ASN aims to focus primarily on several events:

- The 7th review meeting of the Convention on Nuclear Safety in 2017 will be a key date in the international safety calendar. ASN will coordinate the preparation and the drafting of the national report, to be submitted to IAEA on 15th August 2016.
- in the future, taking account of the lessons learned from the Fukushima Daiichi accident as described in the IAEA report published in September 2015 on the occasion of its 59th General Conference;
- the review initiated by INRA concerning the effectiveness of IAEA's IRRS audits and greater coordination of the OSART missions and WANO peer reviews;
- promotion of the HERCA-WENRA approach on transboundary cooperation in the prevention and management of emergency situations, adopted on 21st October 2014.

08

Regional overview of nuclear safety and radiation protection



THE STATE OF NUCLEAR SAFETY AND RADIATION PROTECTION IN 2015:

ASN has 11 regional divisions through which it carries out its regulatory responsibilities nationwide and in the French overseas *départements* and collectivities.

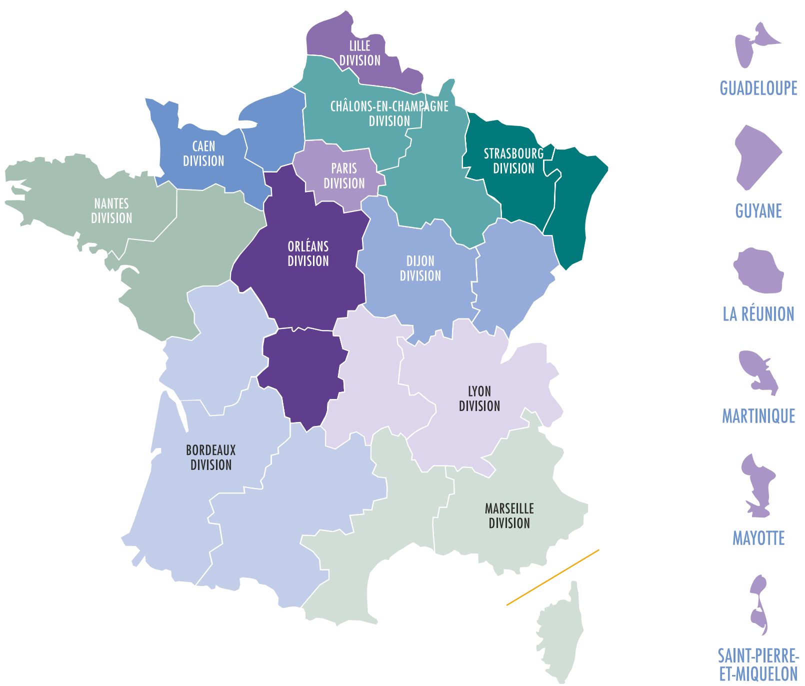
The activities of the ASN regional divisions are carried out under the authority of the regional ASN representatives (see chapter 2 - point 2.3.2).

The ASN regional divisions carry out direct inspections on the Basic Nuclear Installations (BNIs), on radioactive substances transport and on small-scale nuclear activities and investigate most of the licensing applications submitted to ASN by the nuclear activity licensees within their regions. The regional divisions check application within these installations of the regulations relative to nuclear safety and radiation protection, to pressure equipment and to Installations Classified on Environmental Protection grounds (ICPEs). They ensure the labour inspection in the nuclear power plants.

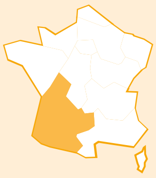
In radiological emergency situations, the regional divisions assist the Prefect of the *département*, who is responsible for protection of the public, and check the measures taken on the site by the licensee to make the installation safe. To ensure preparedness for these situations, they take part in preparing the emergency plans drafted by the Prefects and in periodic exercises.

The ASN regional divisions contribute to the public information duty. They for example take part in the meetings of the Local Information Committees (CLIs) of the BNIs, and maintain regular relations with the local media, elected officials, associations, licensees and local administrations. The purpose of this chapter is to present, in addition to ASN's overall assessment of nuclear safety and radiation protection for each major activity and main licensee, an assessment of the situation observed by the ASN regional divisions. Each section addresses the nuclear safety and radiation protection aspects of the nuclear facilities on the sites in a particular region. It also provides insight into the local issues and identifies certain initiatives that are particularly representative of ASN's regional action, particularly in terms of communication and cross-border relations.

THE REGIONAL ORGANISATION of ASN



* *The Overseas* départements *and regions and the Overseas communities (DROM-COM) are under the responsibility of the Paris division.*



THE STATE OF NUCLEAR SAFETY AND RADIATION PROTECTION IN 2015 IN THE AQUITAINE, POITOU-CHARENTES AND MIDI-PYRÉNÉES REGIONS REGULATED BY **THE BORDEAUX DIVISION**

The Bordeaux division is responsible for regulating nuclear safety, radiation protection and the transport of radioactive substances in the 17 *départements* of the Aquitaine, Poitou-Charentes and Midi-Pyrénées regions.

As at 31st December 2015, the workforce of the Bordeaux division stood at 22 officers: 1 regional division head, 2 deputy heads, 15 inspectors and 4 administrative officers, under the authority of the ASN regional representative.

The activities and installations to regulate comprise:

- the nuclear power plants of Blayais (4 reactors of 900 MWe), Civaux (2 reactors of 1,450 MWe) and Golfech (2 reactors of 1,300 MWe) operated by EDF;
- 23 external-beam radiotherapy departments;
- 9 brachytherapy departments;
- 28 nuclear medicine departments;
- 186 interventional radiology structures;
- 140 tomography devices;
- about 6,900 medical and dental;
  diagnostic radiology devices;
- about 1,500 veterinary diagnostic radiology devices;
- 50 industrial radiography companies;
- 600 industrial research establishments.

In 2015, ASN carried out 167 inspections in the Aquitaine, Poitou-Charentes and Midi-Pyrénées regions, comprising 46 inspections in the area of nuclear safety in the Blayais, Civaux and Golfech NPPs, 5 inspections in the transport of radioactive substances and 116 inspections in small-scale nuclear activities. ASN carried out 34 days of labour inspections in the nuclear power plants.

During 2015, six significant events rated level 1 on the INES scale and one event rated level 2 were notified by nuclear installation licensees in these regions. In the small-scale nuclear activities in these regions, 2 level 2 significant events and 3 level 1 significant events on the INES scale were notified to ASN. Added to these are the events concerning radiotherapy patients, which included 20 events rated level 1 on the ASN-SRFO scale.

Within the framework of their oversight duties in south-west France, the ASN inspectors issued three violation reports. ASN also served formal notice on the head of a nuclear activity at the Jacques Puel de Rodez Hospital Centre to comply with certain provisions of the Public Health Code.

1. ASSESSMENT BY DOMAIN

1.1 The nuclear installations

Blayais nuclear power plant

ASN considers that the nuclear safety, radiation protection and environmental protection performance of the Blayais NPP is, on the whole, in line with its general assessment of EDF's performance.

ASN has noted the smooth running of the four reactor outages for maintenance and refuelling. Although the ten-year outages of reactors 3 and 4 ran concomitantly and the site had occasional problems with procuring various supplies, this situation had no notable effects on the safety of the facilities. In this respect, the regulatory inspections performed by ASN on the main primary system of reactors 3 and 4 and on the main secondary systems of reactor 3 revealed no particular malfunctions of these systems.

However, as in 2014, ASN noted that the site experienced some difficulties in maintenance. The efforts must be maintained with regard to work preparation, particularly by ensuring as a matter of course that experience feedback from similar operations is taken into account.

On the other hand, with regard to radiation protection, ASN notes that the site must improve the control of radiation protection on the worksites conducted during the reactor shutdowns. Several significant radiation protection events particularly noteworthy were thus notified during the shutdowns, one concerning an operator who received a dose exceeding a regulatory limit when working on a heat exchanger of the chemical and volumetric control system of the primary system of reactor 4.

With regard to environmental protection, ASN notes the efforts made by the site to limit cooling fluid discharges.

Civaux nuclear power plant

ASN considers that the nuclear safety and environmental protection performance of the Civaux site is on the whole in line with ASN's general assessment of EDF and that the site's radiation protection performance stands out positively with respect to the said general assessment.

The scheduled outage for partial inspection of reactor 2 went well on the whole. It was marked in particular by the performance of the main secondary system hydraulic test. ASN considers that the licensee must continue the efforts undertaken since 2014 regarding rigour in the preparation, performance and inspection of certain operating and maintenance activities.

ASN inspection at the Civaux NPP, June 2015.

In line with preceding years, ASN notes that radiation protection is integrated satisfactorily in work preparation and performance. It nevertheless considers that the site must increase compliance with the protective measures identified in the risk analyses.

With regard to the environment, ASN considers that the performance of the site is, on the whole, in line with ASN's general assessment of EDF performance. ASN notes that the site has accomplished a substantial amount of document updating further to the in-depth inspection of 2013. ASN does however consider that the site must remain vigilant with regard to the rigour it applies to the operation of the equipment involved in environmental protection.

Golfech nuclear power plant

ASN considers that the nuclear safety and environmental protection performance of the Golfech NPP is on the whole in line with ASN's general assessment of EDF and that the site's radiation protection performance stands out positively with respect to the said general assessment.

The scheduled shutdown for partial inspection of reactor 2 went well on the whole, especially the operations for requalification of the residual heat removal system (RRA) which were carried out for the first time on the nuclear reactor fleet. ASN notes an improvement in the control of maintenance operations with respect to the preceding year. ASN considers however that the licensee must improve monitoring by the control room teams and show greater rigour in application of the operational management baseline requirements. Furthermore, ASN considers that the licensee must improve the formalisation of its integrated management system and the recording and handling of deviations.

With regard to environmental protection, the licensee has undertaken rehabilitation work on its demineralisation station. The licensee has implemented operational management rules in the control room that improve operational control of the equipment contributing to environmental protection. ASN notes however that work is necessary to increase the reliability of the equipment for measuring the environmental impact of discharges.

With regard to radiation protection, the site maintains satisfactory results for collective dosimetry and the radiological cleanliness of the installations.

Labour inspection in the nuclear power plants

ASN continued its inspections on the activities involving an asbestos risk, particularly during reactor outages for maintenance. Several failures to meet regulatory obligations were again observed in 2015. The labour inspectors also conducted inspections regarding protection against noise-related risks, the regulatory verifications of the facilities and work equipment and continued the actions undertaken since 2013 on the lifting equipment. The corrective action plans established by the licensees are still to be carried through to completion. Lastly, specific inquiries were carried out following workplace accidents.

1.2 Radiation protection in the medical field

Radiotherapy

The inspection of the radiotherapy departments in 2015 continued to verify application of the ASN resolution relating to the quality and safety of radiotherapy treatments. ASN carried out 20 inspections, nine of which focused on the commissioning of new particle accelerators. ASN notes that these renewals have doubled compared with 2014 and are accompanied by a significant increase in the deployment of new treatment techniques by radiotherapy departments.

ASN also considers that in 2015 the radiotherapy centres continued their efforts in the implementation of their quality management system. ASN nevertheless observed difficulties in carrying out and keeping up to date the analysis of the potential risks for patients. ASN verified that the controls for which the radiotherapists and medical physicists are responsible at all stages in the treatment of patients undergoing external-beam radiotherapy are performed and correctly recorded. ASN has observed that these controls are on the whole implemented in the centres it inspected in 2015.

ASN also focused on verifying the adequacy of the resources devoted to medical radiation physics, the relevance of the medical physics organisation plan and the performance of quality controls. Its assessment of these areas is satisfactory on the whole.

ASN considers moreover that the occupational radiation protection measures are correctly applied in the radiotherapy departments.

Interventional practices

ASN continued its inspections in the area of interventional practices (see chapter 9, point 1.1.2). Thirty centres were inspected on this theme in 2015.

With regard to patient radiation protection, ASN endeavoured to check the dispensing of training in patient radiation protection, the presence of radiographers and performance of the quality controls of the devices used.

With regard to occupational radiation protection, ASN systematically examined the means of worker dosimetric monitoring, performance of the technical radiation protection controls, performance of the work place analyses and the relevance of the zoning of the premises. ASN observes that operating theatre practitioners rarely comply with the regulations, particularly with regard to dosimetric and medical monitoring.

Particular focus was placed on application of ASN resolution 2013-DC-0349 setting the design rules for premises in which X-ray generators are used, and this will continue in 2016.

Nuclear medicine

ASN continues to inspect the nuclear medicine departments every three years. Its assessment of the integration of the measures designed to ensure the patient and worker radiation protection is positive on the whole.

Progress is nevertheless still required in the management of radioactive effluents.

1.3 Radiation protection in the industrial and research sectors

Industrial radiography

ASN continues to conduct regular inspections of industrial radiography activities in bunkers and on worksites. During the fourteen inspections it carried out in this sector in 2015, ASN observed progress in the areas of scheduling and performance of internal technical controls of radiation protection, the maintenance of industrial radiography devices and the conformity of protected bunkers dedicated to industrial radiography. The general organisation of personnel radiation protection, particularly with regard to training, dosimetric and medical monitoring of the personnel exposed to ionising radiation, remains satisfactory even if a few deviations are observed in these areas from time to time.

ASN considers however that the delimiting of the operation zone around industrial radiography worksites and the signalling of vehicles transporting radiology devices and the securing of these devices must be improved.

Since 2014, ASN has noted that the overall volume of worksite gamma radiography services has dropped in south-west France and that several local service providers have decided to stop this activity.

ASN also observes that several industrial radiography bunkers have been put into service in south-west France. ASN considers this to be a positive development which means that certain ordering customers will no longer have to use services under worksite conditions.

A significant radiation protection event rated level 2 on the INES scale was notified to ASN by the Colomier (Haute-Garonne *département*) agency of Apave Sud-Europe after an operator working in an X-ray radiography bunker exceeded the regulatory annual effective dose limit. The event resulted from intentional disabling of the bunker access door opening safety device (see chapter 10).

Universities and research centres

ASN considers that the research laboratories on the whole comply with the radiation protection requirements concerning training and the dosimetric and medical monitoring of personnel exposed to ionising radiation. Furthermore, the radiation doses received by the workers are low.

Nevertheless, the laboratories must improve their internal technical controls of radiation protection and their management of radioactive sources and contaminated waste. Several significant radiation protection events were notified to ASN further to the incidental discovery of radioactive sources.

More specifically, Bordeaux University informed ASN of the discovery of two radioactive sources in a laboratory room on the Carreire campus. Employees occupying a work station situated closed to the place in which the sources were stored were exposed to ionising radiation for several years. According to the university's evaluations, one of the persons working in the room received an effective dose approaching 20 millisieverts per year (mSv/an), while several other employees received doses slightly above 1 mSv/an. The event was rated level 2 on the INES scale (see chapter 10).

Lastly, ASN has endeavoured to verify that the universities, and especially the Universities of Toulouse and Poitiers, meet their commitments with regard to the disposal of expired sources and contaminated waste. Some progress has been noted but the actions engaged must continue in 2016.

1.4 Nuclear safety and radiation protection in the transport of radioactive substances

ASN carried out five inspections concerning the transport of radioactive substances by NPPs and small-scale nuclear activity licensees in south-west France in 2015.

ASN observes that on the whole, the radioactive substance reception and shipment process in the NPPs is well managed.

In the area of small-scale nuclear activities, ASN observes that the measures for managing radioactive substance transport operations are incomplete. The process for verifying the conformity of packages before shipment or on reception must be improved. The security protocols governing the loading and unloading of radioactive substance packages, as required by the regulations, are still too rarely drawn up.

1.5 Radiation protection of the public and the environment

Contaminated sites and soils

During 2105, ASN was involved in various files concerning sites and soils contaminated by radioactive substances.

Further to a proposal by ASN, a prefectural order was issued to govern the decontamination of a site in Bordeaux contaminated by radium.

ASN also issued an opinion on the remediation of the Boucau site (Pyrénées-Atlantiques *département*) contaminated by natural uranium and thorium as a result of a former monazite crushing activity.

The CLIs sent observers who attended several inspections carried out by ASN's Bordeaux division. The Golfech CLI in particular was involved in the inspections carried out during the second 10-year outage of reactor 2 of the Golfech NPP.

Travelling exhibition "*Nuclear safety ? A key issue!*"

As part of the population information campaign organised during the national emergency exercise held at the Civaux NPP on 22nd September 2015, ASN deployed the travelling exhibition *"Nuclear safety ? A key issue!"* in the municipalities situated near the NPP. The exhibition was set up in ten municipalities in succession between June and September. It received more than 300 visitors.

2. ADDITIONAL INFORMATION

2.1 International action

In 2015, the Bordeaux division received a delegation of inspectors from the South Korean Nuclear Safety and Security Commission (NSSC) and its technical support organization (KINS – Korean Institute of Nuclear Safety). The delegation accompanied the ASN inspectors during an inspection devoted to the control of ageing on the Blayais NPP. Discussions were also organised on inspection practices and flood protection requirements.

A delegation of inspectors from the Bordeaux division travelled to Madrid for a mission of interchange with the inspectors of CSN *(Consejo de Seguridad Nuclear)*, the Spanish safety and radiation protection authority. The interchanges focused on the application of the regulations concerning the radiation protection of people working in operating theatres, especially those using interventional radiology techniques. This mission also included interchanges with the authority in charge of patient radiation protection.

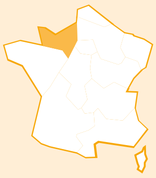
2.2 Informing the public

Press conferences

ASN held press conferences in Toulouse on 20th May 2015 and in Bordeaux on 9th June 2015 to present the state of nuclear safety and radiation protection in the Aquitaine, Poitou-Charentes and Midi-Pyrénées regions.

Work with the Local Information Committees (CLIs)

The Bordeaux division supported the work of the three CLIs in south-west France by participating in their annual general meetings and several technical committee meetings.



THE STATE OF NUCLEAR SAFETY AND RADIATION PROTECTION IN 2015 IN THE BASSE AND HAUTE-NORMANDIE REGIONS REGULATED BY **THE CAEN DIVISION**

The Caen division regulates nuclear safety, radiation protection and the transport of radioactive substances in the five *départements* of the Basse and Haute-Normandie regions. The Caen division also regulates the Brennilis NPP in the Bretagne region, which is undergoing decommissioning.

As at 31st December 2015, the workforce of the Caen division stood at 28 officers: 1 regional division head, 5 deputy heads, 18 inspectors and 4 administrative officers.

The activities and installations to regulate comprise:

- the NPPs of Flamanville (2 reactors of 1,300 MWe), Paluel (4 reactors of 1,300 MWe) and Penly (2 reactors of 1,300 MWe) operated by EDF;
- the Flamanville 3 EPR reactor construction site;
- the Areva NC spent nuclear fuel reprocessing plant at La Hague;
- the Andra Manche repository;
- Ganil National Large Heavy Ion Accelerator (Caen);
- the Brennilis NPP (Finistère *département*) undergoing decommissioning;

- 8 radiotherapy centres (21 machines);
- 3 brachytherapy departments;
- 11 nuclear medicine departments;
- 62 computed tomography departments;
- 35 interventional radiology departments;
- 750 medical diagnostic radiology devices;
- 1,400 dental diagnostic radiology devices;

- 18 industrial radiography companies;
- 250 industrial and research devices (including a cyclotron for the production of radionuclides);
- 6 head offices and 19 agencies of organisations approved for radiation protection controls.

ASN carried out 195 inspections of nuclear facilities in Normandy and Brittany in 2015, comprising 64 inspections on fuel cycle and research facilities, and facilities undergoing decommissioning, - including the Areva NC site at La Hague, the Manche repository, the Ganil and the Brennilis NPP undergoing decommissioning; 62 inspections in the EDF nuclear power plants in operation at Flamanville, Paluel and Penly; 20 inspections of EDF on the construction site of the Flamanville 3 EPR reactor and 49 inspections in small-scale nuclear activities.

In addition, ASN carried out 48 days of labour inspections in the nuclear power plants and on the Flamanville 3 construction site.

Sixteen events rated level 1 on the INES scale were notified by nuclear installation licensees of the Normandie and Bretagne regions in 2015. In addition, 3 events rated level 1 on the ASN-SFRO scale were notified by the heads of radiotherapy departments in the Normandie region. The inspections conducted in 2015 by ASN resulted in 3 violation reports being drawn up and submitted to the competent Public Prosecutors.

1. ASSESSMENT BY DOMAIN

1.1 The nuclear installations

Areva NC plant at La Hague

ASN considers that the situation of the plants operated by Areva NC on the La Hague site is relatively satisfactory with regard to nuclear safety, radiological exposure of the personnel and compliance with environmental discharge limits, but that Areva NC must continue its efforts to ensure the retrieval and packaging of the legacy waste stored on the site within the prescribed deadlines.

In the context of a procedure conducted by the Areva group, during 2015 Areva NC identified more than ten projects to introduce changes in industrial organisation on the La Hague site. ASN reminded Areva NC that a prerequisite for the implementation of such changes is that any impact they might have on safety provisions – especially in the areas of emergency situation management, skills management and the use of outside contractors – should be rigorously taken into account.

ASN considers that the projects for retrieving and packaging the legacy waste stored on the site must be carried out in compliance with the deadlines prescribed by the resolution of 9th December 2014. In 2015 ASN checked the progress of the work prior to construction of the retrieval and packaging units for the waste stored in silo 130; ASN notes that Areva NC is behind schedule in meeting the retrieval deadline set for July 2016. ASN considers that the construction of the waste retrieval unit of the HAO silo is proceeding satisfactorily. ASN observes that Areva NC is still encountering technical difficulties in utilising the specific vitrification crucible allowing the packaging of UMo fission products, which induces further delays. As a general rule, ASN will be particularly attentive to the way in which Areva NC manages the technical difficulties encountered in the waste retrieval and packaging projects with regard to the applicable requirements.

In 2015 Areva NC continued the decommissioning operations on the UP2-400 plant authorised in November 2013, as much for the treatment of large items of equipment as for conducting investigations aiming to consolidate the complete decommissioning scenarios. ASN notes that waste management in the decommissioning workshops must be improved. ASN has started to examine the complete decommissioning files for BNIs 33 and 38 submitted by Areva NC in July 2015, and the periodic safety reviews of the three BNIs of the UP2-400 plant.

The La Hague site includes Nuclear Pressure Equipment (NPE) whose design does not allow direct application of several provisions of the order of 12th December 2005 relating to in-service monitoring. Insofar as the first associated regulatory deadlines were in May 2014, at the beginning of 2014 Areva NC asked - as the regulations permit in such cases - that special conditions be defined for the in-service monitoring of these equipment items, but the files submitted to support the case turned out to be insufficient and were declared inadmissible by ASN. By a resolution of 26th May 2015, ASN gave Areva NC formal notice to comply with the regulatory obligations relative to the in-service monitoring of NPE. This resolution contains compliance deadlines staggered between 31st January 2016 and 31st July 2018.

Areva NC communicated to ASN the results of the thickness checks carried out in 2015 on the fission product concentration evaporators in the R2 and T2 units. The corrosion mechanisms affecting these items are appearing significantly faster than predicted in the design. ASN considers this situation worrying and has urged Areva NC firstly to implement the identified measures aiming to slow the corrosion of these items of equipment and secondly to conduct without delay the additional investigations necessary to determine the impact of the corrosion phenomena on the dependability of the site's evaporation capacities in the coming years.

ASN notes the occurrence of several radioactive effluent transfer errors in late 2014 and early 2015 which must be appropriately addressed by Areva NC; ASN considers that Areva NC must implement the technical and organisational measures adopted to prevent recurrence of these errors as quickly as possible and in all the facilities concerned.

ASN issued two resolutions on 22nd December 2015 revising the regulations governing the La Hague site water intakes and discharges to take into account upgrading of the site's steam plant, the requirements of the order of 7th February 2012, and the current regulatory framework for waste retrieval and packaging, shutdown and decommissioning operations.

Flamanville nuclear power plant

ASN considers that the nuclear safety, radiation protection and environmental protection performance of the Flamanville site is, on the whole, in line with its general assessment of EDF performance, but the occurrence of several incident situations demands particular attention.

With regard to operation, performance of periodic tests and reactor management, ASN considers that the site's performance remains satisfactory on the whole. However, management of the operational control instructions must be improved, particularly as regards the rigour with which these documents are filled out and checked before being put into application. ASN also considers that improvements must be made in the analysis, characterisation and handling of conformity deviations.

ASN observes that, although the overall organisation of the two reactor outages scheduled during 2015 was generally satisfactory, deficiencies in work preparation, in the quality of performance of maintenance work and in the monitoring of outside contractors nevertheless led to two significant incident situations. The first led to the triggering of the on-site emergency plan further to suspicion of a fire in a nuclear zone, which turned out, after verification, to be unfounded. The second led to the loss of the NPP's external electrical power supplies for more than two days, with the safety functions nevertheless remaining fulfilled. ASN considers that the site must ensure the quality and completeness of the information transmitted, from the detection of such events through to their closure.

With regard to radiation protection, the site has embraced the Everest approach for entering the installation's nuclear zones in standard working overalls and ASN notes that the radiological exposure of the workers was satisfactorily controlled during the two reactor outages.

ASN considers that the organisation set up by the site for environmental protection and waste management enables the corresponding requirements to be satisfied on the whole.

Paluel nuclear power plant

ASN considers that the nuclear safety, radiation protection and environmental protection performance of the Paluel NPP is, on the whole, in line with ASN's general assessment of EDF's performance.

ASN inspection at the Paluel NPP, November 2015.

The site has confirmed its satisfactory performance in operational management of the reactors. ASN notes nevertheless that the error reduction techniques relative to the preparation and retrospective verification of the operating, radiation protection and maintenance activities are insufficiently applied by the operators. Cross-site corrective actions must be taken to remedy this situation. ASN notes an improvement – which must be maintained over the long term – in the integration of the analyses produced by the on-site EDF service tasked with conducting an independent safety verification.

A highlight of 2015 was the first part of the 10-year outage of reactor 2 which involved major maintenance operations and system modifications aiming in particular at improving the safety of the reactor. The condenser was affected by a significant industrial fire in the non-nuclear part of the installation. In addition, a lifting beam intended for handling the steam generators fell accidentally, without causing any injuries; ASN asked that a third-party investigation be carried out on this issue. With regard to nuclear safety, ASN considers that the other work programmes were carried out satisfactorily during the two reactor outages in 2015. ASN does however note that increased rigour is necessary in the use of air locks for certain operations involving a contamination risk and that the analyses relating to fire risks must fully meet the particularities of each activity. ASN draws the site's attention to the need to have sufficient resources in 2016, particularly with regard to the reactor outage programme, which includes two simultaneous 10-year outages.

With regard to environmental protection, ASN considers that the site must step up its organisation for ensuring the management, servicing and maintenance of the radioactive effluent storage tanks. In addition, the file submitted by EDF to request modifications in the site's discharge prescriptions has been made available for public consultation and its examination will be continued in 2016.

Penly nuclear power plant

ASN considers that the nuclear safety and radiation protection performance of the Penly site stands out positively with respect to its overall assessment of EDF. The site's environmental protection performance is in line with ASN's general assessment of EDF.

With regard to nuclear safety, ASN considers that the site maintains a satisfactory level in a context where the volume of maintenance work remained low. ASN considers that particular attention must be paid to the preparation of the operational control activities in order to step up implementation of error reduction techniques when working on the equipment. The increase in the number of limited-impact deviations reflects a lack of rigour in application of the operating procedures.

With regard to maintenance, ASN notes that the refuelling outage of reactor 2 was satisfactory on the whole, but work monitoring must be further improved in order to prevent the maintenance quality shortcomings detected on some items of equipment.

The site's organisation in the area of radiation protection is generally satisfactory. ASN has nevertheless observed deviations in the monitoring of devices used for radiation protection checks and in the application of instructions relative to risk identification and the associated protection measures.

With regard to emergency situations, ASN notes that the national emergency exercise carried out on 13th October 2015 was satisfactorily managed by the site, particularly from the technical aspects, even if the quality of external communication must be improved.

In the area of the environment, EDF provided ASN with complementary information concerning the operation, inspection and maintenance of the liquid effluent collection and retention systems; ASN ensured that EDF continued implementing the planned improvements in this area.

Labour inspection in the nuclear power plants

ASN continued its inspection actions concerning subcontracting, situations of illegal lending of labour, the working time of employees of EDF and of certain subcontractors and the conditions of health and safety during maintenance and construction work. ASN's oversight action resulted in the improvement of the working conditions of the operators on the Paluel 2 reactor condenser repair worksite in order to meet the applicable requirements. ASN also examined the circumstances of the fall of the lifting beam for handling the steam generators on the Paluel 2 reactor. On this subject, ASN asked that EDF and the contractor companies involved continue the requisite analysis and implement appropriate corrective action.

With regard to radiation protection, the inspectors continued to check implementation of the Everest initiative on the Flamanville site, an initiative that significantly changes the conditions of access to controlled areas and must still undergo operational adaptations.

ASN continued its inspections during work in hot environments at the beginning of the reactor outage periods: ASN considers that EDF must confirm the practical feasibility of the envisaged response actions should an accident involving a person or person occur in certain poorly accessible areas.

Construction of the Flamanville 3 EPR reactor

After issue of the authorisation decree and the building permit, construction work began on the Flamanville 3 reactor in September 2007.

A predominant part of the activities in 2015 concerned mechanical assemblies, particularly the reactor main primary system, the electrical installations and the performance of the first startup tests (see chapter 12, point 3.3). With regard to civil engineering, the prestressing of the internal containment of the reactor building and construction of the external containment were completed in 2015. ASN carried out a specific inspection of these operations, and examined worker radiation protection, protection of the environment and preparation for reactor operation.

ASN considers that the organisation implemented by EDF remained satisfactory on the whole.

The work of introducing the principle components of the main primary system into the reactor building and then assembling them, which began at the end of 2014, continued during 2015. This system contains the reactor core and is thus of primary importance for safety. ASN examined EDF's monitoring of the outside contractors involved in the assembly of the primary system, especially Areva NP, the system manufacturer. ASN considers that the cleanliness requirements are satisfied on the whole and that EDF's management of concomitant activities conducted near items of equipment is generally adequate. ASN notes the discovery and subsequent treatment in 2015 of several nonconformities that occurred during welding of the equipment; ASN considers that EDF must, in collaboration with the equipment manufacturer, further the analysis of this issue.

With regard to prestressing of the internal containment which began in summer 2014, EDF informed ASN of further difficulties encountered during the tensioning of a prestressing cable in February 2015. EDF suspended the activities concerned as a precautionary measure pending determination of the causes of the deviations and preparation of a corrective action plan. EDF kept ASN regularly informed of the deviations observed during the prestressing activities. ASN adapted its inspection of this activity accordingly, in particular by conducting four specific inspections. ASN considers that EDF responded appropriately to these deviations.

On completion of the inspection of the first startup tests of the ventilation equipment and the continued tests of the equipment installed in the pumping station, ASN considers that EDF's organisational setup for the preparation and performance of the startup tests can be improved. More specifically, EDF must be attentive to the rigour with which deviations encountered during the startup tests are dealt with in order to decide, among other things, on the representativeness of the tests performed and the acceptability of their results, while at the same time integrating experience feedback for subsequent tests. ASN will be attentive to ensure proper performance of the preliminary tests which shall be followed by the overall tests of the reactor systems.

In view of the time frames announced by EDF for reactor commissioning, ASN considers that EDF must remain vigilant with regard to the preservation of the equipment already installed, taking into account the worksite conditions and the ongoing concomitant activities.

ASN examined the organisation put in place by the teams responsible for future operation of the Flamanville 3 reactor, particularly for the production of the operating documentation, preparation for arrival of the nuclear fuel on the site and consideration of organisational and human factors. ASN considers that the organisation implemented by EDF in these areas is satisfactory.

ASN fulfils the labour inspection duties on the Flamanville 3 construction site. In 2015 the inspectors continued to check that the outside contractors working on the site complied with the provisions concerning the safety rules implemented; they drew attention in particular to the impact of the startup tests, which involve powering up systems or putting equipment under pressure.

Andra's Manche repository

ASN considers that the condition and the operation of the Manche repository facilities are basically satisfactory. Andra must continue to reinforce the stability of the repository's cover and continue its efforts to eliminate water infiltrations at the edge of the membrane intended to ensure the water-tightness of the storage volume. In accordance with the commitment made during the last periodic safety review, Andra sent ASN an interim review of the work carried out on the repository cover. Lastly, Andra sent ASN a revision of the repository's on-site emergency plan.

ASN considers that Andra's continuing measurement of tritium using the methods of the study that began in 2012 should lead to a better understanding of the hydrogeological mechanisms involved.

As concerns the maintaining of the repository memory, Andra must continue its work to prioritise the detailed data with a view to proposing a new version of the synthesis by 2016.

Ganil (National Large Heavy Ion Accelerator)

ASN considers that the Ganil licensee continues on the whole to satisfactorily ensure the construction work of phase 1 of the Spiral 2 installation, for which the authorisation decree was published in 2012. The way in which worksite monitoring is organised seems well-founded and functional. During its inspections in 2015, ASN nevertheless detected shortcomings in the performance of the tests relating to safety, which will have to be supplemented. ASN considers that the licensee must improve its organisation for the management of low- and very low-level radioactive waste produced on the site. ASN continued its examination of the commissioning application for phase 1 of the Spiral 2 project.

ASN completed the examination of the first periodic safety review of the installation since it was commissioned in 1983. On completion of this process, ASN set technical prescriptions that supplement the licensee's commitments to bring the installation into compliance with its baseline requirements and the regulations in effect.

The Brennilis nuclear power plant undergoing decommissioning

ASN considers that the conditions of safety for continuation of the partial decommissioning activities on the Monts d'Arrée site have proved to be sub-standard. On 23rd September 2015, a fire broke out on the heat exchanger decommissioning worksite, which was in the final phase of clean-up at the time, resulting in activation on the on-site emergency plan. The heat exchanger and the effluent treatment plant decommissioning worksites have both been suspended since then. ASN notes that the prior analyses and the way the fire risk for these activity phases was specifically taken into account were insufficient.

ASN has asked EDF to undertake all the actions to review all the organisational and human measures implemented to control the risks associated with hot work on the decommissioning worksites as soon as possible.

The effluent treatment plant post-operational clean-out and demolition worksite was interrupted several times, notably after the fall of a rubble-sorting machine.

In addition to this, ASN verified compliance with the commitments made by EDF at the end of the inspection carried out in 2014 concerning the management of the excavations area and compliance with the conditions associated with management of contaminated water on the site.

ASN has received the management plan for the land on which the former effluent treatment station is situated and has asked EDF to submit a new file with a view to complete decommissioning of the installation.

1.2 Radiation protection in the medical field

Radiotherapy

In 2015, ASN continued the two-year inspection cycle covering all the radiotherapy departments in Normandy; an annual inspection is maintained for the departments with identified points requiring particular vigilance. The inspections conducted in 2015 revealed the maintaining of a real process to improve the rigour, organisation and traceability of interventions and the implementation of management systems to ensure the quality and safety of treatments. Nevertheless, in spite of the increased staffing in the majority of the radiotherapy centres, a small number of the centres in Normandy still suffer staff shortages or instability, particularly concerning medical physicists and sometimes radiation oncologists. These difficulties hinder the progress initiatives and led ASN in 2013 to ask one of the centres concerned to take immediate corrective action. This centre was subject to tightened monitoring by ASN in 2014 and 2015, which revealed an improvement in the situation which must be continued and consolidated.

Interventional practices

ASN maintained its tightened monitoring in the departments with interventional activities (see chapter 9, point 1.1.2). The activities in these facilities entail risks for both patients and workers, and these risks must be duly controlled. The inspections carried out revealed a contrasting situation and many areas for improvement, particularly with regard to the training and qualification of the staff using the equipment, equipment quality controls, staff personal protection equipment, medical monitoring of non-salaried workers, or the optimisation of practices in this sector. ASN notes that radiation protection is generally better integrated in the rooms dedicated to interventional practices than in the operating theatres. ASN was informed of two events that led to the appearance of deterministic effects on the skin of the patients involved.

Nuclear medicine

In 2015, ASN inspected a quarter of the nuclear medicine departments in Normandie. The inspections revealed a satisfactory situation, although a few areas for improvement remain in the coordination of the prevention measures for outside contractors and taking account of radiation exposure of workers' extremities (hands).

Computed Tomography

ASN continued its inspections of computed tomography departments in 2015. In the light of these inspections, occupational radiation protection appears to be satisfactory in general. ASN considers that patient radiation protection measures are still somewhat variable and are often based on the use of the optimisation procedures specified by the machine manufacturers. The level of involvement of medical physicists varies from one department to another; increasing their involvement could help to optimise practices. The use of Magnetic Resonance Imaging (MRI) techniques when indicated as an alternative remains limited due to the low availability of MRI scanners.

1.3 Radiation protection in the industrial sector

Industrial radiography

The control of industrial radiography remains a priority for ASN, which carried out unannounced night-time inspections on worksites in 2015. Depending on the companies, these inspections brought to light a widely contrasting picture of the way the risk of worker exposure to ionising radiation is taken into account. Although work conditions are improving on the whole, ASN observes that some companies still have to make significant progress. Following a first similar case in 2014, another unacceptable situation concerning failure to define and delimit a work area was discovered in 2015 during an unannounced inspection, which led ASN to inform the Public Prosecutor.

At the same time, ASN continued, in collaboration with DIRECCTE (Regional Directorate for Enterprises, Competition, Consumption, Labour and Employment) of Haute-Normandie and CARSAT (Retirement and occupational health insurance fund) of Normandie, its promotion of good practices with the signatories of the charter of good practices in industrial radiography in Haute-Normandie. At present, some thirty companies, ordering customers and radiology companies have signed this charter. A reflection on whether to extend this charter to the whole of Normandy is currently in progress.

1.4 Nuclear safety and radiation protection in the transport of radioactive substances

ASN considers that the regional consigners involved in the transport of radioactive substances maintained a level of safety in 2015 that was on the whole satisfactory. Nuclear medicine units, however, must further improve their integration of the requirements of the ADR regulations, particularly when re-shipping packages.

ASN conducted an inspection of the safety of a convoy of vitrified radioactive waste shipped from the Sellafield plant in the United Kingdom to Switzerland, during the transfer of the packages at the Valogne railway terminal; two members of associations represented on the HCTISN (High Council for Transparency and Information on Nuclear Safety) attended part of the inspection. The measurements taken confirmed effective compliance with the regulatory limits for equivalent dose rates and contamination levels. The inspectors considered that the transport safety provisions were satisfactory on the whole (see chapter 11).

With regard to shipments of radioactive substances from BNIs in Normandie, ASN considers that on the whole the requirements specific to these operations are satisfied. ASN nevertheless noted during its inspections of the NPPs that EDF must show greater rigour in the verification and compliance of the documents concerning the conformity of radioactive substance transport packages, as each type of shipment must have a specific file.

In 2015, ASN continued checking progressive implementation of the new regulatory requirements applicable to on-site transport operations in the La Hague site facilities; Areva NC has submitted a draft of general operating rules in this area to ASN.

1.5 Radiation protection of the public and the environment

Contaminated sites and soils

In March 2013 work was undertaken jointly by Andra as part of its public service remit (see chapter 16) and the EPF (Public Land-management Corporation) of Normandie to complete the decontamination and to rehabilitate the industrial site of *Etablissements Bayard,* situated in Saint-Nicolas d'Aliermont in the Seine-Maritime *département*. *Etablissements Bayard* was specialised in the production of pendulum clocks and alarm clocks between 1867 and 1989. From 1949 until the workshops closed in 1989, the site produced and used luminescent paint based first on radium-226, then on tritium. The traces of contamination that remained after the initial decontamination work carried out in the 1990's do not represent a risk for public health or the environment.

In 2015, ASN continued to assist Dreal (Regional directorate of the environment, planning and housing) of Haute-Normandie with operations tracking. ASN considers that the work went satisfactorily, particular with regard to the characterisation, sorting and interim storage of the waste on the site. Demonstration of compliance with the clean-out thresholds and the putting in place of institutional controls are prerequisites before handing over the land for rehabilitation as an open-air public space with car-parking areas.

2. ADDITIONAL INFORMATION

2.1 International action

Given that EPR reactors are being built on the sites of Olkiluoto in Finland and Flamanville in France, the ASN Caen division is participating in the close cooperation between ASN and STUK *(Säteilyturvakeskus),* the Finnish nuclear regulator. The ASN inspectors received their Finnish counterparts in March 2015 to discuss construction work progress and experience feedback. A joint trip was made to the Flamanville worksite.

The Caen division also attended a meeting in China with the NNSA (National Nuclear Safety Administration), the Chinese nuclear safety authority, devoted in particular to cooperation on fuel cycle facilities and the construction of reactors, as two EPR reactors are currently under construction on the Taishan site in China. The Caen division also received a delegation of inspectors from the PAA *(Panstwowa Agencja Atomistyki),* the Polish National Atomic Energy Agency, for a week of technical discussions devoted to the oversight of nuclear power reactors, both in operation and during construction.

2.2 Informing the public

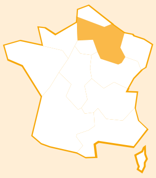
Press conferences

In 2015, ASN held three press conferences on the situation of nuclear safety and radiation protection, in Caen, Rouen and Rennes – the latter was organised jointly with the Nantes division.

Work with the Local Information Committees (CLIs)

ASN participated in the various general meetings of the CLIs of Normandie and Bretagne, which were partly renewed at the term of the electoral deadlines of 2015. ASN was pleased to note that in September 2015, representatives of associations which had decided in 2014 to no longer sit on the CLIs of La Hague, Flamanville and the Manche repository, returned to these CLIs.

During the general meetings of the CLIs, ASN presented, among other things, is assessment of the state of safety of the nuclear facilities concerned, the completed regulatory framework applicable to the waste recovery and packaging operations on the La Hague site, and the process for taking into account of the anomaly affecting the domes of the Flamanville 3 EPR reactor vessel. ASN also presented the files on which the CLIs had been asked to give their opinions, and provided some answers to the questions raised by the CLIs.



THE STATE OF NUCLEAR SAFETY AND RADIATION PROTECTION IN 2015 IN THE PICARDIE AND CHAMPAGNE-ARDENNE REGIONS REGULATED BY **THE CHÂLONS-EN-CHAMPAGNE DIVISION**

The Châlons-en-Champagne division is responsible for regulating nuclear safety, radiation protection and the transport of radioactive substances in the seven *départements* of the Champagne-Ardenne and Picardie regions.

As at 31st December 2015, the workforce of the Châlons-en-Champagne division stood at 12 officers: the regional division head, 1 deputy head, 8 inspectors and 2 administrative officers.

The activities and installations to regulate comprise:

- the NPPs of Chooz B (2 reactors of 1,450 MWe), of Nogent-sur-Seine (2 reactors of 1,300 MWe) operated by EDF;
- the Chooz A NPP (currently being decommissioned);
- the low and intermediate-level short-lived radioactive waste repository (CSA) located at Soulaines-Dhuys in the Aube *département;*
- Andra's underground research laboratory in Bure, in preparation for the creation of a geological repository for high-and medium-level long-lived radioactive waste;
- 12 radiotherapy centres;
- 3 brachytherapy centres;
- 12 nuclear medicine centres;
- 56 tomography devices;
- about 55 interventional radiology departments;
- about 2,500 medical and dental diagnostic radiology devices;

- about 150 veterinary clinics;
- about 300 licensed industrial activities, with more than half of the licenses being for possession of devices to detect lead in paint;
- about ten research laboratories, mainly situated in the universities of Champagne-Ardenne and Picardie.

In 2015, ASN carried out 92 inspections, of which 30 were in the nuclear facilities (EDF nuclear power plants, radioactive waste disposal facilities), 56 in small-scale nuclear activities and 6 in the transport of radioactive substances. ASN carried out 11 days of labour inspections in the nuclear power plants.

During 2015, five significant events rated level 1 on the INES scale were notified by nuclear installation licensees. In the small-scale nuclear activities, 1 significant event rated level 1 on the ASN-SFRO scale was notified to ASN.

1. ASSESSMENT BY DOMAIN

1.1 The nuclear installations

Nogent-sur-Seine nuclear power plant

ASN considers that the nuclear safety, radiation protection and environmental protection performance of the Nogent-sur-Seine NPP is, on the whole, in line with its general assessment of EDF performance.

With regard to the operational control of the reactors and operating rigour, ASN considers that the site's performance is generally satisfactory except during the restarting of reactor 2 after its outage for maintenance, during which five significant events were notified on account of organisational deficiencies in the operational control of the installations or equipment tests. As a general rule, the site must better formalise the rules applicable to the preparation of operational control activities and shifts changes.

With regard to maintenance, ASN considers that the scheduled and unscheduled outages were on the whole satisfactorily managed from the safety aspect. ASN does nevertheless note shortcomings in the preparation of the activities and occasionally in the organisational measures adopted. Some events underline the importance of providing outside contractors with appropriate operating documents that are in conformity with the equipment. Improvements are moreover expected in the tracking of the files for maintenance operations carried out by outside contractors while the reactors are in operation.

With regard to radiation protection, several events that occurred in 2015 – particularly one concerning a spot contamination of a worker which led to skin exposure exceeding a quarter of the regulatory annual individual dose limit(event rated level 1 on the INES scale) – highlight the need for the site to reinforce its radiation protection culture.

Lastly, with respect to environmental protection, ASN observes that shortcomings in the integration of experience feedback and a lack of rigour resulted in failure to avoid occasional discharges *via* a discharge channel not intended for that purpose.

Chooz nuclear power plant

ASN considers that the nuclear safety, radiation protection and environmental protection performance of the Chooz B NPP is, on the whole, in line with its general assessment of EDF's performance.

ASN observes that, despite the measures taken to reinforce and stabilise the operating teams, the situation remains tenuous with respect to the available human resources. More generally, the operating experience feedback from events occurring on the site must be improved.

With regard to maintenance, ASN is still observing shortcomings in the preparation or quality of operations. These shortcomings were the root cause of several significant events in 2015 and led to delays that deteriorated the working conditions during the reactor outages.

With regard to radiation protection, ASN considers that the actions taken to improve the performance of the site in terms of radiological cleanness of the maintenance worksites have so far not been sufficient to prevent the renewal of recurrent deviations, such as noncompliance with the rules for donning personal protective equipment and self-monitoring for entering or leaving areas that could be contaminated. Furthermore, a lack of rigour in individual behaviours hinders the site's performance in this area.

Lastly, with regard to environmental protection, ASN considers that operating experience feedback is adequately integrated, although there are still some traceability and recording deviations. The site must continue its efforts in this area.

Labour inspection in the nuclear power plants

ASN continued its inspections of health and safety conditions given the large number of maintenance activities.

The health and safety measures taken by the licensee are satisfactory in the majority of cases. Nevertheless, ASN still observes that the risk analyses prior to maintenance operations are insufficient and that the working conditions do not always minimise the risks for the personnel.

Lastly, the year 2015 was marked in particular by several falls from height and several cases of radioactive contamination on the sites.

The Soulaines-Dhuys waste repository and the Bure laboratory

ASN considers that operation of the CSA repository is satisfactory, in line with the previous years.

In 2015 Andra completed the modification work on the package inspection facility designed to provide the facility with high-performance inspection ressources to check the quality of the packages received by it. The commissioning by it, planned for 2016, is subject to ASN approval. Construction of the disposal structures of tranche 9, for which ASN has given its agreement, continued in 2015.

ASN also gave its agreement in 2015 on the modification of the general operating rules of the CSA, with the aim of integrating the updating of the regulatory requirements, including those of the BNI Order of 7th February 2012, and making these rules more practical and usable.

ASN considers that works conducted by Andra in the underground laboratory at Bure continued in 2015 with a good standard of quality comparable with that of the preceding years.

ASN inspection of a radioactive waste packaging company, February 2016.

Chooz A reactor undergoing decommissioning

The preparatory work for the decommissioning of the Chooz A reactor vessel continued. The reactor cavity gates were dismantled and the pressuriser, dismantled in 2013, was removed.

With regard to the environment and nuclear safety, ASN considers that the decommissioning operations are being carried out satisfactorily. Vigilance is nevertheless required in the preparation of the activities, particularly in the management of the interfaces between the various contractors on the job and on the verification of the electrical networks.

In the area of radiation protection, the actions deployed in 2014 to improve the monitoring of outside contractors have borne fruit. Although the volume of activities involving risks was lower than in the preceding years, ASN considers that the radiation protection results are satisfactory. The outside contractor training and awareness-raising actions must be maintained.

1.2 Radiation protection in the medical field

Radiotherapy

ASN inspected six of the twelve centres in 2015. These inspections confirmed the positive trends regarding the deployment of quality management systems. The actions must still be continued in some cases for the organisation of the medical physics organisation plans and the updating of the radiotherapy process risk studies to integrate experience feedback, among other things.

Interventional practices

Continuing the actions which have been engaged since 2009, ASN performed eight inspections in operating theatres in 2015. Highly contrasting situations have been observed, most of which require measures concerning the radiation protection training of the personnel and the technical verifications of the machines. Progress is also still required in the tracking and analysis of doses delivered to patients, through more systematic defining and optimising of the intervention protocols (see chapter 9, point 1.1.2).

Nuclear medicine

ASN inspected three of the twelve centres in 2015. These inspections show that radiation protection is duly taken into account. Improvements are nevertheless required regarding the optimisation of occupational exposure and the management of contaminated effluents. Likewise, certain reflections on patient radiation protection must be continued (identity monitoring, optimisation of image acquisition protocols). One nuclear medicine centre was the subject of a study in the area of organisation and organisational and human factors conducted by IRSN under the auspices of ASN, with support of the Regional Health Agency (ARS) of ChampagneArdenne. The results of this study, based on a period of observation of the centre's practices and the identified improvements, were presented at the end of 2015. They will be analysed by ASN in 2016 in order to establish recommendations and draw lessons that can be applied at national level.

Computed Tomography

ASN carried out five inspections in 2015, maintaining its focus on the examination of the patient radiation protection measures taken by the centres. The reason for this is that CT examinations make a significant contribution to exposure to ionising radiation in the French population. It was observed that patient radiation protection is a true concern for the centres. Progress is still required, on a more occasional basis, in the technical verification of the equipment and, more generally in ambient radiological checks and worker monitoring.

Conventional dental radiology

ASN inspected ten dental surgeries or radiology facilities. These inspections revealed that progress remains to be made in the analysis of worker and patient exposure data, the training of professionals in the radiation protection of patients, and more rigorous application of the internal and external technical verifications of the equipment.

ASN also transmit letters to 65 dentists asking them to send documents concerning radiation protection verification and quality organisation. More than half the addressees were in situations justifying corrective action.

1.3 Radiation protection in the industrial sector

Industrial radiography

In view of the potential implications with regard to radiation protection, ASN conducted nine inspections of gamma radiography activities, five of which were unannounced inspections on worksites. The preparatory organisation of the worksites, the precision of the risk assessment, compliance with the device inspection frequencies and preparedness for incident situations still represent areas for progress in this domain.

Devices for detecting lead in paint

Real estate diagnosis professionals use devices containing a radioactive source in their inspections to detect lead in paint. More than 150 professionals have thus been licensed by ASN in Champagne-Ardenne and Picardie. This activity is characterised by limited though not negligible radiation protection risks, a large number of licensees and a radiation protection culture that is sometimes extremely limited. ASN therefore inspected fifteen professionals in this sector in 2015, asking them to communicate various inspection documents. These actions enabled deviations in the performance of radiation protection verifications to be corrected and the cessation of activity of a few professionals to be supervised (recovery of the radioactive sources by the suppliers).

1.4 Nuclear safety and radiation protection in the transport of radioactive substances

In 2015, in the area of small-scale nuclear activities, ASN carried out four inspections of radiopharmaceutical product transporters. These inspections revealed no notable shortcomings with respect to the regulations governing the transport of radioactive substances. Two inspections were moreover carried out on on-site transport operations on the Chooz and Nogent-sur-Seine sites; they underlined the need to be more attentive to the utilisation and filling out of the shipment tracking documents.

1.5 Radiation protection of the public and the environment

Contaminated sites and soils

Continuing in line with the preceding years, ASN contributed – along with decentralised government services and Andra – to the study of the treatment of legacy radioactive contamination resulting from operation of the former Orflam-Plast plant in Pargny-sur-Saulx (Marne *département*). Complementary investigations on plots of land situated outside the industrial site were continued in 2015.

2. ADDITIONAL INFORMATION

2.1 International action

The Châlons division continued to maintain regular relations with the Belgian nuclear regulator, the AFCN. The cross-inspections continued in small-scale nuclear activities and in the field of nuclear safety on the sites of Chooz and Tihange (Belgium). The division took part in the Franco-Belgian management committee meetings and the Franco-Belgian working group on safety.

The Châlons division took part in the work of the fifth review meeting of the Joint Convention on the Safety of Spent Fuel and Radioactive Waste Management held at the head office of the International Atomic Energy Agency (IAEA) in Vienna, Austria, from 11th to 21st May 2015. It also followed attentively the work of the mission organised by the IAEA from 1st to 5th June 2015 on the Chooz site further to the initial OSART (Operational Safety Review Team) mission carried out from 18th June to 4th July 2013.

2.2 Informing the public

Press conference

ASN held a press conference in Châlons-en-Champagne on 20th April 2015 on the status of nuclear safety and radiation protection.

Work with the Local Information Committees (CLIs)

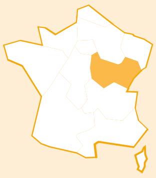
ASN took part in meetings of the Chooz, Nogent-sur-Seine and Soulaines CLIs. During these meetings, ASN presented its assessment of the safety of the regional nuclear installations and its action on the sites, the national and local follow-ups to the Fukushima Daiichi accident, the ASN resolutions concerning the NPPs (resolutions relative to reactor outages, internal authorisation systems, etc.) and the AIEA report drawn up further to the IRRS (Integrated Regulatory Review Service) mission carried out in France in November 2014. The Chooz CLI continued its actions to inform the public (publication of an information bulletin for the local population).

The CLI of the Soulaines repository operated by Andra continued the radioactivity measurement campaign in the environment of the repository (environment, fauna) which began in 2012. The Nogent-sur-Seine CLI continued the experimental process of periodically examining EDF's replies to the follow-up letters sent by ASN further to its on-site inspections.

Lastly, ASN regularly attended the annual general meetings and meetings of the board of the Bure CLIS (Local Information and Monitoring Committee) where it made its contributions with a view to informing the local populations. It more specifically gave a reminder of how it is organized and the principles relative to the management of radioactive waste before the enlarged board of the CLIS on 25th June 2015.

2.3 The other notable events

On account of major risk prevention, the prefect of the Ardennes region updated the on-site emergency plan of the Chooz NPP in February 2015 after the national emergency exercise organised with this NPP on 16th September 2014.



THE STATE OF NUCLEAR SAFETY AND RADIATION PROTECTION IN 2015 IN THE BOURGOGNE AND FRANCHE-COMTÉ REGIONS REGULATED BY **THE DIJON DIVISION**

The Dijon division regulates nuclear safety and radiation protection in the eight *départements* of the Bourgogne and Franche-Comté regions.

As at 31st December the workforce of the Dijon division stood at 6 officers: 1 regional division head, 4 inspectors and 1 administrative officer, under the authority of a regional representative.

The activities and installations to regulate comprise:

- 8 external-beam radiotherapy departments (19 accelerators, 2 contact radiotherapy devices);
- 4 brachytherapy departments;
- 14 nuclear medicine departments;
- 41 medical centres carrying out interventional practices;
- 48 computed tomography scanners;
- about 800 medical diagnostic radiology devices;
- about 2,000 dental diagnostic radiology devices;

- 174 veterinary practices;
- 380 industrial and research establishments, including one cyclotron accelerator used for research and the production of radioisotopes for medical imaging.

In 2015, ASN carried out 52 inspections in the Bourgogne and Franche-Comté regions, comprising 32 inspections in the medical sector, 15 inspections in the industrial sector, one oversight inspection of an agency approved for radiation protection controls, one inspection of a site contaminated by radioactive substances and 3 inspections concerning the transport of radioactive substances.

Twenty-three significant events were notified to the Dijon division and analysed to draw lessons from them. 22 of the events occurred in the medical field and one during the clean-up of a site contaminated by radioactive substances. Among the events notified, one event concerning the environment was rated level 1 on the INES scale and 3 events concerning radiotherapy patients were rated level 1 on the ASN-SFRO scale.

1. ASSESSMENT BY DOMAIN

1.1 Radiation protection in the medical field

Radiotherapy

In 2015, two-thirds of the radiotherapy or brachytherapy departments in the Bourgogne and Franche-Comté regions had their licenses renewed or modified, half of them on account of significant organisational changes. The five inspections carried out in these departments showed that they have now all complied with the ASN resolution requiring a specific organisation to ensure treatment safety and quality. The implementation of this organisation nevertheless varies from one centre to another. The inspections performed in 2015 found that the George-François Leclerc centre in Dijon is still one of the most advanced in analysing the risks run by patients.

In the second quarter of 2015, ASN undertook a tightened inspection of the University Hospital Centre of Besançon (CHRUB) on account of significant changes in its radiotherapy organization, concerning both technical aspects (implementation of new practices) and organisational aspects (department relocating and grouping), and because this centre is one of the least advanced in fulfilling the obligations concerning quality assurance in radiotherapy and radiation protection in the operating theatre.

Seven ASN inspectors were thus mobilised for three days in May 2015 to assess the effectiveness of the actions undertaken by the CHRUB to improve radiation protection of medical staff and patients in radiotherapy and in interventional practices. These inspections showed ASN that the personnel had made great efforts to improve radiation protection. Several deviations discovered during the preceding inspections had been corrected, particularly with regard to the radiation protection of medical staff in rooms dedicated to interventional radiology. ASN nevertheless noted that greater operational coordination was required in the actions contributing to the radiation protection of medical staff and patients in the oncology and imaging units.

In 2015, five significant events concerning radiotherapy patients were reported further to errors in performance of the examination, three of which were rated level 1 on the ASN-SFRO scale. ASN considers that radiotherapy centres must be more attentive to the updating of their procedures when material or organisational changes arise.

Interventional practices

ASN devoted particular attention in 2015 to centres that use image intensifiers in the operating theatre, and carried out seven inspections in this area (see chapter 9, point 1.1.2). Further improvements can be made in the deployment of radiation protection measures and two of the inspected centres have made no progress with respect to the previous years.

With regard to radiation protection of health professionals, the centres have become aware of the role and importance of the Person Competent in Radiation protection (PCR), but the time the PCRs are allocated to carry out their duties is still too short. Significant progress has been noted in the use of dosimeters. On the other hand, improvements can still be made in the use of protective equipment by practitioners, in working practices analyses and in radiation protection training.

With regard to patient radiation protection, ASN has observed progress in the involvement of medical physicists and overall compliance with the obligation to ensure quality control of the devices used. Further progress is required in the optimisation of doses delivered to patients, more specifically by training the physicians in the use of the imaging devices.

Only one significant event concerning a health professional failing to wear a dosimeter was notified to ASN in 2015.

Nuclear medicine

ASN issued four licenses in nuclear medicine in 2015, three of which were on account of significant organisational changes in the departments. The three inspections carried out confirmed the significant improvements in the radiation protection of patients and medical staff which began in 2014. As regards patient radiation protection, the delivered doses are below the diagnostic reference levels in the very large majority of cases and the involvement of a medical physicist in quality control verifications has become general practice. With regard to radiation protection of health professionals, a good level of involvement of PCRs has been noted. The lines of progress concern the depth of the analysis of working practices and conditions, radiological zoning and establishing procedures to prevent errors in the administration of radiopharmaceuticals.

The radiation protection culture in nuclear medicine units is good and they detect anomalies that occur and draw lessons from them. Eleven significant events were notified to ASN in 2015, which represents half the notified events in the medical field. Nearly half of these events concerned patient radiation protection and resulted from errors in the performance of an examination. This highlights the importance of having an organisation for the safety of treatments in healthcare services.

Conventional radiology

In 2015, ASN carried out an inspection campaign focusing on 16 conventional radiology centres in Bourgogne and Franche-Comté. All the centres carry out the risk assessment for delimiting controlled areas and the working environment analyses for the classification of exposed workers. Virtually all the exposed personnel wear passive dosimeters and are monitored by an occupational physician at the regulatory frequency. The internal radiation protection controls are effectively carried out at the regulatory frequency, but 66% of the centres do not have external controls performed. Training in the radiation protection of workers and patients can be improved in 75% of the centres. ASN's final opinion is that the situation of more than 80% of the radiology centres inspected is fairly satisfactory.

1.2 Radiation protection in the industrial and research sectors

Industrial radiography

ASN carried out six inspections in this field in 2015, one of which targeted a contractor company. The inspectors endeavoured to devote equal attention to the radiography conditions in protected bunkers and on worksites. ASN

ASN inspection in a laboratory of the University of Bourgogne in Dijon, November 2015.

renewed 12 licences to exercise this activity, four of which included reservations or a deadline for bringing facilities into compliance.

ASN observed that on the whole the inspected organisations know and comply with the radiation protection requirements. The main lines for improvement concern worker classification, which must match the true level of risk, the regular updating of the documents required by the regulations (analysis of working practices and conditions, radiological zoning, technical control programmes) and compliance of fixed radiography facilities with standards.

Inspection of physical parameters

ASN conducted six inspections in 2015 in organisations using radioactive sources for the inspection of physical parameters, of which four were in industrial protection workshops and units having ICPE status and two in public works contractors. The ICPEs have a good work safety culture, but must better integrate the specifics of the regulations relative to radiation protection. The radiation protection technical controls represent a priority area for progress. The public works contractors must be more rigorous in updating the documents required by the regulations.

Universities, laboratories or research centres

ASN carried out three inspections in the field of research in 2015, one concerning an irradiator and two concerning university laboratories that use unsealed sources. ASN considers that radiation protection is satisfactory in the laboratories in activity but notes that the assessment of risks involved in the management of legacy waste at the University of Franche-Comté can be improved.

1.3 Nuclear safety and radiation protection in the transport of radioactive substances

The three inspections carried out in 2015 showed that the safety of radioactive substance shipments is ensured in accordance with regulatory requirements. Progress can however still be made in occupational radiation protection.

1.4 Radiation protection of the public and the environment

Radon

In 2015, ASN continued its participation in the pluralistic actions carried out in Bourgogne and Franche-Comté to raise awareness of regional authorities, construction professionals and the general public, to the risks caused by exposure to radon.

ASN also worked with the ARS (Regional Health Agency) on the identification of deviations from radon regulations enforceable on the owners of certain sites open to the public in the Nièvre, Saône-et-Loire, Doubs, Haute-Saône et Territoire-de-Belfort *départements*.

In 2015, the Dijon division of ASN and the ARS of Franche-Comté helped organise meetings to inform the mayors and presidents of municipal federations of the Doubs, Territoire-de-Belfort and Haute-Saône *départements* about the health risks associated with exposure to radon in public schools, regulations and the results of their application, the diagnosis of buildings and remediation techniques when radon is present. This approach will enable the elected officials to contribute to the exhaustive listing of the sites concerned and to regularise their situation if necessary.

Contaminated sites and soils

ASN monitored the work carried out in 2015 to clean out a former watchmaking factory in the Haut-Doubs where traces of radium and tritium had been found. ASN's monitoring led more specifically to the stepping up of worker radiation protection measures and the checks performed on the resulting waste.

ASN also asked IRSN to supplement the radiological characterisation of a private site in the Yonne *département* where radioactive sources for lightning conductors are stored, to prepare for complete clean-out of the site.

The former uranium mining sites

In 2009, the State put in place a national action plan for the management of former uranium mines, which provides for Areva to list the sites in which mining waste rock has been reused, and then clean out the areas in which the radiological anomalies are incompatible with land use. In this context, at the end of 2014 Areva identified through aerial surveys followed by ground verifications, 58 sites in municipalities of the Nièvre and Saône-et-Loire *départements* where mining waste rock has been deposited. This inventory was supplemented in 2015 by a radon measurement campaign in the buildings of the municipalities concerned. Areva must propose solutions for remedying the radiological anomalies resulting from the reuse of mining waste rock to the State. ASN will inform the prefectural authority of its opinion on Areva's proposals in 2016.

ASN is particularly attentive to the monitoring of two sites situated in Saône-et-Loire on the municipalities of Gueugnon and Issy l'Evêque, because they contain radioactive substances which are not mining waste rock. In Issy l'Evêque, waste from nuclear installations and mine tailings have been stored in a former uranium mine (Bauzot site). A prefectural Order of 7th April 2011 instructed Areva to improve the knowledge and monitoring of the radioactive substances stored on the site. In 2015, ASN assisted the prefectural authority by having IRSN appraise studies carried out by Areva on the basis of samples taken from the site in 2013. The prefectural authority asked Areva to supplement the assessment of radioactive substances present on the site and the monitoring of the site environment.

In Gueugnon, waste from a uranium ore processing plant which operated there between 1955 et 1980 is stored in an ICPE. As part of the procedure for listing mining waste rock deposit sites, Areva discovered the presence of mine tailings, which constitute radioactive waste, in five sites near the ICPE. Additional investigations have been undertaken to obtain an exhaustive assessment of the radiological condition of the sites, involving taking soil samples and radon measurements in buildings. Areva must present the prefectural authority with solutions to remedy the situation.

2. ADDITIONAL INFORMATION

2.1 Informing the public

Press conference

On 15th June 2015, ASN held a press conference on the status of nuclear safety and radiation protection in the Bourgogne and Franche-Comté regions.

Valduc (Seiva)

A structure providing a forum for discussion and information on the CEA Valduc centre (Seiva) has existed since 1996. This structure, which is funded chiefly by the *conseil général* (General Council) of the Côte-d'Or and ASN, informs the public of the impact of the Valduc centre's activities, insofar as the subjects addressed do not concern confidential aspects covered by its classification as a Secret Basic Nuclear Installation. ASN took part in the annual general meeting of Seiva which was held on 3rd February 2015. Seiva undertook the supplementing of its multi-year environmental monitoring dashboard in 2015 by taking measurements in the sediments.

2.2 The other notable events

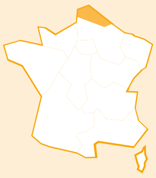
Emergency situation preparedness

On 1st October 2015, the Dijon division took part in the national emergency exercise simulating a radioactive substance transport accident in Saône-et-Loire on the A6 motorway. The aim of this exercise was to verify the response of a non-nuclearised *département* in the event of such an emergency and to test the prefecture's response to media pressure and its interfaces with the national level of the nuclear authorities. The exercise pinpointed areas in which the management of such emergency situations can be improved, such as the involvement of the mayors, triggering and broadcasting the alert, and the method of interchange between the stakeholders.

On 10th December 2015, the Dijon divisions took part in the local emergency exercise organised by the Nievre prefecture to test part of the departmental organisation for the distribution of iodine tablets should the "Orsec" (national emergency response) plan be triggered by the national authorities. The exercise allowed the implementation of some of the measures provided for in the departmental plan for the distribution of iodine tables to the population, and highlighted the need to supplement the local safeguard plans.

Management of emergency situations

The Dijon division assisted the prefectural authorities in the management of the following emergency situations:
- On 23rd July 2015, further to the discovery of a source of caesium and traces of uranium contamination in a private individual's home in Yonne, ASN asked the CEA (French Alternative Energies and Atomic Energy Commission) to ensure the radiological remediation of the site and IRSN to subsequently verify that all added radioactivity had been removed.
- On 16th October and 7th November 2015 in the Jura, following the discovery of an object containing natural uranium in a station of the *Gendarmerie* and an object containing radium in a private individual's home. These objects were recovered by Andra.



THE STATE OF NUCLEAR SAFETY AND RADIATION PROTECTION IN 2015 IN THE NORD - PAS-DE-CALAIS REGION REGULATED BY **THE LILLE DIVISION**

The Lille division regulates nuclear safety, radiation protection and the transport of radioactive substances in the two *départements* of the Nord - Pas-de-Calais region.

As at 31st December 2015, the workforce of the Lille division stood at 17 officers: 1 regional division head, 2 deputy heads, 12 inspectors and 2 administrative officers, under the authority of an ASN regional representative.

The activities and installations to regulate comprise:

- the Gravelines NPP (6 reactors of 900 MWe) operated by EDF;
- the site of *Société de maintenance nucléaire* (Somanu) in Maubeuge (Nord *département*) operated by Areva;
- 12 external-beam radiotherapy departments;
- 2 brachytherapy departments;
- 17 nuclear medicine departments;
- 65 interventional radiology departments;
- 91 tomography devices;
- 1 organisation using blood product ionisers;
- 1 cyclotron producing fluorine-18;
- about 3,000 medical and dental diagnostic radiology devices;
- 200 veterinary diagnostic radiology devices;
- 24 industrial radiography companies;
- about 1,500 industrial devices;
- 32 research units;
- 4 approved organisation agencies.

In 2015, ASN's Lille division carried out 129 inspections in the Nord - Pas-de-Calais region, comprising 24 inspections in the Gravelines NPP, 3 in Somanu (*Société de maintenance nucléaire),* 96 in small-scale nuclear activities and 6 in the field of transport of radioactive substances. ASN also carried out 13 days of labour inspection in the Gravelines NPP.

In 2015, the Lille division was notified of 96 significant events, of which 61 occurred in BNIs, 3 in the transport of radioactive substances and 32 in small-scale nuclear activities. Among the notified events in BNIs, 13 in the Gravelines NPP were rated level 1 on the INES scale. Among the notified events concerning the transport of radioactive substances, one was rated level 2 on the INES scale. Among the 32 notified events concerning small-scale nuclear activities, 4 were rated level 1 on the INES scale, to which can be added 7 events concerning radiotherapy patients, with 1 of them rated level 2+ on the ASN-SFRO scale, 2 rated level 2 and 4 rated level 1.

On 17th December 2015, ASN gave the Gravelines NPP formal notice to comply with certain provisions applicable to the site's liquid effluent tanks. ASN also gave formal notice on 22nd December 2015 to the head of a nuclear activity within the Lille Regional University Hospital Centre (CHRU) to comply with certain provisions of the Public Health Code. The ASN inspectors also issued 2 violation reports.

1. ASSESSMENT BY DOMAIN

1.1 The nuclear installations

Gravelines nuclear power plant

ASN considers that the radiation protection and environmental protection performance of the Gravelines NPP is, on the whole, in line with its general assessment of EDF's performance. However, ASN considers that nuclear safety performance is down with respect to the other sites. The site must take measures to improve more specifically the reliability of practices, operating rigour, the speed of detection of deviations and the application of instructions.

With regard to maintenance, ASN considers that the site has made progress with the general condition of some items of equipment of the facilities. Efforts must be continued on the other corrosion-sensitive equipment items due to their seaside location and their ageing. The maintenance operations wich result in a reduction in equipment reliability are fewer in number, but the site must remain attentive in this respect.

With regard to environmental protection, bringing the tanks storing effluents from the reactor primary and secondary systems into conformity is taking longer than initially planned due to the scale of the work involved, particularly the replacement of the bottoms of all the tanks. Furthermore, ASN considers that the site must continue its efforts in the control of effluent discharges containing tritium.

With regard to emergency situation management, ASN considers that the site personnel in charge of the strategic management command post must participate more actively in the emergency exercises. Efforts must be made in the management of fire loads and fire sectorisation.

With regard to radiation protection, ASN notes recurrent shortcomings in the control of access to some radiological areas. Progress is also required in operator monitoring at zone exits, in the control of worksites with a risk of dispersion of radioactive substances and the monitoring of operators on certain specific-risk worksites.

With regard to health and safety, ASN remains attentive to the training of operators working at height using ropes. There have been no serious accidents, although safety deviations have sometimes been noted on the worksites.

ASN examined the results of the inspections of reactor 1 which displays cracks in an instrumentation penetration in the bottom of the reactor vessel. These inspections did not reveal any development of these defects and their final repair is scheduled for 2016.

On 20th August 2015, ASN issued a resolution stipulating requirements concerning the control of risks associated with the Dunkerque methane terminal and transfers of non-radioactive liquid effluents from the Gravelines NPP installations.

Somanu – Société de Maintenance Nucléaire *(nuclear maintenance company) – in Maubeuge*

ASN considers that operation of Somanu's facilities is satisfactory on the whole. As in 2014, Somanu had a high level of activity due in particular to the maintenance work on the N4 hydraulics of the 1,400 MWe nuclear power plants.

Performance in radiation protection has been maintained at the good level of the preceding year. ASN asks that efforts be maintained, particularly regarding the trend in doses received by the personnel of Somanu and of outside contractors.

ASN has identified areas for improvement, particularly in the inspection and periodic testing of equipment important for the protection of interests (Article L. 593-1 of the Environment Code), in the handling of deviations and the management of radioactive substance shipments.

ASN inspection of the technical galleries of the Gravelines NPP, June 2015.

The actions relating to the periodic safety review will continue in the coming years, with, among other things, examination of the creation authorisation decree modification file and the request to modify the resolution on discharges. ASN asks that the licensees organise themselves to produce the studies substantiating the safety of the facilities and meet the commitments given in the periodic safety review file.

1.2 Radiation protection in the medical field

Radiotherapy

The Nord - Pas-de-Calais region has 12 radiotherapy centres equipped with 29 accelerators, most of which are recent, and implementing innovative techniques. ASN notes that for several years now the centres have been involved in a real drive for progress with the aim of improving the rigour, organisation and traceability of medical interventions. The quality approach implemented in the centres is giving satisfactory results, although ASN notes disparities between centres and a lack of consistency over time.

The seven inspections conducted by ASN in radiotherapy centres in 2015 more specifically examined aspects concerning their organisation, the implementation of a quality management system and the management of the skills of personnel involved in the delivery of treatments. ASN observes that the medical physicist staffing situation is now satisfactory on the whole, although it remains unstable in some centres. Lastly, as in 2014, ASN carried out a campaign of unannounced inspections in a number of radiotherapy centres during summer 2015. The aim was to verify the required minimum presence of radiotherapists and technical personnel (medical physicists and technologists) during the treatments. Today, all the centres in the Nord - Pas de Calais region have undergone this verification.

The procedure for recording and analysing adverse events is now in place in all the centres. However, ASN notes a loss of momentum in the recording and analysis of adverse and precursory events and the number of notifications of significant radiation protection events, which remains relatively low. In 2015 ASN was informed of two significant events rated level 2 on the ASN-SFRO scale relative to patients.

Application of quality assurance to the patient care process is progressing satisfactorily with respect to the applicable regulatory provisions. The procedures must be consolidated by implementing process management verification tools.

Innovative technologies are being increasingly used in radiotherapy, bringing, among other things, greater precision in treatments (image-guided radiotherapy for example). ASN asks that the centres conduct an in-depth reflection on the way their teams embrace these technologies.

Lastly, ASN notes that in the two brachytherapy centres, the procedures for ensuring treatment quality and safety are not as advanced as in the radiotherapy departments.

Interventional practices

In 2015, ASN carried out six inspections in the area of interventional practices, particularly in operating theatres. Interventional practices involve invasive medical procedures – for diagnostic or therapeutic purposes – guided using ionising radiation (see chapter 9, point 1.1.2). ASN has noted progress in the use of personal protective equipment by medical staff. Further efforts are nevertheless required, notably in the wearing of dosimeters – by practitioners in particular, in training in radiation protection of workers and patients, and in the optimisation of doses delivered to patients.

ASN's inspections in interventional practices are based on a study carried out in 2013 with centres in the region performing procedures in operating theatres and dedicated rooms This study served to enhance knowledge of the interventional practices in the region, to study current practices for protecting patients and personnel against ionising radiation, and to gain a better understanding of the medical specialities as a whole and the major implications of radiation protection for personnel and patients.

ASN observes currently that interventional practices are being used more and more and that they have considerably evolved over the last few years. They present two-pronged radiation protection risks: exposure of the practitioner and the medical team, which can be significant, and exposure of the patient, particularly during long or repeated procedures. ASN's 2014 survey of interventional practices in the Nord - Pas-de-Calais region reveals considerable room for progress in addressing these risks, particularly by optimising equipment parameters which enables patient and worker exposure to be reduced.

Nuclear medicine

ASN carried out nine inspections in the field of nuclear medicine in 2015. These inspections reveal progress in the integration of radiation protection rules, but ASN considers that it is nevertheless still too slow. Progress is required more specifically in occupational radiation protection, essentially in the defining of radiological zoning and the analyses of working practices and conditions. The management of liquid effluents can also be improved. Lastly, ASN notes that the centres are committed to a patient dose monitoring and optimisation approach.

Computed Tomography

ASN's inspections of computed tomography facilities involved four centres in 2015. During these inspections ASN found that, on the whole, occupational radiation protection rules are applied satisfactorily. ASN nevertheless notes that improvements must still be made, more specifically by formalising the technical controls of radiation protection to a greater extent, by giving the persons competent in radiation protection sufficient time to accomplish their duties, by better informing the personnel of outside contractors, and by reminding physicians of the need to comply with radiation protection rules. Lastly, ASN considers that progress has been made in the optimisation of doses delivered to patients and that these efforts must be continued.

Inspection of radiology centres

In 2015 ASN carried out a one-off series of inspections in 17 medical radiology centres in the Nord - Pas-de-Calais region. In view of the low radiological risks, this activity is not subject to systematic and periodic field inspections. These inspections revealed a better degree of administrative conformity of the facilities and a significant improvement in the risk assessments performed by the centres compared to the situation found in 2009. ASN nevertheless identified some shortcomings in training, in the frequency of radiation protection controls and facility conformity verifications. The application of radiation protection measures in most of the centres is satisfactory. ASN did nevertheless identify several radiology centres in which immediate corrective actions were necessary.

1.3 Radiation protection in the industrial and research sectors

Industrial radiography

In 2015, ASN carried out 11 inspections in industrial radiography. ASN observes continued improvement in the organisation of radiation protection and the monitoring of workers in the companies. ASN's inspections were primarily unannounced worksite inspections, where it notes repeated deficiencies in compliance with radiation protection rules, particularly in delimiting, signalling and controlling the work areas. These inspections also revealed insufficient checks when introducing sources into gamma ray projectors. Two significant radiation protection events in gamma radiography were notified to ASN in 2015.

Since 2005, in partnership with the DIRECCTE (Regional directorate for companies, competition, consumption, work and employment) and the CARSAT (Retirement and occupational health insurance fund), ASN has instituted a charter of good practices in industrial radiography. The aim of this charter is to optimise the use of ionising radiation in this area of activity. In this context ASN will organise an awareness-raising drive with the ordering customers, contractors and their radiographers to assess the impact of this charter on working conditions and to identify potential areas for improvement.

Universities and research laboratories

ASN oversees the 32 research units of the Nord - Pas-de-Calais region that hold and use sources of ionising radiation. These units use a wide variety of ionising radiation sources. The ASN oversight duties led to six inspections in 2015, in particular on the subjects of occupational radiation protection and the management of radioactive waste and effluents. ASN considers that the integration of radiation protection rules in these research units is gradually improving. Nevertheless, the discovery and management of radioactive sources and the removal of sources and radioactive waste stored in some universities remain issues of concern for ASN. Progress is also necessary with regard to the administrative regularisation of certain nuclear activities, compliance with the Public Health Code and notification of significant radiation protection events to ASN.

Lastly, ASN organised an awareness-raising initiative attended by 70 public research professionals in 2015.

1.4 Nuclear safety and radiation protection in the transport of radioactive substances

ASN carried out in six inspections in nuclear installations and small-scale nuclear activities in the Nord - Pas-de-Calais region in 2015. These inspections did not reveal any major deviations from the regulations. In the medical field, the radiopharmaceutical transport inspections provided a measure of the progress made. Lastly, ASN carried out a reactive inspection following the notification in 2015 of a significant event in the transport of a gamma ray projector, rated level 2 on the INES scale.

2. ADDITIONAL INFORMATION

2.1 International action

For many years the Lille division has been organising international exchanges with the aim of sharing experience in the area of nuclear safety and radiation protection. The main focus of the exchanges in 2015 was five joint inspections conducted with the Belgian Nuclear Safety Authority (AFCN), its technical support organisation (Bel V), and, for the first time, the Dutch Nuclear Safety Authority (KFD, *KernFysische Dienst*). These exchanges provided the opportunity to compare the measures implemented in the nuclear power plants following the Fukushima Daiichi accident and in small-scale nuclear activity inspections, among other things.

Lastly, a member of the Lille division took part in an IRRS (Integrated Regulatory Review Service) mission in Malta.

2.2 Informing the public

Press conferences

In 2015 ASN held two press conferences on the status of nuclear safety and radiation protection, one in Lille, the other in Dunkerque.

Work with the Local Information Committees (CLIs)

ASN has kept the Local Information Committees (CLI) of the Gravelines NPP and Somanu in Maubeuge regularly informed about the files in progress in the two nuclear facilities. More specifically, the Gravelines CLI was consulted when ASN was preparing the prescriptions concerning the continuation of operation and the repair of the bottom-mounted instrumentation penetration of reactor 1 and those concerning the impact of the Dunkerque methane terminal on the facilities.

Public information actions

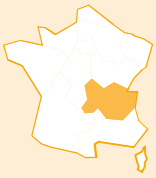
From September to December 2015, ASN and IRSN, in partnership with the urban community of Dunkerque, the Gravelines CLI and the Anccli (National association of local information committees, invited the inhabitants of Dunkerque and the surrounding area to visit the ASN/IRSN exhibition and the other attractions at the *Palais de l'univers et des sciences* in Cappelle-la-Grande (Nord *département*). This exhibition, designed to develop the nuclear risk culture in the general public, enabled adults and children of the Dunkerque region – some of whom live near the Gravelines NPP – to learn about the physical phenomena, risks, and human and environmental implications associated with radioactivity, and to form their own opinions and discuss these issues.

In addition to this, a series of four meetings entitled *"The service life of nuclear power plants"*, *"Thirty years after Chernobyl and five years after Fukushima, what lessons have been learned?"*, *"Systems for alerting and protecting local populations"* and lastly, *"The healing powers of radiation"*, provided the opportunity for discussion and debate with the public.

2.3 The other notable events

During the emergency exercise held at the Gravelines NPP on Tuesday 10th February 2015 and coordinated by the prefecture of the Nord *département*, ASN participated in the deployment of the actions designed to test the measures to protect the population and public buildings – especially schools – provided for in the off-site protection plan, the preparedness of the industrial sites situated near the power plant and certain provisions of the doctrine for managing post-nuclear-accident situations. Carried out in a restricted time frame, this exercise highlighted several areas for improvement, notably the involvement of the members of the Gravelines CLI in the preparation and performance of the exercise, the clarification of the alert procedures and the preparedness of the industrial sites situated near the nuclear power plant.

Lastly, the Lille division of ASN participated, with the representatives of the government departments of the Nord defence zone, in the meetings devoted to the presentation of elements of the doctrine for post-nuclear-accident management and to the national response plan for a major nuclear or radiological accident.



THE STATE OF NUCLEAR SAFETY AND RADIATION PROTECTION IN 2015 IN THE RHÔNE-ALPES AND AUVERGNE REGIONS REGULATED BY **THE LYON DIVISION**

The Lyon division regulates nuclear safety, radiation protection and the transport of radioactive substances in the twelve *départements* of the Auvergne and Rhône-Alpes regions.

As at 31st December 2015, the workforce of the Lyon division stood at 36 officers: 1 regional division head, 3 deputy heads, 27 inspectors and 5 administrative officers, under the authority of the ASN regional representative.

The activities and installations to regulate comprise:

- the NPPs at Bugey (4 reactors of 900 MWe), Saint-Alban/Saint Maurice (2 reactors of 1,300 MWe), Cruas-Meysse (4 reactors of 900 MWe) and Tricastin (4 reactors of 900 MWe) operated by EDF;
- the nuclear fuel fabrication plants of Areva NP (formerly FBFC) in Romans-sur-Isère;
- the nuclear fuel cycle plants operated by Areva and situated on the Tricastin industrial platform;
- the Operational Hot Unit at Tricastin (BCOT) operated by EDF;
- the high flux reactor operated by the Laue-Langevin Institute in Grenoble;
- the Activated waste packaging and storage facility (Iceda), under construction on the Bugey nuclear site operated by EDF;
- the Superphénix reactor undergoing decommissioning at Creys-Malville, and its auxiliary installations;
- reactor 1 undergoing decommissioning at the Bugey NPP operated by EDF;
- the Ionisos irradiation facility in Dagneux;
- the nuclear fuel fabrication plant and pelletising unit of Areva SICN in Veurey-Voroize, waiting to be delicensed;
- the reactors and plants of CEA (French Alternative Energies and Atomic Energy Commission) in Grenoble, undergoing decommissioning;
- the CERN international research centre located on the Swiss-French border;

- 22 external-beam radiotherapy departments;
- 6 brachytherapy departments;
- 23 nuclear medicine departments;
- 150 interventional radiology departments;
- 120 tomography devices;
- about 10,000 medical and dental diagnostic radiology devices;

- 700 veterinary structures (practices or clinics);
- about thirty industrial radiography agencies (requiring the certificate of proficiency to handle industrial radiography devices);
- about 600 users of ionising radiation in the industrial field;
- 100 research units;
- 3 head offices and 8 agencies of approved bodies.

In 2015 the Lyon division of ASN carried out 353 inspections in the Auvergne and Rhône-Alpes regions, of which 94 were in the 4 nuclear power plants, 76 in plants and facilities undergoing decommissioning, 168 in small-scale nuclear activities and 15 in the transport of radioactive substances. ASN also carried out 55 days of labour inspections in the four nuclear power plants and on the Creys-Malville site.

In 2015, the Lyon division was notified of 394 significant events, of which 314 occurred in BNIs, 19 in the transport of radioactive substances and 61 in small-scale nuclear activities. Among the events notified for the BNIs, 25 were rated level 1 on the INES scale. In the small-scale nuclear activities, out of the 61 notified events, 2 were rated level 1 on the INES scale, to which can be added 13 events concerning radiotherapy patients. Among the notified events concerning the transport of radioactive substances, 2 were rated level 1 on the INES scale.

On 4th March 2015, ASN served formal notice on the head of a nuclear activity at the Pont-de-Beauvoisin Hospital Centre to comply with certain provisions of the Public Health Code.

1. ASSESSMENT BY DOMAIN

1.1 The nuclear installations

Nuclear power plants

Bugey nuclear power plant

With regard to nuclear safety, ASN notes that following the significant decline in operating rigour seen in 2013 and early 2014, the start of progress shown by the Bugey NPP towards the end of 2014 was confirmed in 2015. ASN moreover carried out an in-depth inspection in September 2015 which confirmed that measures taken by the site were going in the right direction: the licensee has initiated several structuring actions with regard to safety management to move forward in the areas in which shortcomings had developed over the last few years. The NPP has thus made progress in the alignments and the management of temporary modifications in the operating technical specifications. The NPP's organisation for the monitoring of control room activities remains tenuous.

With regard to maintenance, ASN notes that the first two outages of the 2015 campaign went well on the whole. The reactor 5 outage was marked by damage to the sealing of the reactor building containment. Through ASN resolution 2015-DC-0533 of 1st December 2015, ASN asked EDF to submit the metal liner repair processes to it for approval and to perform the repairs before restarting the reactor.

With regard to environmental protection, ASN considers that the site controls its operating discharges. ASN nevertheless notes shortcomings in the containment of liquids, whether radioactive or chemical. ASN considers that correcting these shortcomings, which result from ageing of the facilities, requires the implementation of an ambitious programme focusing on both equipment maintenance and ensuring better management of non-routine operating activities.

With regard to occupational radiation protection, ASN considers that the results of the Bugey NPP are encouraging. With regard to risk prevention, the first three quarters of 2015 saw an improvement in the occupational safety and risk prevention indicators after two years of mediocre results in this area: ASN observes that these results have once again declined since the outage of reactor 5 began.

Saint-Alban/Saint-Maurice nuclear power plant

ASN considers that the nuclear safety performance of the Saint-Alban/Saint-Maurice NPP is, on the whole, in line with its general assessment of the EDF plants. The quantitative indicators for 2015 are generally pointing in the right direction, showing that the fundamental work – which began in 2011 – to lastingly redress the site's performance is bearing fruit.

Regarding maintenance work, EDF performed two simple reactor refuelling outages in 2015, which were successful on the whole. ASN nevertheless noted some weak points in the application of the maintenance programme schedules.

ASN considers that the environmental protection performance of the Saint-Alban/Saint Maurice NPP is, on the whole, in line with the general assessment of the EDF plants. ASN notes that the operational results for discharges are positive, reflecting improved management of EDF's operational control actions. The site must nevertheless be more diligent in applying certain regulatory requirements and monitoring contractors responsible for certain sampling operations and/or analyses. ASN also notes that the fire outbreak in the site's laundry highlighted shortcomings in the response to the conclusions of the fire risk studies of 2010. Lastly, ASN recommends the Saint-Alban/Saint-Maurice NPP to be more forward-looking in preparing the files it is required to submit to the water policing services.

In the area of worker protection, ASN notes that the radiation protection results for the two reactor outages were on the whole satisfactory, despite some disparities observed on the ground. Work health and safety results are generally satisfactory: ASN notes that the accident frequency rate continued to fall in 2015 for the fifth year running and that no serious accidents occurred.

Cruas-Meysse nuclear power plant

ASN considers that the nuclear safety performance of the Cruas-Meysse NPP falls short of its general assessment of EDF performance. ASN notes that operating rigour at the Cruas-Meysse NPP has been sub-standard since 2014 and that 2015 was marked by shortcomings in compliance with the operating technical specifications and in operating rigour. These shortcomings were revealed above all by the large number of significant safety events that occurred during the peak of activity resulting from simultaneous restarting of two reactors in September 2015. It is an absolute necessity for EDF to improve its safety culture and operating rigour in 2016 to meet the safety challenges of the 10-year outages of reactors 4 (in 2016) and 2 (in 2017).

In a context of a very high maintenance workload, the Cruas-Meysse NPP showed persistent weaknesses in the reliability of maintenance activities in 2015. ASN notes in particular that the third 10-year outage of reactor 1 lasted twice as long as EDF initially planned. The NPP has also had difficulty in making reliable technical diagnoses for several technical problems. Lastly, ASN notes a lack of control of foreign material exclusion from the systems and pools.

ASN considers that the environmental protection performance of the Cruas-Meysse NPP remains below its general assessment of the EDF fleet. ASN notes that the Cruas-Meysse NPP made considerable efforts in 2014 and 2015 and demonstrated greater rigour in waste management. Nevertheless, several events notified in the second half of 2015 raise further questions on the site's management of liquid containment.

With regard to radiation protection, 2015 continues in line with the preceding years: dosimetry is under control but there are difficulties in obtaining satisfactory levels of radiological cleanness during reactor outages and deficiencies in controlling access to areas with high dosimetric risks.

From the aspect of health and safety at work, ASN observes that the workplace accident results remain sub-standard and the site's performance is below that of the EDF nuclear fleet for the third year running, with a poor accident frequency rate, even though there were no serious accidents in 2015. Lastly, labour relations on the site remain complex, despite the improvements noted in the last few years: more specifically, the committee for health, safety and working conditions must start functioning more smoothly again.

Tricastin nuclear power plant

ASN considers that the nuclear safety performance of the Tricastin NPP on the whole matches its general assessment of the EDF plants, as it has done over the last three years. Although EDF has made progress in the periodic tests, ASN observes a deterioration in the results of system configuring actions (alignments and lockout/tagout), resulting from weaknesses in organisational and human factors.

Regarding maintenance, ASN observes that the Tricastin NPP's management of reactor outages remains good on the whole, even though technical events resulting from errors in work performance were discovered during the restarting phases, particularly concerning the outage of reactors of 1 and 2.

ASN considers that the environmental protection performance of the Tricastin NPP is in line with the general assessment of the EDF plants. Although the operational results for radioactive discharges are on the whole good, ASN notes that the plant must be attentive to its chemical discharges. ASN notes that waste management can be improved: the lack of space in the site's conditioning auxiliaries building has reached a worrying level that requires the licensee to implement lasting measures to restore appropriate management of this building. Lastly, ASN considers it vital for the licensee to improve the containment of liquids (whether radioactive or chemicals) in view of the numerous deviations observed in this area in 2015.

With regard to occupational health and safety, the results of the Tricastin NPP meet the objectives it had set itself and there were no serious accidents. The management of lockouts remains tenuous and the site must remain attentive to electrical risks.

Lastly, labour relations remain constructive, but ASN nevertheless draws EDF's attention to the conditions of taking on contractors' employees in the context of renewal of a major worksite assistance contract.

Fuel cycle installations

Areva NP (formerly FBFC) - Nuclear fuel fabrication plants in Romans-sur-Isère

In 2015, Areva NP continued its actions to improve the safety of the two facilities in the context of increased ASN scrutiny of the site since 2014. Areva has met the majority of the initial deadlines set in the safety improvement action plan it presented to ASN.

The work to consolidate the facilities has begun, but several major upgrades have not yet been completed. This is why, through a resolution of 8th January 2015, ASN required that some facilities be brought into compliance or, failing this, the radioactive substances be removed. In this same resolution, ASN set Areva NP additional requirements concerning the "hardened safety core"and emergency situation management resulting from the lessons learned from the Fukushima Daiichi accident.

ASN has also started examining the periodic safety review file of BNI 98 which was completed in January 2015. The periodic safety review report for BNI 63 was submitted at the end of 2015. Once ASN has finished examining these reports it will state its position on the continued operation of these installations.

ASN inspection of the Areva NP (formely FBFC) site, Romans-sur-Isère plant, October 2015.

As part of the follow-ups to the in-depth inspection of safety management and operating rigour which it coordinated in 2014, ASN noted the first improvements in operating rigour.

On the environmental front, in its resolution of 4th February 2014, ASN had given Areva NP formal notice and 18 months to bring the effluent treatment plant retention structure into conformity by summer 2015. At the end of July 2015, ASN observed the compliance work had effectively been carried out and deemed that Areva NP had satisfied the conditions of the resolution.

ASN considers it vital for Areva NP to improve its management of nuclear waste routes. ASN nevertheless notes with approval the work to repair the stormwater drainage system and build a new storm-water tank.

In view of all these elements, ASN will maintain heightened vigilance over the Areva NP Romans-sur-Isère site in 2016. ASN will more specifically check that the licensee continues to implement the improvement actions to which it has committed itself.

Nuclear fuel cycle plants situated on the Tricastin industrial platform

In 2015 Areva continued to deploy pooled organisational structures in the areas of logistics, laboratories, utilities, effluents, waste and safety, security, radiation protection and the environment on the Tricastin platform.

ASN endeavoured to ensure that these mutualisation measures did not lead to any disorganisation, even temporary, in the activities important for protection. More specifically, on 21st and 22nd October 2015, it carried out unannounced inspections of senior management and all the site installations on the theme of radiation protection. It observed that the site's radiation protection department had defined a baseline of rules applicable to the five installations, but that the licensees had to continue their efforts to implement them.

At the end of 2014, Areva also proposed to ASN the implementation of an on-site emergency plan based on an organisation common to the platform. ASN judged this proposal inadmissible because it did not enable the licensees to fully maintain their prime responsibility as nuclear licensees, particularly in an emergency situation. A new proposal from Areva is currently being examined.

Areva NC - TU5 and W plants in Pierrelatte

ASN considers that the facilities situated within the perimeter of BNI 155 of Areva NC are operated with a level of safety that is relatively satisfactory. The licensee must nevertheless continue to make progress in operating rigour, application of and compliance with instructions. In effect, several significant events in 2015 again revealed shortcomings in this respect, their main consequences being containment losses. ASN moreover observed that the monitoring of outside contractors is not always satisfactory, despite the licensee's commitment, which has already been pushed back, to deploy the Areva group's directive at the end of 2014.

For the TU5 facility, 2015 started with clean-out work to allow its restarting following the event of December 9th 2014 involving a significant leak of uranyl nitrate, which was limited to the premises of the installation. ASN conducted an inspection to verify the licensee's repair work before the facility was put back into service. On the basis of its findings, ASN asked Areva to improve the management of the prerequisites for return to service. ASN has moreover started examining the periodic safety review file for this installation. Once the examination is completed, ASN will state its position on the continuation of operation of these installations at the end of 2016.

For the W facility, the start of 2015 was marked by the entry into service of the new hydrofluoric acid storage area, which went smoothly. The examination of this modernisation work led ASN to update all the technical requirements applicable to this ICPE, which is classified Seveso high-threshold, through its resolution of 6th January 2015.

With regard to the new emission unit (EM3) whose entry into service has been prescribed by ASN for 2018, examination of the file began in 2015 along with the preparation of the worksite for work to start at the end of 2015. This new unit will meet the safety requirements set by ASN following the Fukushima Daiichi nuclear accident.

Areva NC (Formerly Comurhex) Fluorination plant in Pierrelatte

ASN considers that the facilities situated within the perimeter of BNI 105 are operated with a satisfactory level of safety.

Particularly noteworthy in 2015 was the examination of the request to extend operation of the Comurhex I plants until the end of 2017. This request from Areva stems directly from the fact that construction of the new Comurhex II plants is well behind schedule. This extension has been framed by ASN CODEP-LYO-2015-024792 resolution of 30th June 2015, which set out the main reinforcement works for these plants. On 11th August 2015, ASN carried out an unannounced inspection to find out whether these principal improvements had been effectively carried out, at the end of which it asked that the layout of a newly installed mitigation system be improved.

ASN therefore remains attentive to ensuring that sufficient rigour in the operating and maintenance procedures for these plants is maintained. This latter point must be put into perspective with the ongoing renewal of personnel skills which remains a subject of attention for ASN, particularly with a view to the transition between the facilities of Comurhex I and those of Comurhex II in the years to come.

With regard to the environmental aspects, the discharge resolutions of BNI 105 were revised in 2015 by ASN resolutions 2015-DC-0496 and 2015-DC-0497 of 27th January 2015.

ASN also observed an unsatisfactory situation in the management of the conventional waste areas of BNI 105. The licensee reacted promptly and deployed a plan of action to restore conformity.

Eurodif Georges Besse - Uranium enrichment plant in Pierrelatte

The last rinsing operations were continued until October 2015, under conditions that ASN considers satisfactory. Since the end of these operations, there is no longer any chlorine trifluoride (ClF_3) in the facility.

Due to technical difficulties, particularly concerning the qualification of new equipment items, the operations to hydrolyse and introduce air into the cascade did not start until 2015 and will continue in 2016.

ASN moreover authorised the operations to hydrolyse and introduce air into the DPR unit and the final shutdown of the units of annex U for treating substances extracted from the diffusion cascade. It is currently examining the hydrolysis authorisation application for the annex U systems. Following all these operations, which will have eliminated the majority of the source term, the plant will be in a surveillance phase until the first decommissioning operations are started.

In accordance with the Decree of 2nd November 2007, the licensee submitted its final shutdown and decommissioning application for the installation at the end of March 2015. Examination of its admissibility revealed that further information was required before the examination could proceed. These shortcomings concern general aspects in the decommissioning strategy adopted by Eurodif Production, more particularly in the management of radioactive waste and the description of the initial and final states of the installation.

SET Georges Besse II - Uranium enrichment plant in Pierrelatte

The Georges Besse II (GB II) plant operated by *Société d'enrichissement du Tricastin* (SET), displayed a satisfactory level of safety in 2015. The technologies deployed in the plant enable high standards of safety, radiation protection and environmental protection to be met.

The gradual entry into production of the enrichment cascades was completed in 2015. The internal cascade startup authorisation commission functioned satisfactorily.

After an inspection carried out by ASN in 2014 to examine the criticality risk which gave unsatisfactory results, ASN verified in 2015 that SET had taken measures to improve control of the criticality risk.

ASN also authorised entry into service of the REC II unit through ASN resolution 2014-DC-0461 of 7th October 2014. In 2015 it verified the conditions of entry into service of this facility. Although the first operations of the unit were carried out with rigour, ASN considers that the operating reliability of the facility must be improved.

Socatri - Company operating a clean-up and recovery installation - Bollène plant

ASN detected shortcomings in the management of the operational safety of Socrati's activities in 2015.

With regard to the commitments made by Socatri in 2014 following the periodic safety review of BNI 138, ASN observed that the licensee had difficulties in meeting the commitment deadlines and content, and then in deploying them operationally, particularly the commitments concerning control of the criticality risk.

ASN also detected several nonconformities of elements classified as important for protection with respect to the defined design requirements. Lastly, numerous shortcomings in fire risk control were detected during an unannounced inspection on this theme in 2015.

ASN therefore expects Socatri to demonstrate greater operating rigour and improve the facility's compliance with its baseline safety requirements.

Installations undergoing decommissioning

Superphénix reactor at Creys-Malville

ASN considers that the safety of the Superphénix reactor decommissioning operations and of operation of the APEC (fuel storage facility) is ensured satisfactorily. The progress ASN observed in 2014 with regard to operating rigour and monitoring the performance of maintenance operations and periodic tests was maintained in 2015.

In 2015 ASN asked EDF to rapidly take organisational measures to improve management of the retention structures and in particular the treatment of hazardous substances that could accumulate in them.

ASN will shortly make a statement on the treatment of the residual sodium of the reactor vessel and its filling with water. Preparation and performance of these operations represent the main risk activities for the coming year.

The periodic safety review has started on the site's two installations. EDF must submit the conclusions to ASN in March 2016. After examining them, ASN will adopt a position on the conditions of its continued operation.

Bugey nuclear power plant reactor 1 undergoing decommissioning

ASN considers that the decommissioning of reactor 1 is proceeding under generally satisfactory safety conditions but that EDF must remain vigilant to the safety of the workers performing the activities.

The decommissioning work outside the reactor vessel continued in 2015.

CEA centre reactors and plants in Grenoble

Particularly notable in 2015 was the finalising of the operations to clean-out and delicense the waste zoning of the LAMA (active materials analysis laboratory), which took place in February. CEA submitted its delicensing application file for the BNI in March 2015.

The technical discussions between ASN and the CEA concerning the remediation of the soil of the STED (effluent and waste treatment plant) continued. ASN asked the CEA to continue the remediation operations that can be technically achieved at a cost that remains acceptable.

The other industrial and research facilities

High Flux Reactor (RHF) in the Laue-Langevin Institute (ILL) in Grenoble

ASN considers that the safety of the RHF is managed in a responsive and determined manner in the areas considered as priorities by ILL.

Thus, in response to the lessons learned from the Fukushima Daiichi accident, ILL rapidly introduced substantial consolidation measures, which continued smoothly in 2015. ASN notes however that these improvements are not always implemented with the rigour necessary to ensure traceability of the activities and updating of the baseline requirements.

Besides, the ILL must improve and clarify the baseline safety requirements of the installation, then ensure that the installation complies with this baseline.

In 2015, in response to several requests from ASN, ILL proposed putting in place an integrated management system that meets the requirements of the BNI regulations, and revamping its safety organisation to make it more independent.

In response to the ASN compliance notice, ILL submitted requests to be granted particular conditions for application of Title III of the Decree of 13th December 1999 relative to nuclear pressure equipment for the 22 equipment items displaying deviations from regulations. Each of these files describes the proposed measures to compensate for the verifications that cannot be performed on account of the particularities of the RHF equipment. After analysing the proposals, ASN defined these particular arrangement conditions through two resolutions in March 2015.

The Activated waste packaging and interim storage installation (Iceda) at Bugey

The purpose of the Iceda facility will be to process and store activated waste from operation of the EDF installations and from the decommissioning of first-generation reactors and the Creys-Malville NPP.

After a break of several years, work on the construction site resumed fully in early April 2015. After completing its inspections, ASN considers that the restart was managed with rigor and that the worksite is well kept. The level of surveillance put in place by EDF is appropriate for the risks.

Ionisos irradiator in Dagneux

The Dagneux irradiator – BNI 68 – operated by the company Ionisos, displayed a satisfactory level of safety in 2015. The pool water treatment whose malfunctioning had been detected by ASN during an inspection in 2014, was brought back into compliance with the installation's baseline safety requirements.

The periodic safety review of the installation will be examined in 2016, following which ASN will state its position on the continuation of its operation.

EDF BCOT - Operational Hot Unit on the Tricastin site in Bollène

On completion of its inspections, ASN considers that the level of safety of the BCOT is satisfactory. In 2015, ASN verified performance of the tests prior to starting cutting up the control rod drive mechanisms for packaging as waste.

CERN - Accelerator and Research Centre (Geneva)

Following the signing of an international agreement between France, Switzerland and CERN on 15th November 2010, ASN and the OFSP (Swiss Federal Office of Public Health) - the Swiss radiation protection oversight body - are contributing to the verification of the safety and radiation protection requirements applied by CERN.

The joint actions concern transport, waste and radiation protection.

ASN and the OFSP have thus approved the site's nuclear waste management study and the safety case of a new linear accelerator built on the CERN site and called Linac 4. A joint inspection of this linear accelerator was carried out with the Swiss authorities in 2015.

A protocol for notifying and sharing information concerning significant events and their rating on the INES scale between the organisations (CERN, ASN, OFSP) has also been drawn up. CERN made its first significant event notification in 2015, which is positive with regard to transparency and the improvement of experience feedback.

1.2 Radiation protection in the medical field

Radiotherapy

ASN carried out 11 inspections in the 22 radiotherapy centres in the Rhône-Alpes and Auvergne regions in 2015.

ASN's inspections focused in particular on the management of treatment safety and quality, preparation of treatments, control of patient positioning during treatment and implementation of the professional practices evaluation process. Particular attention was also devoted to centres that implement innovative treatment technologies, those whose staffing levels are considered potentially vulnerable, and those that are behind schedule with implementation of the quality assurance system.

The results of these inspections show that all centres have taken organisational steps since 2009 to implement a quality assurance approach to improve the delivery of treatments to patients. These quality assurance systems are now increasingly used on a daily basis by all the personnel in the centres as part of a process for continuous improvement of quality of medical care.

The radiotherapy centres have all put in place a system for detecting significant events. In the majority of cases, these events concern a patient over one or a few treatment sessions and have no expected clinical consequences. ASN was notified of 23 events in 2015 and is making sure that the centres concerned draw the appropriate lessons from these events.

Interventional practices

In the light of the 16 inspections carried out in 2015, ASN considers that patient and worker radiation protection practices must be further optimised in interventional radiology (see chapter 9, point 1.1.2). Significant disparities between departments have been observed. Although progress has been observed in the rooms dedicated to interventional practices, especially with regard to training, the same cannot be said for the operating theatres. The optimisation of doses delivered to patients and received by personnel is not yet sufficiently developed. Medical physicists are still insufficiently involved in this activity. The training of practitioners in good patient and worker radiation protection practices must be continued.

Nuclear medicine

The 7 inspections carried out in 2015 reveal that radiation protection of workers, patients and the public is on the whole taken into account in the nuclear medicine facilities in the Auvergne and Rhône-Alpes regions. Improvements are nevertheless required in the performance of the internal technical controls of radiation protection, in the updating of the working environment analyses for exposed workers, in the management of radioactive effluents and the analysis of events.

Computed Tomography

ASN conducted 13 inspections in computed tomography facilities in the Auvergne and Rhône-Alpes regions in 2015, including one inspection in a centre performing teleradiology examinations. ASN verified that the centres have initiated a dose optimisation approach when performing computed tomography procedures. This process must be continued and developed, particularly by generalising the involvement of medical physicists in this area.

Inspection campaign in the dental radiology sector

En 2015, the Lyon division conducted an inspection campaign in some twenty dental surgeries in the Auvergne and Rhône-Alpes regions equipped with Cone Beam Computerized Tomography (CBCT) radiology devices. The utilisation of these devices effectively presents a particular radiological risk, as the doses delivered by CBCT are higher than those in conventional dental radiography. More generally, this operation provided the opportunity to assess the way in which worker and patient radiation protection regulations are taken into consideration in dental surgeries, to raise the awareness of professionals to the measures to be put in place and to take stock of any difficulties encountered.

In each dental surgery, some thirty points relating to regulatory requirements in worker and patient radiation protection were verified. Despite disparities between the inspected surgeries, ASN considers that the radiation protection measures can on the whole be improved by more regular inspection of the devices and systematic verification of the conformity of the layout of the premises. ASN also noted qualitative differences in the services provided by different external persons competent in radiation protection.

1.3 Radiation protection in the industrial sector

Industrial radiography

ASN considers that radiation protection of workers is taken into account relatively satisfactorily in the industrial radiography sector in the Auvergne and Rhône-Alpes regions. The inspections carried out in 2015 revealed no significant regulatory deviations, although improvements are required in the delimiting of worksite operating zones (installation of warning signs and markings) and the performance of estimated dosimetry evaluations.

1.4 Nuclear safety and radiation protection in the transport of radioactive substances

In 2015, ASN carried out 15 inspection operations in the transport of radioactive substances in the Rhône-Alpes and Auvergne regions. Firstly, 11 inspections were carried out on the premises of nuclear installation licensees, in nuclear medicine departments and in technical inspection companies (gamma radiography, gamma densitometry, lead detection). During these inspections, ASN checked the organisation put in place by licensees to comply with the regulations relative to the transport of radioactive substances and the operations relative to the shipping and reception of packages in these installations. In addition, four roadside inspections were carried out in 2015 in collaboration with other State services (Regional directorate for the environment, planning and housing – Dreal, customs, *gendarmerie*). These roadside inspections were carried out as random checks at motorway toll barriers and resulted in the sending of three inspection follow-up letters.

ASN's inspections in 2015 revealed no situations giving cause for concern in the Rhône-Alpes and Auvergne regions. Progress has been made in the transport of packages "not subject to approval" used to transport the least hazardous radioactive substances which represent the majority of radioactive substance transport operations in France.

1.5 Radiation protection of the public and the environment

Radon

In 2015, ASN continued its inspections to verify compliance with the regulations relating to management of the radon risk in facilities open to the public in the Rhône-Alpes and Auvergne regions, and schools in particular.

With regard to junior and senior secondary schools, ASN met the departmental and regional councils. It found situations that varied from one *département* and one region to another. Generally speaking, radon measurements were taken to identify the schools requiring remedial work. Work has been carried out in several schools to reduce the radon content. This work must nevertheless be continued and further radon content measurements must be taken to assess its effectiveness. In 2015, the Lyon division met the regional authorities whose action in terms of prevention of radon exposure risks in state junior and senior secondary schools had been considered to have room for improvement during previous meetings.

At the same time, ASN, the eight prefectures and two regional health agencies concerned conducted a remote campaign in 2014-2015 on the measures taken to limit the risks of radon exposure in state schools (nursery and primary schools). This campaign targeted the largest municipalities in the *départements* classified with priority status for the radon risk. The result of this campaign reveals a situation that is generally satisfactory, even if the radon screening periodicity of ten years is not always respected.

In addition, during a meeting with the Interregional Directorate of Prison Administration, responsible for the large majority of prisons in Rhône-Alpes and Auvergne, ASN was able to verify that the radon risk was duly taken into account in these establishments.

Contaminated sites and soils

In 2015, ASN monitored the finalising of the clean-out operations on two sites in the Auvergne and Rhône-Alpes regions, situated in Annemasse and Lyon, where traces of radium had been found. The Lyon site clean-out was finalised in 2015; the Annemasse site requires further investigations.

Former mining site of Saint-Priest-la-Prugne

In 2015 Areva withdrew its file for the redevelopment of the Saint-Priest-la-Prugne site. This project planned to make the site safe over the long term by eliminating the dam behind which the mine tailings are stored and replacing the hydraulic cover with a solid cover. ASN considers that, although the site is safe in the short and medium term, given the nature of the radionuclides stored there, Areva must find a solution to improve its safety over the long term.

In addition, ASN notes with satisfaction that following the identification of mine tailings situated in the vicinity of the former Saint-Priest-la-Prugne mine, Areva has started the first phase of work to remove these materials. ASN and the Dreal will ensure that this work continues in 2016.

2. ADDITIONAL INFORMATION

2.1 International action

The Lyon division continued its bilateral exchanges with the Japanese and Chinese nuclear safety authorities concerning inspection practices and measures implemented further to the Fukushima Daiichi accident.

The Lyon division received a delegation of inspectors from the NRA (Nuclear Regulation Authority), the Japanese Nuclear Safety Authority. The discussions focused on the safety culture and consideration of social, organisational and human factors. A visit to the Flamanville EPR worksite was also organised.

In January 2015, three inspectors from the Lyon division contributed to an in-depth inspection conducted by NNSA (National Nuclear Safety Administration), the Chinese Nuclear Safety Authority, concerning the preparation of the first outage of reactor 1 of the YangJiang nuclear site in the south of China. The site will ultimately count six 1,000 MWe reactors. In return, three inspectors from the NNSA participated in an ASN inspection of a worksite on the Cruas-Meysse NPP reactor 2 in November 2015. They also visited Areva's nuclear fuel manufacturing site in Romans-sur-Isère.

The Lyon division also received a delegation of inspectors from the South-African Nuclear Safety Authority, the NNR (National Nuclear Regulator), which wanted to obtain ASN's assistance for the oversight of steam generator replacements (SGR), as an SGR is scheduled to take place shortly on one of the reactors of the Kœberg NPP.

The Lyon division also made a trip to Switzerland to discover the good practices of its counterparts in the oversight of small-scale nuclear activities in the industrial field.

Lastly, within the framework of multilateral actions, the Lyon division represents ASN in the inspection practices working group of the Nuclear Energy Agency (NEA) of the Organisation for Economic Cooperation and Development (OECD). This working group more particularly implements an observation programme of inspections conducted in the different member countries.

The Lyon division actively participated in this cross-inspection programme in 2015:

- An inspector of ASN's Lyon division participated as an observer in a week of inspections on the Darlington NPP in Canada in April 2015.
- Three foreign inspectors (from the nuclear regulators of Poland, the USA and Canada) participated as observers in the in-depth inspections carried out by ASN on the Bugey NPP from 7th to 11th September 2015.

As a general rule, these exchanges allowed the sharing of best practices in the methods for overseeing those responsible for nuclear facilities.

2.2 Informing the public

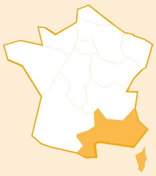
Press conference

ASN held one press conference on 29th April 2015 in Lyon on the state of nuclear safety and radiation protection in the Auvergne and Rhône-Alpes regions and the French follow-up to the Fukushima Daiichi nuclear accident.

Work with the Local Information Committees (CLIs)

All nuclear facilities in the Rhône-Alpes region, apart from the Ionisos irradiator in Dagneux, have a CLI. These CLIs, whose activity has developed considerably since 2009 through the coordination and realisation of diverse assessments, held regular meetings in 2015.

The Lyon division of ASN participated in 14 CLI meetings in 2015. The subjects addressed concerned the ongoing files in the nuclear facilities. The CLIs were consulted during preparation of the ASN prescriptions relative to water intakes and discharges of all types from the installations, like the Cruas-Meysse NPP CLI and the Tricastin Major Energy Facility Local Information Committee (CLIGEET). Some CLI members took part as observers in inspections conducted by ASN.



THE STATE OF NUCLEAR SAFETY AND RADIATION PROTECTION IN 2015 IN THE PROVENCE-ALPES-CÔTE-D'AZUR, LANGUEDOC-ROUSSILLON AND CORSE REGIONS REGULATED BY **THE MARSEILLE DIVISION**

The Marseille division regulates nuclear safety, radiation protection and the transport of nuclear substances in the 13 *départements* of the Provence-Alpes-Côte-d'Azur (PACA), Corse and Languedoc-Roussillon regions.

As at 31st December 2015, the workforce of the Marseille division stood at 20 officers: 1 regional division head, 2 deputy heads, 14 inspectors and 3 administrative officers, under the authority of the ASN regional representative.

The activities and installations to regulate comprise:

In Cadarache (Bouches du Rhône département):
- CEA Cadarache research centre (21 BNIs);
- ITER.

In Marcoule (Gard département):
- the Mélox plant;
- CEA Marcoule research centre (Atalante and Phénix BNIs);
- the Centraco plant;
- the Gammatec ioniser.

In Narbonne (Aude département):
- the Ecrin facility on the Malvési site.

In Marseille (Bouches du Rhône département):
- the Gammaster ioniser.

- 20 external-beam radiotherapy departments;
- 6 brachytherapy departments;
- 28 nuclear medicine departments;
- 170 interventional radiology departments;
- 160 tomography devices;
- about 2,500 medical diagnostic radiology devices;
- about 4,500 dental diagnostic radiology devices;
- some 111 laboratories possessing radiation sources;
- 2 cyclotrons producing radioisotopes;

- 13 head offices and 8 branch offices of industrial radiography companies;
- some 180 industrial organisations possessing radiation sources;
- 460 users of lead detectors;
- some 60 veterinary surgeons using diagnostic radiology devices;
- 5 head offices of laboratories approved for taking environmental radioactivity measurements;
- 10 head offices of organisations approved for radiation protection controls.

The Marseille division of ASN carried out 162 inspections in the Provence - Alpes - Côte d'Azur, Languedoc-Roussillon and Corse regions in 2015, of which 70 were in the BNIs, 83 in small-scale nuclear activities and 9 in the transport of radioactive substances.

One hundred and fifty-six significant events were notified to the Marseille division, of which 69 occurred in BNIs, 3 in the transport of radioactive substances and 84 in small-scale nuclear activities. Among the notified events concerning BNIs, 6 were rated level 1. Amon the notified events in small-scale nuclear activities, 2 were rated level 1, to which can be added the events concerning radiotherapy patients, of which 1 was rated level 2 on the ASN-SFRO scale and 6 were rated level 1.

1. ASSESSMENT BY DOMAIN

1.1 The nuclear installations

Cadarache site

CEA Cadarache centre

ASN carried out 42 inspections of the Cadarache centre and its 21 BNIs in 2015. ASN considers that the centre's management maintains a good level of involvement in the safety of the BNIs. The BNIs are operated under generally satisfactory conditions of safety although there are still disparities between BNIs. The activity of the centre is characterised by numerous ongoing or planned works of diverse scale and nature.

With regard to the decommissioning work, ASN is monitoring with attention the withdrawal of Areva NC from the Plutonium Technology Facility (ATPu) and the Chemical Purification Laboratory (LPC) and the means implemented to define and then reach an acceptable final state for the Enriched Uranium Processing Facility (ATUE). ASN observes that the legacy waste retrieval and packaging operations on the radioactive waste storage yard (BNI 56); which had fallen seriously behind schedule due to various worksite contingencies over the last years, have resumed at a more sustained pace. Despite some persistent difficulties, the schedules are better controlled, particularly on the "Vrac FI", pools P1 and P2 and trench T2 worksites. ASN notes that the licensee had difficulties in adjusting the ventilation on this latter worksite which led to one significant event rated level 1 on the INES scale and to modifications in 2015.

With regard to BNI construction or redevelopment work, ASN considers that the safety of construction of the Jules Horowitz Reactor (RJH) is generally satisfactory. Moreover, ASN has authorised restarting of the Cabri reactor in its new pressurised water loop configuration.

As regards lessons learned from the Fukushima Daiichi accident, ASN underlines that the prescribed 30th September 2018 deadline for the construction of new emergency situation management premises built to the "hardened safety core" earthquake design standards must be met. With regard to the 10-year periodic safety reviews, more than half the centre's BNIs are concerned by a safety review whose examination is recent or is in progress or is expected by 2017, as several of them are old. ASN considers more specifically that for the Waste Treatment Station (STD) to continue operating, renovation work must be carried out. ASN will issue a resolution in 2016 setting the work timing and the protective measures to take pending its completion.

ASN considers that the development of the integration of Social, Organisational and Human Factors (SOHF) in the centre is satisfactory, supported by a dynamic network of SOHF representatives. The SOHF analyses provided in the modifications files and in the significant event reports are judged positively. The organisational measures implemented to successfully transfer the research activities of the LEFCA (Laboratory for research and experimental fabrication of advanced nuclear fuels) to the Atalante facility in Marcoule are also satisfactory. On another front, ASN notes that the process for changing CEA's organisation regarding radiation protection, which resulted in a major labour movement in late 2014, was the subject of a consultation in 2015 on the site, involving

ASN inspection of the Jules Horowitz Reactor site, April 2015.

the personnel under more satisfactory conditions. ASN considers that the current organisation is robust.

ASN underlines that CEA must continue its efforts in the planning and performance of periodic inspections and tests, the monitoring of outside contractors, the operational control documentation for normal and accident situations, and protection against the fire risk.

Management of the waste produced by the facilities and management of on-site transport operations are judged positively. Improvements are however expected in the management of sealed radioactive sources, the management of pressure equipment and the coordination of feedback from significant events that could be of interest to several of the centre's BNIs.

Environmental issues must be given greater consideration in the modification files submitted by CEA. In this context, ASN is continuing the revision - which it began in 2014 - of the prescriptions concerning water intake and consumption and the discharge of liquid and gaseous effluents from the centre's BNIs in order to integrate the lessons learned from significant events notified by the licensee in recent years, the planned entry into service of the groundwater drains at the LEFCA and various modifications of installations which have taken place since 2010.

ITER

ASN performed five inspections of ITER in 2015. It notes significant efforts in project organisation and in the embracing of the safety culture since the start of construction. ASN nevertheless remains vigilant regarding these subjects, given the complex international organisation of the project and the scalable design of the installation.

The year 2015 saw organisational changes in ITER following the appointment of a new director general, more specifically with the setting up of integrated project teams involving the domestic agencies of seven countries or groups of ITER member countries. Moreover, despite significant delays, the installation construction work continued with the building of the first level of the tokamak complex and erection of the metallic framework of the assembly hall. Manufacture of the equipment that will constitute the installation has also progressed.

Further to an inspection in South Korea into the manufacture of sectors of the vacuum chamber (see diagram in chapter 14, page 451), ASN notes that the specified requirements for this work package have been properly taken into account. One inspection also concerned the supply of drainage tanks by the US domestic agency when they were delivered to the ITER site. Efforts must be made in formalising and substantiating the inspections certifying equipment conformity, in handling deviations and in document archiving and accessibility.

The impact of the organisational changes has also been examined with regard to the regulations applicable to the monitoring of outside contractors, the domestic agencies being the forefront of these organisational changes. Under the auspices of a project team made up of personnel of the licensee and of the European domestic agency, fabrication of a drainage tank for level B2 of the tokamak complex was started without complying with the organisation set up by the licensee to satisfy safety requirements, resulting in several belatedly detected failures. Improvements must be made in the detection of deviations and in outside contractors' compliance with the licensee's requirements.

Marcoule platform

ASN has finalised seven resolutions relative to water intake and consumption and the discharge of liquid and gaseous effluents from Mélox, Centraco, Atalante and Gammatec. The examination was carried out in collaboration with the Defence Nuclear Safety Authority (ASND) tasked with revising the discharge order for the secret basic nuclear installation of Marcoule, in accordance with a procedure aiming at stepping up public information on the risks associated with the impact of all the installations on the platform. ASN is currently carrying out a similar examination of the Phénix plant decommissioning.

Mélox plant

ASN carried out six inspections of the Mélox plant in 2015. ASN considers that the level of safety remains satisfactory. The containment barriers remain effective and robust. The radiation protection and criticality risks are handled with rigour.

ASN notes that the radiation protection studies prescribed further to the 10-year periodic safety review of the facility is bearing fruit and resulting in the optimisation of certain work stations and the implementation of additional radiological protections. On the other hand, ASN notes delays in the prescribed work to improve control of fire risks and in implementing the licensee's commitments regarding the monitoring of subcontracted operations.

Deviations in the application of the regulatory provisions for in-service monitoring of pressure equipment were identified and corrected in 2015. The deviations consisted in failing to apply the particular technical specifications applicable to these items of equipment regarding the performance of initial inspections, periodic controls, requalification and the lack of in-service monitoring. ASN expects improvements in the management of pressure equipment, including better embracing of the regulations applicable to these items and closer monitoring of their servicing.

ASN also remains attentive to the examination of the facility's projects, particularly those concerning the development of fuel for the Astrid project and the transfer to Mélox of MOX rods stored in the FBFC plant in Dessel, Belgium, as part of its decommissioning.

CEA Marcoule centre

ASN carried out 11 inspections of the Marcoule centre's two BNIs in 2015, one inspection of the projected BNI Diadem, and two cross-cutting inspections. ASN considers that safety management of the civil BNIs at the CEA Marcoule centre is satisfactory on the whole. The inspections of the centre showed ASN that the on-site transport operations and monitoring of the site environment were correctly organised and carried out in 2015.

Preparation of decommissioning of the Phénix reactor continued in 2015 with the carbonation of the residual films of sodium of the secondary system No.1. Decommissioning of the installation will be the subject of a Decree in 2016. Shortcomings in the monitoring of outside contractors were also noted during an inspection conducted jointly with ASND concerning a shipment of containers of waste between the power plant and a storage facility of the Secret BNI of Marcoule.

ASN carried out tightened investigations of the Atalante installation in 2015 following the occurrence of three significant events between 2013 and 2015 concerning the electrical power supply and the instrumentation and control systems, in order to check that the licensee was actively implementing the planned actions further to these events. These actions focus more particularly on the sizing of the electrical power supplies, their maintenance and verification of the programming of all the general services' instrumentation and control controllers. ASN will remain particularly vigilant regarding this subject during the inspections and the examination of the BNI's periodic safety review.

On 12th November 2015, ASN issued a favourable opinion on the draft decree authorising CEA to create the Diadem BNI.

Centraco plant

ASN carried out eight inspections in the Centraco plant in 2015. A highlight of the year was the restarting of the melting unit authorised by resolution of 9th April 2015. With regard to experience feedback, a significant event involving the introduction of greasy scrap metal into the melting furnace was rated level 1 on the INES scale. ASN conducted a reactive inspection and observed that the furnace had been shut down in compliance with the applicable procedures and that the greasy parts had been removed from the feeder circuit. Improvements in personnel training and checking of parts to be melted were requested by ASN and implemented to prevent the recurrence of this event.

In early 2015, the incineration unit underwent a technical shutdown during which the quench tower was replaced. After observing some difficulties in the waste drum introduction airlock, which had no impact on the safety of the facility, incineration began functioning correctly again.

On a different subject, the licensee was unable to obtain the renewal of approvals relating to certain categories of ultimate waste within time frames allowing their removal before exceeding the maximum authorised duration of on-site storage, which was considered a significant event rated level 1 on the INES scale. ASN expects these situations to be better anticipated.

Gammatec ioniser

ASN conducted an inspection of the Gammatec ioniser in 2015 and considers the level of safety to be satisfactory. Improvements are however expected in the management of modifications to the installation, the handling of nonconformities and putting the personnel into simulated situations during exercises.

Ecrin facility on the Malvési site

ASN carried out an inspection of the Ecrin facility in 2015 and considers that environmental monitoring is satisfactory. 2015 saw the regularisation of the facility by the Decree of 20th July 2015 authorising storage of radioactive waste for a period of thirty years. ASN will set prescriptions in 2016 to regulate the conditions of transfer of liquid effluents and monitoring of the facility's environment. These prescriptions constitute a prerequisite for the facility commissioning authorisation which will consist in development work to limit the impact of the facility.

Gammaster ioniser in Marseille

ASN carried out one Gammaster inspection in 2015. The licensee performed a sealed sources requalification operation in 2015 with a view to extending their service life by ten years. The result of this operation is positive in terms of safety and radiation protection.

The general operating rules and the on-site emergency plan for the facility have been revised. The facility's waste management study is also being revised. These revisions bolster the licensee's emergency response organisation and integrate the latest changes in regulations.

ASN considers that the licensee must continue its efforts to embrace the regulations and be particularly attentive to the time frames for performing its verifications and periodic tests. ASN is attentive to the fact that the licensee must prepare the first periodic safety review of the BNI before November 2017 while maintaining sufficient human resources for its two BNIs.

Meetings with the professionals

After the national seminar of 21st March 2014, the Marseille division pursued the discussions with the licensees at the regional seminar held in Marseille on 6th October 2015, in order to address the specific points relative to the BNIs coming under the competence of the Marseille division with the licensees concerned. This seminar provide a forum for expression and free questioning on the texts applicable to the BNIs, shedding light and introducing perspectives on the issues which arise in practice and fostering the sharing of experience between licensees.

1.2 Radiation protection in the medical field

Radiotherapy

ASN carried out 13 inspections in external-beam radiotherapy and brachytherapy in 2015. A target volume error during a second stereotactic radiotherapy treatment resulted in an event rated level 2 on the ASN-SFRO scale.

ASN considers that the setting up and effective implementation of a treatment quality and safety management system are on the whole satisfactory. Improvements are still required in the interconnection between specified requirements to be satisfied and studies of the risks run by the patients.

ASN expects improvements in the implementation of true multi-year training plans with inputs from the annual personnel interviews in particular, in the preparation of medical physics organisation plans that are representative of staffing requirements and not staff numbers present, and in conducting management reviews that take account of experience feedback, audits and the measurement of patient satisfaction.

Several centres are putting in place new treatment techniques or new equipment, the project management culture being insufficiently developed. Improvements are expected in the identification of specific training and documentation needs.

ASN also expects to see progress in the performance of external quality controls and audits of the internal and external quality controls.

One radiotherapy centre had been summoned by ASN in 2014 further to an inspection which revealed failure to meet several commitments. The efforts made to meet the commitments given following this summons were measured during a new inspection at the end of 2015.

Interventional practices

ASN carried out 11 inspections focusing on interventional practices in 2015 (see chapter 9, point 1.1.2). Although it was found that radiation protection is well catered for in small structures, some major centres did not demonstrate satisfactory involvement in this matter. This particularly concerns the operating theatres of the medico-technical building of the La Timone Hospital in Marseille, for which ASN noted the recent putting into service of operating theatres that do not comply with the regulatory provisions in effect.

ASN observes a pronounced lack of radiation protection culture in the operating theatres, particularly among the medical staff. The main weaknesses in the radiation protection of patients concern the medical physics organisation plan, the generally insufficient number of medical physicists and technologists, the technical training of the practitioners in the use of the machines, the writing of protocols from the most common procedures, the indication of the dosimetric information in the procedures reports, the performance of dosimetric reviews and the post-interventional follow-up. With regard to occupational radiation protection, weaknesses are noted in the zoning, the collective protective equipment, the provision and wearing of dosimeters and the performance of radiation protection technical controls.

Nuclear medicine

ASN carried out six inspections in nuclear medicine in 2015. The generally positive dynamics regarding the integration of radiation protection within the inspected services is maintained.

The departments coming under the competence of the Marseille division have increasingly modern premises and equipment, with the relocating of departments and replacement of old equipment. Thus, more than 30 authorisations were delivered in 2015 or under examination as at 31st December 2015, which is a relatively significant increase with respect to 2014. The year 2015 was marked by the follow-ups to the case concerning the nuclear medicine unit of the La Timone Hospital in Marseille, particularly the compliance notice issued in 2014. ASN considers that AP-HM (Public Assistance - Marseille Hospitals) must continue its efforts to bring this unit into compliance regarding the radiation protection requirements for persons and the environment.

With regard to waste and effluent management, significant improvements were noted in the content of the management plans, which represent the starting point for putting in place preventive measures for monitoring the radioactive pipes. ASN also notes that the majority of the units have mapping of the pipes constituting the contaminated effluents collection system. With regard to delivery of an authorisation to discharge waste water other than domestic water into the public network, about one third of the units have such an authorisation. The other units have at least undertaken to make contacts in order to obtain this authorisation.

In addition, all the centres now have a programme of periodic regulatory checks and better compliance with the frequency of these checks is noted. Progress is however still required with regard to the contamination checks when leaving controlled areas.

Computed Tomography

ASN carried out 6 inspections in computed tomography in 2015. The culture of notifying significant events is now well established in this activity. ASN considers that patient and worker radiation protection is understood, even if there is room for progress in the formalising of the patient identity monitoring process and compliance with regulatory check frequencies. Improvements are also required in training in occupational and patient radiation protection and in formalising the treatment of nonconformities detected during radiation protection technical controls. Prevention coordination and medical monitoring of outside contractors' personnel and of private practitioners are not sufficiently ensured.

1.3 Radiation protection in the industrial and research sectors

Industrial radiography

ASN carried out 12 inspections in industrial radiography in 2015, including nine unannounced worksite inspections. The inspections revealed situations that are satisfactory on the whole, with worksites properly organised in compliance with the majority of the regulatory requirements and integrating good radiation protection practices. ASN nevertheless notes persistent difficulties and shortcomings in the communication of work schedules.

Further to the irradiation incident caused by the jamming of a gamma radiography source in June 2012 in a refinery in Fos-sur-Mer, the company Applus RTD has finally brought the gamma ray projector back to the supplier's premises for examination. The company's lateness in analysing this event led ASN to serve a compliance notice on Applus RTD in 2014.

Universities and laboratories or research centres

ASN conducted eight inspections of research facilities in 2015, including one waste management inspection on the Nice University site.

ASN notes progress in the management of radioactive sources within the inspected universities. The stakeholders must nevertheless maintain their efforts, particularly in the management of legacy waste. Recurrent shortcomings are also observed in radiological zoning, in waste zoning, and in the scheduling, performance and monitoring of radiation protection controls.

To achieve a significant and lasting improvement in radiation protection, senior management's involvement must be increased and the role of the person responsible for radiation protection and their responsibilities within the establishment must be further consolidated.

1.4 Nuclear safety and radiation protection in the transport of radioactive substances

ASN continued its verifications in the area of transport in 2015 by carrying out nine inspections of varied players: BNIs, hospitals, research centres and small transport companies. The inspected transport companies generally comply with the applicable regulations.

ASN considers that the regulations are correctly applied in the BNIs and the industrial sector of small-scale nuclear activities. Among the more notable findings in 2015 were the anomalies in dose rate measurement on tankers used by the CEA to transport liquid effluents. The tankers are going to be modified accordingly and protocols for checking the dose rate on contact have been revised. With regard to on-site transport operations in the BNIs, ASN notes and approves the measures taken by the licensees to supplement their general operating rules following publication of the BNI Order.

In the medical field, ASN observes that nuclear medicine units are becoming increasingly aware of their regulatory obligations.

1.5 Radiation protection of the public and the environment

Contaminated sites and soils

ASN is continuing its drive to identify sites contaminated by radioactive substances and render them secure. In 2015, this drive resulted in ASN assisting the PACA Dreal (Regional directors for the environment, planning and housing) in the analysis of the next phases of remediation by Andra of the Ganagobie site contaminated with carbon-14 and tritium as a result of the activity of the company Isotopchim from 1987 to 2000. ASN also stepped in following the accidental discovery of legacy contamination by tritium and radium in a conventional waste disposal area on the perimeter of a facility of the French Air Force's aeronautical industrial plant in Cuers-Pierrefeu.

Mining sites

ASN provided assistance to the Languedoc-Roussillon Dreal following the discovery of abnormally high levels of radon in a number of houses in Lozère. This discovery was made under the programme carried out by Areva at the request of the State to inventory the sites of reuse of uranium mining waste rock in the areas concerned by mining works.

2. ADDITIONAL INFORMATION

2.1 International action

In 2015 the Marseille division hosted four inspectors from the Polish nuclear regulator PAA (*Panstwowa Agencja Atomistyki* or National Atomic Energy Agency), who were able to share ASN's experience in the oversight of facilities in the design and construction phase. They thus participated in an inspection of the RJH construction site.

The Marseille division also accompanied inspectors from the United States NRC (Nuclear Regulatory Commission) during a visit to the Mélox facility on the Marcoule site in order to discuss the safety requirements of MOX fabrication facilities.

2.2 Informing the public

Press conferences

In May 2015, ASN held three press conferences in Marseille, Montpellier and Nice on the state of nuclear safety and radiation protection which addressed the restarting of the Centraco melting furnace.

Work with the Local Information Committees (CLIs)

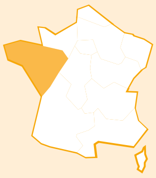
The Marseille division continued to support the CLIs in 2015 by participating in several dozen meetings of the CLIs of Cadarache, ITER and Gard-Marcoule, and by making contributions at public meetings organised by these CLIs. ASN underlines the dynamism of these CLIs and the degree of investment of their members on the national scale.

The Cadarache CLI will initiate several studies in 2016 following the study of the radiological status of the Durance River, the conclusions of which were presented at the public meeting of 12th November 2015. ASN will contribute to the funding of these studies.

2.3 The other notable events

Emergency situation preparedness

ASN was mobilised during two emergency exercises concerning the CEA Cadarche centre. These two exercises covered the occurrence of accident situations in several BNIs simultaneously. The initial feedback is positive for both the licensee and the public authorities. The mobilisation of the various actors involved will enable the lessons to be fully drawn from the exercises.



THE STATE OF NUCLEAR SAFETY AND RADIATION PROTECTION IN 2015 IN THE PAYS DE LOIRE AND BRETAGNE REGIONS REGULATED BY **THE NANTES DIVISION**

The Nantes division is responsible for regulating nuclear safety, radiation protection and the transport of radioactive substances in the 9 *départements* of the Pays de la Loire and Bretagne regions.

As at 31st December 2015, the workforce of the Nantes division stood at 11 officers: 1 regional division head, 1 deputy head, 7 inspectors and 2 administrative officers, under the authority of the ASN regional representative.

The activities and installations comprise:

- the NPP of the Monts d'Arrée site*;
- the Ionisos irradiator in Sablé-sur-Sarthe;
- the Ionisos irradiator in Pouzauges;

- 16 radiotherapy centres (17 locations);
- 9 brachytherapy units;
- 19 nuclear medicine departments;
- 85 sites practising interventional radiology activities;
- 94 tomography devices;
- some 5,000 medical and dental radiology devices;

- 44 industrial radiography companies (including 10 gamma radiography contractors);
- about 750 industrial and research equipment licences (including more than 300 users of devices for detecting lead in paint);
- 9 agencies for radiation protection technical controls;
- 7 radon screening organisations;
- 4 head-offices of laboratories approved for taking environmental radioactivity measurements.

** The Monts d'Arrée site (Brennilis NPP currently being decommissioned) is regulated by the ASN Caen division.*

In 2015, ASN's Nantes division carried out 109 inspections, of which 2 were in BNIs, 96 in small-scale nuclear activities and 11 in the transport of radioactive substances.

Among the 56 significant events notified to the Nantes division, 3 events were rated level 1 on the INES scale and 12 events in radiotherapy were rated level 1 on the ASN-SFRO scale.

1. ASSESSMENT BY DOMAIN

1.1 The nuclear installations

The company Ionisos operates two industrial irradiation facilities used chiefly for two applications: product sterilisation (essentially medical equipment, and to a lesser extent foodstuffs) and the treatment of plastic materials to improve their mechanical characteristics.

Two inspections conducted in 2015 served to examine compliance with the baseline safety requirements of the installations in Pouzauges end Sablé-sur-Sarthe and assess the progress in implementing the provisions of the Order of 7th February 2012 setting the general rules for BNIs.

These inspections confirmed that the requests made during the previous inspections concerning the verification of the lifting devices and satisfactory performance of the periodic tests for verifying operation of the safety systems had been taken into account. The requirements of the Order of 7th February 2012 seem to be well complied with on the whole, even though improvements in the monitoring of outside companies are to be planned for.

In June 2015, Ionisos submitted a periodic safety review summary file for the irradiator in Sablé-sur-Sarthe, as agreed. ASN requested IRSN's opinion on this file, asking it to examine more particularly the relevance of the licensee's proposed action plan and the corresponding implementation schedule. This periodic safety review will also be used to study the additional measures to be put in place concerning accesses to the irradiation cell, further to the incident of June 2009 involving the untimely opening of the irradiation cell access door on the Pouzauges site.

Ionisos will carry out the periodic safety review of the Pouzauges site in 2017, which must integrate the lessons identified by ASN during the examination of this safety review.

1.2 Radiation protection in the medical field

Radiotherapy

The technical and organisational changes (relocations, groupings) undertaken by the radiotherapy centres in the Bretagne and Pays de la Loire regions over the last few years continue while preserving the regional meshing of their locations is preserved. In this context, nine of the fourteen radiotherapy centres in the Bretagne and Pays de la Loire regions were inspected in 2015.

All the radiotherapy centres in these two regions meet the criteria relative to the control of treatment planning and delivery. The radiotherapy centres have also engaged in a treatment quality and safety management process in a generally similar and satisfactory manner. The disparities observed between the two regions until 2013 thus seem corrected and today the centres are entering a phase of consolidation and enrichment of their treatment quality and safety management system. In this context, several radiotherapy centres, particularly in Bretagne, have started a process of inter-centre cross-audits supported by the AFQSR (French Association for Quality and Safety in Radiotherapy) created in 2013.

Nevertheless, the mobilisation of the centres must continue their efforts to ensure that their documentation system, the study of risks run by patients and the procedures for stopping or continuing the treatments associated with these new techniques are kept up to date overtime and as technical and material development occur.

With regard to the identification and treatment of adverse events, all the centres have tools for managing internal reporting of adverse events and have undertaken to conduct new awareness-raising campaigns for their personnel on these subjects. Their systems for managing and analysing events that could arise during the radiotherapy treatment process are also operational, but retrospective analyses of events nevertheless remain brief and must still be taken further in nearly 40% of the centres.

Finally, the efforts made in the last few years to recruit medical physicists, dosimetrists and physical measurement technicians enable all the centres to ensure the presence of at least one medical physicist during the treatment periods each day while freeing medical radiation physics time for the deployment of new treatment techniques. Nonetheless, some centres occasionally had to review their organisation in 2015 to ensure this presence due to temporary and unforeseen vacancies in medical physics positions.

Interventional practices

A regional investigation carried out in 2013 with the healthcare centres of the Bretagne and Pays de la Loire regions provided more detailed knowledge of interventional practices (see chapter 9, point 1.1.2). ASN has stepped up its oversight actions since then: 21 centres were inspected in 2015 compared with 16 in 2014 and nine in 2013.

The effort made in terms of inspection volumes and prioritisation has also enabled the largest centres in the two regions to be re-inspected and the tracking of identified areas for progress to be tightened. It has resulted among other things in significant improvement in the levels of training in occupational and patient radiation protection.

On the other hand, for the other centres inspected, the findings remain relatively similar to those of the previous years, with occupational radiation protection generally being better catered for than patient radiation protection. In this latter domain, there is still much room for improvement, whether in the presence and

ASN inspection of the nuclear medicine unit of the Eugène Marquis regional cancer centre in Rennes, July 2015.

involvement of medical physicists or the defining of dose levels for risky or iterative procedures, procedures for detecting deterministic effects and specific monitoring of patients having undergone this type of procedure. With regard to occupational radiation protection, continued efforts are required in the quantification of doses and protection of the lens of the eye and the extremities of health professionals. Training on the whole is still insufficient, both in occupational radiation protection and patient radiation protection.

Lastly, these inspections show that the initiatives taken with the Bretagne ARS (Regional Health Agency) to write quality criteria into the multi-year agreements on objectives and ressources of the healthcare centres constitutes a good lever for enhancing integration of the radiation protection requirements.

Nuclear medicine

Five nuclear medicine units were inspected in 2015. The inspections focused on effluent management, brachytherapy and control of the radiopharmaceutical delivery process using automated preparation or injection devices.

Despite the strong involvement of Persons Competent in Radiation protection (PCR), application of the regulatory requirements applicable to patient and worker radiation protection is very variable. In the units where radiation protection is not catered for satisfactorily, the employer must ensure that the PCRs are allocated the means and the time necessary to correct the deviations in occupational radiation protection.

The conformity of the facilities with the requirements of ASN resolution 2014-DC-0463 relative to the layout of nuclear medicine units, applicable since 1st July 2015, will be examined in depth in the next inspections.

Computed Tomography

Seven centres were inspected in 2015, with one of the inspections concerning the specific activity of teleradiology. The inspections concentrated more particularly on patient radiation protection, which is generally well implemented in the inspected centres. Nevertheless, the tracking of personnel training in patient radiation protection can be improved in half the centres. The facility quality controls have been carried out and patient dose optimisation protocols have been established.

As regards occupational radiation protection, improvements are required in the allocation of the necessary means to the PCR, in the posting of restricted area access instructions and rules, in the delineation of restricted areas and the drafting of analyses of working practices and conditions. Occupational dosimetric monitoring is correctly ensured. Substantial efforts remain to be made in occupational radiation protection training, since only one of the centres inspected complies with the applicable regulatory training frequencies.

1.3 Radiation protection in the industrial and research sectors

Industrial radiography

Eleven inspections were carried out in 2015, enabling all the gamma radiography professionals of the Pays de la Loire and Bretagne regions to be inspected over a period of three years. ASN notes that the inspected organisations on the whole satisfy the regulatory requirements concerning the organisation of radiation protection, operator training, monitoring exposed workers and equipment maintenance.

Progress nevertheless remains to be made in internal and external radiation protection controls, particularly following reception, maintenance or reloading of the devices, and in terms of the analysis of doses received by workers, bringing exposure bunkers into conformity and setting up operation zones on worksites.

Universities and laboratories or research centres

Four inspections were carried out in the field of public research in 2015, which means that ASN has inspected more than 85% of the organisations in this sector over the last ten years. ASN observes the continued regularisation of administrative situations, which also results in the cessation of activities. The involvement of the persons competent in radiation protection enables practices to be turned towards techniques that reduce personnel exposure, and even techniques that no longer use radioactive sources. Progress is still expected with regard to the waste and effluent management plans, the tracking of source and waste inventories and the formalising of the periodic radiation protection control programmes. The internal radiation protection technical controls are not carried out exhaustively.

1.4 Nuclear safety and radiation protection in the transport of radioactive substances

ASN carried out 11 inspections focusing specifically on radioactive substance transport operations in 2015. These inspection more specifically concerned six companies specialised in the transport of radiopharmaceuticals and two companies receiving and shipping radioactive sources.

The theme of radioactive substance transport was also addressed during several inspections of companies transporting sources in order to use them in their main activity (transport of gamma radiography devices to worksites, for example).

The inspections of radiopharmaceuticals transport companies reveal a generally good standard of compliance with applicable regulatory requirements. The main findings concern the quality of package tie-down in the vehicle and the operating condition of certain on-board equipment items required by regulations (flashlights in particular). In two cases it was noted that driver protection could be improved by introducing additional protections.

With regard to the companies that ship and receive packages or perform transport operations as part of their main activity, the main regulatory requirements are properly complied with. Progress is nevertheless required in the formalising of responsibilities and putting in place a management system, and in the filling out of transport documents. Several deviations were moreover noted in the training of workers, in the absence of follow-up to the recommendations made by the safety advisor of the entities concerned, and in the completeness of the on-board equipment.

1.5 Radiation protection of the public and the environment

Radon

ASN has participated with the city of Nantes in organising campaigns for radon measurement in private homes since 2009. These campaigns form the subject of two public meetings, the first ending with the issuing of dosimeters to the inhabitants of the districts concerned by the campaign, and the second at which the measurement results are returned and remediation actions are proposed. In 2015, the Nantes division made contributions during these information meetings.

Moreover, within the framework of the Pays de la Loire region's Regional Health and Environment Plan (PRSE2) coordinated by the Dreal and the ARS, the Nantes division is a member of the steering committee which published an information brochure on radon in the Pays de la Loire enabled a drafting of a guide to the development of training modules on the radon issue for building industry professionals. Furthermore, ASN responded to the requests of *UFC-Que Choisir*, funded by the PRSE2, to speak at the public information meetings on radon in the home.

Still in Pays de la Loire, the Nantes division participated in the working group on the PRSE3 in order to be a source of proposals and to coordinate the radon-related actions, alongside the ARS and Dreal. ASN will participate in the same manner in Brittany, where the working groups will meet in 2016.

Mining sites

ASN conducted two inspections on the former mining sites: one in the Morbihan and the other in Pays de la Loire as part of the tracking of the actions defined in the MEEDDM/ASN Circular of 22nd July 2009.

ASN also took an active part in the information and discussion meetings organised by the prefectures of the Morbihan, Loire-Atlantique and Vendée *départements* on the subject of the former uranium mines.

ASN is continuing its participation in the analysis of Areva's environmental assessments of the former mining sites in collaboration with the Dreals of the Bretagne and Pays de la Loire regions. At the same time, ASN is keeping a watchful eye on the progress of the actions carried out by Areva to inventory radiologically marked areas around the former mining sites and sites in the public domain where uranium mining waste rock has been reused. The 18 work sheets associated with places in which mining waste rock has been reused have thus been analysed jointly by the services of Dreal and ASN. The resulting redevelopment work should start in 2016. Lastly, ASN has analysed the draft public information notices relating to the disposal measures for the products from the redevelopment work.

2. ADDITIONAL INFORMATION

2.1 International action

On the international front, the Nantes division was involved in an expert appraisal and technical support mission of the International Atomic Energy Agency (IAEA) carried out in Madagascar for the Madagascan radiation protection authority. The Nantes division participated in the Integrated Regulatory Review Service (IRRS) in Croatia. It also took part in a training course entitled *"School of Drafting Regulations"* organised by the IAEA in Vienna (Austria) for the heads of the Asian authorities.

The Nantes division also participated in a workshop in Brussels on the radiation protection of patients in medical imaging organised by HERCA (Heads of the European Radiological protection Competent Authorities), and a workshop in Paris on the management of radioactive sources organised by the IAEA.

2.2 Informing the public

Press conferences

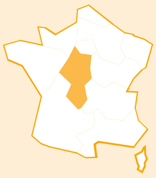
In 2015, ASN held two press conferences in Nantes and Rennes on the state of nuclear safety and radiation protection.

Work with the Local Information Committees (CLIs)

The Nantes division of ASN participated in the Pouzauges CLI meeting of 22nd October 2015 and the Sablé-sur-Sarthe CLI meeting in January 2016, concerning the Ionisos nuclear installations.

Public information actions

Lastly, in 2015 the Nantes division of continued its involvement in the radiation protection workshops, more specifically by giving a talk in the *Lycée Clémenceau* high school in Nantes on the subject of interventional imaging.



THE STATE OF NUCLEAR SAFETY AND RADIATION PROTECTION IN 2015 IN THE CENTRE, LIMOUSIN AND ILE-DE-FRANCE REGIONS REGULATED BY **THE ORLÉANS DIVISION**

The Orléans division is responsible for regulating nuclear safety and radiation protection in the 9 *départements* of the Centre and Limousin regions. The Orléans division is also at the disposal of the ASN Paris regional representative, under whose authority it regulates the safety of the BNIs of the Ile-de-France region.

As at 31st December 2015, the workforce of the Orléans division stood at 27 officers: 1 regional division head, 4 deputy heads, 18 inspectors and 4 administrative officers, under the authority of the ASN regional representative.

The activities and installations to regulate comprise:

- the Belleville-sur-Loire NPP (2 reactors of 1,300 MWe);
- the Dampierre-en-Burly NPP (4 reactors of 900 MWe);
- the Saint-Laurent-des-Eaux site: the NPP (2 reactors of 900 MWe) in operation, as well as the 2 French gas-cooled reactors (GCR) undergoing decommissioning and the irradiated graphite sleeve storage silos;
- the Chinon site: the NPP in operation (4 reactors of 900 MWe), the 3 French GCRs undergoing decommissioning, the Irradiated Material Facility (AMI) and the Inter-Regional Fuel Warehouse (MIR);
- the 8 BNIs in the CEA Saclay centre, including the Osiris and Orphee experimental reactors;
- the UPRA (Artificial Radionuclide Production Plant) operated by CIS bio international in Saclay;
- the 2 BNIs undergoing decommissioning in CEA's Fontenay-aux- Roses centre;

- 12 radiotherapy centres;
- 5 brachytherapy departments;
- 12 nuclear medicine departments;
- 48 interventional radiology departments;
- 65 tomography devices;
- 1,600 medical radiology devices;
- 2,100 dental radiology devices;

- 20 industrial radiography companies (including 6 gamma radiography contractors);
- about 400 industrial, veterinary and research devices subject to the licensing system;
- about 120 industrial, veterinary and research devices subject to the notification system.

In 2015, ASN carried out 201 inspections in the Centre, Limousin and Ile-de-France regions in 2015, comprising 82 inspections of nuclear installations on the EDF sites of Belleville-sur-Loire, Chinon, Dampierre-en-Burly and Saint-Laurent-des-Eaux, 35 inspections of nuclear sites in Ile-de-France (CEA Saclay and Fontenay, CIS bio international Saclay), 77 inspections in small-scale nuclear activities and 7 inspections in the transport of radioactive substances. ASN also ensured 18 days of labour inspection in the nuclear power plants.

A campaign of tightened inspections on the theme of the environment were carried out on the Chinon, Dampierre-en-Burly, Saint-Laurent-des-Eaux NPPs, and also the Nogent-sur-Seine NPP, with the aim of identifying areas for improvement in this domain at both local and national level.

In 2015, 7 significant events rated level 1 on the INES scale were notified by the licensees of EDF nuclear installations in the Centre region, and 4 significant events of level 1 were notified by the licensees of the Ile-de-France nuclear sites. In the small-scale nuclear activities, 3 events of level 1 on the ASN-SFRO scale were notified in the Centre and Limousin regions.

On the basis of the inspections conducted by the Orleans division, ASN inspectors drew up one violation report which was submitted to the competent Public Prosecutor.

1. ASSESSMENT BY DOMAIN

1.1 The nuclear installations

Belleville-sur-Loire nuclear power plant

ASN considers that the performance of the Belleville-sur-Loire NPP is on the whole in line with the general assessment of EDF in the areas of safety, security and radiation protection. Its environmental performance has improved with respect to 2014.

With regard to nuclear safety, although operating rigour has improved in certain activities (satisfactory configuring of the systems and compliance with the operating technical specifications), other activities, notably those relating to the periodic tests of equipment, deteriorated very markedly in 2015 and must constitute one of the site's main focuses for improvement in 2016. In addition, ASN considers that the licensee must continue its efforts in the implementation and adaptation of its national technical directives.

In the area of occupational radiation protection, the site's performance is in line with the average for the EDF reactors. However, several events that occurred essentially during the reactor 2 outage indicate weaknesses in maintaining the radiological cleanness of the premises even though activity scheduling and work quality were not faulted in 2015.

With regard to pollution prevention and control of the impact and nuisance for the public and the environment, the site's performance made significant progress in 2015 and is approaching the general assessment of EDF. The actions undertaken by the site since ASN resolution 2013-DC-0390 of December 2013 and the "environmental rigour plan" implemented by the licensee have contributed to the site's recovery and confirm that environmental issues are being truly taken into account in the site's general organisation, which must now be developed and sustained over the long term with all the actors.

Chinon site

ASN considers that the performance of the Chinon NPP is on the whole in line with the general assessment of EDF in the areas of safety, and environmental protection. It considers that the plant's radiation protection performance stands out positively with respect to the general assessment of EDF.

With regard to safety, ASN had indicated in 2015 that the Chinon site's performance was showing an improvement, which justified the return to a normal inspection rhythm in 2015, after the tightened surveillance measures which had prevailed from 2010 to 2014. It observes that management of the periodic tests, which was still identified as a weak point in 2014, has improved. Although the organisation put in place seems satisfactory, particular vigilance is required in the monitoring of outside contractors. Taken generally, ASN considers that the procedures deployed by the Chinon site over the last few years to anchor the error-reduction practices in the activities must be continued.

The radiation protection organisation of the Chinon NPP is considered satisfactory. The inspections carried out during the reactor outages have revealed good management of the worksites. Despite due consideration of the radiation protection rules in the preparation and performance of work in controlled areas, ASN nevertheless observed a number of deviations, often linked to an insufficiently questioning attitude on the part of the workers.

Chinon's performance with regard to the environment has significantly improved. In particular, ASN notes that the plant's delays in assessing the conformity of the equipment necessary to meet the environmental regulations and in setting up an organisation to guarantee long term monitoring thereof have been eliminated. Apart from a few points highlighted during the tightened inspection on the theme of the environment and focusing on rigorous application of the prescriptions applicable to discharges from facilities, the organisation for the prevention of nuisance and pollution is considered satisfactory.

ASN considers that the level of safety of the nuclear facilities of the former Chinon NPP is satisfactory. The decommissioning of the heat exchangers of Chinon A3 continued in 2015. The licensee's monitoring of outside contractors on the worksite remains a major issue in the decommissioning of these installations.

The fire risk is well managed by the licensee, who has put in place a continuous improvement process. Under the new regulations, the requirements associated with equipment important for protection which must be protected against fire nevertheless remain to be defined.

ASN will also continue to keep track of the various actions carried out by the licensee concerning the monitoring and implementation of a plan for managing legacy contamination of soils.

Operation of the Irradiated Materials Facility (AMI) is marred by malfunctions in work management and performance and in the implementation of tests. This situation is unsatisfactory with respect to the rectification request made by ASN in 2013. The fire-fighting provisions must be more robust. In a context in which the organisation of the facility is due to change significantly in 2016, ASN will be particularly attentive to the licensee's compliance with the facility's baseline requirements and to operating rigour.

The year 2015 saw the gradual transfer of the expert appraisal activities to a new facility on the site – the Lidec (integrated Laboratory of the CEIDRE) – which is not classified as a BNI. ASN is devoting particular attention to the management of this transfer, particularly for the operations that were subject to its agreement.

The final shutdown and decommissioning authorisation application file submitted by the licensee in June 2013 must be supplemented to indicate the state of the installation when the decommissioning decree is published, which should be towards the end of 2017. Specific provisions must be made for the packaging and storage of certain types of legacy waste, pending appropriate management

ASN inspection at the Dampierre-en-Burly NPP, July 2015.

routes. ASN will be attentive to the legacy waste recovery and packaging operations, given the lateness accumulated over the last few years.

The Inter-regional store at Chinon is a storage facility for fresh fuel assemblies pending their use in the EDF power plant reactors.

ASN considers that the tracking of the commitments made further to inspections and significant events has improved. Several physical improvements are thus in progress, notably in the area of fire protection.

ASN's examination of the periodic safety review file for the facility submitted by EDF in 2015 revealed too many shortcomings and inconsistencies for it to be examined as is. ASN has therefore asked EDF to rectify this situation.

Dampierre-en-Burly nuclear power plant

ASN considers that the nuclear safety and radiation protection performance of the Dampierre-en-Burly site is on the whole in line with the general assessment of EDF. The environmental performance is judged to be above the average for the EDF fleet.

ASN finds that the organisational set-ups for ensuring the safety of the installations are satisfactory. It nevertheless notes that several significant events notified in 2015 resulted from EDF's failure to carry out regular verifications which are necessary to guarantee correct operation of its equipment. Although the retrospective verifications revealed no malfunctions, these events necessitate a high level of vigilance to prevent their recurrence, whether they resulted primarily from poor integration of the verifications within the NPP's organisation or insufficiently rigorous application of the instructions.

Occupational radiation protection issues are covered by an appropriate organisational set-up. ASN observes satisfactory management of the installations during the reactor outages. However, certain practices observed by the inspectors and certain significant events still reveal a lack of rigour. ASN underlines the need to maintain a high level of worker awareness of the radiation protection measures to implement.

As concerns the quality of operation with regard to the environment, the inspections in 2015 confirm the assessment of the preceding years: although a few deficiencies were found in the handling of deviations, the documentation and information displays, the organisation for preventing pollution and the provisions for effluent management and monitoring discharges and the environment appear satisfactory.

Saint-Laurent-des-Eaux site

ASN considers that the performance of the Saint-Laurent-des-Eaux NPP with respect to environmental protection stands out positively with respect to its assessment of EDF as a whole. The safety and radiation protection performance is in line with the average.

With regard to nuclear safety, the Saint-Laurent-des Eaux site remains at a satisfactory level. The organisational changes made in the preparation and organisation of reactor outages have proved their effectiveness. ASN notes that the action plans deployed in the areas in which the Saint-Laurent-des-Eaux NPP has identified weaknesses are producing results. It nevertheless observes an increase in events linked to poorly performed periodic tests. ASN considers that the risk analysis procedure and the ergonomics of the operating documentation can be further improved.

In the area of radiation protection, the site's performance is in line with the average for the EDF reactors. ASN nevertheless underlines emerging weak spots such as control of the "orange zone" process[1].

The organisation defined and implemented by the licensee in the area of the environment is satisfactory. Putting good practices in place for certain environmental themes is to be underlined. The organisation of the engineering specialised in the area of the NPP's environment, especially the functioning of the independent environment organisation, has been bolstered. However, through the observations made during inspections, ASN perceives a slackening in the management of radioactive and conventional waste. Moreover, a number of deviations in the integration of regulatory provisions has been observed.

ASN considers that on the whole the level of safety of the nuclear installations of the former Saint-Laurent-des-Eaux NPP is satisfactory. Safety management in the structure responsible for dismantling is of a good standard, with a proactive continuous improvement approach. The licensee must however be attentive to its management of deviations from the operations risk analyses.

The licensee has progressed in the advancement of the installation's legacy waste and effluents treatment work, despite the unforeseen events that yet again affected the worksites. A plan of action has been successfully applied to improve operating rigour further to several deviations on one of the worksites in 2014 and 2015. The licensee must therefore continue its actions in order to be able to start the decommissioning operations apart from concrete containment structure A2 under satisfactory conditions in 2016.

The fire risk is well managed by the licensee. Under the new regulations, the licensee nevertheless still has to draw up a list of the equipment important for protection which must be protected against fire and define the associated requirements.

Labour inspection in the nuclear power plants

The ASN labour inspectors carried out various inspections in the areas of health and safety at work during 2015, particularly during reactor outages. Specific inspections were carried out on the themes of the explosion risk, lifting, work in confined spaces and specific types of pollution.

Investigations were also conducted further to workplace accidents to determine the exact causes and the corrective actions implemented by the plants concerned.

Labour inspection remained attentive to employee working times and especially those of managerial staff, an area in which the NPPs' management can be further improved.

Nuclear research facilities or facilities undergoing decommissioning, nuclear plants and units

CEA's Saclay centre

ASN considers that the BNIs of the CEA Saclay centre are operated under generally satisfactory conditions of safety. The CEA must nevertheless be attentive to compliance with the operating baseline requirements of the facilities and the regulatory texts. Several deviations from the baseline requirements have effectively been detected during inspections or have formed the subject of significant event notifications by the licensee. The inspections carried out by ASN in 2015 also revealed several deviations concerning implementation of the regulatory procedures for managing BNI modifications. ASN asked the licensee to review its organisation and draw up an improvement action plan to prevent these deviations from recurring.

ASN has observed progress in the management of waste storage areas, particularly in BNI 35 with the defining of operating instructions. Improvement measures are nevertheless required for the Orphée reactor (BNI 101) with regard to management of the installation's waste zoning

1. In order to protect the workers against the risks associated with ionising radiation, regulations provide for nuclear installations to be divided into different areas classified according to the conditions of radiological exposure, with specific access rules imposed for each of these areas. Thus, access to the limited stay areas (called "orange zones" in French) where the equivalent dose rate is likely to be between 2 millisieverts per hour (mSv/h) and 100 mSv/h requires the prior agreement of the radiation protection department and is reserved for personnel employed on Unlimited Term Contracts (CDI).

and formalising the storage area operating instructions. BNI 49 must also be vigilant with regard to the management of decommissioning waste movements and storage areas which have led to the notification of two significant events.

The centre's organisation of transport management was considered generally satisfactory.

The CEA has also again notified events concerning the monitoring of gaseous discharges from the installations. One event in particular revealed that the steps taken by CEA to ensure compliance with the resolutions regulating the discharges from the centre had not been carried out exhaustively and with the necessary rigour.

Operation of the BNIs

ASN considers that the physical upgrades necessary to start decommissioning of the Ulysse reactor have been carried out. In 2015, ASN examined the updating of the operating baseline requirements, which was a prerequisite for decommissioning.

The arrival of a new industrial operator to run the Stella facility represents a potential risk for the licensee who must be vigilant with regard to the management and monitoring of this activity. The operations to remove legacy effluents from BNI 35 must also be continued in compliance with the time frames of resolution 2014-DC-0441 of 15th July 2014.

The OSIRIS reactor was shut down at the end of 2015. The prospect of this shutdown led to the updating of the decommissioning plan and the defining of final shutdown preparation operations which are to start in 2016 in order to benefit from the skills and experience of the operating team in place.

ASN notes that the BNI 49 decommissioning operations are proceeding to the set schedules. The level of subcontracting is particularly high on this BNI. Control of the operations performed by the outside contractors is therefore an important issue.

In BNI 50, ASN has observed that the planned measures to improve the performance and traceability of technical verifications and periodic tests have been implemented.

The removal from storage work in progress on BNI 72 is technically well controlled, but the effectiveness of monitoring outside contractors still needs to be improved.

ASN underlines that management of the replacement of high-activity sources of BNI 77 in 2015 led to noncompliant storage in the centre's installations lasting several weeks and late notification of the fact. The CEA must examine the internal causes of this situation and the lack of transparency.

The Orphée reactor licensee must bolster its organisation for the planning and tracking of performance of verifications and periodic tests. ASN's inspections have shown compliance with the planned actions and the conditions for restarting after the two significant events concerning the handling of fuel elements which occurred at the end of 2014.

The CIS bio international plant in Saclay

ASN considers that the operating safety performance of CIS bio international must be significantly improved.

ASN considers that the efforts made by CIS bio international to reinforce its integrated management system, its human resources and operatiing conditions that promote cross-functionnality put in place in 2015, have not yet produced lasting concrete results. The verification of the conformity of operations, compliance with the baseline requirements of the installation and those of the regulations for the implementation of modifications must be reinforced.

Further to noncompliance with the ASN prescriptions issued after the periodic safety review, ASN applied coercive administrative policing measures in 2014 and 2015. Formal compliance notices were sent first of all, then, further to the failures to comply with these notices, padlocking procedures were applied to oblige CIS bio international to equip the installation with automatic fire extinguishing systems in accordance with predetermined deadlines. Pending finalising of the works whose deadlines were not met, ASN prescribed compensatory measures to step up control of the fire risk through a resolution of 14th April 2015.

A large amount of work contributing to improving safety, which has been in progress for several years, is not completed. As a general rule, the large-scale undertakings of CIS bio international are never completed within reasonable time frames.

A new laboratory has been put into service and the automatic fire extinguishing systems are partially installed and functional. Complementary studies concerning the consequences of accident situations remain to be finalised.

The stated time frames for performing the actions defined further to inspections and events are exceeded too frequently. The deviations observed during inspections and the predominance of organisational and human factors in the causes of events reveal persistent weaknesses in operating rigour, in intervention processes and in assessing the importance of the deviations. Equipment maintenance must be improved in particular.

ASN will be attentive to CIS bio international's compliance with prescriptions, the meeting of its commitments and its improvement of safety in operation. ASN expects an increase in the effectiveness of the current organisation and the industrial approach implemented. Consequently, it will keep the facility under tightened surveillance in 2016.

The CEA's centre in Fontenay-aux-Roses

ASN considers that the level of safety of the facilities of the CEA Fontenay-aux-Roses centre has improved, particularly in the control of the fire risk, but is not yet satisfactory.

In terms of organisation, ASN considers that a substantial formalisation effort was made in 2015 by the BNI licensee, particularly with regard to the monitoring of outside contractors, commitment tracking and deviation management. Their due implementation over time must still be confirmed. This effort must be extended to the other entities of the CEA Fontenay-aux-Roses centre, which are involved in the BNIs either directly or through contractors. The precise formalisation of the interfaces between the BNIs, the centre's services and outside contractors is also an area for progress. The notified significant events and some of the deviations examined during inspections reveal deficiencies in the control of the services of certain outside contractors. This is a recurrent finding in work carried out under the centre's multi-technique contract. ASN observes that this service is still not properly controlled by the CEA.

In this context, ASN will be particularly attentive to the consideration of human and organisational factors in the progress plan that the CEA is to implement in 2016 and in the results of this plan.

The CEA has sent the Minister responsible for Nuclear Safety a file aiming firstly to push back the set deadline for completion of the decommissioning and soil remediation operations, and secondly to propose a revision of the planned final state. ASN will be particularly attentive to the justification for this deadline extension and to the adequacy of the means engaged to carry out these operations.

1.2 Radiation protection in the medical field

Radiotherapy

ASN considers that the patient radiation protection issues are satisfactorily catered for in the radiotherapy centres of the Centre and Limousin regions. The awareness-raising and oversight action carried out by ASN in 2015 focused on the control of the quality system, the external audit of the quality controls of the facilities and the organisation dedicated to internal notifications and continuous improvement of the quality and safety of radiotherapy treatments.

The inspections carried out in 2015 highlighted the efforts made by the radiotherapy centres to formalise practices. Areas for progress have nevertheless been identified in the tracking and evaluation of the effectiveness of improvement actions. These inspections also provided the opportunity to inform the centres of the recommendations of the Advisory Committee of Experts in radiation protection for Medical and forensic applications of ionising radiation (GPMED) on the conditions of use of the new radiotherapy techniques and the associated practices, given the recent deployment and the projected deployment in the short- or medium-term by several centres in the Centre and Limousin regions.

Seven significant events were notified to ASN in 2015. The deviations associated with these events primarily concern patient set-up, patient identification and the delivered dose (difference in dose due to measuring instrument calibration error). Five of these events were rated level 1 on the ASN-SFRO scale, which has eight levels. The level-1 rating is assigned to events having no expected clinical consequences for the patient.

Interventional practices

In view of the 11 inspections it carried out in the interventional imaging services in the Centre and Limousin regions in 2015, ASN considers that occupational radiation protection is better catered for in the majority of the inspected units. Surprisingly, it is in some of the major healthcare establishments of both the public and private sectors that the inspectors found distinct shortcomings in making optimum use of equipment functions to reduce doses delivered to the patient, in equipment quality controls and in equipment acceptance processes. ASN considers that means must be provided in medical radiation physics and radiation protection to correct these deviations and to establish protocols for monitoring patients suffering from serious illnesses.

Two significant events were notified in 2015. They confirm some of the inspection findings. This being said, the relatively small number of notifications to the authorities compared with the number of centres or departments using these techniques, reveals the necessity to continue putting in place tools for the identification and analysis of abnormal situations.

ASN has again observed situations where practitioners fail to comply with radiation protection measures.

Nuclear medicine

The nuclear medicine departments in the Centre and Limousin continue their modernisation drive, with a large number of licence modification requests, particularly for changes of premises. A few of the requests included the introduction of new radionuclides for therapeutic purposes. Their utilisations, which introduce new radiation protection implications, nevertheless remained limited. Alongside this, ASN stepped up its inspections relating to the transport of unsealed sources. Serious shortcomings were observed in certain centres.

ASN also notes a more uniform contribution of the nuclear medicine centres in the notification of significant radiation protection events. Nevertheless, ASN notes a reduction in the number of notifications in 2015. Consequently, ASN will increase its checks on the organisation dedicated to detecting, recording and analysing events.

Computed Tomography

ASN carried out seven inspections in computed tomography departments in 2015, stepping up the verification of measures taken for patient radiation protection. Progress in the optimisation of doses delivered during examinations is fostered by the modernisation of equipment, thanks to intensity modulation software among other things. Nevertheless, ASN observes that all the possibilities in this area are not always turned to good account.

Ten significant events were notified in this sector. ASN considers that this figure obliges medical personnel to maintain increased vigilance in the application of patient identification procedures and in informing women of the risks of exposure of the foetus.

Conventional radiology

In 2015, the Orléans division conducted an inspection campaign in private conventional radiology practices. This campaign started in spring as a documentary survey addressed to 80 practices in the Centre - Limousin regions. At the end of this first stage, 16 practices were selected for an on-site inspection.

ASN considers that patient radiation protection is generally well ensured, given the risks and the doses delivered, which are generally low. Nevertheless, although the practices comply with regulations through comparison of the applied doses with the diagnostic reference levels, the exposure protocols are not always formalised in writing. Medical staff monitoring and dosimetry are ensured. Radiation protection controls are carried out. Two deviations from regulations were nevertheless detected relatively frequently, namely the signalling of the radiological risk and the radiological zoning of the premises on the one hand, and the absence of active dosimetry when performing procedures requiring the presence of a practitioner near the patient on the other.

1.3 Radiation protection in the industrial and research sectors

Industrial radiography

Three inspections of worksites using gamma radiography were carried out in 2015. The results were relatively satisfactory. ASN is particularly vigilant with regard to this high-risk sector of activity.

Research

ASN considers that radiation protection in the 29 research departments or units using ionising radiation authorised by ASN in the Centre, Val de Loire and Limousin regions is ensured satisfactorily. ASN is particularly attentive to the use of lead-212, especially for *in vivo* studies on the treatment of cancers.

Veterinary

ASN considers that the application of radiation protection measures by veterinary surgeons is generally satisfactory, thanks in particular to the support of a specialised training organisation. ASN is attentive to the implications of the spread of new devices in the practices. Two veterinary practices have acquired a computed tomography scanner.

1.4 Nuclear safety and radiation protection in the transport of radioactive substances

ASN carried out four inspections in BNIs and three inspections in small-scale nuclear activities in 2015.

The inspections focused chiefly on the organisational structures in place, the measures applied, and compliance with package approvals and operational specifications.

These inspections revealed incomplete application of the regulatory requirements in one nuclear medicine department. For the BNIs, the mains areas requiring improvement are the management of deviations, rigour in pre-shipment inspections and application of procedures, the completeness of the management systems and the general rules for on-site transport operations.

1.5 Radiation protection of the public and the environment

Radiation protection technical controls

Four organisations approved for radiation protection controls (out of 42 in France) have their head office in the Centre and/or Limousin regions. ASN maintained its oversight action in 2015 by auditing three organisations and holding three supervisory checks.

The findings of these latter checks concern the conditions of measurement of ionising radiation and the search for anomalies in radiation attenuation devices.

Former uranium mines

In application of the Circular of 22nd July 2009, Areva has made an inventory of the mining waste rock storage sites in the Limousin region. The maps were presented to the region's three site monitoring committees in 2012.

The legacy licensee has drawn up for each site a sheet summarising the data concerning the radiological exposure measurements, the use of the land, the location of the waste rock deposits, particularly when close to housing. Lastly, treatment options are proposed – most often removal of the contaminated materials – with the aim of ensuring that the clean-up is as complete as possible. These proposals have been approved by the State services.

Public information notices concerning the sites planned to receive these materials have been issued in the three *départements* of the Limousin region.

At the same time, Areva is continuing the radon screening measures on all sites on which waste rock was reused and buildings have been constructed.

2. ADDITIONAL INFORMATION

2.1 International action

2015 saw a further meeting between ASN's Orléans division and the Swedish Safety Authority (SSM, *Strål Säkerhets Myndigheten)* to discuss oversight practices. A visit to the Ringhals NPP in Sweden, which focused on presenting the modifications made to the facilities further to the Fukushima Daiichi accident, was organised on this occasion.

The Orléans division was also involved in an OSART (Operational Safety Review Team) mission at the Dampierre-en-Burly NPP in September. The report on this audit carried out by a group of international experts is published on the ASN website.

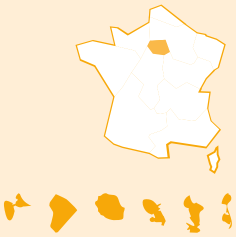
2.2 Informing the public

Press conferences

In 2015, ASN held two joint press conferences in Orléans and Paris on the state of nuclear safety and radiation protection.

Work with the Local Information Committees (CLIs)

The Orléans division took part in various meetings of the CLIs in the Centre and Ile-de-France regions. During these meetings, the Orléans division more specifically presented its assessment of the safety situation of the nuclear facilities concerned and the administrative sanctions taken against the licensees where applicable. The division also invited the CLIs to attend inspections of nuclear power plants in the Centre region as observers.



THE STATE OF NUCLEAR SAFETY AND RADIATION PROTECTION IN 2015 IN THE ILE-DE-FRANCE REGION AND FRENCH OVERSEAS *DÉPARTEMENTS* AND COLLECTIVITIES REGULATED BY **THE PARIS DIVISION**

The Paris division regulates radiation protection and the transport of radioactive substances in the 8 *départements* of the Ile-de-France region and the 5 overseas *(Outre-Mer) départements* (Guadeloupe, Martinique, Guyane, La Réunion, Mayotte).
It also fulfils duties as expert to the competent authorities of French Polynesia and New Caledonia *(Nouvelle-Calédonie)*.

As at 31 December 2015, the workforce of the Paris division stood at 22 officers: 1 regional division head, 2 deputies, 16 radiation protection inspectors and 3 administrative officers, under the authority of an ASN regional representative.

The small-scale nuclear facilities to be regulated in the Ile-de-France region and in the overseas *départements* represent about 20% of the French total. The two particularities are the diversity and the number of facilities to be regulated. It comprises:

- 31external-beam radiotherapy departments (nearly 90 accelerators);
- 16 brachytherapy departments;
- 67 nuclear medicine departments;
- more than 250 interventional imaging departments;
- more than 250 computed tomography devices;
- about 900 medical diagnostic radiology centres;
- about 8,000 dental diagnostic radiology devices;

- about 700 users of veterinary diagnostic radiology devices;
- 12 industrial radiography companies using gamma radiography devices;
- about 200 authorisations relative to research activities;
- 14 approved organisations.

The BNIs in Ile-de-France are regulated by the Orléans division of ASN.

In 2015, ASN's Paris division carried out 203 inspections in small-scale nuclear activities and 5 inspections in the transport of radioactive substances. Among these inspections, 182 were carried out in Ile-de-France and 26 in the overseas *départements* and regions.

The Paris division was notified of 150 significant events, of which 7 occurring in the transport of radioactive substances and 143 were significant Radiation Protection Events (ESR) in small-scale nuclear activities.

Among the events notified in small-scale nuclear activities, 4 were rated level 1 on the INES scale. Added to this are 46 events concerning radiotherapy patients, among which 34 were rated level 1 on the ASN-SFRO scale and 4 were rated level 2. Two transport events were rated level 1 on the INES scale

1. ASSESSMENT BY DOMAIN

1.1 Radiation protection in the medical field

Radiotherapy

ASN carried out 31 inspections of radiotherapy departments in the Île-de-France region and the overseas *départements* in 2015.

In the majority of the inspected departments these inspections revealed progress in the development of quality assurance procedures and compliance with the regulatory requirements demanded by ASN. The four centres which were subject to tightened monitoring in this respect in 2015 are now compliant. One centre in which substantial lateness and organisational weaknesses were observed in a first inspection in 2015 underwent a tightened monitoring inspection six months later. This centre will continue to remain under close scrutiny in 2016.

Two brachytherapy departments display failings in their compliance with the regulatory requirements relating to occupational radiation protection. These two sites will be re-inspected on this theme in 2016 to check that the measures decided by the departments further to the 2015 inspections have effectively been implemented.

Otherwise, three inspections resulted from events concerning radiotherapy patients rated level 2 on the ASN-SFRO scale. Two events concerned errors in defining the target volumes in the medical prescription or in delimiting the contours of the organs to treat. The third event rated level 2 concerned an undetected overlapping[1] of irradiation fields[2].

Interventional practices

ASN carried out 41 inspections in 2015 (compared with 34 in 2014) in the field of interventional imaging in Ile-de-France and the overseas *départements*. The inspections during 2015 confirmed the strong radiation protection implications for patients and personnel during interventions carried out using ionising radiation. ASN noted that the way the radiation protection requirements have been integrated in this sector varied greatly according to the departments and specialities. Radiation protection is better integrated in the medical specialities of interventional cardiology and neuroradiology, where procedures are carried out in dedicated rooms with professionals who are more aware of the radiation protection issues than in specialities in which the practitioners carry out interventional or fluoroscopy-guided procedures in operating theatres. As in 2013 and 2014, progress is expected in particular in the optimisation of doses delivered to patients and the development of the radiation protection culture of the operators.

Seven significant radiation protection events were notified to the Paris division, divided almost equally between patients and medical staff.

An inspection was carried out in Guadeloupe further to the notification of a significant radiation protection event on 10th August 2015. This inspection revealed serious shortcomings in compliance with the provisions of the Public Health Code and the Labour Code with regard to radiation protection of patients and workers. The effectiveness of the corrective actions put in place by the centre will be assessed by inspection in 2016.

Nuclear medicine

ASN carried out 21 inspections in 2015, including five inspections of the commissioning of new facilities.

ASN observed that further progress is still required in occupational radiation protection, as the risk of external and internal contamination is often insufficiently taken into account. With regard to the management of contaminated effluents and waste, improvements are required in the conformity of the waste management plans.

Twenty-three significant radiation protection events were notified by nuclear medicine departments. Fourteen events involved errors in the preparation or injection of radionuclides to the patient, leading to either administration of the wrong radiopharmaceutical or an error in the administered dose.

The second professional seminar on the subject of radiation protection of patients, workers and the environment in nuclear medicine organised by ASN was held on 29th September 2015. This seminar was attended by more than 140 people, including 94 nuclear medicine professionals from the Ile-de-France region and the overseas *départements*, that is to say 93% of the Ile-de France and overseas nuclear medicine units.

Computed Tomography

ASN carried out 16 inspections in computed tomography in 2015, one of the aims of which was to verify application of the principle of optimisation of doses delivered to patients. The main area for improvement detected concerned the training of workers in radiation protection at the frequency required by regulations. The efforts made to control the dose delivered to patients must be continued, particularly through greater involvement of the medical physicists on the ground.

1. Superpositioning
2. Area of the body on which the radiation is projected during radiotherapy treatment.

1.2 Radiation protection in the industrial and research sectors

Industrial radiography

ASN continued its oversight of industrial radiography activities, and users of gamma radiography in particular, in Ile-de-France and the overseas *départements*, performing 18 inspections in 2015.

The inspections and the license renewals were specifically monitored with regard to the regularisation of the old pool of exposure bunkers, particularly as concerns their conformity with the applicable standards. Seven unannounced inspections were carried out in worksite conditions.

Three significant radiation protection events were notified to ASN.

Universities and laboratories or research centres

ASN carried out 21 inspections of research facilities in 2015. The most frequent deviations concerned the waste storage facilities, the management of this waste, the lack of prevention plans for situations where outside contractors have to work in controlled areas, and poor knowledge of the methods of managing radiation protection events.

In the major research institutions, joint inspections of all the authorised departments on a given site were favoured. This type of inspection allowed cessations of activity to be regularised, among other things.

Six Significant Radiation protection Events (ESR) were notified in this area in 2015, according to different criteria: loss/discovery of sources, loss of source integrity, dispersion of radionuclides, or unauthorised discharge of radioactivity into the environment.

Inspection of Installations Classified on Environmental Protection grounds (ICPE) under the Public Health Code

Further to the modification of the ICPE nomenclature introduced by Decree 2014-996 of 2nd September 2014, about one hundred ICPEs in Ile-de-France and overseas, formerly notified or licensed under section 1715, are likely to switch to a licensing system on account of the Public Health Code for holding and using sealed and unsealed radioactive sources.

ASN has started to list and inspect these installations with the aim of assessing the situation of radiation protection implementation and to assist the licensees in this change of regulations. Six inspections were carried out in Ile-de-France and two in La Réunion, which enabled ASN to observe that the level of integration of radiation protection was generally satisfactory on the majority of the inspected sites.

1.3 Nuclear safety and radiation protection in the transport of radioactive substances

Twenty-five inspections were carried out on the transport of radioactive substances in small-scale nuclear activities.

The inspections relative to the transport of radiopharmaceutical products reveal that the regulatory obligations concerning the training of the personnel performing the transport operations, the receiving inspections and the shipping of the packages are still insufficiently well known in the nuclear medicine centres.

In 2015, ASN continued the partnership initiated in 2014 with the Department of Public Order and Traffic of the Prefecture of Police of Paris and the Transport Safety Service of the Regional and Interdepartmental Directorate of Infrastructure and Regional Planning in order to carry out unannounced roadside inspections.

The inspections took place in the municipality of Saint-Cloud.

Seven significant events in radioactive substance transport were notified to ASN. Two of these events were rated level 1 on the INES scale.

1.4 Radiation protection of the public and the environment

Contaminated sites and soils

In 2015, as part of its public information and radiation protection oversight duties with regard to the management of contaminated sites and soils, ASN oversight of sites contaminated by radioactive substances, such as the site of the company 2M Process in Saint-Maur-des-Fossés, the Curie Institute (Paris 5th district), the CEA Fontenay-aux-Roses site, the CEA Saclay site, the Coudraies and Clos-Rose quarters in Gif-sur-Yvette, and the former CEA site of Fort de Vaujours.

The former CEA site of Fort de Vaujours, on which experiments involving natural and depleted uranium were carried out, was purchased by the *Placoplâtre* company with the aim of operating an open pit gypsum quarry. On 20th March 2015, ASN issued an opinion on the radiological monitoring protocol for the Fort de Vaujours buildings demolition operations. This opinion was presented at the meeting of the Fort de Vaujours Site Monitoring Committee (CSS) on 5th May 2015. In addition, at the request of the Prefects of Seine-et-Marne and Seine-Saint-Denis, ASN inspectors accompanied by officers from the Regional Health Agency (ARS) and labour inspection went to the Fort de Vaujours site to verify compliance with the radiological monitoring protocol drawn up by *Placoplâtre* and the requests formulated by ASN in its opinion of 20th March 2015. The conclusions of this inspection were reported to the members of the Fort de Vaujours CSS on 9th July 2015. On 13th November 2015, *Placoplâtre* presented the responses to the observations it had received to the members of the CSS. Lastly, a second unannounced inspection was also carried out on 17th December 2015 to verify that the radiological characterisation and environmental monitoring measures had been carried out.

In collaboration with the ARS of Ile-de-France and the nuclear safety and radiation protection mission of the Ministry of the Environment, Energy and the Sea, ASN helped define a strategy for monitoring and managing the scattered radioactive contaminations of the Coudraies and Clos Rose quarters of Gif-sur-Yvette resulting from the past activities of the company *Société Nouvelle du Radium*. The proposed measures consist in updating the prescriptions and recommendations of the local urban development plan of Gif-sur-Yvette and in 2016 conducting a campaign of radon measurement in the interior air of the houses concerned.

Seminar on radiation protection of patients, workers and the environment in nuclear medicine, September 2015.

Lastly, the Radium Diagnostic operation has been launched in Ile-de- France since 21st September 2010. The government decided to perform the diagnoses free of charge in order to detect, and where applicable treat, any legacy radium pollution. This operation, which is placed under the responsibility of the Prefect of the Ile-de-France region, the Prefect of Paris, and is coordinated by ASN, concerns 84 sites in Ile-de-France.

Thirty-six sites had been examined by the end of 2015. Eight of these 36 sites were able to be excluded outright because the buildings are too recent with respect to the period of potential manipulation of radium to be able to have any radioactive contamination. On the remaining 28 sites, more than 430 diagnoses were carried out; most of the sites concern one building with many apartments, or several individual plots. Twenty-one diagnoses revealed traces of radium in premises that are now undergoing rehabilitation. The measured levels of activity are low and the exposure does not present a health risk for the occupants.

For the occupants and owners of the contaminated premises, personalised assistance is being provided to apply the necessary protection measures and start the rehabilitation work, paid for by the State. The rehabilitation work has been completed on six sites, is in progress on ten sites and under preparation for five sites.

2. ADDITIONAL INFORMATION

2.1 Monitoring of organisations approved for radiation protection controls

In 2015, ASN carried out six head-office audits and seven unannounced supervisory inspections as part of the monitoring of organisations approved for radiation protection controls in Ile-de-France. These turned out to be satisfactory on the whole. This being said, many approved organisations do not notify their operations exhaustively on the specific tool put in place by ASN, even though this notification is mandatory so that ASN can carry out unannounced inspections.

2.2 Informing the public

ASN held a press conference in the Paris division on 9th June 2015 to present the results of its regional action.

2.3 ASN's action in the overseas *départements*

ASN carried out three inspection campaigns in the overseas *départements*, which represented 26 inspections. Two campaigns were scheduled and one was carried out further to the notification of a significant radiation protection event in interventional imaging in Guadeloupe.

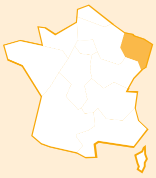
ASN considers that the way radiation protection is taken into account in the overseas facilities is, on average, comparable with that in the metropolitan facilities, with specific difficulties inherent to the distance and the absence of certain types of permanent service providers.

2.4 ASN's action in New Caledonia and French Polynesia

During 2015 ASN continued its cooperation work with French Polynesia and New Caledonia as part of their operations to regulate activities involving ionising radiation and to update the regulatory framework governing nuclear activities in these territories. This cooperation is governed by multi-year agreements signed between the overseas communities and ASN.

Although no trips were made to French Polynesia in 2015, ASN continued to remotely assist the local authorities. It was more specifically called upon in the examination of a licensing request concerning the opening of a nuclear medicine department, and in the handling of significant radiation protection events relating to accidental discoveries of orphan sources.

With regard to New Caledonia (*Nouvelle Calédonie*), a mission went there in 2015. Five inspections were carried out with the local authorities in the medical and industrial sectors, based on the regulatory baseline requirements applicable in France and its overseas territories. The training measures for the local authorities in charge of licenses and oversight were continued. Lastly, the drafting of the future regulations has been completed, which will enable New Caledonia to start the work of having the texts adopted by its assembly and government.



THE STATE OF NUCLEAR SAFETY AND RADIATION PROTECTION IN 2015 IN THE ALSACE AND LORRAINE REGIONS REGULATED BY **THE STRASBOURG DIVISION**

The Strasbourg division regulates nuclear safety, radiation protection and the transport of radioactive substances in the six *départements* of the Alsace and Lorraine regions.

As at 31st December 2015, the workforce of the Strasbourg division stood at 14 officers: 1 regional division head, 2 deputy heads, 8 inspectors and 3 administrative officers, under the authority of the ASN regional representative.

The activities and installations to regulate comprise:

- the Fessenheim NPP (2 reactors of 900 MWe) and Cattenom NPP (4 reactors of 1,300 MWe);
- 9 external-beam radiotherapy departments;
- 3 brachytherapy departments;
- 14 nuclear medicine departments;
- some fifty departments practising interventional activities;
- about 70 scanners;
- 4,000 medical and dental diagnostic radiology devices;

- 200 industrial research establishments;
- 3 cyclotrons producing fluorine-18.

In 2015, the Strasbourg division carried out 94 inspections, of which 37 were on the nuclear sites of Fessenheim and Cattenom, 52 were in small-scale nuclear activities and 5 in the transport of radioactive substances. ASN also carried out 7 days of labour inspection in the nuclear power plants.

The Strasbourg division was notified of 111 significant events in 2015, 78 occurring in BNIs and 33 in small-scale nuclear activities. Among the events notified for the BNIs, 6 were rated level 1 on the INES scale. Among the events notified in small-scale nuclear activities, 1 was rated level 1 on the INES scale, to which can be added the events concerning radiotherapy patients, of which 1 was rated level 2 on the ASN-SFRO scale and 11 rated level 1.

In the context of their oversight duties, the ASN inspectors issued three violation reports. In application of its sanctioning powers, ASN issued compliance notices to one industrial licensee in small-scale nuclear activities and to the Cattenom NPP.

1. ASSESSMENT BY DOMAIN

1.1 The nuclear installations

Fessenheim nuclear power plant

ASN considers that the nuclear safety performance and environmental protection performance of the Fessenheim site stand out positively with respect to ASN's general assessment of EDF, and that its radiation protection performance is in line with ASN's general assessment of EDF.

Daily operation of the reactors is satisfactory on the whole. The workers' practices comply with requirements and on several occasions the site's personnel has demonstrated a questioning attitude leading to relevant situational analyses. However, several deviations from safety baseline requirements were noted. Furthermore, one noteworthy event in 2015 was a water leakage in the turbine hall. Although it had no real consequences on safety, and operational control of the reactor was well managed, insufficient analysis of the causes of the crack in the pipe led to another rupture of the pipe during its return to service.

The maintenance operations carried out in 2015 were well planned and well managed. The licensee must continue to pay particular attention to equipment that is not considered to be important for safety but whose failure can have consequences on the safety of the installations.

The site's organisation for protection of the environment is satisfactory, the effluent sampling facilities are well equipped and well monitored. The site demonstrates greater rigour in the management of waste compared with preceding years.

Occupational radiation protection is well integrated in the performance of the activities and the site has appropriate measurement and protection means. A lack of worker vigilance was however noted on several occasions, leading to practices which do not comply with requirements in this area.

Cattenom nuclear power plant

ASN considers that the nuclear safety and environmental protection performance of the Cattenom NPP is on the whole in line with ASN's general assessment of EDF but that the site's radiation protection performance remains below average.

With regard to operation of the reactors, ASN considers that the site's performance is on the whole satisfactory, even if the number of significant events detected by the licensee has increased compared with the previous year. In particular, ASN noted deviations in application of the operational control rules and in the performance of equipment tests.

This being said, appropriate measures are implemented promptly as soon as the deviations are detected. Beyond the technical aspects, the organisational and human factors are correctly taken into account.

Reactor maintenance work, which was of a moderate scale in 2015, was well planned and managed. The site mobilises itself to efficiently manage the unpredicted events occurring on the facilities. Nevertheless, several events still indicate a lack of rigour in formalising, analysing and handling deviations.

ASN considers that the Cattenom site is making progress in environmental protection. The necessary means have been put in place to correct the deviations detected in the preceding years, particularly in the management of radioactive waste and the control of copper discharges.

With regard to occupational radiation protection, ASN notes the licensee's mobilisation and progress is observed. However, improvements are required in the behaviour of the personnel on the ground, and this necessitates efforts over the long term. Radiological cleanness and the containment of radioactive substances must remain a priority.

Labour inspection in the nuclear power plants

ASN continued its inspections concerning subcontracting, the working times of employees of EDF and of certain subcontractors, and the conditions of health and safety during maintenance work and plant operation.

No serious accident occurred in 2015 on either of the two nuclear power plants. Worker safety on the Fessenheim site remains a priority subject, but improvements are required in the application of the prevention measures in the field.

On the Cattenom site, ASN noted several deviations in the field regarding the taking into account of risks relating to asbestos, falling from height and lifting operations.

1.2 Radiation protection in the medical field

Radiotherapy

ASN carried out 6 inspections in the 9 radiotherapy departments in Alsace and Lorraine in 2015.

These inspections showed that all the inspected departments have effectively implemented a quality assurance and risk management procedure. ASN considers that the treatment quality and safety management systems are now up and running within the departments. ASN also underlines with satisfaction the investment of personnel in the continuous improvement of treatments initiative. This investment has resulted, for example, in

ASN inspection on an industrial radiography worksite, July 2015.

a distinct improvement in the detection of malfunctions (15 significant events report to ASN in 2015 compared with 9 in 2014) and in experience feedback analysis, including in the centres were the initiative was less developed.

For the coming years, ASN considers that deployment of the continuous improvement initiative must be pursued, notably by the implementation of internal practices evaluation audits, and that the goodness of fit between the documentation system and actual practices must be ensured.

Interventional practices

For several years now, interventional practices (see chapter 9, point 1.1.2) have represented a regulation area with significant implications for ASN, which carried out six inspections in departments exercising these activities in Alsace and Lorraine in 2015. In order to cover the entire territory, ASN's Strasbourg division also conducted a survey with all the centres in 2015. The returns from the departments have enabled a precise map of the centres practising these activities to be drawn up and their radiation protection practices to be evaluated.

ASN considers that radiation protection of patients and medical staff is better applied in fixed and dedicated facilities than in operating theatres in which mobile devices are used. ASN has also taken positive note that the centres performing the procedures with the highest radiological risk are developing good practices which limit the doses delivered to the patients and workers. On the whole, the Persons Competent in Radiation protection (PCR) and the medical physicists appeared to be extremely involved in their missions. Nevertheless, vigilance must be maintained regarding the means allocated to medical physicists so that they can fully ensure their radiation protection duty.

On the other hand, ASN underlines the persistent difficulties the centres have in improving occupational radiation protection in operating theatres, particularly with regard to the training of exposed personnel and the systematic wearing of appropriate dosimetry equipment by the medical staff.

Nuclear medicine

ASN inspected four nuclear medicine departments in Alsace and Lorraine in 2015, in one case because the department was implementing a new radium treatment. These inspections revealed a situation that is generally satisfactory. ASN underlines in particular the high level of involvement of the personnel in charge of radiation protection and the overall quality of integration of radiation protection of both patients – by appropriate use of hybrid gamma cameras for example – and workers, who are well informed in the area of radiation protection.

The identified points requiring vigilance mainly concern the implementation of zoning and radiation protection technical controls that are appropriate for the contamination risks prevailing in these departments.

Computed Tomography

ASN carried out three inspections of computed tomography departments in 2015 and observes that the delivered doses are controlled. The teams now have an awareness of patient radiation protection. On the other hand, the doses delivered could be further optimised and rendered more uniform between the professionals by putting in place protocols defined in collaboration with the medical physicists on a more systematic basis.

ASN has again noted several events involving unnecessary exposure of persons due to errors in the identification of the patients having to undergo the examinations.

Dental radiology

In 2015, the Strasbourg division conducted a remote verification campaign on the documentation of dental surgeries using radiology devices. ASN observed disparities in the application of regulatory requirements, depending in particular on the quality of service of the external PCRs used by many dentists.

1.3 Radiation protection in the industrial and research sectors

Industrial radiography

Industrial radiography activities present major risks in terms of radiation protection. ASN continued its inspection drive in these companies and observed very variable situations depending on the companies and the types of inspections they carry out. As a general rule, the exposures carried out in facilities designed specifically for this purpose raise less issues than those carried out on worksites. During its inspections, ASN remains particularly attentive to the work area signalling to be put in place around the radiation sources. No approximation can be tolerated in the implementation of this measure, which is essential for the protection of the workers and the public.

In particular, in 2015 ASN continued to closely monitor a company which had been subject to tightened monitoring since 2013. The observed improvements remain tenuous and this company will continue to be specifically inspected in 2016. The inspections carried out in 2015 also led a second company to be placed under tightened surveillance. A violation report concerning the company was transmitted to the Public Prosecutor.

Gamma densitometry

In 2015, ASN conducted a campaign of unannounced inspections of public works companies which hold sealed radioactive sources for taking density and humidity measurements in road surface coatings. This campaign revealed that the radiation protection rules are well defined by the companies but their actual application on the worksites must be improved.

Installations Classified on Environmental Protection grounds (ICPE) under the Public Health Code

The inspections carried out in 2015 by ASN in the ICPEs possessing radioactive sources confirmed a good standard of integration of radiation protection rules in these facilities.

Universities and laboratories or research centres

ASN observed in 2015 that the doses received by workers in research centres and laboratories using radioactive sources remain at a very low level. Personnel have good knowledge of the risks and know how to prevent them. ASN also emphasises the effort made by many centres to comply with the applicable regulatory provisions and to guarantee the updating of the licenses, which indicates an improvement on the previous years.

Monitoring of approved organisations

In 2015, ASN continued its major campaign to monitor the organisations responsible for external radiation protection controls by carrying out six inspections. These ASN-approved organisations are subject to unannounced inspections when performing their services, audits of their head offices, and examination of their procedures as part of the approval application.

The inspections revealed a very variable standard of service. Some organisations will be subject to particular scrutiny on this account. Deviations were noted in particular in the controls performed in operating theatres.

1.4 Nuclear safety and radiation protection in the transport of radioactive substances

In 2015, ASN conducted five inspections concerning the transport of radioactive substances in the Alsace and Lorraine regions.

ASN considers that the Fessenheim site has good control over these activities; no deviations were noted in this area in 2015. The Cattenom site also displays satisfactory management in this area, even if progress is required in the documentation and traceability of on-site transport operations.

In the medical field, ASN did not observe any particularly problematic situations in the Alsace and Lorraine regions in 2015.

2. ADDITIONAL INFORMATION

2.1 International action by the Strasbourg division

In the framework of the bilateral exchanges with its German, Luxembourger and Swiss counterparts, the Strasbourg division of ASN took part in several cross-inspections in nuclear power plants and hospitals, either as a guest in foreign countries, or as host to its counterparts.

The Strasbourg division moreover ensured spokesmanship for the 2015 meeting of working group 1 of the Franco-German commission on nuclear safety, dedicated to reactor safety. The Strasbourg division also responded to the various requests of its German, Swiss and Luxembourg partners concerning the Cattenom and Fessenheim NPPs.

2.2 Informing the public

Press conferences

In 2015, the Strasbourg division held two press conferences in Strasbourg and Metz on the situation of nuclear safety and radiation protection.

Work with the Local Information Committees (CLIs)

The Strasbourg division took part in various meetings of the CLIs of Fessenheim and Cattenom. During these meetings, ASN more specifically presented its assessment of the safety situation of the nuclear facilities concerned, and its analysis of events that occurred in the nuclear power plants during the year. Subjects relating to the management of waste in the nuclear power plants and the control of discharges into the environment were also broached.

The Strasbourg division also invited the CLI members to attend inspections performed in the EDF facilities as observers on several occasions. They were thus able to have a more precise view of ASN's inspections and relations with the licensee.

Public information actions

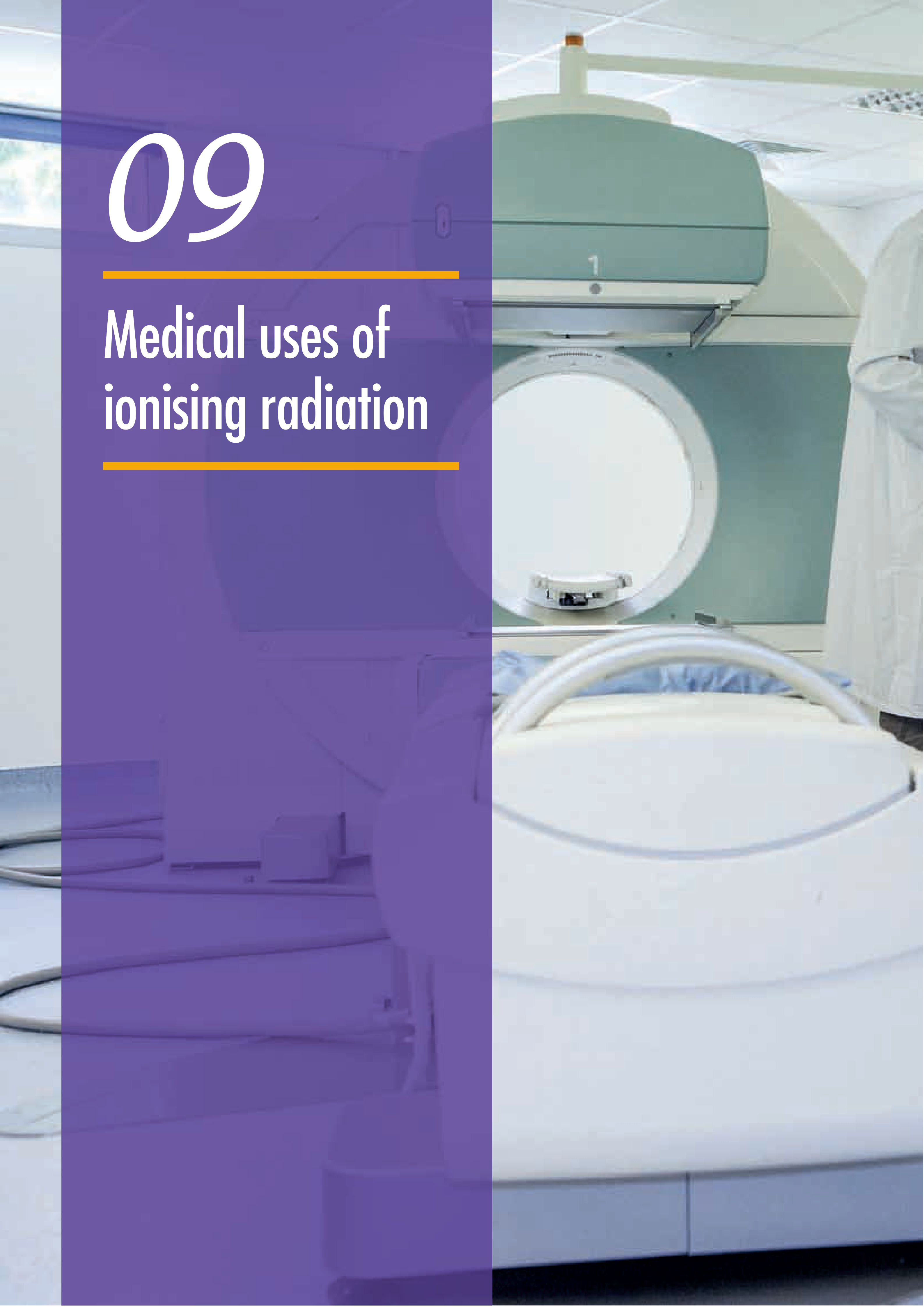
Within the framework of a teachers training week organised by the *"Maison pour la science en Alsace"*, the Strasbourg division gave a talk to some twenty junior secondary school science teachers to present them the role of ASN, as well as basic nuclear safety and radiation protection concepts.

2.3 The other notable events

Management of emergency situations

On 28th May 2015, the one-site emergency plan was triggered at the Cattenom NPP when a valve on the reactor 1 secondary system jammed in the open position. ASN was informed immediately and deployed its emergency response organisation. The Strasbourg division seconded an officer to the Moselle prefecture to provide technical support, and a team of inspectors went to the emergency management premises of the Cattenom NPP. ASN also carried out an on-site inspection the very next day.

This event was rated level 1 on the INES scale. No increase in radioactivity was measured in the environment of the nuclear power plant. The investigations showed that the incident was caused by an equipment failure. ASN considers that the events were well managed by the licensee.



09

Medical uses of ionising radiation

For more than a century now, for both diagnostic and therapeutic purposes, medicine has made use of ionising radiation produced either by electric generators or by radionuclides in sealed or unsealed sources. The benefits and usefulness of these techniques have long been proven, but they nevertheless contribute significantly to the exposure of the population to ionising radiation. They effectively represent the second source of exposure for the population (behind exposure to natural ionising radiation) and the leading source of artificial exposure (see chapter 1).

Protection of the staff working in facilities using ionising radiation for medical purposes is regulated by the provisions of the Labour Code. The medical facilities and devices emitting ionising radiation, including sealed and unsealed sources, must satisfy technical rules and procedures defined in the Public Health Code (see chapter 3).

The protection of patients undergoing medical imaging examinations or receiving therapeutic treatments involving ionising radiation is regulated by specific provisions of the Public Health Code (see chapter 3). The principles of justification of procedures and optimisation of the doses delivered are the basis of these regulations. However, contrary to the other applications of ionising radiation, the principle of dose limitation does not apply to patients due to the need to adapt the dose delivered to each individual patient according to the therapeutic objective or to obtain an image of adequate quality to make the diagnosis.

1. MEDICAL AND DENTAL RADIODIAGNOSIS INSTALLATIONS

1.1 Presentation of the equipment and inventory

Medical diagnostic radiology is based on the principle of differential attenuation of X-rays by the organs and tissues of the human body. The information is most often collected on digital media allowing computer processing of the resulting images, and their transfer and filing.

Diagnostic X-ray imaging is one of the oldest medical applications of ionising radiation; it encompasses all the methods of morphological exploration of the human body using X-rays produced by electric generators. It occupies an important place in the field of medical imaging and comprises various techniques (conventional radiology, radiology associated with interventional practices, computed tomography, mammography) and a very wide variety of examinations (radiography of the thorax, chest-abdomen-pelvis computed tomography scan, etc).

The request for a radiological examination by the physician must be part of a diagnostic strategy taking account of the patient's known medical history, the question posed, the expected benefit for the patient, the exposure level and the possibilities offered by other non-irradiating investigative techniques. A guide intended for medical doctors (*Guide to good medical imaging examination practices*) updated in 2013 indicates the most appropriate examinations to request according to the clinical situations (see point 5.5).

1.1.1 Medical radiodiagnosis

Conventional radiology

Conventional radiology (producing radiographic images, or radiographs), if considered by the number of procedures, represents the large majority of radiological examinations performed.

The examinations mainly concern the bones, the thorax and the abdomen. Conventional radiology can be carried out in fixed facilities reserved for diagnostic radiology or, in certain cases, using portable devices if justified by the clinical situation of the patient.

Angiography

This technique, used for exploring blood vessels, involves injecting a radio-opaque contrast agent into the vessels which enables the arterial (arteriography) or venous (venography) tree to be visualised. Angiography techniques benefit from computerised image processing (such as digital subtraction angiography).

Mammography

Given the composition of the mammary gland and the fineness of the details that must be seen in order to diagnose mammary pathologies, specific devices (mammography units) are used. They operate at low voltage and provide high resolution and high contrast. They are used in particular in the national breast cancer screening programme.

The use of a new three-dimensional imaging technique called "tomosynthesis", which involves reconstruction of the breast into a series of slices is growing in Europe. The evaluation of this technique, currently in progress in several European countries, should enable its advantages compared with the traditional planar technique to be determined. At present, this technique is not recognised in the context of organised breast cancer screening.

Computed Tomography

Computed Tomography (CT) scanners use a beam of X-rays emitted by a tube which moves in a spiral around the body of the patient (spiral or helical CT scanner). Based on a computerised image acquisition and processing system, these scanners produce a three-dimensional reconstruction of the organs with very much better image quality than that of conventional radiology devices. The number of rows of detectors (multi-detector-row CT scanner) has been increased in recent machines, enabling thinner slices to be produced.

This technique can, like Magnetic Resonance Imaging (MRI), be associated with functional imaging provided by nuclear medicine in order to obtain fusion images combining functional information with structural information.

The technological developments over the last few years have made examinations easier and faster to perform, and led to an increase in exploration possibilities (example of dynamic volume acquisitions) and in the indications. On the other hand, these technological developments have led to an increase in the number of examinations, resulting in an increase in the doses delivered to patients and thus reinforcing the need for strict application of the principles of justification and optimisation (see chapter 1).

As at 31st December 2015, the French pool of radiological devices included slightly more than 1,000 computed tomography facilities covered by an ASN license.

Teleradiology

Teleradiology provides the possibility of guiding the performance and interpreting the results of radiology examinations carried out in another location. The interchanges must be carried out in strict application of the regulations (relating to radiation protection and the quality of image production and transfer in particular) and professional ethics.

UNDERSTAND

Medical imaging: several imaging techniques can be used for a given organ

Complementary examinations (medical imaging, biological analysis, samples, etc.) supplement the physician's diagnostic approach based on the history of the illness and the clinical examination of the patient.

There are four broad medical imaging techniques. They use X-rays (radiology), gamma rays (nuclear medicine), ultrasounds (ultrasonography) and magnetic fields (MRI - Magnetic Resonance Imaging). These techniques enable the morphology of an organ to be analysed or its function to be studied; the intrinsic qualities and the medical interpretation of the resulting images are fundamentally dependent on the physical principle used:

- Radiology reveals differences in density in a tissue (due to the presence of a tumour, for example) or between different organs. Radiology, mammography and X-ray computed tomography are radiological examinations. The scanner enables an organ to be reconstructed in 3D and slices of an organ to be created (slice imaging or tomography).
- Nuclear medicine analyses the distribution of a radiopharmaceutical (drug consisting of a vector marked by a radioactive isotope or isolated radionuclide) injected into the human body. This is functional imaging which enables the physiopathological processes to be studied and provides important information on the normal or pathological functioning of a tissue or organ. The radiopharmaceutical is chosen according to the target and the studied organ.
- Ultrasonography uses ultrasounds: the sudden changes in acoustic properties of the tissues at the boundaries of the organs and any other interface produce echoes which are used to construct images. By combining the Doppler effect with this, it is also possible to measure the rate of blood flow in the vessels.
- MRI uses the magnetic properties of hydrogen nuclei placed in a strong and stable magnetic field. The proton (H^+) is the main constituent of the molecule of water, an element that is present to a greater or lesser extent in all the tissues of the human body. After excitation by radiofrequency waves, the signals from the protons in the water of the human body are picked up by dedicated antennas and analysed by computer in order to reconstruct a slice image.

Radiology and nuclear medicine that use ionising radiation are regulated by ASN. Ultrasonography and MRI do not use ionising radiation.

The *Guide to good medical imaging examination practices,* produced by the French Society of Radiology (SFR) and the French Society of Nuclear Medicine and Molecular Imaging (SFMN), helps physicians to choose the most appropriate examination according to the symptomatology, the suggested diagnoses and the patient's medical history. It takes into account the proof of the level of diagnostic performance of the examinations in each of the situations (analysis of international publications), whether the examination involves radiation or not, and if so, the corresponding doses. No technique is universal; a technique that gives good results for one organ or function of that organ may be less effective for another organ, and *vice versa.*

Essentially two methods of interchange are used:
- telediagnosis, which enables a doctor on the scene (ex: an emergency doctor), who is not a radiologist, to perform the radiological examination and then send the results to a radiologist in order to obtain an interpretation of the images. If necessary the radiologist can guide the radiological operator during the examination and imaging process. In this case, the doctor on the scene is considered to be the doctor performing the procedure and assumes responsibility for it;
- tele-expertise, which is an exchange of opinions between two radiologists, where one asks the other – the "expert radiologist" (teleradiologist) – for a remote confirmation or contradiction of a diagnosis, to determine a therapeutic orientation or to guide a remote examination.

The data transmissions are protected and preserve medical secrecy and image quality.

Teleradiology involves many responsibilities which must be specified in the agreement binding the practitioner performing the procedure to the teleradiologist. The teleradiology procedure is a medical procedure in its own right, like all other imaging procedures, and cannot be reduced to a simple interpretation of images. Teleradiology therefore fits into the general healthcare organisation governed by the Public Health Code and obeys the rules of professional ethics in effect (see the good practices recommendations issued by the professionals).

1.1.2 Interventional practices using ionising radiation

Interventional practices using ionising radiation comprise *"all invasive diagnostic and/or therapeutic medical procedures, as well as surgical procedures that use ionising radiation for guidance, including monitoring[1]"*.

The machines used are either fixed machines installed in rooms dedicated to this activity, chiefly vascular (neurology, cardiology, gastroenterology, etc.), in which case one talks of interventional radiology, or mobile radiology machines used in operating theatres in several medical specialities, notably digestive surgery, orthopaedics and urology. They involve techniques that use fluoroscopy with an image intensifier or digital images (flat panel detector) which require special equipment.

Interventional techniques using computed tomography are on the increase, mainly thanks to recent technical developments (acquisition speed, miniaturisation, mobile CT scanners, etc.). These techniques are used during diagnostic interventions (coronarography or examination of coronary arteries, etc.) or for therapeutic purposes (dilation of coronary arteries, angioplasty, vascular embolization, etc.) as well as during surgical procedures using ionising radiation to guide or monitor the surgeon's actions. They can require long-duration exposure of the patients who then receive high doses which can, in some cases, lead to deterministic effects on tissues due to the ionising radiation (cutaneous lesions, etc.).

The staff usually work in the immediate vicinity of the patient and are also exposed to higher dose levels than during other radiological practices. In these conditions, given the exposure risks for both the operator and the patient, practices must be optimised to reduce doses and ensure the radiation protection of operators and patients alike.

ASN does not know exactly how many facilities are used for interventional procedures, mainly due to a rapid increase in interventional practices in medical specialities as a whole in recent years. Only the numbers of rhythmology, interventional cardiology and interventional neuroradiology units are known with precision since these healthcare activities require an authorisation from the Regional Health Agency (ARS). The regional divisions of ASN make increasing use of the data on hospital activities to have better insight into the activities and the risks associated with medical imaging. More than 1,000 centres (lower bracket) practising interventional radiology and fluoroscopy-guided procedures have thus been inventoried in France.

1.1.3 Dental radiodiagnosis

Intra-oral radiography

Intra-oral radiography generators, which are usually mounted on an articulated arm, are used to take localised planar images of the teeth (the radiological detector is placed in the patient's mouth). They operate with low voltage and current and a very short exposure time, of about a few hundredths of a second. This technique is most often associated with digital systems for processing and filing the radiographic images.

Panoramic dental radiography

Panoramic radiography (orthopantomography) gives a single picture showing both jaws in full, by rotating the radiation generating tube around the patient's head for a few seconds.

Cone-beam computed tomography

Cone-beam computed tomography (3D) is developing very rapidly in all areas of dental radiology, due to the exceptional quality of the images produced (spatial resolution of about 100 microns). The price of this better performance is that these devices deliver significantly higher doses than in conventional dental radiology.

1. Definition from the GPMED Advisory Committee for Radiation Protection for the Medical and Forensic Applications of Ionising Radiation (reporting to ASN).

1.2 Technical rules for fitting out radiology and tomography installations

Radiology installations

A conventional radiological facility usually comprises a generator (high-voltage unit, X-ray tube), associated with a support (the stand) for moving the tube, a control unit and an examination table or chair.

The mobile facilities that are commonly used in the same room, such as the X-ray generators used in operating theatres, are to be considered as fixed facilities.

As of 2013, radiological facilities must be installed in accordance with the provisions of the new ASN technical resolution 2013-DC-0349 of 4th June 2013 (see chapter 3). This resolution requires that the layout and access to the facilities comply with the radiation protection rules set by French Standard NFC 15-160 in its March 2011 version.

The new standard NFC 15-160 common to all medical radiology facilities, including computed tomography and dental radiology, introduces a method of calculating the required thickness of the protection screens in all facilities that use X-ray generators.

This resolution came into effect on 1st January 2014 and is being applied progressively according to the schedule appended to it. It is to be noted that it does not concern radiology devices used at the patient's bedside.

2. NUCLEAR MEDICINE

2.1 Presentation of nuclear medicine activities

Nuclear medicine includes all uses of unsealed radioactive sources for diagnostic or therapeutic purposes. Diagnostic uses can be divided into *in vivo* techniques, based on administration of radionuclides to a patient, and exclusively *in vitro* applications (medical biology). Functional exploration examinations can combine *in vitro* and *in vivo* techniques.

This sector of activity comprises 225 nuclear medicine units with associated *in vivo* and *in vitro* facilities and 62 biology laboratories, of which 40 are independent of the nuclear medicine units.

At the end of 2014 the inventory stood at 131 Positron Emission Tomography (PET) cameras and 477 Single-Photon Emission Tomography (SPECT) devices (including 215 hybrids, that is to say combining a CT scanner with the SPECT. Forty-four nuclear medicine units[2] accommodate a total of 161 Targeted Internal Radiotherapy (RIV – brachytherapy) rooms.

Nuclear medicine involves about 700 specialist practitioners in this field[3], to which must be added some 1,000 physicians from other specialities working with the nuclear medicine units (internal medicine specialists, cardiologists, endocrinologists, etc.).

2.1.1 *In vivo* diagnosis

This technique consists in examining an organ or a function of the organism with a specific radioactive substance – called a radiopharmaceutical – administered to a patient. The nature of the radiopharmaceutical depends on the studied organ or function. The radionuclide can be used directly or fixed to a carrier (molecule, hormone, antibody, etc.). For example, table 1 presents some of the main radionuclides used in various investigations.

The administered radioactive substance – often technetium-99m – is localised in the organism using a specific detector and scintigraphy techniques. This detector, called a scintillation camera or gamma camera, consists of a crystal of sodium iodide (in the majority of cameras) coupled to a computerised acquisition and analysis system. This equipment produces images of the functioning of the explored tissues or organs. The physiological or physiopathological processes can be quantified.

The majority of gamma cameras allow tomographic acquisitions, cross-sectional imaging and a three-dimensional reconstruction of the organs (Single-Photon Emission Tomography – SPECT).

Fluorine-18, a positron-emitting radionuclide, is commonly used today, frequently in the form of a marked sugar, fluorodeoxyglucose, particularly in oncology. Its utilisation necessitates the use of a special camera. The principle of operation of PET (Positron-Emission Tomography) cameras is the detection of the coincidence of the photons emitted when the positron is annihilated in the matter near its point of emission. Other radiopharmaceuticals marked with other positron emitters, notably gallium-68, are starting to be used.

Nuclear medicine enables functional images to be produced. It is therefore complementary to the purely morphological images obtained using the other imaging techniques, such as conventional radiology, X-ray computed tomography, ultrasonography or Magnetic Resonance Imaging (MRI). In

2. Source: Review of nuclear medicine department inspections (2012-2014).
3. Source: dashboard (SFMN website) 2014.

order to make it easier to merge functional and morphological images, hybrid appliances have been developed: Positron-Emitting Tomography (PET) scanners are now systematically coupled with a CT scanner (PET-CT) and gamma-cameras are equipped with a CT scanner (SPECT-CT).

2.1.2 *In vitro* diagnosis

This is a medical biology technique for assaying certain compounds contained in biological fluid samples taken from the patient, such as hormones, drugs, tumour markers, etc., and it does not involve administering radionuclides to the patients. The technique uses assay methods based on immunological reactions (antigen-antibody reactions labelled with iodine-125), hence the name RIA (Radioimmunology Assay). The activities contained in the analysis kits designed for a series of assays do not exceed a few thousand becquerels (kBq). Radioimmunology is currently challenged by techniques which make no use of radioactivity, such as immuno-enzymology and chemiluminescence. A few techniques use other radionuclides such as tritium or carbon-14. Here again the activity levels involved are of the order of the kBq.

2.1.3 Targeted internal radiotherapy

Internal radiotherapy aims to administer a radiopharmaceutical emitting ionising radiation, which will deliver a high dose to a target organ for curative or remedial purposes. Two areas of therapeutic application of nuclear medicine can be identified: oncology and non-oncological conditions (treatment of hyperthyroidism, synoviorthesis).

Several types of cancer treatment can be identified:
- systemic treatments (thyroid cancer by iodine-131, non-Hodgkin lymphoma by monoclonal antibodies marked with yttrium-90, prostate cancer with bone metastases by radium-223, etc.);
- treatments administered by selective routes (treatment of liver cancers by administering microspheres marked with yttrium-90 into a hepatic artery through a catheter).

Some treatments require patients to be hospitalised for several days in specially fitted-out rooms in the nuclear medicine unit to ensure the radiation protection of the personnel, of people visiting the patients and of the environment. The radiological protection of these rooms is adapted to the nature of the radiation emitted by the radionuclides, and the contaminated urine of the patients is collected in tanks. This is particularly the case with the post-surgical treatment of certain thyroid cancers. The treatments are performed by administering varying activities of iodine-131 (1.1 GBq, 4 GBq, 5.5 GBq).

Other treatments can be on an out-patient basis. Examples include administering iodine-131 to treat hyperthyroidism, strontium-89 or samarium-153 for painful bone metastases, and radium-223 for prostate cancer with bone metastases. Joints can also be treated using colloids labelled with yttrium-90, erbium-169 or rhenium-186. Finally, radioimmunotherapy can be used to treat certain lymphomas using yttrium-90 labelled antibodies.

2.1.4 Biomedical research in nuclear medicine

Biomedical research in nuclear medicine has been particularly dynamic in the last few years: protocols are regularly developed for new radionuclides and vectors. These innovations mainly concern:
- Positron Emission Tomography (PET) with fluorine-18, gallium-68 and rubidium-82;
- targeted internal radiotherapy with radium-223, microspheres labelled with yttrium-90, vectors labelled with yttrium-90 or lutetium-177.

The use of new radiopharmaceuticals means that the radiation protection requirements associated with their handling must be integrated as early as possible in the process. Indeed, given the activity levels involved, the characteristics of certain radionuclides and the preparations to produce, appropriate measures must be implemented with regard to operator exposure and environmental impact.

TABLE 1: Some of the main radionuclides used in the various *in vivo* nuclear medicine examinations

TYPE OF EXAMINATION	RADIONUCLEIDES USED
Thyroid metabolism	Iodine-123, Technetium-99m
Myocardial perfusion	Thallium-201, Technetium-99m, Rubidium-82
Lung perfusion	Technetium-99m
Lung ventilation	Technetium-99m, Krypton-81m,
Osteo-articular process	Technetium-99m, Fluorine-18
Oncology - search for metastasis	Technetium-99m, Fluorine-18, Gallium-68
Neurology	Technetium-99m, Fluorine-18

ASN inspection of the nuclear medicine unit of the Eugène-Marquis regional cancer centre in Rennes, July 2015.

2.2 Layout rules for nuclear medicine facilities

Given the radiation protection constraints involved in the use of unsealed radioactive sources, nuclear medicine units are designed and organised so that they can receive, store, prepare and then administer unsealed radioactive sources to patients or handle them in laboratories (radioimmunology for instance). Provision is also made for the collection, storage and disposal of radioactive wastes and effluents produced in the facility, particularly the radionuclides contained in patients' urine.

From the radiological viewpoint, the personnel are subjected to a risk of external exposure, in particular on the fingers, due in particular to the handling of certain radionuclides (case with fluorine-18, iodine-131 or yttrium-90), and a risk of internal exposure through accidental intake of radioactive substances. Given these conditions, the nuclear medicine units must satisfy the rules prescribed by ASN resolution 2014-DC-0463 of 23rd October 2014 relative to the minimum technical rules of design, operation and maintenance that *in vivo* nuclear medicine facilities must satisfy, approved by the Order of 16th January 2015.

This resolution more specifically introduces new rules for the ventilation of nuclear medicine units (cancellation of the negative pressure requirements and hourly air renewal rates figuring in the Order of 30th October 1981) and of the rooms accommodating patients being treated for thyroid cancer with iodine-131 in particular (new negative pressure requirement). Furthermore, the facilities equipped with a CT scanner coupled with a gamma camera or a PET camera must comply with the provisions of ASN resolution 2013-DC-0349 of 4th June 2013 (see chapter 3). This resolution requires that the layout and access to these facilities comply with the radiation protection rules set by French Standard NFC 15-160 in its March 2011 version

3. EXTERNAL-BEAM RADIOTHERAPY AND BRACHYTHERAPY

3.1 Description of the techniques

Alongside surgery and chemotherapy, radiotherapy is one of the key techniques employed to treat cancerous tumours. Some 175,000 patients are treated each year. Radiotherapy uses ionising radiation to destroy malignant cells (and non-malignant cells in a small number of cases). The ionising radiation necessary for treatment is either produced by an electric generator or emitted by radionuclides in the form of a sealed source. There are thus two ways of delivering the radiation: external-beam radiotherapy, where the source of radiation produced by a particle accelerator or radioactive sources (Gamma knife® for example) is external to the patient, and brachytherapy, where the source is placed in direct contact with the patient, within or as close as possible to the area to treat.

At the end of 2014, external beam radiotherapy installations comprised 476 treatment devices, including 461 conventional linear accelerators. These devices are installed in 176 radiotherapy centres, of which roughly half have public status and the other half private status.

Elekta Gamma Knife® system used in intracranial radiosurgery and radiotherapy.

There are six hundred and fifty three (653) registered radiation oncologists (source: French Radiotherapy Observatory).

3.1.1 External-beam radiotherapy

The irradiation sessions are always preceded by preparation of a treatment plan which defines the dose to be delivered, the target volume(s) to be treated, the irradiation beam setting and the estimated dose distribution (dosimetry) for each patient. Preparation of this plan, which aims to set conditions for achieving a high dose in the target volume while preserving surrounding healthy tissues, requires close cooperation between the radiation oncologist, the medical physicist and, when applicable, the dosimetrists.

In the vast majority of treatments, irradiation is ensured using linear particle accelerators with an isocentric arm emitting beams of photons produced at a voltage varying from 4 to 25 megavolts (MV) or electrons with an energy level of between 4 and 25 megaelectronvolts (MeV) and delivering dose-rates that can vary from 2 to 6 grays per minute (Gy)/min, although some latest-generation linear accelerators can deliver much higher dose-rates of up to 25 Gy/min (in the case of photon beams).

For certain specific therapeutic indications, several centres propose treatments that are made possible thanks in particular to the use of:
- a linear accelerator equipped with specific functions (micro multileaf collimator, additional imaging systems, robotic arm and/or table, etc.);
- a gammatherapy device equipped with more than 200 sources of cobalt-60;
- a cyclotron producing proton beams.

Stereotactic radiotherapy

Stereotactic radiotherapy is a treatment method which aims to offer millimetre-precise, high-dose irradiation using multiple mini-beams converging in the centre of the target, for intra- or extra-cranial lesions. In stereotactic radiotherapy treatments, the total dose is delivered either in a single session or in a hypofractionated manner, depending on the disease being treated. The term radiosurgery is used to designate treatments carried out in a single session.

This technique firstly requires great precision in defining the target volume to irradiate, and secondly that the treatment be as conformal as possible, that is to say that the irradiation beams follow the shape of the tumour as closely as possible.

It was originally developed to treat surgically-inaccessible non-cancerous diseases in neurosurgery (artery or vein malformations, benign tumours) and uses specific positioning techniques to ensure very precise localisation of the lesion.

It is more and more frequently used to treat cerebral metastases, but also for extra-cranial tumours.

This therapeutic technique essentially uses three types of equipment:
- specific systems such as Gamma Knife® which directs the emissions from more than 200 cobalt-60 sources towards a single focal spot (4 units are currently in service in three establishments in France), and CyberKnife® which consists of a miniaturised linear accelerator mounted on a robotic arm;
- "conventional" linear accelerators equipped with additional collimation means (mini-collimators, localisers) that can produce mini-beams.

3.1.2 Specific external-beam radiotherapy techniques

Helical radiotherapy

Helical radiotherapy, marketed under the name TomoTherapy®, enables radiation treatment to be delivered by combining the continuous rotation of an accelerator with the longitudinal movement of the patient during the treatment. The technique employed is similar to the principle of helical image acquisitions obtained with computed tomography. A photon beam, emitted at a voltage of 6 MV and a dose-rate of 8 Gy/min, shaped by a multileaf collimator enabling the intensity of the radiation to be modulated, allows the irradiation of large volumes of complex shape as well as extremely localised lesions, which may be in anatomically independent regions. It is also possible to acquire images in treatment conditions and compare them with reference computed tomography images, in order to improve the quality of patient positioning.

At the end of 2014, France totalled 19 sites equipped with facilities of this type.

Intensity modulated arc therapy

An extension of Intensity Modulated Radiation Therapy[4] (IMRT), Intensity Modulated Arc Therapy is now used in France. This technique consists in irradiating a target volume by continuous irradiation rotating around the patient. Several parameters can vary during the irradiation, including the shape of the multileaf collimator aperture, the dose-rate, the rotation speed of the arm or the orientation of the multileaf collimator.

This technique, designated under different terms (VMAT®, RapidArc®) depending on the manufacturer, is achieved using isocentric linear accelerators equipped with this technological option.

Robotic stereotactic radiotherapy

Stereotactic radiotherapy with a robotic arm consists in using a small particle accelerator producing 6 MV photons, placed on an industrial type robotic arm with 6 degrees of freedom, marketed under the name CyberKnife®. Furthermore, the treatment table is also positioned on a robot of the same type. By combining the movement possibilities of the two robots, it is possible to use multiple, non-coplanar beams to irradiate small tumours that are difficult to access using surgery and conventional radiotherapy. This technique enables irradiation to be carried out under stereotactic conditions, and with respiratory tracking.

4. The collimator leaves move during irradiation, which modulates the delivered dose in a complex manner.

Patient set-up for a tomotherapy session.

Given the movement capabilities of the robot and its arm, the usual standards do not apply to the radiation protection of the treatment room and a specific study is therefore required.

At the end of 2014, France totalled 9 sites equipped with facilities of this type.

Intraoperative radiotherapy

Intraoperative radiotherapy combines surgery and radiotherapy, performed concomitantly in the operating theatre environment. The dose of radiation is delivered to the tumour bed during surgical intervention.

In March 2011, the French National Cancer Institute (INCa) launched a call for proposals to support the installation of intraoperative radiotherapy equipment for the treatment of breast cancer patients. One of the objectives of this call for proposals is to carry out a medico-economic evaluation of radiotherapy treatments involving a small number of sessions compared with standard breast cancer treatments. Seven projects deploying an INTRABEAM® accelerator producing X-rays with a voltage of 50 kV were selected and launched between 2011 and 2012. The HAS (French National Authority for Health) is currently finalising a synthesis of the clinical results.

Cover of Bulletin No. 8, *Patient safety*.

Hadron therapy

Hadron therapy is a treatment technique based on the use of beams of charged particles – protons and carbon nuclei – whose particular physical properties ensure highly localised dose distribution during treatment (Bragg's peak). Compared with existing techniques, the dose delivered around the tumour to be irradiated is lower, therefore the volume of healthy tissue irradiated is drastically reduced. Hadron therapy allows the specific treatment of tumours.

Hadron therapy with protons is currently practised in two centres in France – the Curie Institute in Orsay (equipment renewed in 2010) and the Antoine Lacassagne Centre in Nice (equipment currently being renewed).

According to its advocates, hadron therapy with carbon nuclei is more appropriate for the treatment of the most radiation-resistant tumours and could bring several hundred additional cured cancer cases per year. The claimed biological advantage is reportedly due to the very high ionisation of these particles at the end of their path, combined with a reduced effect on the tissues they pass through before reaching the target volume.

3.1.3 Brachytherapy

Brachytherapy allows specific or complementary treatment of cancerous tumours, particularly in the head and neck, the skin, the breast, the genitals and the bronchial tubes.

This technique consists in implanting radionuclides, exclusively in the form of sealed sources (with the exception of iridium-192 wires, considered to be unsealed sources), either in contact with or inside the solid tumours to be treated.

The main radionuclides used in brachytherapy are caesium-137, iridium-192 and iodine-125.

Brachytherapy techniques involve three types of applications:

a - Low Dose-Rate (LDR) brachytherapy:
- delivering dose-rates of between 0.4 and 2 Gy/h;
- using iodine-125 sources in the form of seeds implanted permanently.

For the treatment of prostate cancers, iodine-125 sources are used. These sources (seeds), 4.5 mm long and 0.8 mm in diameter, are positioned permanently inside the patient's prostate gland. Their unit activity is between 10 and 30 MBq and treatment requires about a hundred seeds representing a total activity of 1 to 2 gigabecquerels (GBq).

Low Dose-Rate brachytherapy using sources of iridium-192 and caesium-137 is in the process of being phased out. Conversely, the technique using iodine-125 sources (prostate and ophthalmic brachytherapy) has developed over the last few years. The use of iridium wires stopped in 2014, as they are no longer manufactured.

b - Pulsed Dose-Rate (PDR) brachytherapy:
- delivering dose-rates of between 2 and 12 Gy/h;
- using iridium-192 sources in the form of a source 3.5 mm long, 1 mm in diameter and with maximum activity of 18.5 GBq, implemented with a specific source afterloader.

This technique requires patient hospitalisation for several days in a room with radiological protection appropriate for the maximum activity of the radioactive source used. It is based on the use of a single radioactive source which moves in steps, and stops in predetermined positions for predetermined times.

The doses delivered are identical to those of low dose-rate brachytherapy, but are delivered in sequences of 5 to 20 minutes, or sometimes even 50 minutes, every hour for the duration of the planned treatment, hence the name pulsed dose-rate brachytherapy.

Pulsed dose-rate brachytherapy offers a number of radiation protection advantages:
- no handling of sources;
- no continuous irradiation, which enables the patient to receive medical care without irradiating the staff or having to interrupt the treatment.

However, it is necessary to make provisions for accident situations related to the operation of the source afterloader and to the high dose-rate delivered by the sources used.

c - High Dose-Rate (HDR) brachytherapy:
- delivering dose-rates in excess of 12 Gy/h;
- using iridium-192 sources in the form of a source 3.5 mm long, 1 mm in diameter and with maximum activity of 370 GBq, implemented with a specific source afterloader. Some recently installed source afterloaders use a high-activity (91 GBq) cobalt-60 source.

This technique does not require patient hospitalisation in a room with radiological protection and is performed on an outpatient basis, in a room with a configuration comparable to that of an external- beam radiotherapy room. The treatment is performed with an afterloader containing the source and involves one or more sessions of a few minutes, spread over several days.

High dose-rate brachytherapy is used mainly for gynaecological cancers. This technique is being developed for treatment of prostate cancers, usually in association with an external beam radiotherapy treatment.

d - Brachytherapy in France

In 2013, 64 radiotherapy centres held an ASN license to perform brachytherapy treatments. These 64 centres are spread over the French territory as a whole (metropolitan France and its overseas *départements)* covering two sectors: 60% of the centres belong to the public or non-profit private health care (ESPIC) sector and 40% to the private sector.

The number of centres using these different techniques at the end of 2014 is indicated in table 4.

DISTRIBUTION of brachytherapy centres according to status in 2013 (%)

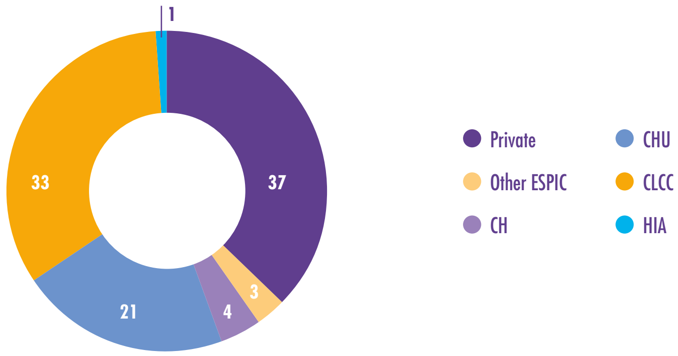


TABLE 4: Number of centres using the different brachytherapy techniques

TECHNIQUE USED		NOMBER DE CENTRES
Low dose-rate	Iodine seed	38
	Cs-137 afterloader	10
PDR		23
HDR		39

Source: ASN 2014.

3.2 Technical rules applicable to installations

3.2.1 Technical rules applicable to external-beam radiotherapy installations

The devices must be installed in rooms specially designed to guarantee radiation protection of the staff, turning them into veritable bunkers (wall thickness can vary from 1 m to 2.5 m of ordinary concrete). A radiotherapy installation comprises a treatment room including a technical area containing the treatment device, a control station outside the room and, for some accelerators, auxiliary technical premises.

The protection of the premises, in particular the treatment room, must be determined in order to respect the annual exposure limits for the workers and/or the public around the premises. A specific study must be carried out for each installation by the machine supplier, together with the medical physicist and the Person Competent in Radiation protection (PCR).

This study defines the thicknesses and nature of the various protections required, which are determined according to the conditions of use of the device, the characteristics of the radiation beam and the use of the adjacent rooms, including those vertically above and below the treatment room. This study should be included in the file presented to support the application for a license to use a radiotherapy installation, examined by ASN.

In addition, safety systems must indicate machine status (operating or not) and must switch off the beam in an emergency or if the door to the irradiation room is opened.

3.2.2 Technical rules applicable to brachytherapy installations

The rules for radioactive source management in brachytherapy are comparable to those defined for all sealed sources, regardless of their use.

Low Dose-Rate brachytherapy

In cases where permanent implant techniques are used (seeds of iodine-125 in particular for treating prostate cancer), the applications are carried out in the operating theatre with ultrasonography monitoring, and do not require hospitalisation in a room with radiation protection.

Pulsed Dose-Rate brachytherapy

This technique uses source afterloaders (generally 18.5 GBq of iridium-192). The treatment takes place in hospital rooms with radiological protection appropriate for the maximum activity of the radioactive source used.

High Dose-Rate brachytherapy

As the maximum activity used is high (370 GBq of iridium-192 or 91 GBq of cobalt-60), irradiation can only be carried out in a room with a configuration comparable to that of an external beam radiotherapy room.

4. BLOOD PRODUCT IRRADIATORS

4.1 Description

The irradiation of blood products is used to prevent post-transfusion reactions in blood-transfusion patients. The blood bag is irradiated with an average dose of about 20 to 25 grays. Irradiation is ensured by a self-shielded device (radiological protection by lead), therefore it can be installed in a room which does not require additional radiation protection. Depending on the models, the irradiators are equipped either with radioactive sources (1, 2 or 3 sources of caesium-137) with a unit activity of about 60 terabecquerels (TBq) or with electrical X-ray generators.

The policy initiated in 2009 to gradually replace the source-equipped irradiators by X-ray generators has reversed the composition of the equipment pool which now comprises more X-ray generators than irradiators with sources. As at 1st November 2015, the irradiator pool comprised 30 machines, 5 of which are equipped with radioactive sources (including one irradiator undergoing decommissioning), that is to say 16% of the irradiator pool.

4.2 Technical rules applicable to facilities

A blood product irradiator must be installed in a dedicated room designed to provide physical protection (fire, flooding, break-in, etc.). Access to the device, which must have a lockable control console, must be limited to authorised persons only.

The layout of irradiators equipped with X-ray generators must comply with the provisions of ASN's new technical resolution 2013-DC-0349 of 4th June 2013 (see chapter 3). This resolution requires that the layout and access to the facilities comply with the radiation protection rules set by French Standard NFC 15-160 in its March 2011 version.

5. THE STATE OF RADIATION PROTECTION IN THE MEDICAL SECTOR

Radiation protection in the medical sector concerns patients receiving treatment or undergoing diagnostic examinations, health professionals (physicians, medical physicists, medical radiation technologists, nurses, nursing auxiliaries, etc.) using or participating in the use of ionising radiation, and also the population, such as members of the public who can be present within a health facility, or population groups that could be exposed to waste or effluents from nuclear medicine units.

Since 2008, ASN has periodically produced documents presenting a national synthesis of the main lessons learned from inspections, based on indicators that determine compliance with the regulatory radiation protection requirements. These syntheses enable the state of radiation protection in the different areas (radiotherapy, nuclear medicine, interventional radiology, etc.) to be assessed for publication in the annual report. The syntheses are based on the findings established during the year preceding their publication. ASN also publishes annual or several-year national appraisals of inspection results; they are available at *www.asn.fr*.

Several appraisals were published in 2015: one on computed tomography (inspections of 2014), one on teleradiology (inspections of 2014), one on radiotherapy (inspections of 2014) and one on nuclear medicine covering three years (inspections of 2012, 2013, 2014).

It should be noted that since 2014, ASN checks the implementation of the assessments of professional practices exposing persons to ionising radiation for medical purposes, which is compulsory in application of Article R. 1333-73 of the Public Health Code[5].

5. This provision entered into effect on 9th November 2007 with Decree 2007-1582 of 7th November 2007, but the conditions of implementation were not specified until 2012. In November 2012, the HAS – in collaboration with ASN and the professionals – thus published a guide to the evaluation of professional practices entitled Radiation protection of the patient and analysis of professional practices, continuous professional development and certification of health centres.

5.1 Exposure situations in the medical sector

5.1.1 Exposure of health professionals

The risks for health professionals arising from the use of ionising radiation are firstly the risks of external exposure generated by the medical devices (devices containing radioactive sources, X-ray generators or particle accelerators) or by sealed and unsealed sources (particularly after administering radiopharmaceuticals). When using unsealed sources, the risk of contamination must be taken into consideration in the risk assessment (particularly in nuclear medicine).

The prevention of risks of exposure of health professionals to ionising radiation is required by provisions of the Labour Code concerning occupational radiation protection.

5.1.2 Exposure of patients

The exposure of patients to ionising radiation must be distinguished from the exposure of workers and the public insofar as it is subject to no dose limits whatsoever. The

TO BE NOTED

ASN's action plan in the field of medical imaging

In May 2015 ASN published a first assessment of the programme of actions to control the doses of ionising radiation delivered to patients during medical imaging examinations. Faced with the increase in radiation doses used for medical diagnostic purposes, ASN had effectively adopted a position as of 2011 on radiation protection in interventional radiology and computed tomography, and initiated a programme comprising 32 actions involving the health authorities and learned societies.

As a positive point, ASN underlines the publication of the good practices guides distributed by the learned societies, particularly concerning medical imaging and medical physics. These guides give the professionals the means to reinforce practical application of the principles of justification of the examinations and optimisation of doses delivered to patients during these examinations.

Significant actions have also been initiated with regard to training:

- the university training of physicians, and more particularly the initial training given to specialists (surgeons, neurosurgeons, cardiologists, urologists, rheumatologists, orthopaedic surgeons, etc.) who make increasing use of X-rays to guide their surgical procedures, should in the long term include courses on patient radiation protection;
- the system of continuous training in patient radiation protection, which has been compulsory since 2004, is currently being updated with the aim of making it more practical and extending it to all the health professionals concerned, and in particular physicians referring patients for radiological examinations;
- lastly, the training dispensed to operators when new equipment is acquired should come with recommendations to ensure that the dose optimisation potential of the new machines is used in full.

The convergence of several actions of ASN's programme with those of Cancer Plan 3 covering the 2014-2019 period, published by INCa in February 2014, should ultimately enable certain equipment utilisation procedures which help reduce doses delivered to patients, to be placed under quality assurance, while at the same time guaranteeing the quality of the images and therefore the appropriateness of the diagnosis or the reliability of the surgical procedure.

Shortcomings nevertheless subsist with regard to human resources:

- Although the number of medical physicists has doubled since 2006, particularly to reinforce staff numbers in radiotherapy, ASN still observes that their involvement, which is necessary to optimise the doses delivered to patients, particularly during interventional procedures and in computed tomography, remains too limited.
- Providing a regulatory framework for the conditions of involvement of nurses in the use of medical imaging equipment in the operating theatre is also urgent, insofar as they participate in the delivery of the doses received by the patients.

only principles applicable remain those of justification and optimisation (see introduction to this chapter).

The patient's exposure situation differs depending on whether diagnostic or therapeutic medical applications are being considered. In the first case, it is necessary to optimise the exposure to ionising radiation in order to deliver the minimum dose required to obtain the appropriate diagnostic information or to perform the planned interventional procedure; in the second case, it is necessary to deliver the highest possible dose needed to destroy the tumour cells while at the same time preserving the healthy neighbouring tissues to the best possible extent.

Whatever the case however, control of the doses delivered during imaging examinations and treatments is a vital requirement that depends not only on the skills of the patient radiation protection professionals but also on the procedures for optimising and maintaining equipment performance.

The steps undertaken by ASN since 2011 in collaboration with the health Authorities and medical imaging professionals are designed to progressively ensure fully effective control over the doses delivered to patients. Many measures have been taken in this respect, including the updating and reinforcement of training in patient radiation protection for interventional practitioners in particular, the development of a quality assurance baseline in the radiology departments and centres provided for in Cancer Plan 3, the development of access to MRI and the defining of reference levels for the most highly irradiating interventional procedures.

5.1.3 Exposure of the general public and environmental impact

With the exception of incident situations, the potential impact of medical applications of ionising radiation is likely to concern:
- members of the public who are close to facilities that emit ionising radiation but do not have the required protection;
- persons close to patients having received a treatment or a nuclear medicine examination, particularly those using radionuclides such as iodine-131, or a brachytherapy with iodine-125;
- the specific professional categories (e.g. sewage workers) liable to be exposed to effluents or waste produced by nuclear medicine unit.

The available information concerning radiological monitoring of the environment carried out by IRSN (Institute of Radiation Protection and Nuclear Safety), in particular the measurement of ambient gamma radiation, on the whole reveals no significant exposure level above the variations in the background radiation. On the other hand, radioactivity measurements in major rivers or wastewater treatment plants in the larger towns occasionally reveal the presence of artificial radionuclides used in nuclear medicine (e.g. iodine-131) exceeding the measurement thresholds. The available data on the impact of these discharges indicate doses of a few tens of microsieverts per year for the most exposed individuals, in particular people working in the sewerage networks and wastewater treatment plants (source: IRSN studies, 2005 and 2014). Furthermore, no trace of these radionuclides has ever been measured in water intended for human consumption (see chapter 1).

The persons close to patients having been treated with radiopharmaceuticals (e.g. treatment of thyroid cancer or hyperthyroidism with iodine-131) can be exposed to ionising radiation for a few days due to the residual activity in the patient. ASN published recommendations in this subject in 2007, and in February 2012, the association of Heads of European Radiological Protection Competent Authorities (HERCA) proposed a model of a European card to be given to each patient leaving hospital after treatment with iodine-131. This card provides information to those who may be concerned, such as health professionals having to treat the patient or border authorities, that the person has been administered radionuclides.

5.2 Some general indicators

5.2.1 Licences and declarations

In 2015, ASN issued:
- 4,794 acknowledgements of receipt of declarations of medical and dental diagnostic radiology devices, of which nearly 77% concerned dental radiology devices;
- 663 licenses (for entry into service, renewal or cancellation), of which 48% were in computed tomography, 26% in nuclear medicine, 20% in external-beam radiotherapy, 5% in brachytherapy and 1% for blood product irradiators.

5.2.2 Dosimetry of health professionals

According to the data collected in 2014 by IRSN, 226,013 people working in sectors using ionising radiation for medical and veterinary purposes were subject to dosimetric monitoring of their exposure. Medical radiology (52%) and dental care (22%) alone account for nearly 74% of the medical personnel exposed.

More than 98% of the health professionals monitored in 2014 received an annual effective dose below 1 millisievert (mSv). Seven exceedances of the annual effective dose limit of 20 mSv were recorded (one in nuclear medicine and 6 in interventional and diagnostic radiology) and one case where the annual dose limit at the extremities (500 mSv) was exceeded was reported in diagnostic radiology.

5.2.3 Significant Radiation protection Events

Significant Radiation protection Events (ESR) have been notified to ASN since 2007. These notifications provide professionals with increasingly valuable experience feedback, helping to improve radiation protection in the medical field.

Since July 2015, radiotherapy departments can notify significant radiation protection events on line. The on-line notification portal is shared with the ANSM (French Health Products Safety Agency); it enables the professionals to notify ESRs and medical device vigilance events relating to radiotherapy. This portal falls within the framework of the single vigilance portal created by the Ministry of Health. It will be extended to the entire medical domain in 2016.

After increasing steadily from 2007 to 2014, the number of ESRs dropped slightly in 2015. Since 2012, the number of ESRs has totalled about 500 per year. In 2015, the number of ESRs notified to ASN in the medical field stood at 525 (557 in 2014).

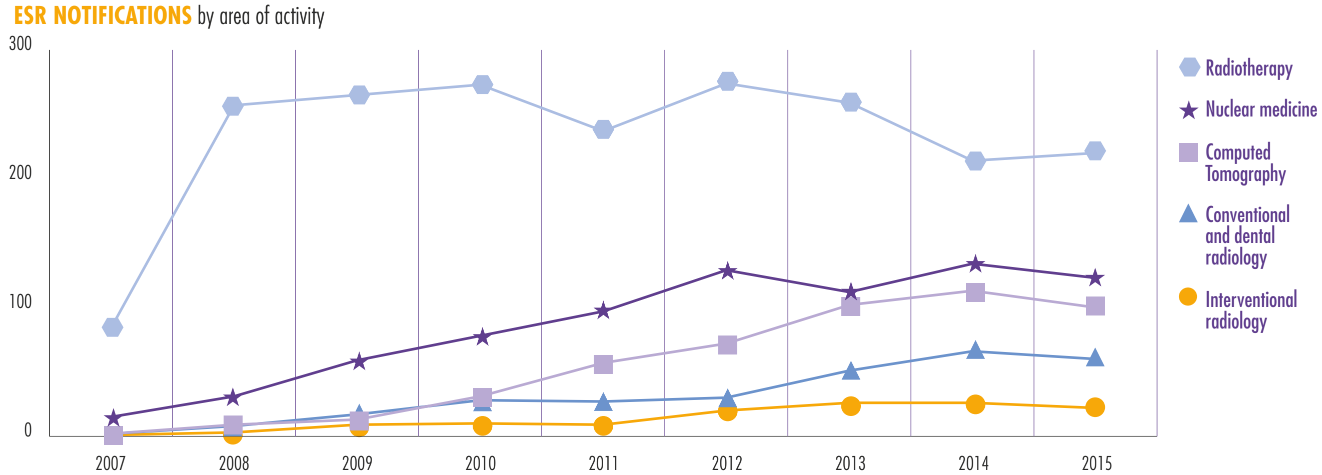
ASN receives two notifications of ESRs in the medical field per working day on average. The incident notices are published on *www.asn.fr*.

Significant events concerning workers (6% of notified ESRs)

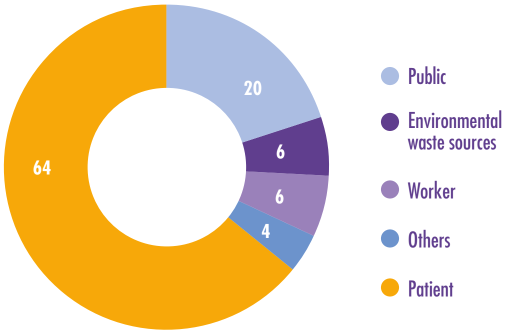
The majority of ESRs concerning workers notified in 2015 occurred in nuclear medicine. The most significant include:
- contaminations of nuclear medicine workers primarily with technetium-99m due to handling errors (inappropriate syringe piston, incorrect use of catheters, dropping of a syringe, breaking of a flask of chromium-51 in the waste storage room);
- external exposure of workers in a hospital department who were required to take care of a female patient who had received radioactive iodine therapy before her transfer. This ESR was rated level 1 on the INES scale because the PCR had not been consulted.

MEDICAL ESRS

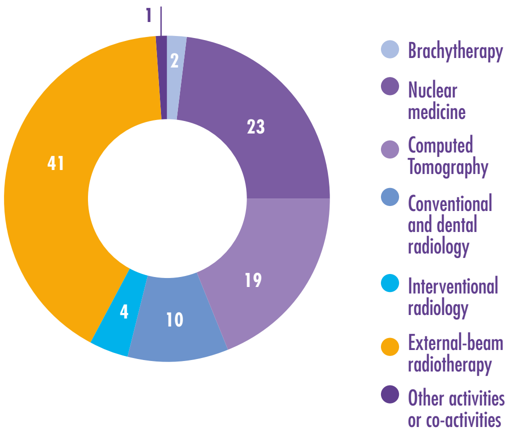
ESR NOTIFICATIONS by area of activity



NOTIFICATION CRITERIA FOR ESRS in the medical field notified to ASN in 2015 (%)



ESR IN THE MEDICAL FIELD notified to ASN in 2015 (%)



Significant events concerning patients (64% of notified ESRs)

In radiotherapy

The majority of events concerning patients notified in 2015 occurred in radiotherapy departments (60%). Most of them resulted from a patient positioning error. The large majority of ESRs concerning patients (95%) had no clinical consequences. 65% of these events were rated level 1 on the ASN-SFRO scale, which comprises 8 levels from 0 to 7, and were included in the quarterly appraisals published on *www.asn.fr*;

2015 saw an increase in the number of ESRs rated level 2 on the ASN-SFRO scale. Eight ESRs of level 2 were notified (3 in 2014) and 1 ESR of level 2+ (2 patients concerned). They concerned errors in the target volume to treat (4 ESRs), the side to treat, dose fractionation, patient identity and lastly an error in activity level in a prostate brachytherapy treatment with permanent implants of iodine-131 seeds. In this latter event, the error was facilitated by the use of several units of measure of which one was not the international unit. The errors are all the more serious in that they concern hypofractionated treatments (3 ESRs).

These events highlight the organisational weaknesses in managing the movements of patients' files, in validation steps that are not sufficiently explicit - particularly that concerning the prescription - and in the upkeep of patients' files to ensure an overall view and access to the necessary information at the right time. Identified risk situations include the treatment of multiple locations such as cerebral metastases, the succession of radiotherapy treatments for a given patient, the absence of a tumoral syndrome on the image (after surgery, for example), non-routine treatments, non-harmonisation of practices within a same given centre, frequent interruptions in tasks, and lastly a heavy work load with, in particular, an impact on treatment amplitudes, if the work load is not properly managed.

In nuclear medicine

The number of ESRs notified in nuclear medicine in 2015 is lower than in the preceding years. About 70 ESRs were notified in 2015 whereas between 2011 and 2014 the number exceeded one hundred per year. As in the preceding years, the errors concern the administration of inappropriate pharmaceuticals, patient identity and the activity administered.

Eight ESRs concern cohorts of patients (2 to 11 patients). In one of these cases, incorrect use of the activity meter was identified. The effective doses received by error, when they were estimated, range from 2 to 9 mSv for diagnostic treatments.

Five ESRs were related to extravasations and led to radiodetermatitis.

With the exception of a few failures (cooling system, peristaltic pump), the majority of the errors result from organisational and human causes. Among the causes we can note problems with personnel training (newcomers, resident doctors, trainees), insufficient preparation for technical or organisational changes, and the absence of medical validation. ASN observed on several occasions that the departments do not wait for the quality control results before starting the examinations.

The analysis of these events reveals shortcomings in the quality management and risk management culture in the nuclear medicine departments concerned.

In radiology

The number of ESRs notified remains low compared with other fields, with 3%, 8% and 3.5% of the notified ESRs concerning patients in computed tomography, conventional radiology and interventional radiology respectively.

Although they are few in number, the ESRs notified in the area of interventional radiology display the most serious consequences with the appearance of deterministic effects for the patient. In 3 cases of events notified in 2015, the occurrence of tissular effects in patients was observed.

Significant radiation protection events concerning radioactive sources, waste and effluents (6% of notified ESRs)

These ESRs are associated with the loss of radioactive sources or the dispersion of radionuclides (leaks of radioactive effluents from pipes or tanks, blocking of pipes, uncontrolled discharge of effluents into the collective sewerage network, removal of waste to an inappropriate disposal route). The number of ESRs notified dropped very markedly in 2015 with 28 ESRs notified compared with 47 in 2014. Despite the feedback from ASN to all the nuclear medicine units in 2009 and 2012, events concerning radioactive effluent leaks from nuclear medicine units are still observed. They are linked to deficiencies in the maintenance and monitoring of facilities that are becoming obsolete.

In 2015, ASN rated 2 events concerning losses of sources as level 1 on the INES scale on account of a safety culture deficiency.

Medical exposure of women unaware of their pregnancy (20% of the ESRs notified)

The notifications made to ASN concern exposure of the foetus in women who were unaware of their pregnancy when they underwent a medical imaging examination (radiology and nuclear medicine). For the radiology events notified in 2015, the doses received were without expected consequences for the foetus or the child after birth (ICRP, 2007). Further to the notification of several events in nuclear medicine, the SFMN has, at ASN's request, updated its recommendations concerning measures to detect pregnancy in women of child-bearing age.

The analysis of these notifications rarely reveals deficiencies in the information given to the women prior to the examination when making their appointment, immediately before the examination and via posters in the changing booths. These notifications represent 99% of the notifications made under the "public" criterion.

Synthesis of the significant radiation protection events notified in 2015

The events notified to ASN in 2015 show that the most significant consequences from the radiation protection aspect concern:
- for workers: nuclear medicine (contamination of workers, external exposure) and interventional radiology (external exposure of operators and, in particular, exposure of the extremities) although it is difficult to have exhaustive knowledge of these situations because the wearing of dosimeters is not common among interventional practitioners;
- for patients: interventional radiology with deterministic effects observed in patients having undergone long and complex procedures, radiotherapy - particularly for hypofractionated treatments, and lastly nuclear medicine, radiopharmaceutical administration errors for cohorts of patients;
- for the public and the environment, nuclear medicine, with leaks from pipes and radioactive effluent containment systems.

The analyses of the ESRs notified to ASN once again underline the need to increase the involvement of Persons Competent in Radiation protection (PCR) and medical physicists in the management of radiation protection, to develop training of the professionals who use ionising radiation, to implement procedures for quality and safety management and for the evaluation of professional practices.

The experience feedback measures included the issuance of two periodic radiotherapy information bulletins based on the capitalisation of the notified ESRs (more than 2,000 incidents in radiotherapy since 2007), produced by radiotherapy professionals and ASN (bulletins No. 7

TO BE NOTED

Regional University Hospital Centre of Lille. Inversion of two patients receiving Gamma Knife® treatment

Due to the inversion of two patients who were each to be treated with a single radiotherapy session, one of the patients was treated with the treatment parameters defined for the other patient and vice versa. The first patient received the entire dose planned for the second patient; the second patient's treatment session was interrupted when the personnel noticed the error on returning the first patient to their hospital room.

ASN's investigations, carried out during the two inspections of 9th January and 2nd March 2015, revealed that the immediate causes resulted firstly from the lack of a verification of the identity of each of the patients before starting their treatment, and secondly the lack of a schedule indicating the order in which the patients were to be taken, even though the patients were waiting for their treatment at the same time in the same waiting room. The root causes are due to a poorly managed organisational environment (late starting of treatments, task interruptions due to technical problems, constraints in access to imaging, etc.),and all this in a context of high workload. Although corrective measures have been taken, such as putting in place a check-list in which double-checking of the patient's identity is formalised and tracked, formalising the organisation for determining the order in which patients are taken, and revising patient routing, ASN considers that improvements are necessary, particularly in the management of patient routing and in redefining the responsibilities at each stage of the treatment process.

and 8 on patient safety in radiotherapy published in 2015 concerning the recording faults in the Record and Verify systems and pulsed high dose rate brachytherapy). In addition, recommendations were addressed to all radiotherapy departments in May 2015 in order to prevent the occurrence of radiation protection events associated with beam asymmetries in external-beam radiotherapy and to improve their detection.

5.3 Radiation protection situation in radiotherapy

The safety of radiotherapy treatments has been a priority area of ASN oversight since 2007. In view of the results of the inspections and the progress made in terms of treatment safety, as of 2012 radiotherapy centres will be checked every two years. An annual inspection frequency is nevertheless maintained for the centres with vulnerabilities in terms of human resources or organisation, and those which are behind schedule in ensuring compliance with ASN resolution 2008-DC-0103 of 1st July 2008. Moreover, particular attention is paid to departments having undergone major modifications (organisational or material), and centres implementing new techniques.

A four-year inspection programme had been defined for the 2012-2015 period with systematic inspections and variable inspections for the 2012-2013 and 2014-2015 periods respectively.

Over the 2014-2015 period, the inspectors focused more particularly on:
- the management of jobs and skills of the personnel assigned to dosimetry and of the radiographers assigned to the preparation of treatments and patient set-up during the simulation;
- the management of the equipment (quality control, maintenance);
- the management of treatment preparation and performance (appropriateness of the procedures and their implementation during treatment preparation and the verification of positioning during treatment).

5.3.1 Radiation protection of radiotherapy professionals

When the facilities are correctly designed, the radiation protection implications for the professionals in radiotherapy are limited due to the protection provided by the walls of the irradiation room.

In 2014 the inspectors inspected the methods of verification and maintenance of the radiotherapy and computed tomography facilities:
- 72% of the centres inspected had formalised the maintenance and verification methods in writing;
- the number of quality controls of scanners (applied during treatment preparation) has increased significantly since 2010, since 93% of the centres inspected carried out this quality control in 2014.

Performance of the internal quality control and external quality control of external-beam radiotherapy facilities must be audited by an approved organisation. Three organisations are now approved to perform this audit, the first having been approved in August 2013. Nevertheless, in 2014, 41% of the inspected centres had not yet had this audit performed, or placed an order with an approved organisation to have it performed.

ASN moreover verifies the radiation protection requirements for the personnel when it delivers the licenses to possess and use the devices, particularly during the facility conformity inspection.

5.3.2 Radiation protection of radiotherapy patients

The ASN inspections carried out in 2014 concerned 92 centres, representing nearly 52% of the radiotherapy departments. They confirm the positive trend begun in 2008 with regard to the increased human resources deployed in medical radiation physics. At the end of 2014, all the centres had more than one Full-Time Equivalent (FTE) medical physicist. Nevertheless, ASN counts 19 centres with less than two FTE medical physicists, and in 5 centres the inspectors noted temporary situations where the presence of a physicist was not guaranteed for the entire duration of the treatments.

Implementation of a quality management system

Although the implementation of a management system for the safety and quality of care delivered to patients is progressing, it varies greatly from one centre to another and some are still late with respect to the regulatory deadlines set by ASN technical resolution 2008-DC-0103 of 1st July 2008.

The results of the inspections performed in 2014 show in particular that:
- 3% of the inspected centres had not designated an operational quality manager (compared with 29% in 2011 and 11% in 2013); however, when a quality manager is appointed, the means at their disposal to fulfil their mission are not always defined (in 10% of the centres inspected);
- 93% of the centres inspected have a mapping of the processes;
- although 87% of the centres inspected have defined care quality and safety objectives, in 12% of the centres these objectives are not all tracked and/or updated;
- 49% of the centres perform internal audits and process reviews but 31% of the centres only conduct a management review and 20% of the centres have still not defined continuous improvement methods;

- the risks run by the patients are analysed in 100% of the centres inspected in 2014 but the analysis is updated in only 65% of the centres, even though this updating is essential, especially when new techniques are introduced.

Noting reluctance on the part of the centres to embrace these risk analyses, ASN has produced - in collaboration with radiotherapy professionals - an assessment of the difficulties encountered with a view to issuing recommendations to facilitate application of this procedure. An IRSN appraisal requested by ASN was carried out in 2014 and recommendations were published in 2015. This appraisal underlines the need to improve the assistance given to radiotherapy units, to reduce the complexity of the risk analyses and to improve the feasibility and practicality of the risk analyses.

The figure below illustrates the progress in the approach to the management of treatment safety and quality since 2010.

Control of treatment procedures

Based on the analysis of the events notified to ASN, inspections have targeted certain treatment steps in order to verify the existence of procedures formalising the practices and their effective implementation. In 2014, treatment preparation (computed tomography and dosimetry) and the verification of patient positioning during treatment were examined.

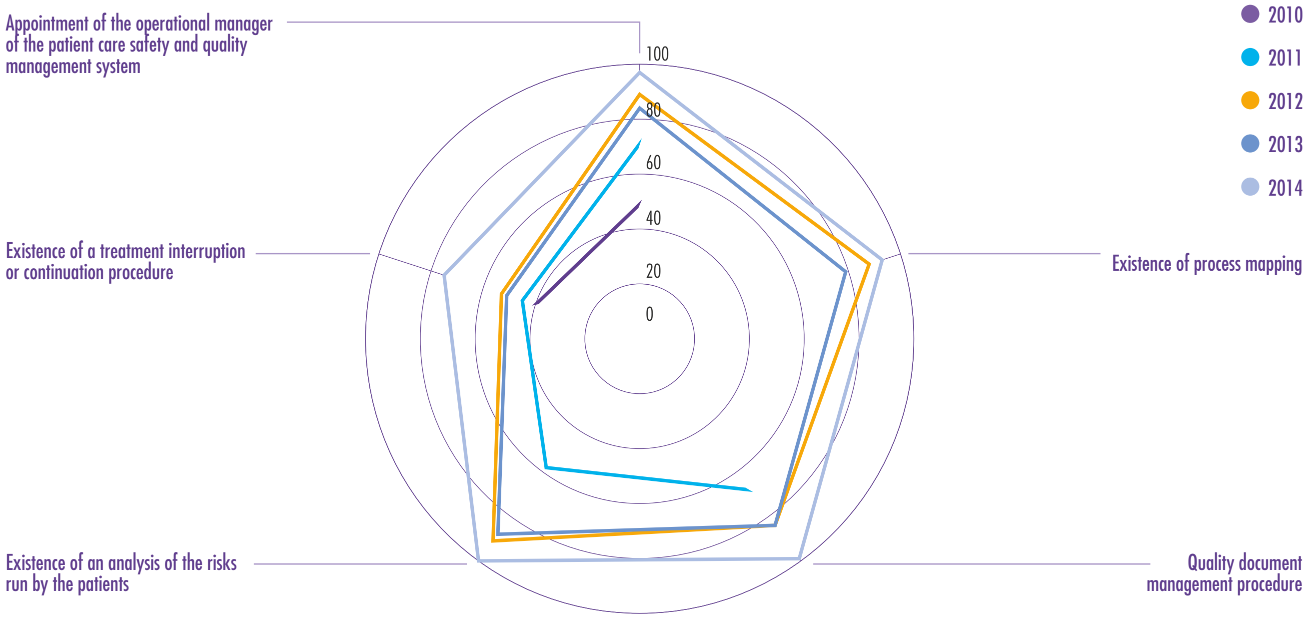
It was observed that:
- 93% of the inspected centres have devised a procedure for setting up the patient under the scanner for the principal locations treated;
- 98% of the inspected centres have the dosimetric treatment plan approved by the medical physicist and the radiation oncologist before delivering the treatment;
- 98% of the inspected centres check the position by imaging at least once per week. Progress is nevertheless required with regard to the methods of performing and supervising the positioning verifications, as only 76% of the centres have formalised the criteria for determining when a medical opinion must be requested.

Management of risks and addressing malfunctions

Internal listing of malfunctions has been put in place in virtually all the centres, given that 98% of the inspected centres have such a list and use it.

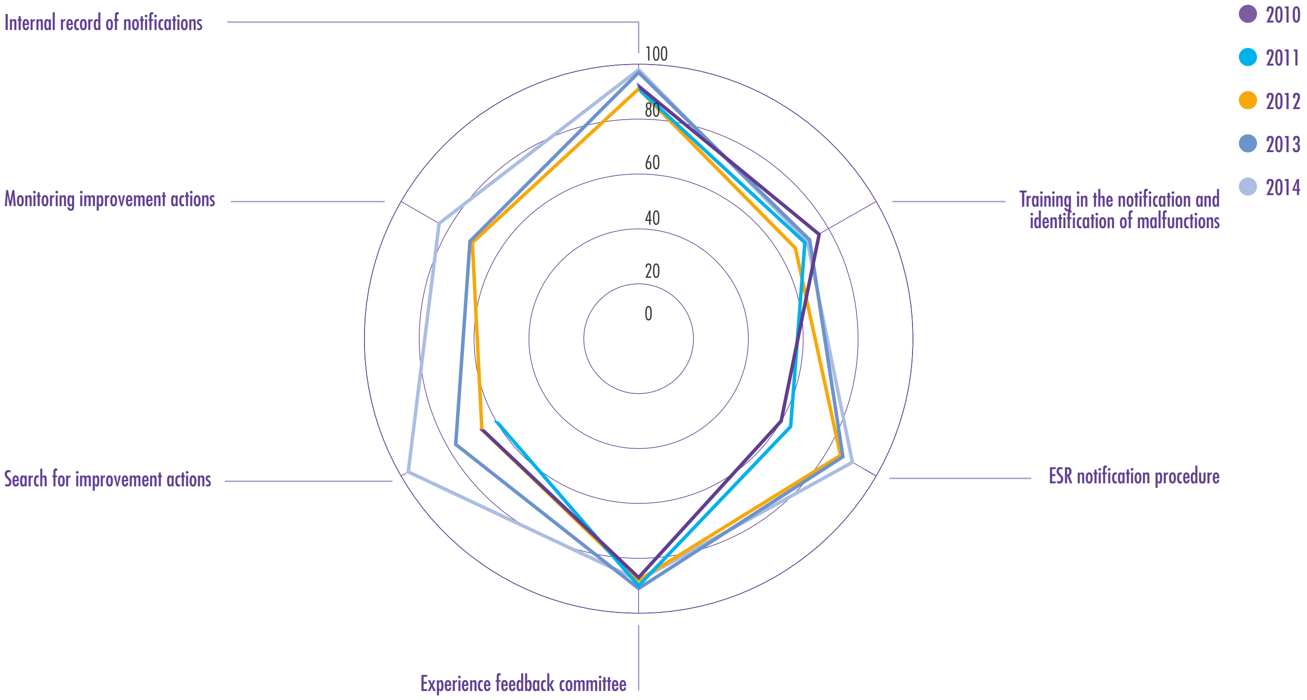
ASN observed in 2014 that 88% of the inspected centres have an organisational set-up enabling them to regularly bring together multidisciplinary skills to analyse significant radiation protection events. 97% of the centres have identified improvement measures after analysing the

DEVELOPMENT OF CRITERIA since 2010 concerning the deployment of section 1 of ASN resolution 2008-DC-0103 ASN (%)



Source: inspections ASN.

RESULTS OF THE INDICATOR concerning the management of risks and events (%)



Source: inspections ASN.

TO BE NOTED

The new techniques in radiotherapy

In August 2013, ASN asked the GPMED (Advisory Committee of Experts on Medical Exposure) to issue recommendations concerning the conditions of implementation of new techniques in radiotherapy and the associated practices, focusing in particular on the techniques of intensity-modulated radiotherapy and stereotactic irradiation, and on new treatment devices.

The opinion of the GPMED was delivered on 10th February 2015 and transmitted by ASN to the Ministry responsible for Health, to the INCa and the HAS and to the learned societies, requesting that the necessary actions corresponding to the 12 recommendations issued be defined and undertaken.

ASN will be particularly attentive to the monitoring of these actions, especially those concerning the adaptation of the means necessary to deploy these new techniques and practices, the implementation of the clinical audit procedures, the prospective collection of data concerning the patients so that the benefits and the risks can be assessed, and the reinforcement of patient involvement.

events but 13% do not monitor or monitor only partially the implementation of these improvement measures. The involvement of the Management of medical establishments in this area is essential and must be maintained over the long term.

5.3.3 Summary

To conclude, ASN has observed continuous improvement in the implementation of the quality and safety management requirements in radiotherapy departments since 2008 and considers that the findings established at the end of 2014 confirm this analysis, while at the same time underlining variability between centres, particularly in seeing to the continuous improvement of the documentary system. Although the quality systems are increasing in number, the analysis of events shows that the systems are not evaluated and do not take practices sufficiently into account.

Risk management is now integrated in the radiotherapy departments, with the internal listing of malfunctions and their analysis being set up. But efforts must still be made in monitoring the envisaged improvement actions over time, as this is a vital step to ensure the effectiveness of the measures taken.

5.4 Radiation protection situation in brachytherapy

Fourteen inspections were carried out in brachytherapy in 2014 (about 22% of the centres).

5.4.1 Worker radiation protection

The majority of the centres have put in place appropriate measures for:
- having a PCR designated by the employer (100% of the centres);
- defining the PCR's duties (100% of the centres) and resources (100% of the centres) ;
- passive dosimetry monitoring of workers that could be exposed (100% of the centres);
- active dosimetry monitoring of personnel working in controlled areas (95% of the centres).

The organisation put in place by the brachytherapy units for worker radiation protection is judged satisfactory. 93% of the brachytherapy units inspected in 2014 have a PCR dedicated to this activity. The inspectors noted that the necessary means for fulfilling their assignments were available in 100% of the centres inspected in 2014.

Training actions for paramedical personnel are held at the required frequency on the whole. However, training in worker radiation protection is rarely provided for physicians and medical physicists. The radiation protection of nurses present in the brachytherapy unit, when they belong to a structure other than the radiotherapy centre concerned, needs to be improved (training, dosimetric monitoring, analysis of working practices and conditions). The external technical verifications of radiation protection are carried out in 86% of the centres inspected. Only 63% of the centres inspected perform internal technical verifications and produce a technical schedule for the verifications.

Progress is required in the performance of analyses of working practices and conditions (carried out in 8% of the centres inspected in 2014).

5.4.2 Radiation protection of patients

The treatment quality and safety management system

The majority of the centres have put in place appropriate measures for:
- appointing the manager of the treatment quality and safety management system (93% of the centres);
- producing the document management procedure;
- internal communication.

The inspections performed since 2013 have shown that two requirements concerning the implementation of the care quality and safety management system have not been satisfactorily met. They concern the formalising of process mapping which is only carried out in 64% of the inspected centres, and the conducting of the analysis of risks run by the brachytherapy patient.

Although the brachytherapy units are assisted by the external-beam radiotherapy departments in the deployment of the quality approach, further progress is required.

Training and information

Training in patient radiation protection has made progress and is carried out in 89% of the centres inspected in 2014.

The mandatory inclusion of the necessary information in the report for medical procedures using ionising radiation was not considered satisfactory for the inspections carried out in 2014. More specifically, in 62% of the centres the reports did not contain any information on the identification of the treatment device.

Maintenance and quality controls

In 2014, the majority of the centres had an inventory of the medical devices and a register for recording maintenance operations and quality controls. In 20% of the inspected centres however, the organisation for carrying out and tracking maintenance operations and quality controls remains to be finalised. It was noted more specifically that the traceability of the internal verifications and maintenance operations is not always ensured satisfactorily.

In the absence of an ANSM decision defining the quality controls for brachytherapy devices, the nature of the quality controls results from past practices and is based on recommendations provided by device manufacturers or professionals.

Maintenance of the HDR and PDR afterloaders is ensured by the manufacturers. More specifically, the manufacturers perform the afterloader operating verifications when the sources are replaced. The brachytherapy units rely on these verifications to guarantee correct operation of the devices. The source activity is verified at each delivery and source removal verifications are also carried out.

5.4.3 Management of sources

The majority of the centres have put in place appropriate measures for:
- recording the movements of sources (93% of the centres);
- transmitting the inventory of sources to IRSN each year (86% of the centres);
- managing waste and sources after implanting iodine seeds, with systematic verification of the remaining sources (number) with respect to the implanted and ordered sources (100% of the centres).

Management of the brachytherapy sources is satisfactory; nevertheless, 85% of the centres inspected in 2014 still hold expired sealed sources.

5.4.4 Emergency situations and the management of malfunctions

The majority of the centres have put in place appropriate measures for:
- internal recording of events foreshadowing malfunctions or undesirable situations;
- an organisation allowing the multidisciplinary analysis of the causes of internal malfunctions or ESRs;
- the implementation of an events management procedure;
- seeking improvement actions for the analysed events.

Only 68% of the centres monitor improvement actions following an event or a malfunction.

An event involving source jamming of an HDR afterloader led to the exposure of workers and a female patient. This event brought home the importance of defining emergency measures, particularly within the framework of the on-site emergency plan, and of reinforcing worker training in these emergency measures. Instructions on the risk of source jamming are provided in the brachytherapy units. However, exercises to prepare for and assess intervention methods are very rare. Compliance with the requirements relative to advanced training in worker radiation protection for the use of high-activity sealed sources is judged satisfactory (62% of the centres have carried out this training). This advanced training must focus in particular on the emergency measures to implement in the event of possible loss of control of the high-activity source (example: jamming of a high-activity source).

With regard to PDR brachytherapy, the centres have response procedures if an incident arises. However, these procedures do not detail all the possible scenarios for identifying the operations to perform, the people who can perform them and the response time to optimise worker and patient protection and thus avoid inappropriate exposures. Actions are therefore required in this respect.

5.4.5 Summary

ASN considers that the findings of the inspections carried out in 2013 and 2014 are encouraging. With regard to the deployment of a quality management system, the brachytherapy units benefit from the organisation set up in external-beam radiotherapy for both worker and patient radiation protection.

Lateness in the deployment of aids specific to brachytherapy is nevertheless observed. Efforts must thus be made regarding compliance with the regulatory requirements relative to process mapping, training in patient radiation protection and advanced training in worker radiation protection when high-activity sources are held, the removal of expired sources, the scheduling and performance of internal technical controls of radiation protection, the completeness of the procedure report, the conducting of the analysis of risks run by patients and the monitoring of improvement actions following a significant radiation protection event.

5.5 Radiation protection situation in nuclear medicine

Over the period from 2012 to 2014, 263 inspections were carried out in the 225 *in vivo* nuclear medicine units. Compared with results established over the 2009-2011 period, it was observed that the radiation protection of workers, patients and the environment is taken into account in an increasingly satisfactory manner.

5.5.1 Radiation protection of nuclear medicine professionals

The main strong points have been confirmed:
- performance of the risk assessment, even if the risk of external and internal contamination is not always taken into consideration;
- implementation of dosimetric monitoring of the personnel, appropriate for the modes of exposure, notably the wearing of dosimetric rings and referring to the recommendations of ORAMED (Optimization of Radiation Protection for Medical Staff)[6];
- the writing of a radiation protection control programme and the performance of external technical controls;
- the use of automated systems for preparing the doses and/or injecting radiopharmaceuticals marked with fluorine-18.

However, particular efforts must still be made in order to meet the following regulatory requirements:
- the performance of working practices and conditions analyses for all the professionals involved, taking into

6. *www.oramed-fp7.eu/en/D52Guidelines3_FR_PDF*

account all the exposure pathways (hands and internal exposure);
- training of all the exposed personnel in occupational radiation protection, particularly medical personnel, with the required regulatory frequency;
- tightened medical monitoring of the medical personnel;
- performance of comprehensive internal technical controls of radiation protection and the ambient environment, in compliance with the regulatory frequencies;
- the utilisation of a contamination meter at each exit from the unit;
- the coordination of prevention measures when outside contractors are required to work in controlled areas, with the preparation of a risk prevention plan.

The attention of the units is drawn to the fact that ASN resolution 2014-DC-0463 has done away with the negative pressure requirements for radionuclide handling rooms. Consequently, containment is now based exclusively on the radiation-proof enclosure, hence the importance of using the gloves attached to the radiation-proof enclosure.

5.5.2 Radiation protection of patients in nuclear medicine

Radiation protection measures are properly taken into account with regard to:
- the principle of justification of nuclear medicine procedures for diagnostic or therapeutic purposes with prior approval by a nuclear medicine physician of any nuclear medicine procedure request;
- the use of a medical physicist;
- the preparation of medical physics organisation plans by the centres;
- the training of paramedical staff in the radiation protection of patients;
- transmission to IRSN of dosimetric data to participate in the development of the Diagnostic Reference Levels (DRL);
- the inclusion of dosimetric information in the medical procedure reports;
- the production of protocols for the medical procedures performed.

The units must continue to make efforts with regard to:
- the training of medical staff in the radiation protection of patients, and ensuring the traceability of their training;
- exploitation of the dosimetric data transmitted to IRSN for the purpose of exposure optimisation;
- performance of external quality controls;
- formalising the methods of performing maintenance and quality controls;
- pregnancy screening of women of child-bearing age before conducting nuclear medicine procedures.

5.5.3 Protection of the general public and the environment

During this 2012-2014 period, the following points were considered to be positive findings:
- the establishing of a waste and effluents management plan, even if it does not cover all the points requested by ASN resolution 2008-DC-0095 of 29th January 2008 relative to contaminated effluents and waste;
- the installation of decay tanks and systems delaying the discharge of contaminated liquid effluents coming from the units into the public network;
- the traceability of the verifications of waste and effluents contaminated by radionuclides.

On the other hand, few units obtained an authorisation to discharge non-domestic effluents into the sewerage networks in application of Article L. 1331-10 of the Public Health Code. ASN recommendations should be available in 2016 to facilitate delivery of these authorisations by the sewerage network administration services.

5.5.4 Summary

The points considered unsatisfactory in the assessment for the 2012-2014 period will be reassessed in the coming years by the inspectors. Since 2014, three priority subjects have been undergoing detailed inspections:
- management of contaminated effluents after the analysis of significant radiation protection events. Greater attention is paid to the knowledge, identification and monitoring of pipes carrying radioactive effluents and to the formalising of a response protocol in the event of leakage;
- the use of automatons for the preparation and/or injection of doses. The units are questioned on protocol quality assurance and protective measures regarding administration of the radiopharmaceutical;
- the radiation protection measures associated with the use of targeted internal radiotherapy rooms with the provision of work equipment, the existence of access instructions, the conditions and means of protection during the transport of sources outside the nuclear medicine unit.

The tightened oversight of the above three points will be continued in 2016. Furthermore, the compliance of the units with ASN resolution 2014-DC-0463 of 22nd October 2014 will be assessed by the inspectors, given that the majority of the requirements are already in force.

5.6 Radiation protection situation in conventional radiology and computed tomography

ASN has maintained the oversight of radiation protection in computed tomography among its priorities because CT examinations contribute significantly to the exposure of the French population to ionising radiation of medical origin. In 2012, computed tomography procedures effectively accounted for 71% of the mean effective dose received by the population, although they represent just 10% of the volume (see chapter 1).

Inspection results

In 2014, a new sample of 98 computed tomography facilities was inspected. The inspection results confirm the year-on-year trends which reveal a radiation protection situation that is more satisfactory for workers than for patients. Examination of the trends recorded on the 367 facilities inspected over the 2011 to 2014 period (36% of the pool) confirms this assessment by highlighting a more pronounced deficiency in the practical application of the principle of justification in patient radiation protection.

With regard to the assessment of professional practices, 70% of the inspected units conducted an assessment. This is based essentially on the compulsory listing and analysis of the diagnostic reference levels. To a lesser extent, the computed tomography assessments focused on the implementation of the principle of justification (conformity of the imaging request and relevance of the imaging examinations for diagnostic purposes).

Improvements are necessary, and more particularly by reinforcing the analysis prior to referral for examinations, the training of the personnel concerned in the radiation protection of patients, the optimisation of the examination protocols provided with CT scanners, the analysis of the dosimetric data transmitted to IRSN for DRL updating, and the assessment of professional practices. In 2014, ASN initiated a first assessment of the radiation protection of patients undergoing computed tomography examinations by teleradiology which revealed shortcomings, particularly in the practical application of the principle of justification.

In 2013, ASN asked the GPMED to establish recommendations on measures to improve the participation of imaging centres in the collection and analysis of dosimetric data associated with the DRLs and on any changes to be considered in the regulatory provisions for radiology and nuclear medicine. The opinion of the GPMED was published in 2015 and an update of the Order of 24th November 2011 is expected in 2016.

ASN remains highly involved in the activities of the HERCA working group responsible for medical applications of ionising radiation and for which it ensures the technical secretariat. This working group held two seminars in 2015, one involving the stakeholders in the application of the principle of optimisation, while the other allowed discussions on inspection practices in the field of imaging.

5.7 Radiation protection situation in interventional practices

For several years now, significant radiation protection events have been regularly notified to ASN following the appearance of lesions (radiodermatitis, necrosis) in patients having undergone particularly long and complex interventional procedures. In addition to these events which emphasise the major implications of radiation protection for patients, one must consider the notifications concerning professionals whose exposure sometimes exceeds the regulatory limits.

The verification of radiation protection in the area of interventional practices has been a priority for ASN since 2009.

The appraisal of radiation protection in radiology is based on indicators allowing an assessment of the implementation of the regulations relative to the radiation protection of the medical staff and the patients and the regulations concerning the medical devices (maintenance, quality inspection, dose measuring systems).

5.7.1 Radiation protection of interventional radiology professionals

The findings established on completion of the inspections in 2014 confirm the observations made over the last few years. Thus, radiation protection of medical staff is still applied to a greater extent in the fixed and dedicated radiology facilities (interventional radiology) than in the operating theatres in which mobile devices are used.

The inspections on the whole still reveal inadequacies in the performance of the analyses of working practices and conditions, particularly with respect to doses to the extremities and to the lens of the eye, and in dosimetric monitoring (active and at extremities).

The lack of training of medical staff, especially private practitioners, working in operating theatres is a fact and a poor radiation protection culture can be observed in this sector. Moreover, collective radiation protection equipment is available for the dedicated activities, but still too rarely in operating theatres. With regard to Personal Protective Equipment (PPE), it is available and is worn, with the exception of lead glasses. Furthermore, the personnel in question show little concern for their own radiation protection and are not aware of the doses they can and/or do receive, due in particular to the failure to wear the appropriate and regulatory dosimeters.

ASN inspection on the theme of interventional radiology, Villefranche-de-Rouergue hospital, December 2010.

Moreover, the still incomplete use of dosimetry and the lack of appropriate dosimetric monitoring, in particular of the extremities for certain fluoroscopy-guided procedures, and the absence of medical monitoring of the practitioners, make it difficult to assess the status of worker radiation protection in this sector. ASN does nevertheless observe improvements in the inspected departments and greater awareness of the professionals as a result of the information feedback from notified events.

For the PCRs, there are still methodological and organisational difficulties and they do not always have the means enabling them to perform their duties in full. Moreover, in the private sector, the analyses of private practitioners' working practices and conditions, their dosimetric monitoring, their medical monitoring and, where applicable, that of their employees, represent a recurrent difficulty.

5.7.2 Radiation protection of patients in interventional radiology

The findings established on completion of the inspections in 2014 with regard to patient radiation protection also confirm the observations made over the last few years. This holds true for the shortcomings observed in the application of the principle of dose optimisation, be it in the setting of the machines and the protocols used or in the practices. They result from insufficient operator training in patient radiation protection and sub-optimal use of the radiology devices, as the dose optimisation functions of the devices are insufficiently well known.

A significant improvement is however observed in the dedicated facilities, particularly in cardiology and neuroradiology, where dosimetric reviews are becoming more widespread with a view to optimising procedures; reference levels for the most common examinations are increasingly set at local level. This approach also enables appropriate medical monitoring of the patient to be organised according to the dose levels received.

Assessments of professional practices are rare in the areas of interventional radiology and fluoroscopy-guided procedures. The specialities in which in the assessment of practices is most widespread are neuroradiology, vascular surgery and coronarography, for which between 20 and 30% of the departments inspected had conducted an assessment. These assessments of practices are virtually inexistent in the other specialities, although it must be said that the number of departments inspected was very low.

The low level of use of medical physicists in departments practicing interventional radiology hinders implementation of the principle of optimisation: greater involvement of medical physicists would more specifically allow better use of the equipment and the application of protocols adapted to the procedures performed. When medical centres call upon outside medical physics service providers, it is observed that the centres rarely adopt the procedures and documentation used by these service providers. The analysis of the notified events, detailed in an ASN circular letter dated 24th March 2014[7], has already highlighted substantial reductions in delivered doses, ranging from 40 to 70%, following the optimisation measures implemented by the medical physicist.

These findings confirm insufficient application of the optimisation principle and can lead to potential risk situations.

5.7.3 Summary

As in 2014, ASN considers that the urgent measures it has been recommending for several years to improve the radiation protection of patients and professionals in the exercise of interventional practices, particularly in operating theatres, have still not been taken. These measures concern increasing medical physicist staff numbers and user training and quality assurance, organising professional practice audits, increasing the means allocated to PCRs, training medical professionals in patient radiation protection and the publication of good practices guides by the learned societies.

In the field of medical physics in particular, the efforts made since 2007 to boost the numbers of medical physicists must be continued in order to meet the medical imaging needs.

ASN also asked the HAS (French National Authority for Health) to draw up national recommendations for monitoring patients having undergone interventional radiology procedures that could lead to effects on tissues. These recommendations were published in 2014 by the HAS[8]. In connection with this publication, ASN considers that the implementation of dosimetric reviews in order to establish reference levels for the most common and/or most irradiating procedures is to be continued for all the specialities, and in particular in the operating theatre. These evaluations will enable physicians to analyse their practices and initiate appropriate patient monitoring if necessary.

The review of the actions recommended by ASN in medical imaging, published in 2015, provided the opportunity to assess the situation concerning specific subjects in the interventional areas, such as the issuance of good practice guides for the various specialities, the training of medical professionals in patient radiation protection, the definition of DRLs, or the increase in means assigned to the PCRs.

Due to the implications - as much for the radiation protection of professionals, where limit exceedances are still observed, as for that of patients, where significant radiation protection events are notified - and because of the shortcomings in the radiation protection culture of medical workers, particularly in operating theatres, ASN is maintaining the inspection of interventional radiology as a national priority in its 2016 inspection programme.

7. *http://professionnels.asn.fr/Activites-medicales/Radiologie-interventionnelle/Lettres-circulaires-en-radiologie-interventionnelle*
8. *"Improving patient monitoring in interventional radiology and fluoroscopy-guided procedures – reducing the risk of deterministic effects".*

6. OUTLOOK

In radiotherapy, the measures taken since 2007 concerning human resources and in the areas of training, equipment control, quality and risk management, have enabled the safety of treatments to be improved. However, although ASN's inspections enable the progress of the centres to be measured, weaknesses are still observed in quality management and risk management. The reason for this is that although the quality systems are becoming more precise and effective as time goes by and risk analyses are spreading, quality and risk management are not sufficiently assessed and their integration into working practices is proving difficult. The events notified to ASN underline the major radiation protection implications of hypofractionated treatments for the patients.

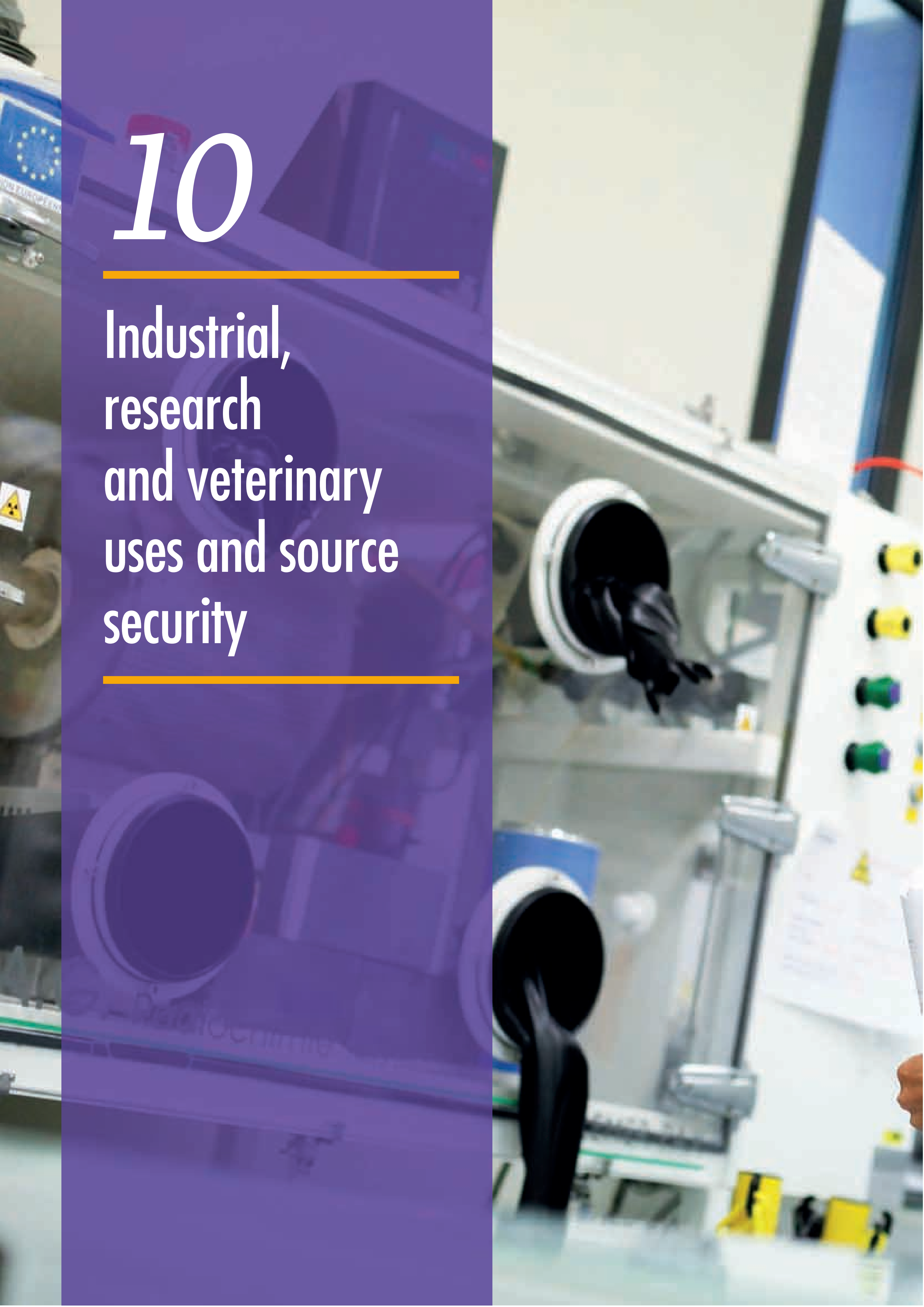
With regard to the recommendations issued by the GPMED on the conditions of implementation of high-precision irradiation techniques in radiotherapy and the associated practices, particularly those leading to the delivery of hypofractionated treatments, ASN will undertake – with the Ministry responsible for Health, the INCa, the HAS and the learned societies – the necessary actions to reinforce the safety and the protection of patients during their implementation. ASN will be particularly attentive to the monitoring of these actions, especially those concerning adaptation of the means necessary for the deployment of these new techniques or practices, the implementation of the clinical audit procedures, the prospective collection of data concerning the patients so that the benefits and the risks can be assessed, and involving the patients more actively in their personal safety.

2015 saw the completion of the four-year (2012-2015) inspection programme for the radiotherapy centres. The new ASN inspection programme for the years 2016-2019, taking into account the recommendations made by a working group comprising radiotherapy professionals, will be widely communicated at the beginning of 2016. Risk management - particularly the evaluation of the organisational and human barriers put in place, hypofractionated treatments and the deployment of new techniques or practices will be the focal points of its inspections.

Verification of the control of doses in medical imaging still remains a priority for ASN, particularly when associated with interventional practices. The recent and rapid development of new imaging techniques and their implementation by specialists (surgeons, neurosurgeons, cardiologists, urologists, rheumatologists, orthopaedic surgeons, etc.) who too frequently are insufficiently trained in matters of radiation protection, justifies the reinforcing of the actions conducted by ASN. Thus, the implementation of practical training programmes, as much in the university degree courses as in continuous occupational training, must represent a priority objective to which the professionals and the health centres must commit over the long term.

The emerging efforts to involve medical physicists in the optimisation of doses delivered to patients during both interventional practices and computed tomography examinations are still too half-hearted. In the context of the transposition of the new Euratom Directive defining the basic radiation protection standards, ASN will have to propose requirements to regulate the medical physics services which are necessary in these areas.

The justification of radiological examinations, particular CT scans, is also a priority question for which actions must be taken not only to inform but also to train the physicians requesting the examinations. Initiatives agreed jointly with the health authorities, professionals and patients' associations will also be taken in 2016.



10

Industrial, research and veterinary uses and source security


SÛRETÉ NUCLÉAI

Industrial and research sectors have been using sources of ionising radiation in a wide range of applications and locations for many years now. The purpose of the radiation protection regulations is to check that the safety of workers, the public and the environment is ensured. This protection involves more specifically ensuring proper management of the sources, which are often portable and used on worksites, and monitoring the conditions of their possession, use and disposal, from fabrication through to end-of-life. It also involves monitoring the main stakeholders, that is to say the source manufacturers and suppliers, and enhancing their accountability.

The regulatory framework governing nuclear activities in France falls within the scope of the Public Health Code and the Labour Code, and guides the regulation activities for which ASN is responsible. It results from the transposition of the Euratom Directives and will evolve in the coming years with the transposition of Council Directive 2013/59/Euratom that sets the basic standards for protection against the dangers arising from exposure to ionising radiation and puts in place a verification of the protection of ionising radiation sources against malicious acts (see chapter 3).

The radiation sources used are either radionuclides – essentially artificial – in sealed or unsealed sources, or electrical devices generating ionising radiation. The applications presented in this chapter concern the manufacture and distribution of all sources, the industrial, research and veterinary uses (medical activities are presented in chapter 9) and activities not covered by the basic nuclear installations system (these are presented in chapters 12, 13 and 14).

1. INDUSTRIAL, RESEARCH AND VETERINARY USES OF RADIOACTIVE SOURCES

1.1 Sealed radioactive sources

Sealed radioactive sources are defined as sources whose structure or packaging, in normal use, prevents any dispersion of radioactive substances into the ambient environment. Their main uses are presented below.

1.1.1 Industrial irradiation

Industrial irradiation is used for sterilising medical equipment, pharmaceutical or cosmetic products and for the conservation of foodstuffs. It is also a means of voluntarily modifying the properties of materials, for example, to harden polymers.

These consumer product irradiation techniques can be authorised because, after being treated, these products display no residual artificial radioactivity (the products are sterilised by passing through radiation without themselves being "activated" by the treatment).

Industrial irradiators often use cobalt-60 sources, whose activity can be very high and exceeds 250,000 terabecquerels (TBq). Some of these installations are classified as BNIs (see chapter 14). In many sectors, X-ray generators are gradually replacing high-activity sealed sources for the irradiation of products (see point 2).

1.1.2 Gamma radiography

Gamma radiography is a very frequently used method for detecting defects in materials, such as in the inspection of weld beads. This technique primarily uses sources of iridium-192, cobalt-60, and selenium-75, whose activity can reach about twenty terabecquerels. A gamma radiography device is usually a mobile device which can be moved from one worksite to another. It consists primarily of:
- a source holder containing the radioactive source;
- a source applicator, which acts as a storage container and ensures radiological protection when the source is not in use;
- a guide tube and an end-piece for guiding movement of the source between the source applicator and the inspected object;
- and a remote control cable allowing remote manipulation by the operator.

Gamma radiography devices mainly use high-level sources and can present significant risks for the operators in the event of incorrect operation, failure to comply with radiation protection rules, or operating incidents. As such, it is an activity with high radiation protection implications that figures among ASN's inspection priorities.

UNDERSTAND

Selenium-75 gamma radiography

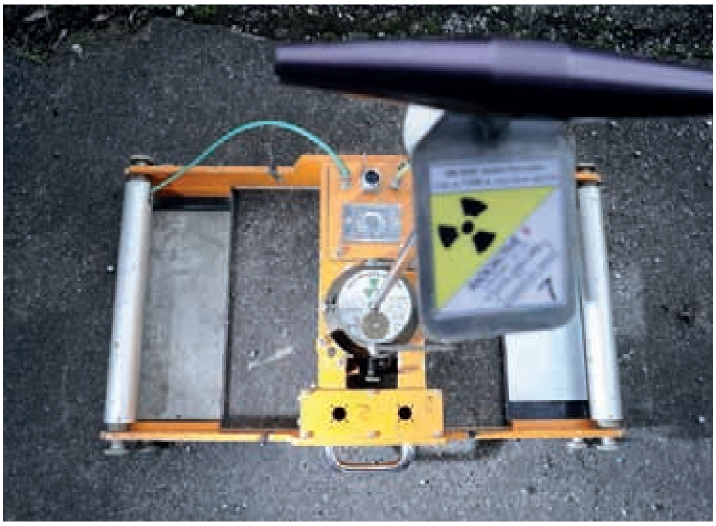
The use of selenium in gamma radiography has been authorised in France since 2006. Implemented in the same devices as those functioning with iridium-192, selenium-75 offers significant radiation protection advantages in gamma radiography. The equivalent dose rates are about 55 millisieverts (mSv) per hour and per TBq one metre from the source, as opposed to 130 for iridium-192. In France about 10% of gamma radiography devices are equipped with selenium-75, and although its utilisation has been increasing for a few years, ASN considers that it is still too little used in industry. Yet it can be used in place of iridium-192 in numerous industrial fields, especially the petrochemical industry, and allows a significant reduction in the safety perimeters required and facilitates intervention in the event of an incident (see point 5).

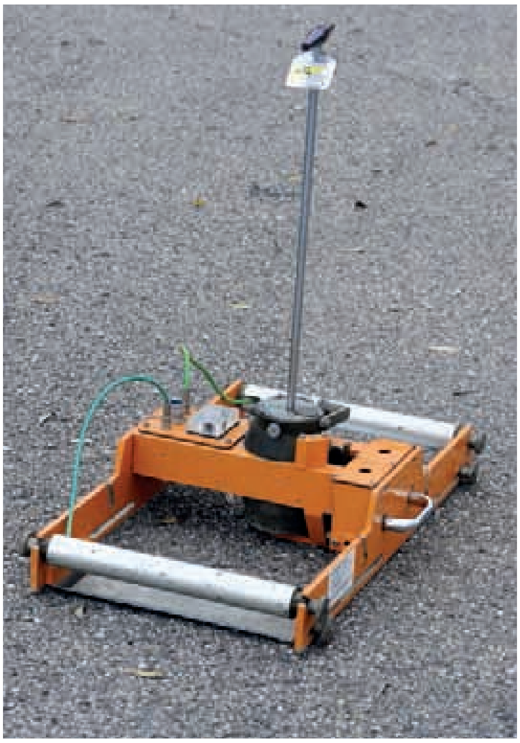
1.1.3 Verification of physical parameters

The operating principle of these physical parameter verification devices is the attenuation of the signal emitted: the difference between the emitted signal and the received signal can be used to assess the information looked for.

The radionuclides most frequently used are carbon-14, krypton-85, caesium-137, americium-241, cobalt-60 and promethium-147. The source activity levels are between a few kilobecquerels (kBq) and a few gigabecquerels (GBq).

These sources are used for the following purposes:
- atmospheric dust measurement; the air is permanently filtered through a tape running at a controlled speed, placed between source and detector. The intensity of radiation received by the detector depends on the amount of dust on the filter, which enables this amount to be determined. The most commonly used sources are carbon-14 (activity level: 3.5 MBq) or promethium-147 (activity level: 9 MBq). These measurements are particularly used for air quality monitoring by verifying the dust content of discharges from plants;
- paper weight (grammage) measurement: a beta radiation beam passes through the paper and is then received by a detector. The signal attenuation on this detector gives the paper density and thus the grammage. The sources used are generally krypton-85, promethium-147 and americium-241 with activity levels not exceeding 3 GBq;
- liquid level measurement: a gamma radiation beam passes through the container holding the liquid. It is received by a detector positioned opposite. The signal attenuation on this detector indicates the filling level of the container and automatically triggers certain operations (stop/continue filling, alarm, etc.). The radionuclides used depend on the characteristics of the container and the content. As applicable, americium-241 (activity level: 1.7 GBq), caesium-137 – barium-137m (activity level: 37 MBq) are generally used;





Mobile gamma ray densitometer.

- density measurement and weighing: the principle is the same as for the above two measurements. The sources used are generally americium 241 (activity level: 2 GBq), caesium-137, barium-137m (activity level: 100 MBq) or cobalt-60 (30 GBq);
- soil density and humidity measurement (gammadensimetry) in particular in agriculture and public works. These devices operate with a pair of americium-beryllium sources and a caesium-137 source;
- diagraphy (logging), which enables the geological properties of the subsoil to be examined by inserting a measurement probe comprising a source of cobalt-60, caesium-137, americium-241 or californium-252.

1.1.4 Neutron activation

Neutron activation consists in irradiating a sample with a flux of neutrons to activate the atoms in the sample. The number and the energy of the gamma photons emitted by the sample in response to the neutrons received are analysed. The information collected enables the concentration of atoms in the analysed material to be determined.

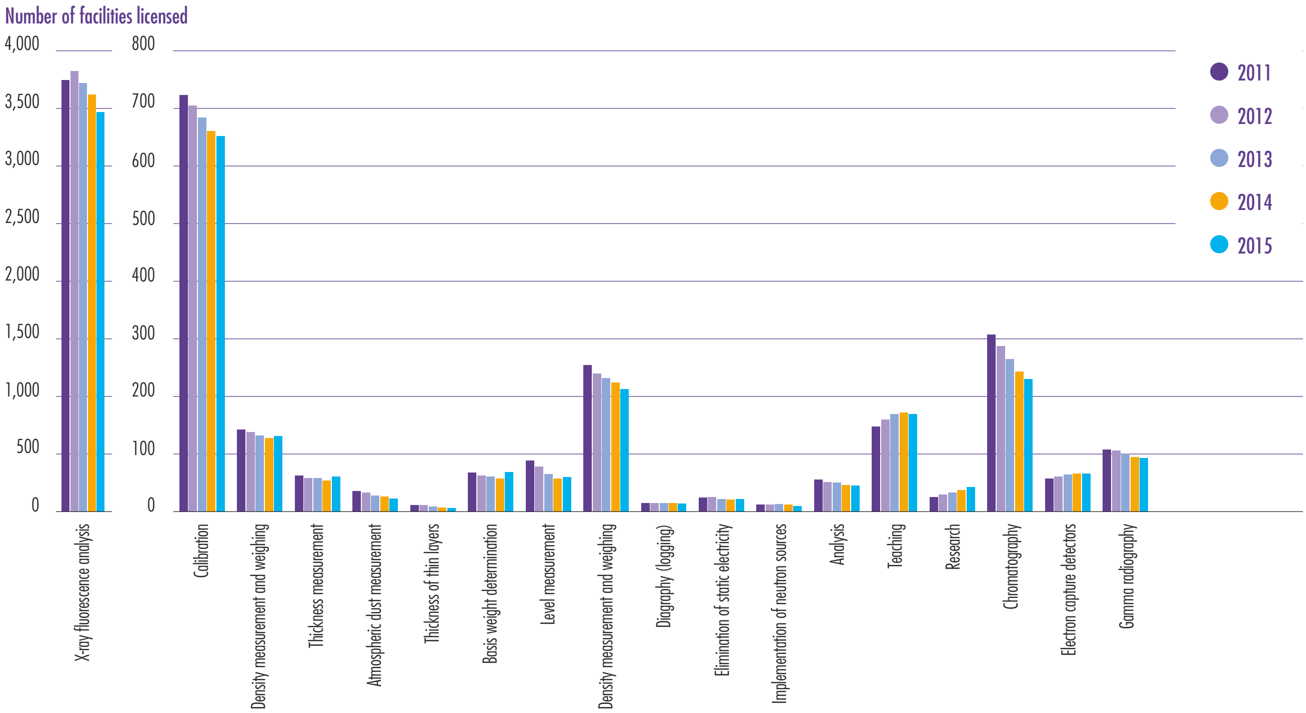
This technology is used in archaeology to characterize ancient objects, in geochemistry for mining prospecting and in industry (study of the composition of semiconductors, analysis of raw mixes in cement works).

Given the activation of the material analysed, this requires particular vigilance with regard to the nature of the objects analysed. Article R. 1333.3-of the Public Health Code in fact prohibits the use of materials and waste originating from a nuclear activity for the manufacture of consumer goods and construction products, if they are or could be contaminated by radionuclides, including by activation (see point 4.3).

1.1.5 Other common applications

Sealed sources can also be used for:
- eliminating static electricity;
- calibrating radioactivity measurement devices (radiation metrology);
- practical teaching work concerning radioactivity phenomena;
- detection by electron capture. This technique uses sources of nickel-63 in gaseous phase chromatographs and can be used to detect and dose various chemical elements;
- ion mobility spectrometry used in devices that are often portable and used to detect explosives, drugs or toxic products;
- detection using X-ray fluorescence. This technique is particularly useful in detecting lead in paint. The portable devices used today contain sources of cadmium-109 (half-life 464 days) or cobalt-57 (half-life of 270 days). The activity of these sources can range from 400 MBq to 1,500 MBq. This technique, which uses a large number of radioactive sources nationwide (nearly 4,000 sources), is the result of a legislative system designed to prevent lead poisoning in children by requiring a check on the lead concentration in paints used in residential buildings constructed before 1st January 1949, on the occasion of any sale, any new rental contract or in the case of work significantly affecting the coatings in the common parts of the building.

GRAPH 1: Use of sealed radioactive sources



Graph 1 specifies the number of facilities authorized to use sealed radioactive sources for the applications identified. It illustrates the diversity of these applications and their development over the last five years (from 2011 to 2015).

It should be noted that a given facility may carry out several activities, and if it does, it appears in graph 1 and the following diagrams for each activity.

1.2 Unsealed radioactive sources

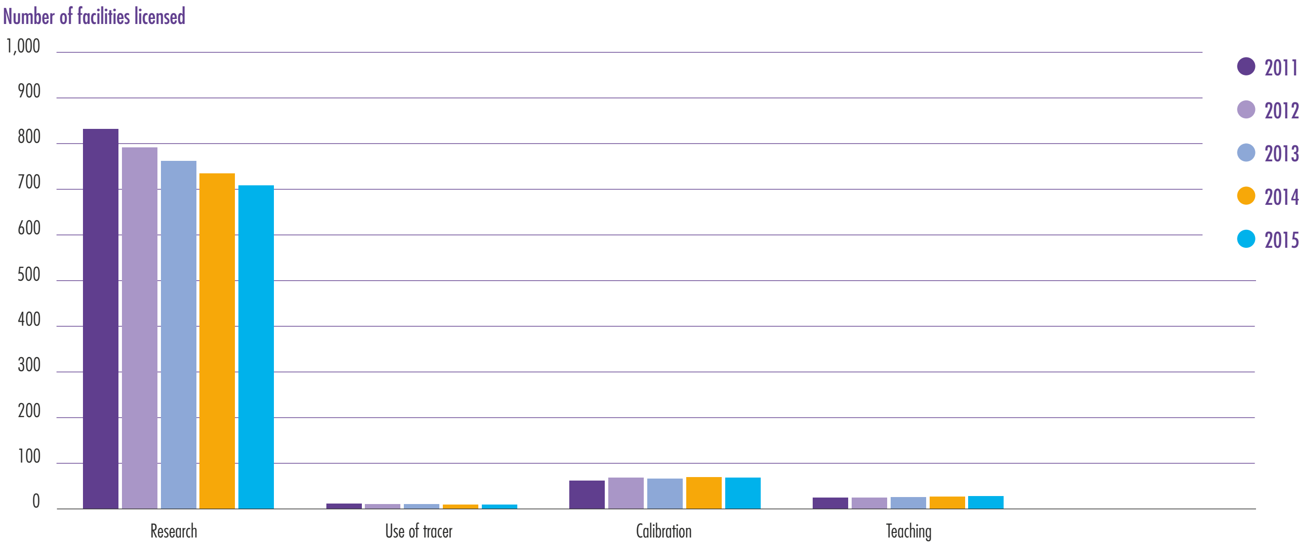
The main radionuclides used in the form of unsealed sources in non-medical applications are phosphorus-32 or 33, carbon-14, sulphur-35, chromium-51, iodine-125 and tritium. They are in particular used in the research sector and in pharmaceutical establishments. They are a powerful investigative tool in cellular and molecular biology. Using radioactive tracers incorporated into molecules is common practice in biological research. There are also several industrial uses, for example as tracers or for calibration or teaching purposes. Unsealed sources are used as tracers for measuring wear, searching for leaks or friction spots, for building hydrodynamic models and in hydrology.

As at 31st December 2015, the number of facilities authorised to use unsealed sources stood at 813.

Graph 2 specifies the number of facilities authorized to use unsealed radioactive sources in the applications identified in the last five years (from 2011 to 2015).

ASN inspection at the University of Bourgogne (unsealed sources), November 2015.

GRAPH 2: Use of unsealed radioactive sources



2. INDUSTRIAL, RESEARCH AND VETERINARY USES OF ELECTRICAL DEVICES EMITTING IONISING RADIATION

In industry, electrical devices emitting ionising radiation are used mainly in non-destructive testing, where they replace devices containing radioactive sources. They are also used in veterinary diagnostic applications. Graphs 3, 4 and 6 specify the number of facilities authorised to use electrical devices generating ionising radiation in the listed applications. They illustrate the diversity of these applications which have evolved over the last five years (from 2011 to 2015). This evolution is closely related to the regulatory changes introduced in 2002 and later in 2007, which created a new licensing or notification regime for use of these devices. At present, the situation of the professionals concerned is being brought into compliance in many activity sectors.

2.1 Industrial applications

The electrical devices emitting ionising radiation are chiefly X-ray generators. They are used in industry for non-destructive structural analyses (analysis techniques such as tomography, diffractometry, also called X-ray crystallography, etc.), for checking the quality of weld beads or inspecting materials for fatigue (in aeronautics in particular).

The applications of these devices, which work using the principle of X-ray attenuation, include use as industrial gauges (measurement of drum filling, thickness measurement, etc.), inspection of goods containers or luggage and also the detection of foreign bodies in foodstuffs.

The increasing number of types of device available on the market can be explained more particularly by the fact that when possible, they replace devices containing radioactive sources. The advantages of this technology with regard to radiation protection are linked in particular to the total absence of ionising radiation when the equipment is not in use. Their utilisation does however lead to worker exposure levels that are comparable with those resulting from the use of devices containing radioactive sources.

Radiography for checking the quality of weld beads or for the fatigue inspection of materials

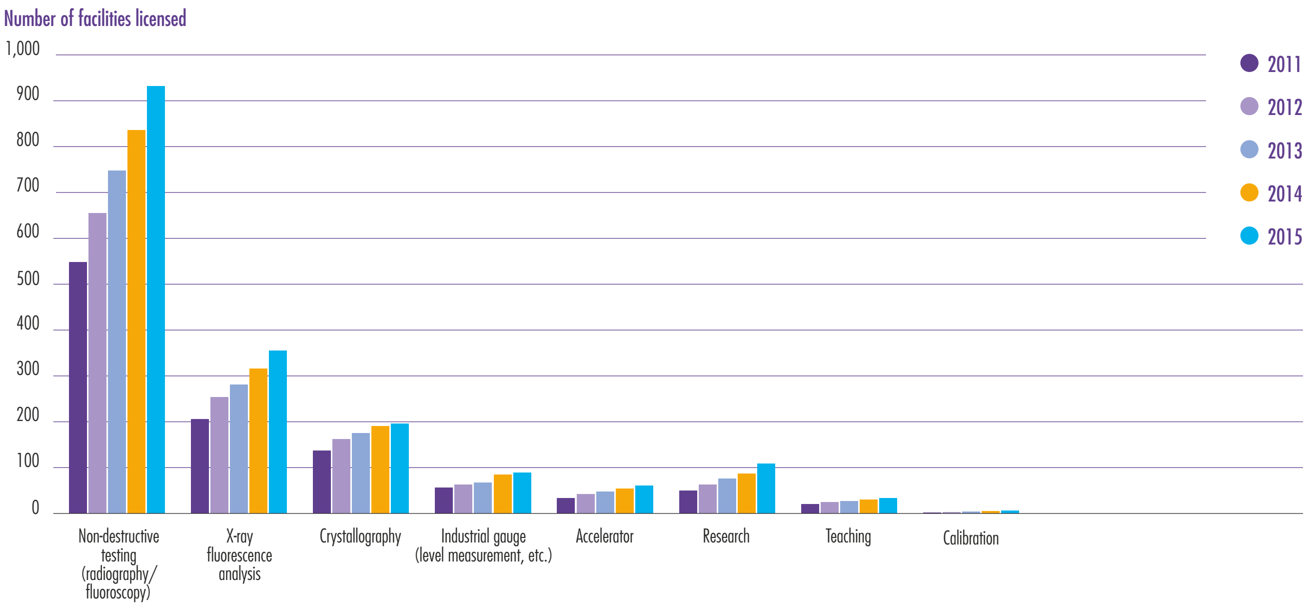
These are fixed devices or worksite devices using directional or panoramic beams which replace gamma radiography devices (see point 1.1.2) if the utilisation conditions so permit.

These devices can also be put to more specific uses, such as radiography for restoration of musical instruments or paintings, archaeological study of mummies or analysis of fossils.

Baggage inspection

Ionising radiation is used constantly in security screening checks, whether for the systematic verification of baggage or to determine the content of suspect packages. The smallest and most widely used devices are installed at the inspection and screening checkpoints in airports, in museums, at the entrance to certain buildings, etc.

GRAPH 3: Use of electrical devices generating ionising radiation (outside the veterinary sector – see point 2.2)



Natural gas pipeline construction site. Marking out for radiographic exposure.

The devices with the largest inspection tunnel cross-section are used in airports for screening air freight, large baggage items and hold baggage in airports. This range of devices is supplemented by tomographs, which give a series of cross-sectional images of the object being examined.

The irradiation zone inside these appliances is sometime delimited by doors, but most often simply by one or more lead curtains.

X-ray body scanners

This particular application is given for information only, since the use of X-ray scanners on people during security checks is prohibited in France (in application of Article L. 1333-11 of the Public Health Code). The experiments carried out in France are based on non-ionising imaging technologies (millimetre wave scanners).

Inspection of consumer goods

The use of devices for detecting foreign bodies in certain consumer products has developed over the last few years, such as for detecting unwanted items in food products or cosmetics.

X-ray diffraction analysis

Research laboratories are making increasing use of small devices of this type, which are self-shielded. Experimental devices used for X-ray diffraction analysis can however be built by experimenters themselves with parts obtained from various suppliers (goniometer, sample holder, tube, detector, high-voltage generator, control console, etc.).

X-ray fluorescence analysis

Portable X-ray fluorescence devices are intended for the analysis of metals and alloys.

Measuring parameters

These appliances, which operate on the principle of X-ray attenuation, are used as industrial gauges for measuring fluid levels in cylinders or drums, for detecting leaks, for measuring thicknesses or density, etc.

Irradiation treatment

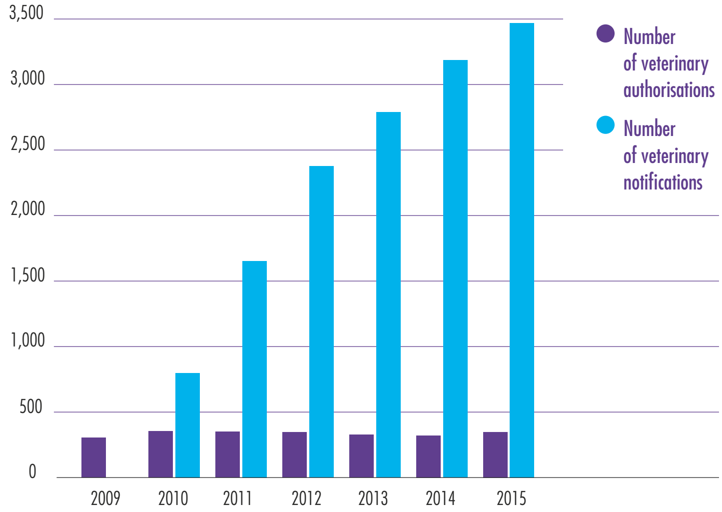
More generally used for performing irradiations, the self-shielded appliances exist in several models that sometimes differ only in the size of the self-shielded chamber, while the characteristics of the X-ray generator remain the same.

2.2 Veterinary diagnostic radiology

The profession counts approximately 16,000 veterinary surgeons and 14,000 non-veterinarian employees. Veterinary surgeons use diagnostic radiology devices in a context similar to that of the devices used in human medicine. Veterinary diagnostic radiology activities essentially concern pets:
- 90% of the 5,793 veterinary structures in France have at least one diagnostic radiology device;
- about thirty computed tomography scanners are used in veterinary applications to date;
- other practices drawn from the medical sector are also implemented in specialised centres: scintigraphy, brachytherapy and external-beam radiotherapy.

The treatment of large animals (mainly horses) requires the use of more powerful devices installed in specially equipped premises (radiography of the pelvis, for example) and of portable X-ray generators, used either indoors – dedicated or other premises – or outside in the open air. This activity has significant radiation protection implications for veterinary surgeons and grooms.

GRAPH 4: Use of electrical devices generating ionising radiation for veterinary activities



The devices used in the veterinary sector are sometimes derived from the medical sector. However, the profession is increasingly adopting new devices specially developed to meet its own specific needs.

2.3 Particle accelerators

The Public Health Code defines an accelerator as a device or installation in which electrically charged particles undergo acceleration, emitting ionising radiation at an energy level in excess of 1 megaelectronvolt (MeV).

When they meet the characteristics specified in Article 3 of Decree 2007-830 of 11th May 2007 concerning the list of BNIs, these facilities are listed as BNIs.

Certain applications require the use of particle accelerators which produce photon or electron beams, as applicable. The inventory of particle accelerators in France, whether linear (linacs) or circular (cyclotrons – see point 3 – and synchrotrons), comprises about 60 identified installations (excluding BNIs) which can be used in a wide variety of fields:
- research, which sometimes requires the coupling of several machines (accelerator, implanter, etc.);
- radiography (fixed or mobile accelerator);
- radioscopy of lorries and containers during customs checks (fixed-site or mobile accelerators);
- modification of material properties;
- sterilisation;
- conservation of foodstuffs;
- etc.

In the field of research, two synchrotron radiation production facilities can be mentioned in France: the ESRF (European Synchrotron Radiation Facility) in Grenoble, and the Soleil (Optimised source of energy light) synchrotron in Gif-sur-Yvette.

Recently, particle accelerator imaging systems have been used in France to combat fraud and large-scale international trafficking. This technology, which is felt by the operators to be effective, must however be used under certain conditions in order to comply with the radiation protection rules applicable to workers and the public, in particular:
- a ban on activation of construction products, consumer goods and foodstuffs as specified by Article R. 1333-2 of the Public Health Code, by ensuring that the maximum energy of the particles emitted by the accelerators used rules out any risk of activation of the materials being verified;
- a ban on the use of ionising radiation on the human body for purposes other than medical. Thus, the use of ionising technologies to seek out illegal immigrants in transport vehicles is prohibited in France;
- the setting up of procedures to ensure that the checks conducted on the goods or transport vehicles do not lead to accidental exposure of workers or other individuals. During customs inspections of trucks using tomographic techniques, for example, the drivers must be kept away from the vehicle and other checks must be performed prior to irradiation to detect the presence of any illegal immigrants, in order to avoid unjustified exposure of persons during the inspection.

2.4 Other electrical devices emitting ionising radiation

This category covers all the electrical devices emitting ionising radiation other than those mentioned above and not excluded by the license and notification exemption criteria set out in Article R. 1333-18 of the Public Health Code.

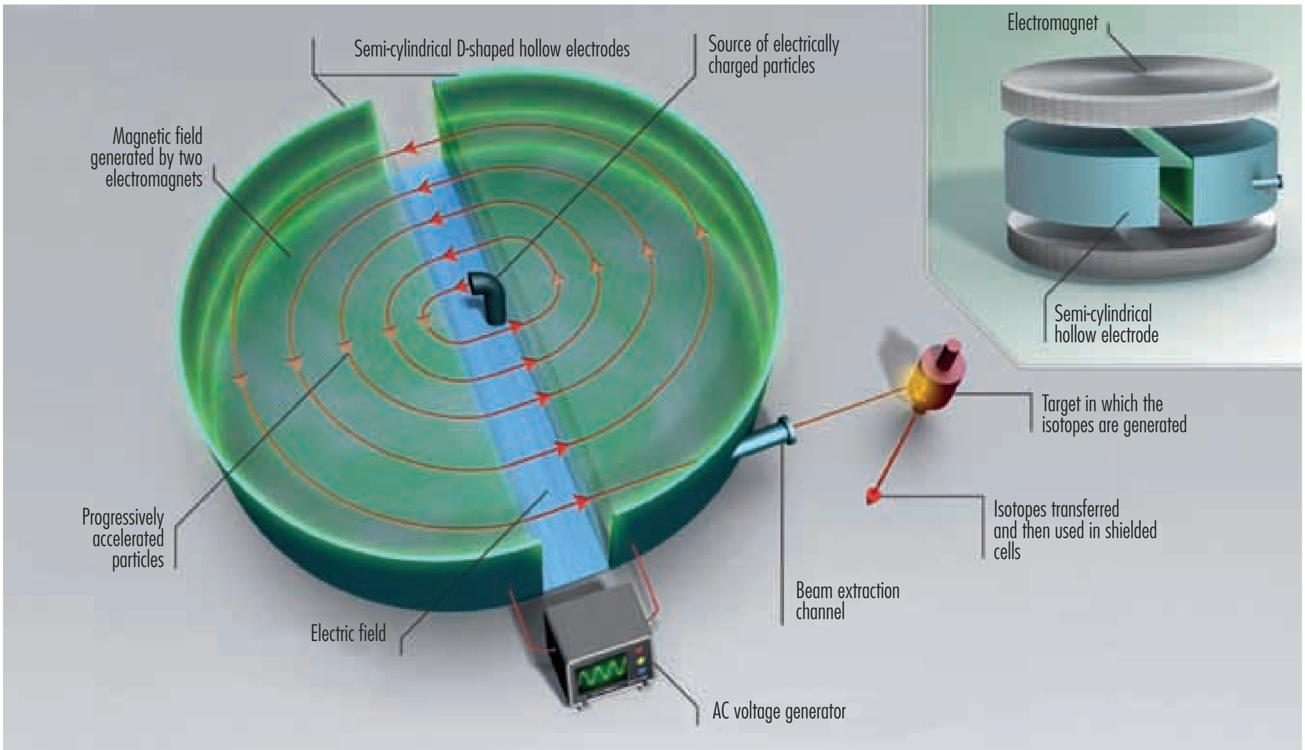
This category notably includes devices generating ionising radiation but not used for this property, such as ion implanters, electron-beam welding equipment, klystrons, certain lasers, certain electrical devices such as high-voltage fuse tests.

UNDERSTAND

Synchrotrons

The synchrotron is a member of the same circular particle accelerator family as the cyclotron (see point 3), but is far larger, enabling energies of several gigaelectronvolts (GeV) to be achieved by means of successive accelerators.
Owing to the low mass of the particles (generally electrons), the acceleration created by the curvature of their trajectory in a storage ring produces an electromagnetic wave when the speeds achieved become relativistic: this is synchrotron radiation. This radiation is collected at various locations called beam lines and is used to conduct scientific experiments.

SIMPLIFIED DIAGRAM of the operation of a cyclotron

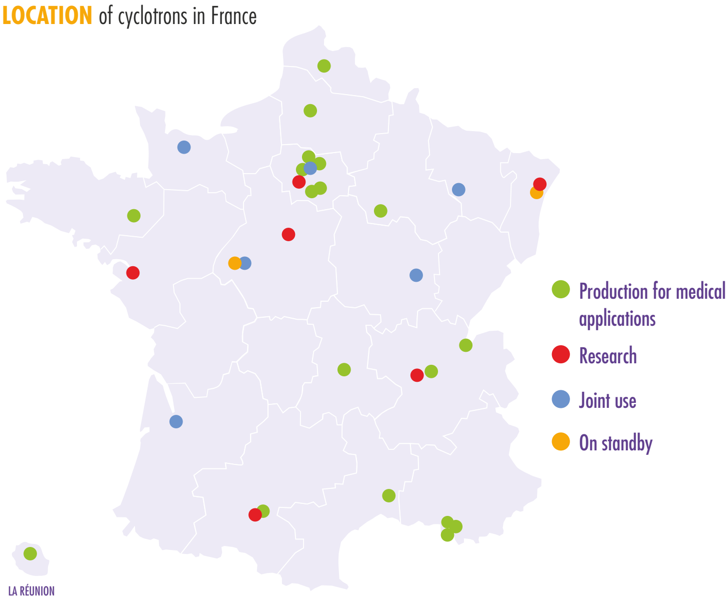


3. MANUFACTURERS AND DISTRIBUTORS OF RADIOACTIVE SOURCES

ASN oversight of the suppliers of radionuclide sources or devices containing them is crucial to ensuring the radiation protection of the future users. It is based on the one hand on the technical examination of the appliances and sources with respect to operating safety and radiation protection conditions during future utilisation and maintenance. It also allows the tracking of source movements and the recovery and disposal of disused or end-of-life sources. Source suppliers also play a teaching role with respect to users.

At present, only the suppliers of sealed radioactive sources or devices containing them, and of unsealed radioactive sources, are regulated in France (see point 4.4). There are about 150 suppliers listed, and among them, 32 low and medium-energy cyclotrons are currently licensed under the Public Health Code in France. As at 31st December 2015, 30 cyclotrons are in operation. Among these, 16 are used exclusively for the daily production of radiopharmaceuticals, 6 are used for research purposes and 8 are used exclusively for joint production and research purposes.

LOCATION of cyclotrons in France



UNDERSTAND

Cyclotrons

A cyclotron is a device 1.5 to 4 metres in diameter, belonging to the circular particle accelerator family. The accelerated particles are mainly protons, with energy levels of up to 70 MeV. A cyclotron consists of two circular electromagnets producing a magnetic field and between which there is an electric field, allowing the rotation of the particles and their acceleration at each revolution. The accelerated particles strike a target which is activated and produces radionuclides.

Low and medium energy cyclotrons are primarily used in research and in the pharmaceutical industry to produce positron emitting isotopes, such as fluorine-18 (^{18}F) or carbon-11. The radionuclides are then combined with molecules of varying complexity to form radiopharmaceuticals used in medical imaging. The best known of them is ^{18}F-FDG (fluorodeoxyglucose marked by fluorine-18), which is an industrially manufactured injectable drug, commonly used for early diagnosis of certain cancers.

Other radiopharmaceuticals manufactured from ^{18}F have also been developed in recent years, such as ^{18}F-Choline, ^{18}F-Na, ^{18}F-DOPA, as well as radiopharmaceuticals for exploring the brain. To a lesser extent, the other positron emitters that can be manufactured with a cyclotron of an equivalent energy range to that necessary for the production of ^{18}F and ^{11}C areoxygen-15 (^{15}O) and nitrogen-13 (^{13}N). Their utilisation is however still limited due to their very short half-life.

The levels of activities involved for the ^{18}F usually found in pharmaceutical facilities vary from 30 to 500 GBq per production bombardment. The positron emitting radionuclides produced for research purposes involve activities that are usually limited to a few tens of GBq.

4. REGULATION OF INDUSTRIAL, RESEARCH AND VETERINARY ACTIVITIES

The provisions of the Public Health Code relating specifically to the industrial and research applications provided for in the Public Health Code are specified in this section. The general rules are detailed in chapter 3 of this report.

4.1 The Authorities regulating the sources of ionising radiation

ASN is the Authority that grants the licenses and receives the notifications, in accordance with the system applicable to the nuclear activity concerned.

However, to simplify administrative procedures for licensees already licensed under another system, the Public Health Code makes specific provisions and the notification or licensing obligation does not apply. This concerns more specifically:

- The radioactive sources held, manufactured and/or used in installations licensed under the Mining Code (Article 83) or the unsealed radioactive sources held, manufactured and/or used in Installations Classified on Environmental Protection Grounds (ICPE) which come under Articles L. 511-1 to L. 517-2 of the Environment Code, and have a licensing system. In this case the Prefect is responsible for including prescriptions relative to radiation protection for the nuclear activities exercised on the site in the delivered licences.
- The installations and activities relating to national defence; ASND (Defence Nuclear Safety Authority) is responsible for regulating the radiation protection aspects.
- The installations authorised under the BNI system. ASN regulates the radioactive sources and electrical devices emitting ionising radiation necessary for the operation of these installations as defined by this system. Holding and using other sources within the perimeter of the BNI remain subject to licensing pursuant to Article R. 1333-17 of the Public Health Code.

These provisions do not exempt the beneficiary from compliance with the prescriptions of the Public Health Code and particularly those relative to source acquisition and transfer; they do not apply to the distribution, importing and exporting of radioactive sources, which remain subject to licensing by ASN under the Public Health Code.

Since the publication of Decree 2014-996 of 2nd September 2014 amending the nomenclature of the ICPEs, some facilities previously licensed by Prefectural order under the Environment Code for the possession and use of radioactive substances are now regulated by ASN under the Public Health Code.

The following are now subject to the Public Health Code system:
- establishments holding or using sealed radioactive sources subject to notification or licensing on account of section 1715 of the ICPE nomenclature;
- establishments holding unsealed radionuclides in quantities of less than 10 m^3 previously subject to notification or licensing under section 1715 of the ICPE nomenclature.

The prescriptions applicable to these installations are now those of the Public Health Code and the Labour Code. However, Article 4 of the abovementioned Decree provides that the license or notification delivered under section 1715 shall continue to be valid as a license or notification under the Public Health Code until a new license is obtained under the Public Health Code or, failing this, for a maximum period of five years, that is to say until 4th September 2019 at the latest. Any change relating to the license shall either be notified to ASN or form the subject of a new license application, depending on the case.

Only the establishments holding unsealed radioactive substances in quantities exceeding 10 m^3 are henceforth subject to the system for classified installations (excluding the medical sector and particle accelerators). Any sealed radioactive sources also possessed or used by these establishments are regulated by ASN under the Public Health Code.

Nuclear materials are subject to specific regulations provided for in Article L. 1333-2 of the Defence Code. Application of these regulations is overseen by the Minister of Defence with regard to nuclear materials intended for defence needs, and by the Minister in charge of Energy with regard to nuclear materials intended for any other use.

4.2 Licensing and notification of ionising radiation sources used for non-medical purposes

4.2.1 Integration of the principles of radiation protection in the regulation of non-medical activities

ASN verifies application of the three major principles governing radiation protection and which are written into the Public Health Code (Article L. 1333-1), namely justification, optimisation of exposure and dose limitation (see chapter 2).

Assessment of the expected benefit of a nuclear activity and the corresponding health drawbacks may lead to prohibition of an activity for which the benefit does not seem to outweigh the risk. Either a generic prohibition is declared, or the license required on account of radiation protection is not issued or is not extended. For existing activities, justification is reassessed when license renewal applications are made if the current state of knowledge and technology warrants it.

Optimisation is a notion that must be considered in the technical and economic context, and it requires a high level of involvement on the part of the professionals. ASN considers in particular that the suppliers of devices are at the core of the optimisation approach (see point 3). They are responsible for putting the devices on the market and must therefore design them such that the exposure of the future users is minimised. ASN also checks application of the principle of optimisation when examining the license application files, when conducting its inspections, and when analysing the various significant events notified to it.

4.2.2 Applicable licensing and notification systems

Applications relating to the holding and use of ionising radiation sources are reviewed by the regional divisions of ASN. License applications for the manufacture and distribution of sources or devices containing sources are examined at a central, national level.

The licensing system

As part of a simplification process with a graded approach based on the radiological risks and implications, ASN has produced and deployed licensing application forms adapted to each activity which are available on *www.asn.fr*. Several forms were revised in 2015 to incorporate changes in regulations and experience feedback.

To better integrate the true situation of responsibilities in the non-medical sectors, where the radioactive sources and devices are often managed more by an entity than by an individual, these new forms allow representatives of artificial persons to apply for a license, pursuant to Article R. 1333-24 of the Public Health Code. They also list the documents that must be enclosed with the application. All the other documents listed in the appendix to ASN resolution 2010-DC-0192 of 22nd July 2010 must of course be held by the applicant and kept at the disposal of the inspectors in the event of verification. It is moreover possible that ASN will request further information during its examination of the license application.

Small-scale nuclear activities stand out by their considerable diversity and the large number of licensees involved. ASN must therefore adapt its efforts to their radiation protection implications to ensure effective oversight of these activities. In this perspective, it is continuing to implement its graded approach which consists in adapting the regulatory constraints and the level of oversight to the risks that the nuclear activity presents. Furthermore, as part of the transposition of Directive 2013/59/Euratom of 5th December 2013, ASN has started an overall revision of the regulatory provisions (see chapter 3).

The notification system

To achieve a balance in the sectors of activity subject to notification or licensing, and therefore better adapt the regulatory requirements to the radiation protection implications, ASN introduced a notification system for the industrial, research and veterinary sectors in 2009. This led to the publication of several approved resolutions (see chapter 3) defining on the one hand the scope of application of this system and on the other, its implementation procedures.

The following are concerned:
- veterinary diagnostic radiology devices (fixed only) meeting one of the following conditions:
  - the emission beam is directional and vertical, except for all tomography devices;
  - the device is used for intra-oral radiography (ASN resolution 2009-DC-0146 of 16th July 2009, amended by resolution 2009-DC-0162 of 20th October 2009, *Official Journal* of 26th February 2010).
- electrical devices emitting ionising radiation, for which the equivalent dose rate 10 cm from all accessible surfaces in normal conditions of use and as a result of their design, is less than 10 microsieverts per hour (µSv/h).

Through ASN resolution 2015-DC-0531 of 10th November 2015, ASN widened the scope of activities subject to notification to all users and holders of these devices in order to integrate unambiguously into the notification system all the activities using devices in these categories, that is to say putting into service, inspection, maintenance, training, etc., insofar as these uses do not lead to modifications in safety systems or radiological protection shielding.

The notification form drawn up by ASN to facilitate application of amended resolution 2009-DC-0148 of 16th July 2009 defining the detailed content of the information to be appended to the notifications has been designed so as to simplify its utilisation and processing. No document has to be added to the notification form if the devices declared meet the requirements specified in ASN's resolutions and are eligible for this system. ASN reviewed this form in 2015 to incorporate the latest regulatory changes and is continuing an ongoing on-line notification project to further simplify the procedures.

In a completely different field, the notification system was extended in 2012 to include companies installing, maintaining or removing Ionisation Chamber Smoke Detectors (ICSD) (see point 4.3). Following the publication on 15th March 2012 of ASN resolution 2011-DC-0252 of 21st December 2011, a notification form was produced and placed on-line on *www.asn.fr*.

4.2.3 Statistics for 2015

Suppliers

In the light of the fundamental role played in the radiation protection of future users by the suppliers of sources or devices containing them (see points 3 and 4.2.1), ASN exercises particularly strict control in this field. During the course of 2015, 94 license or license renewal applications were examined by ASN, and 53 inspections were carried out.

Users

Case of radioactive sources

In 2015, ASN reviewed and notified 218 new licenses, 1,017 license renewals or updates and 396 license cancellations. Graph 5 presents the licenses issued or cancelled in 2015 and trends in this area for the last five years.

Once the license is obtained, the licensee can procure sources. To do this, it collects supply request forms from IRSN, enabling the institute to verify – as part of its duty to keep the inventory of ionising radiation sources up to date – that the orders are in conformity with the licenses of both the user and the supplier. If the order is correct, the movement is then recorded by IRSN, which notifies the interested parties that delivery can take place. If there is any difficulty, the movement is not validated and IRSN refers the case to ASN (see box below).

TO BE NOTED

Procedures for recording and tracking radioactive sources

Articles R. 1333-47 to 49 of the Public Health Code provide for prior recording by IRSN (French Institute of Radiation Protection and Nuclear Safety) of movements of radioactive sources and Article R. 1333-50 for tracking these sources.

ASN resolution 2015-DC-0521 of 8th September 2015 relative to the tracking and methods of recording radioactive sources and products or devices containing them has defined a clear regulatory framework governing the methods of recording and the rules for tracking movements of radioactive sources.

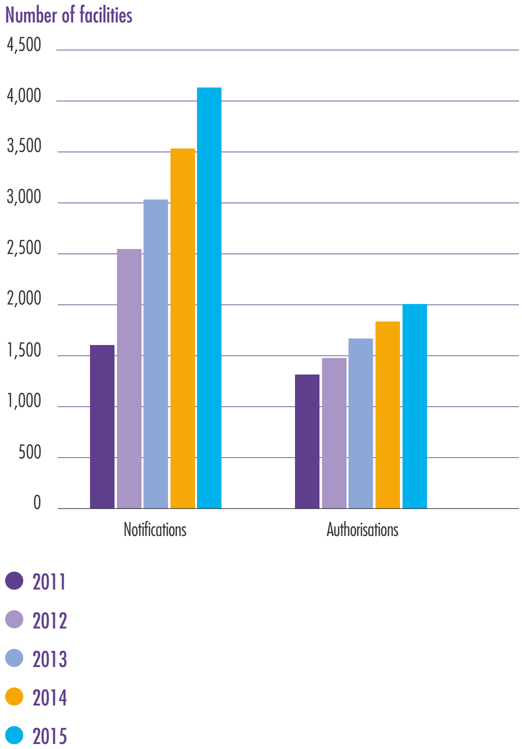
This resolution, applicable as of 1st January 2016, takes into account the existing mode of functioning and supplements it as follows by:
- graded source inspections according to how dangerous the sources are;
- confirming the absence of recording for sources whose activity is below the exemption thresholds;
- imposing deadlines between the recording of source movements and the actual movement;
- making it an obligation for each source to be accompanied by a "source certificate" indicating all its characteristics and which must be transmitted to IRSN within two months after receiving the source.

Case of electrical generators of ionising radiation

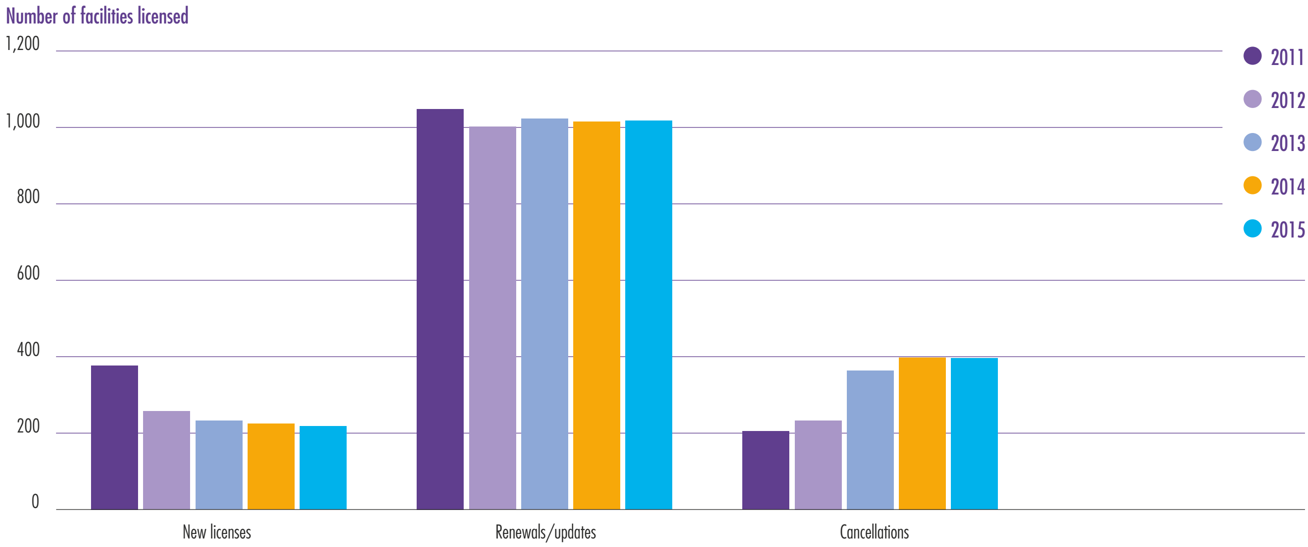
ASN has been responsible for regulating these devices since 2002, and is gradually building up its capacity in this area where numerous administrative situations need to be regularised. It granted 193 licenses and 256 license renewals for the use of X-ray generators in 2015. Given the new regulatory provisions allowing the implementation of a notification system in place of the licensing system since 2010, ASN also delivered 601 notification certificates in 2015.

A total of 2,007 licenses and 4,131 notification certificates have been delivered for electrical devices emitting ionising radiation since Decree 2002-460 was issued. Graph 6 illustrates this trend over the past five years.

GRAPH 6: Total number of "user" license and notifications for devices generating ionising radiation



GRAPH 5: Radioactive source "user" licenses delivered each year



4.3 Unjustified or prohibited activities

4.3.1 Application of the ban on the intentional addition of radionuclides in consumer goods and construction products

The Public Health Code indicates *"that the intentional addition of radionuclides to consumer goods and construction products is prohibited"* (Articles R. 1333-2 and 3).

The trading of radioactive stones or decorative objects, accessories containing sources of tritium such as watches, key-rings, hunting equipment (sighting devices), navigation equipment (bearing compasses) or equipment for river fishing (strike detectors) is specifically prohibited.

Article R. 1333-4 of this same Code states that waivers to these prohibitions can, if the advantages they bring outweigh the health risks they can represent, be granted by order of the Minister responsible for Health and, depending on the case, by the Minister responsible for Consumption or the Minister responsible for Construction, after consulting ASN and HCSP (French High Public Health Council). No waiver is possible for foodstuffs, toys, jewellery and cosmetic products.

ASN considers that this system of waivers to the regulations must remain very limited. It was implemented for the first time in 2011 for a waiver request concerning the use of a neutron analysis device in several cement works (Order of 18th November 2011 from the Ministers responsible for Health and Construction, ASN opinion 2011-AV-0105 of 11th January 2011 and ASN opinion 2011-AV-0124 of 7th July 2011). It was then used in 2014 for light bulbs containing very small quantities of radioactive substances (krypton-85, thorium-232 or tritium), serving mainly for applications requiring very high intensity lighting such as public places, professional environments, or for certain vehicles (Order of 12th December 2014 of the Ministers responsible for Health and Construction, ASN opinion 2014-AV-0211 of 18th September 2014).

A waiver request to allow the addition of radionuclides (tritium) in certain watches was also refused (Order of 12th December 2014, ASN opinion 2014-AV-0210 of 18th September 2014).

The list of consumer goods and construction products concerned by an ongoing waiver request or for which a waiver has been granted is published on the website of the French High Committee for Transparency and Information on Nuclear Security (HCTISN).

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4.3.2 Application of the justification principle for existing activities

The justification of existing activities must be re-assessed periodically in the light of current knowledge and technological changes in accordance with the principle described in point 4.2.1. If the activities are no longer justified by the benefits they bring, or with respect to other non-ionising technologies that bring comparable benefits, they must be withdrawn from the market. A transitional period for definitive withdrawal from the market may be necessary, depending on the technical and economic context, particularly when a technological substitution is necessary.

Smoke detectors containing radioactive sources

Devices containing radioactive sources have been used for several decades to detect smoke in buildings, as part of firefighting policy. Several types of radionuclides have been used (americium-241, plutonium-238, nickel-63, krypton-85). The activity of the most recent sources used does not exceed 37 kBq, and the structure of the detector, in normal use, prevents any propagation of radioactive substances into the environment.

New non-ionising technologies have gradually come to compete with these devices. Optical devices now provide comparable detection quality, and can therefore satisfy the regulatory and normative fire detection requirements. ASN therefore considers that smoke detection devices using radioactive sources are no longer justified and that the seven million ionic smoke detectors installed on 300,000 sites must be progressively replaced.

The regulatory framework governing their removal was put in place by the Order of 18th November 2011 and two ASN resolutions of 21st December 2011.

This regulatory framework aims at:
- planning the removal operations over ten years;
- supervising the maintenance or removal operations that necessitate certain precautions with regard to worker radiation protection;
- preventing any uncontrolled removals and organising the collection operations in order to avoid detectors being directed to an inappropriate disposal route, or even simply being abandoned;
- monitoring the pool of detectors.

Four years after the implementation of the new regulatory system for ionic smoke detector removal and maintenance activities, as at 31st December 2015 ASN has delivered 263 notification certificates and 7 national licenses (delivered to industrial groups with a total of 104 agencies) for ICSD removal and fire safety system maintenance activities.

With regard to the tracking of the pool of ionisation chamber smoke detectors, in 2015 IRSN put in place, in collaboration with ASN, a computerised system enabling the professionals working on a facility (maintenance technicians, installers or removers) to file annual activity reports electronically. IRSN, which is tasked with centralising and processing the reports, considers that the information available to date does not permit a significant assessment of the state of the pool. Reminders are currently being issued to raise the awareness of those involved and enable a first assessment to be drawn up rapidly.

ASN maintains close relations with Qualdion, an association created in 2011 which certifies the companies that comply with the regulations relative to radiation protection and fire safety. The list of Qualdion-certified companies is available on the association's website page: *www.lne.fr/fr/certification/certification-label-qualdion.asp.* ASN participates with the association in communication campaigns targeting the holders of ionic detectors and professionals (Expoprotection trade fair, Mayors' trade fair, etc.).

Surge suppressors

Surge suppressors (sometimes called lightning arresters), not to be confused with lightning conductors, are small objects with a very low level of radioactivity used to protect telephone lines against voltage surges in the event of lightning strike. These are sealed devices, often made of glass or ceramic, enclosing a small volume of air containing radionuclides to pre-ionise the air and facilitate sparkover. The use of surge suppressors has been gradually abandoned since the end of the 1970s, but the number remaining to be removed, collected and disposed of is still very high (several million units). When installed, these devices represent no risk of exposure for individuals. There can be a very low risk of exposure and/or contamination if these objects are handled without the necessary precautions or if they are damaged. ASN issued a reminder of this to Orange (formerly *France Télécom)*, which has begun an experimental process of inventorying, removing, sorting and disposing of surge suppressors in the Auvergne region and has proposed a national removal and disposal plan. This plan was presented to ASN and led in September 2015 to the delivery of a license governing the removal of all surge suppressors containing radionuclides present on the Orange network in France and their storage on identified sites. The search for a disposal route is in progress in collaboration with Andra, the French national agency for radioactive waste management. This removal plan will be implemented progressively over an eight-year time frame.

Lightning conductors

Radioactive lightning conductors were manufactured and installed in France between 1932 and 1986. The ban on the sale of radioactive lightning conductors was declared in 1987. This Order did not make the removal of installed radioactive lightning conductors compulsory. Consequently, there is no obligation to remove the radioactive lightning conductors installed in France at present, apart from in certain ICPEs (Order of 15th January 2008 setting the removal deadline at 1st January 2012) and certain installations under Ministry of Defence responsibility (Order of 1st October 2007 setting the removal deadline at 1st January 2014).

ASN nevertheless wants all radioactive lightning conductors to be removed given the risks they can represent, in particular depending mainly on their physical condition. For several years ASN has been informing professionals to ensure that these objects are removed in compliance with radiation protection requirements for workers and the public. ASN has stepped up its action in this respect by reminding the professionals concerned of their obligations, particularly that of having an ASN license for the activity of removing and storing the lightning conductors pursuant to Articles L. 1333-1, L. 1333-4, and R. 1333-17 of the Public Health Code. ASN has been carrying out field checks on the companies involved in the recovery of these objects. These actions were further increased in 2015 with unannounced inspections on removal worksites.

After several measurement campaigns by IRSN, and working with companies to assess the necessary means of protection when removing radioactive lightning conductors, ASN has coordinated the drafting of a guide for professionals. This guide, which is currently being finalised by ASN, Andra and IRSN, should be published in 2016.

Andra estimated that there were 40,000 radioactive lightning conductors installed in France. Nearly 10,000 have been removed and recovered by Andra. The current rate of removal is about 450 per year.

Additional information on radioactive lightning conductors is available on *www.andra.fr* and the website of the association Inaparad *www.paratonnerres-radioactifs.com*.

4.4 Reinforcement of the regulation of electrical devices generating ionising radiation

With regard to the design of facilities, ASN resolution 2013-DC-0349 of 4th June 2013 setting the minimum technical design rules for facilities in which X-rays are used has taken into account the revision of standard NF-C 15-160. This resolution concerns industrial and scientific (research) facilities such as industrial radiography using X-rays in a bunker, veterinary radiology and medical facilities such as conventional radiology, interventional radiology, dental radiology and scanners (see chapters 3 and 9). It came into effect on 1st January 2014 and replaced the Order of 30th August 1991 determining the required installation conditions for X-ray generators. Its application becomes mandatory for facilities put into service as of 1st January 2016, while facilities put into service prior to this and meeting the

November 1975 version of standard NF C 15-160 and its associated standards, are deemed to be in conformity with the resolution if they remain in conformity with these standards.

With regard to the design of devices, ASN wishes to supplement the provisions introduced into the Public Health Code in 2007, and thus complete the development of the regulatory framework allowing the distribution of electrical devices for generating ionising radiation to be subject to licensing in the same way as the suppliers of radioactive sources. Experience shows that in this respect, the joint technical examination of files by ASN and the device suppliers/manufacturers brings substantial gains in radiation protection optimisation (see points 3 and 4.2.1).

For electrical devices used for non-medical purposes, there is no equivalent of the mandatory CE marking for medical devices, such as to confirm conformity with several European standards covering various fields, including radiation protection. Furthermore, experience feedback shows that a large number of devices do not have a certificate of conformity to the standards applicable in France. These standards have been mandatory for many years now, but some of their requirements have become partly obsolete or inapplicable due to the lack of recent revisions.

ASN therefore established contacts with the LCIE (Electrical Certification and Testing Entity for Bureau Veritas), CEA and IRSN as of 2006 and started looking into the updating of the technical requirements applicable to the devices. After presenting the first orientations to the Advisory Committee for Radiation Protection, for Industrial Applications and Research into Ionising Radiation and the Environment (GPRADE) in June 2010, ASN continued its work with the support of IRSN and the assistance of other reference players such as CEA and the LCIE, with a view to developing a baseline technical standard for this type of device.

On the basis of this work, draft texts have been produced with the aim of defining minimum radiation protection requirements for the design of X-ray generators, and an informal technical consultation of the stakeholders (suppliers, French and foreign manufacturers and the principal users) conducted in 2015 is currently being analysed.

4.5 Detection of abnormal radioactivity in materials and goods in France

ASN considers that the increase in the number of cases of detection of abnormal radioactivity in metals and consumer goods across the world is worrying. It registers five events per year on average relating to the presence of radioactivity in shipments transported to or from France.

The products mainly involved are the following:
- contaminated finished products including consumer, equipment and production goods (kitchen utensils, handbags, sports equipment, valves, axles, machine tools, radiator grilles, steel bars, etc.);
- contaminated semi-finished products (ingots, scrap, etc.);
- sealed sources themselves.

In the majority of cases the radionuclide detected is artificial in origin. This concerns radionuclides initially manufactured and packaged in the form of sealed radioactive sources intended for use in industry or the medical sector. Owing to a lack of controls in the country of origin, these radioactive sources end up entering scrap recycling routes.

If not detected in time, they are melted down in metal ingot production plants, thus contaminating the raw material and all the semi-finished and finished products made with these raw materials worldwide.

In the other cases, the radionuclides are natural in origin. This phenomenon is new, widespread and expanding rapidly. It is due to the use of thorium-based ceramics (tourmaline) notably in the textile industry. In 2011, following a number of notifications, ASN contacted IRSN for an analysis of several marketed products. The conclusions of this study show that exposure of an individual to radiation from these textiles remains very slight, but can in certain cases be higher than the annual regulatory limit for the public (1 mSv). In such cases, ASN informs the industrial firms concerned if they have been identified and has additional analyses conducted if necessary. ASN maintains its vigilance over these products and conducted a further analysis campaign on new products in 2015.

At present, France does not have systematic means of detection at strategic points, particularly transport hubs: ports and airports. Some companies are equipped with detection systems installed either to comply with the regulations in force pursuant to the Environment Code (landfills, hospitals, waste disposal facilities, etc.), or for commercial reasons dictated by their partners (international trade with the United States).

Between 2001 and 2009, pushed by the United States, 27 countries including Greece, the Netherlands, the United Kingdom, Belgium, Spain and Portugal acquired at least one detection facility. There is currently no European or international protocol for the detection of radioactivity in goods at borders.

At present the only information at the disposal of France is that received from its neighbouring countries. Belgium thus informs ASN whenever its portals are triggered by shipments coming from or intended for France. In such cases, additional investigations are carried out to identify the companies concerned (traders, manufacturers and importers) and/or the exporting country, and to determine the fate of the goods.

In some cases it is necessary to sort the package(s) to identify and segregate the incriminated products and have them disposed of in authorised facilities. If they are returned to the consignor, the transport of the goods must comply with the regulations applicable to the carriage of dangerous goods. These operations (transport, sorting, packaging, disposal, etc.) involve significant cost which is generally borne by the French manufacturer.

ASN considers that France must rapidly adopt a national strategy for radioactivity detection on its territory, and make the corresponding investments in equipment and training.

Given the possible economic side-effects of these incidents, ASN recommends that all firms involved in commercial trading of metal-based products with countries outside the European Union, conduct checks on the radioactivity level of the imported products.

4.6 Implementation of monitoring of radioactive source protection against malicious acts

Even if the safety and radiation protection measures as a result of the regulations do guarantee a certain level of protection against the risk of malicious acts, they cannot be considered sufficient for all radioactive sources. Reinforced oversight of protection against malicious acts using hazardous sealed radioactive sources was thus strongly encouraged by International Atomic Energy Agency (IAEA) which published a code of conduct for the safety and security of radioactive sources (approved by the Board of Governors on 8th September 2003) and guidelines for the import and export of radioactive sources (published in 2005). The G8 supported this approach, notably at the Evian summit in June 2003, and France sent IAEA confirmation that it was working towards application of the guidelines laid out in the code of conduct (undertakings by the Governor for France of 7th January 2004 and 19th December 2012). The general aim of the Code is to obtain a high level of safety and security for those radioactive sources which can constitute a significant risk for individuals, society and the environment.

Monitoring sources for radiation protection and safety purposes and monitoring them to combat malicious acts have many aspects in common and mutually consistent objectives. This is why ASN's counterparts abroad are usually responsible for monitoring both domains. ASN has the necessary hands-on knowledge of the sources concerned and of the entities responsible for nuclear activities, which are regularly inspected by its regional divisions.

The Government has decided to entrust ASN with the monitoring of the measures – incumbent on the entities responsible for nuclear activities – to track and protect sources against malicious acts. It could in particular consist of limiting source access to duly authorised persons only, of placing one or more physical protective barriers between the source and unauthorised persons, of making intruder detection systems mandatory, or of ensuring source tracking. The legislative process started in 2008 by the Government with the assistance of ASN was integrated into Act No. 2015-992 of 17th August 2015 (Energy Transition for Green Growth Act – TECV) and the Ordinance of 10th February 2016 which divides up the competences for oversight in the various facilities by including protection against malicious acts among the concerns that the services examining licence applications must take into account. Without waiting for these provisions to come into effect, ASN has instructed all holders of high-activity sealed sources to exercise great vigilance with regard to the conditions of storage, transport and utilisation of these sources, and the restriction of access to the associated information. ASN also reminded them of the obligations that are already applicable.

As it had announced, ASN continued its work to prepare the implementing texts necessary for actual deployment of the controls and reinforced its measures to inventory the existing facilities. This identification process, which focused on establishments holding high-activity sealed sources, led ASN to carry out a total of 220 visits. At present, virtually all the licensees holding high-activity sealed sources who will be inspected by ASN for the protection of sources against malicious acts have received such a visit.

Furthermore, in order to obtain a harmonised view of the country as a whole, to reinforce the training of ASN's radiation protection inspectors in this new area of competence and prepare for rapid and effective deployment of this new mission, the ASN inspectors conducted these visits using tools produced by ASN especially for this purpose. Additional training modules will be developed as the work progresses and will be incorporated into the inspectors' initial training.

These check-out visits will more specifically make it possible to assess the impact of the technical prescriptions envisaged and currently being defined by a working group coordinated by the Defence and Security High Official at the Ministry for the Environment, in which ASN plays an active role, more specifically by contributing its knowledge of the facilities.

5. THE MAIN INCIDENTS IN 2015

The inspections conducted on radiation sources and a complete round-up of radiation protection events in the non-BNI field notified to ASN are presented in chapter 4 of this report.

Industrial radiography

Several incidents occurred in 2015, including one rated level 2 on the INES scale concerning the use of an X-ray generator in a bunker which resulted in a person being exposed to a dose measured (by the passive dosimeter) of 82 mSv and a reconstructed dose estimated by IRSN at 1.5 Sv at the extremities and 144 mSv to the abdomen (see box on page 341).

Graph 7 illustrates the trends in incident numbers notified in the last few years. Graph 8 indicates the main causes of these incidents.

The series of incidents recorded in 2014 caused by rupture of the plug on GAM 80/120 devices had led ASN to ask the supplier to implement preventive measures during annual maintenance of the devices. No incidents involving this type of failure were notified to ASN in 2015.

Other source jamming incidents were however reported, caused by failures such as non-connection of the remote control cables or guides or of the guide tubes. These incidents were correctly managed by the operators and managers of the companies concerned, and were rapidly resolved. Even though the French regulations are on the whole adhered to and are more stringent than the international standards, ASN considers that improvements are required in worksite preparation and incident management.

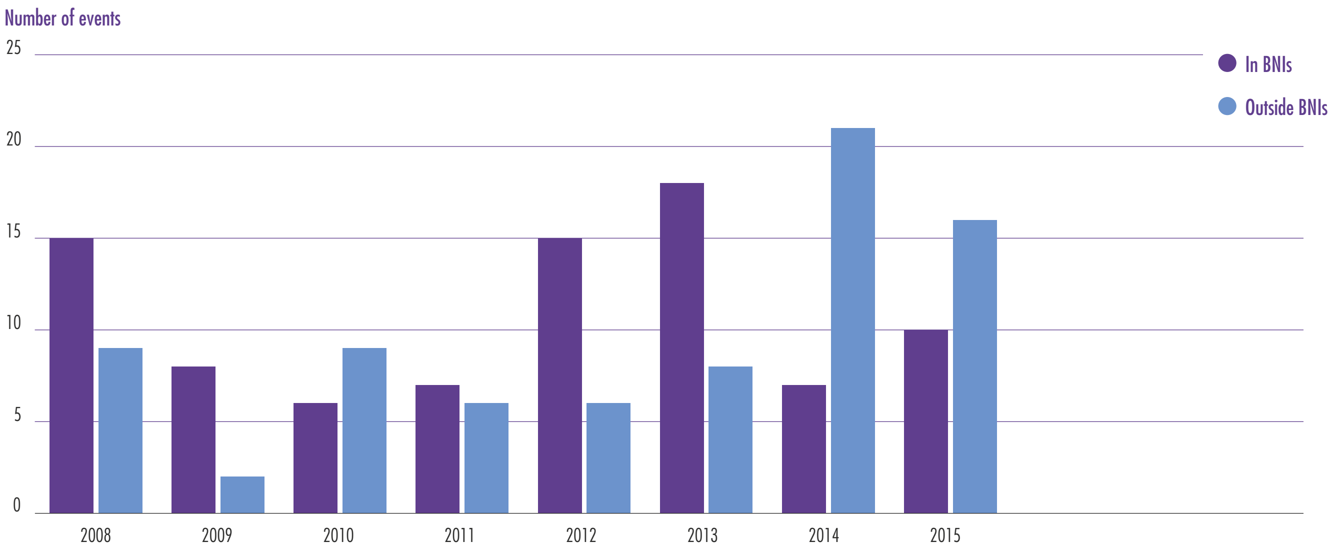
Research activities

Since 2011, ASN has registered notification of 15 significant events per year on average in this sector. Even though this number remains low, it does nevertheless represent a change with respect to the past since only 28 events were notified over the 2008-2010 period. The significant events fall into two main categories:
- the discovery or loss of radioactive sources;
- the detection of contamination.

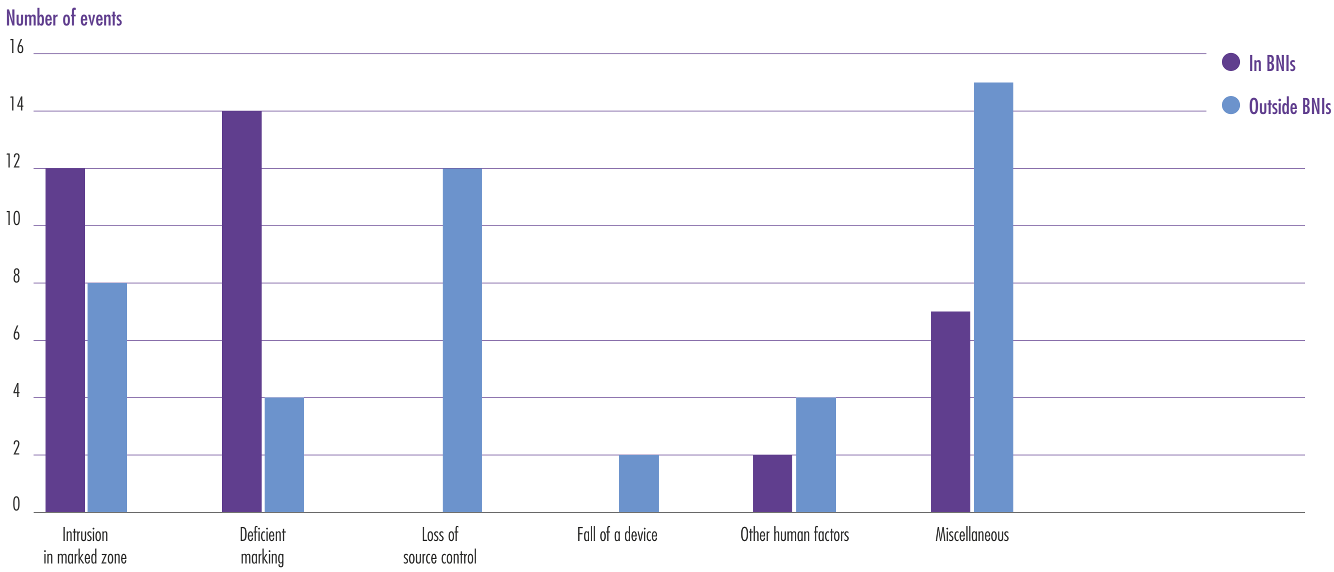
For the aspects concerning sources, the absence of source disposal measures when laboratories ceased their activities in the past combined with the persistence of poor source management are the cause of this situation.

For the 2011 to 2015 period, 9 incidents were rated level 1 on the INES scale, while the others were rated level 0. One incident was rated level 2 in 2015 (see box on page 343).

GRAPH 7: Trend in the number of industrial radiography events notified to ASN



GRAPH 8: Main causes of industrial radiography events notified to ASN in 2013-2015



TO BE NOTED

Over-exposure of a female operator employed by an industrial radiography contractor – Apave Sudeurope SAS, in Colomiers (Haute-Garonne *département)*

On 31st July 2015, a female operator of the Colomiers agency of the company Apave Sudeurope was accidentally exposed in the agency's bunker to radiation emitted by an X-ray generator used for industrial radiography.

The operator entered the bunker without realising that the device was emitting ionising radiation. She was directly exposed to the beam from the X-ray tube for several minutes. As soon as this abnormal situation was detected, Apave Sudeurope suspended utilisation of the facility and requested emergency development of the operator's passive dosimeter. It notified ASN of this event on 4th August 2015.

On 5th August 2015, ASN inspectors and a labour inspector conducted an on-site inspection in the presence of the company's occupational physician. Apave Sudeurope informed the inspectors that the safety device that stops X-ray emission when the bunker doors are open had been intentionally disabled shortly before the event on account of a technical failure (see diagram of bunker). This constitutes a deviation from the regulations and a serious failure in the radiation protection organisation.

The operator's passive dosimeter measured an effective dose of 82 millisieverts, substantially higher than the regulatory annual effective dose limit (20 millisieverts for a person exposed to ionising radiation in the course of their professional activity).

As the whole-body exposure of the operator was not uniform, some parts of the body may have received higher doses. ASN mandated IRSN, its technical expert, to conduct a finer reconstruction of the received doses. These were evaluated at 1.5 Sv in equivalent dose on the skin of the hands and 144 mSv at the body trunk in the primary beam.

ASN rated this event level 2 on the INES radiological events scale which comprises 8 levels from 0 to 7.

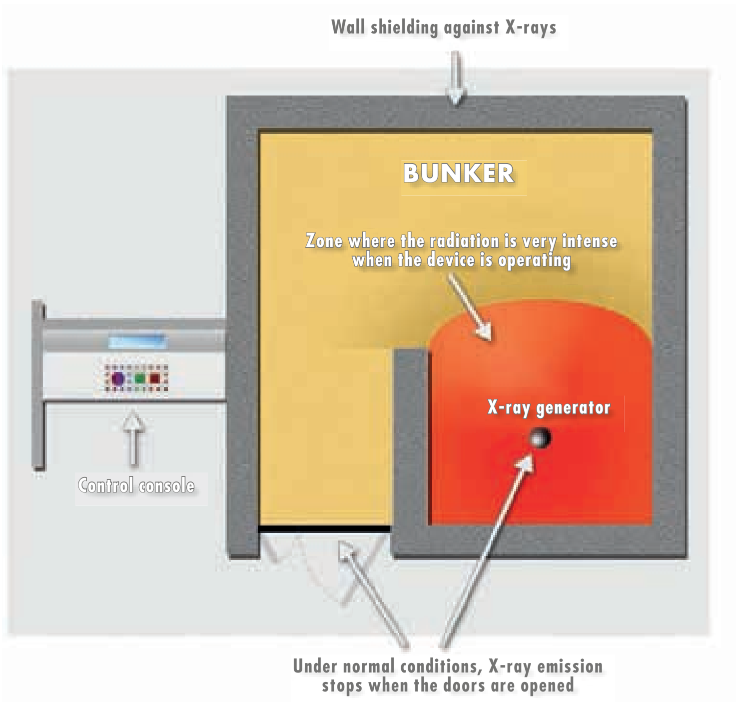


Diagram of the bunker.

UNDERSTAND

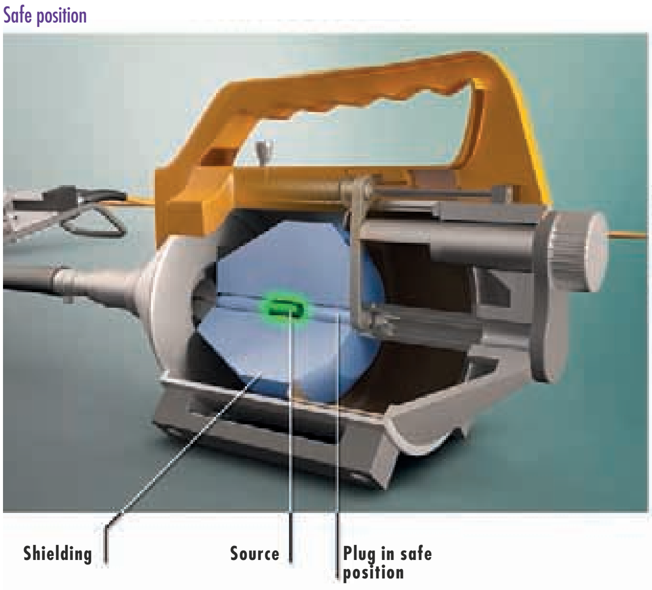
Gamma radiography
Serious accidents abroad

Gamma radiography accidents in France have remained limited in number and consequences since March 1979, when a worker had to have a leg amputated after having picked up a 518 GBq source of iridium-192 and put it in his pocket. This incident had led to a tightening of the regulations in effect at the time. ASN continues to keep itself informed of significant accidents around the world which have had major deterministic effects. Recent examples brought to ASN's attention include:

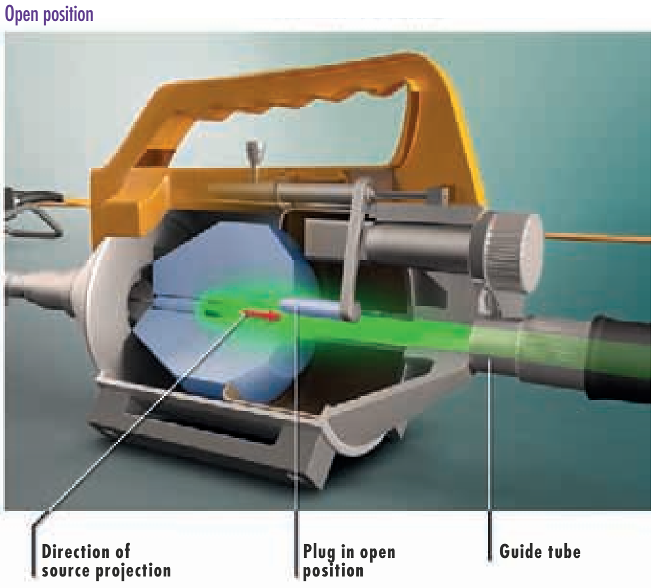
- In 2015, in Iran, two operators were exposed to an effective dose of 1.6 and 3.4 gray (Gy) respectively. The gamma ray projector source (^{192}Ir of 1.3 TBq) became disconnected and remained blocked in the guide tube without the operators realising it. The operators then spent the night in their vehicle near the guide tube and the source.
- In 2014 in Peru, an employee was exposed to 500 mSv whole body and 25 Gy on the left hip when he moved a guide tube and a collimator without realising that the source was disconnected from the remote control cable and had remained in the collimator (^{192}Ir, 1.2 TBq, 30 minutes of exposure).
- In 2013, in Germany, an employee of a non-destructive testing company was exposed to more than 75 mSv whole body and 10 to 30 Gy at the extremities (hands) while attempting to release a source from a guide tube.
- In 2012, a Peruvian employee was admitted to Percy hospital in Clamart following exposure of 1 to 2 Gy (whole body) and of 35 Gy to the hand (70 Gy at the fingertips) after handling a guide tube with his bare hands, without first checking the position of the source. The industrial radiographer required partial amputation of the fingers of the left hand.
- In 2011, 5 Bulgarian workers were admitted to Percy hospital in Clamart for major treatment following irradiation of 2 to 3 Gy owing to an error in the handling of a gamma ray projector, from which they believed the source had been removed.
- In 2011, in the United States, an apprentice radiographer disconnected the guide tube, noticed that the source was protruding from the source applicator and tried to push the source into the device with his finger. The estimated dose received at the extremities is 38 Gy.

CROSS-SECTIONAL VIEW of a gamma ray projector

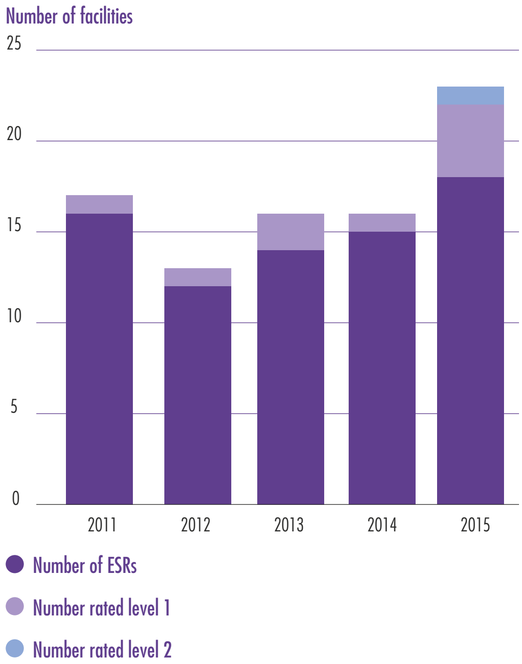
Safe position



Open position



GRAPH 9: Trends in the number of events notified to ASN in the research sector



UNDERSTAND

Loss of control of the source in gamma radiography

Gamma radiography is a non-destructive testing technique consisting in positioning a radioactive source close to the element to be inspected in order to obtain a radiographic image which can subsequently be used to check the quality of the part.

The loss of control of the sources is one of the main causes of incidents in this field. It can lead to significant exposure of the workers nearby, or even of the public if used in an urban area. This loss of control is primarily encountered in two situations:
- The radioactive source remains jammed in its guide tube. The cause of jamming is often the presence of foreign bodies in the tube, or deterioration of the tube itself.
- The source-holder containing the radionuclide is no longer connected to the remote control. The cable joining the source and the remote control is not correctly connected and the source can no longer be operated.

France has an inventory of gamma radiography devices compliant with technical specifications that are stricter than the international standards. However, equipment failures can never be ruled out, especially in the event of poor upkeep of the equipment. Operator errors are also observed as being the cause of incidents.

ASN also notes that the procedures and steps to be taken by the radiologists when faced with these situations are insufficiently understood and adhered to.

TO BE NOTED

Level 2 incident at Bordeaux University: discovery of radioactive sources and incidental exposure of persons

On 18th September 2015, Bordeaux University – Carreire Campus – informed ASN of the discovery of two radioactive sources in a room in the Inserm laboratory. The laboratory in question has not had a license to hold radioactive sources for many years now due to the cessation of its activities involving radioactive sources.

The two radioactive sources were discovered by the Bordeaux University prevention service in a very cluttered and regularly frequented room during a housekeeping operation carried out at the end of June 2015.

As soon as the sources were discovered, they were transferred and placed in safe storage in a room provided for that purpose within the university campus. On 4th September the university's radiation protection service conducted an inspection to determine the radiological characteristics of the retrieved sources. Risks of irradiation and contamination were evidenced around one of the two sources, which displayed a dose rate of 3.4 mSv/h in contact.

Radiological inspection of the room did not reveal any radioactive contamination. On the other hand, according to the first received dose estimates, one person working in this room reportedly received a dose approaching 20 mSv/year and several others persons, having been exposed more briefly, reportedly received a dose slightly above the annual regulatory limit for the general public (1 mSv). ASN conducted an inspection at Bordeaux University on 1st October 2015 to examine the circumstances of this event and asked that an action plan be undertaken to prevent recurrence of a similar event.

The shortcomings in radiation protection culture and the dose potentially received by the exposed persons led ASN to rate this event level 2 on the INES scale.

6. ASSESSMENT OF RADIATION PROTECTION IN THE INDUSTRIAL, RESEARCH AND VETERINARY FIELDS, AND OUTLOOK FOR 2016

In the field of regulating applications of ionising radiation in the industrial, research and veterinary sector, ASN is working to ensure that the operators take full account of the risks involved in the use of ionising radiation.

Industrial radiography

Industrial radiology activities have serious radiation protection implications for the workers and are an inspection priority for ASN, with some 100 inspections carried out per year in this field, including unannounced night-time inspections on the worksites. The system of on-line notification of worksite schedules for industrial radiography contractors put in place by ASN in 2014 facilitates the organisation of these inspections. A lack of reliability of the information communicated by some contractors has nevertheless been observed.

From its inspection findings, ASN considers that the way risks are taken into account varies between companies. The regulations relating to worker training and the periodic external inspection of sources and devices and worker dosimetry are on the whole satisfied. However, despite the progress made, preparation of the interventions still requires close attention from the various parties involved, more specifically on the worksite to mark out the work zones, for the forecast dose evaluations and for coordination between the ordering customers and the contractors in order to reinforce the preparation of the work and allow effective preventive measures to be taken. ASN is worried by the zoning defects observed because this constitutes the main safety barrier in the worksite configuration, in particular to prevent inadvertent exposure.

The work conditions on the site (poor accessibility, night work, etc.), equipment maintenance (projectors, guide tubes, etc.) are major factors affecting personnel safety. The incidents often result from sources getting jammed outside the safe shielded position. ASN notes that the exposure rates and condition of the equipment are not unrelated to the probability of an incident. It moreover underlines that if any equipment operating anomalies are observed when using a gamma ray projector, such as abnormal source projection or retraction forces, operations should be immediately stopped and the equipment inspected. Furthermore, if a source becomes jammed, no attempt should be made to free it, and the on-site emergency plans required by the regulations – though rarely drawn up – must be implemented.

With regard to justification and optimisation, the work undertaken by the non-destructive inspection professionals has resulted in the production of guidelines with the aim of promoting the use of alternative methods. The professionals have continued the work, in particular with regard to the updating of the construction and maintenance codes for industrial equipment, in order to favour the use of non-ionising inspection methods.

ASN considers that implementation of these guidelines and recommendations and work progress are insufficient, and that the ordering customers have an essential role to play in ensuring progress in radiation protection in the field of industrial radiography.

Since the notable incidents that occurred early in the 2010's involving jamming of industrial gamma radiography sources, ASN has been conducting an in-depth examination with the stakeholders and IRSN based on the analysis of the incidents in order to identify generic technical solutions that will facilitate the recovery of gamma radiography sources following loss of control (see box on page 343).

Several circular letters have been sent to all operators reminding them of the regulations and asking that improvements be made in worksite preparation and incident management. A report presenting the conclusions of the work carried out with the stakeholders to define typical scenarios for loss of source control, to develop technical recovery solutions and to define good practices in the event of incidents involving loss of control of sources should be published in early 2016.

According to the survey carried out by ASN in the sector, 70% of the industrial radiography agencies have a specialised fixed facility (bunker) and 70% of the agencies also operate in "worksite" configuration. 50% of the industrial radiography tests performed are in worksite configuration. In this configuration, iridium-192 gamma ray projectors are the most commonly used, representing two-thirds of the worksites. X-ray generators are mainly used on the other worksites. Very few tests are conducted outside the bunker with particle accelerators or gamma ray projectors using cobalt-60 or selenium-75. On the whole, one test in three uses iridium-192 in the worksite configuration. These worksites are primarily located in industrial units and processes and in BNIs.

The significant percentage of tests in "worksite" configuration within industrial units suggests insufficient application of the justification principle because in many cases parts could probably have been transported to a secure bunker for inspection.

ASN has continued the initiatives undertaken with the DGT (General Directorate for Labour) to overhaul the existing regulatory texts with tightening of requirements regarding justification, given that recognised alternative methods exist.

The design of the devices and of the facilities, the use of devices, notably on the worksites, and the training of the operators were examined during this regulatory overhaul process and within the working group comprising all the stakeholders. This tightening of the regulations will also involve the ordering customers with regard to justification and the human and material resources available in the event of incidents.

Regional initiatives to establish Charters of best practices in industrial radiography have been in progress for several years at the instigation of ASN and the labour inspectorate, particularly in the Provence-Alpes-Côte d'Azur, Haute-Normandie, Rhône-Alpes, Nord-Pas-de-Calais and Bretagne/Pays de la Loire regions and enabled regular exchanges between the various participants to continue in 2015. The ASN regional divisions and other regional administrations concerned also organise regional awareness-raising and discussion symposia which are attracting growing interest from the stakeholders of this branch.

Research establishments

ASN's monitoring of establishments and laboratories using radioactive sources for research purposes shows a distinct improvement in radiation protection in this sector. Generally speaking, the steps taken in recent years have produced significant results in the incorporation of radiation protection into research activities and an overall rise in awareness of radiation protection issues.

The most notable improvements concern the involvement of the Person Competent in Radiation protection (PCR), the training of exposed workers, radiation protection technical controls and waste and effluent storage conditions. Considered on the whole, an improvement in the formalising of procedures is observed, but this trend must be confirmed by actually implementing the scheduled actions: internal radiation protection controls, management and tracking of significant events and disposal of old sealed sources.

UNDERSTAND

Research activities

The use of ionising radiation in research activities extends to various fields such as medical research, molecular biology, the agri-food industry, materials characterisation, etc. It primarily involves the use of unsealed sources (iodine-125, phosphorous-32, phosphorous-33, sulphur-35, tritium-3, carbon-14, etc.). Sealed sources (barium-133, nickel-63, caesium-137, cobalt-60, etc.) are also used in gas chromatographs or scintillation counters or, with higher-activity sources, in irradiators. Electric generators emitting X-rays are used for X-ray fluorescence or X-ray diffraction spectrum analyses. One should also note the existence of scanners for small animals (cancer research) in research laboratories and medical schools. Particle accelerators are for their part used in research into matter or for the manufacture of radionuclides.

The number of licenses issued by ASN in the research sector is stable at around 800. Each year, ASN carries out an average of 60 inspections in this sector.

UNDERSTAND

Mössbauer spectrometry

Mössbauer spectrometry is a technique for exploring matter. From the observation of gamma ray absorption by samples of matter, it enables a magnetic "identity card" of matter to be drawn up at microscopic level and the properties of matter to be estimated at macroscopic level. It enables scientific studies to be conducted for diverse practical applications such as the magnets used in electric motors or in cooling systems. This technique only applies to metallic materials in solid state and is used mainly on iron and tin analysed by the gamma rays of cobalt-57 and tin-199m respectively.

In practice, a sample is placed between a vibrating source and a gamma ray detector. The set-up is coupled to a signal processing system. For cobalt-57 – the most commonly used radionuclide – the activity involved is about 1 to 2 GBq.

In 2015 the ASN regional divisions conducted an inspection campaign in the laboratories that use Mössbauer spectrometry. A review of these inspections will be drawn up in 2016 in order to assess the standard of radiation protection in this sector and to highlight good practices and areas for improvement.

As mentioned in point 5, the notification criteria and the regulatory requirements with regard to notification are still to a large extent poorly-known in research facilities and ASN notes that there is little supervision of radiation protection event tracking and notification in the inspected entities, where more than half of them do not have procedures for managing significant events.

The technical, economic and regulatory difficulties concerning the disposal of old sealed sources are often raised by licensees. The work of the ad hoc working group created to address this issue as part of the French National Radioactive Material and Waste Management Plan (PNGMDR) for 2012-2015 has led to a modification in the regulations (Decree 2015-231 of 27th February 2015 relative to the management of disused sealed radioactive sources) which came into effect on 1st July 2015. This modification, which aims to facilitate the disposal of sealed sources, gives source holders the possibility of seeking different disposal routes with source suppliers or Andra without making it obligatory to return sources to the original supplier.

ASN is continuing its collaboration with the General Inspectorate of the French Education and Research Administration. An agreement signed in 2014 formalises discussions on inspection practices and the setting up of reciprocal information procedures for improving the effectiveness and complementarity of the inspections.

Veterinary surgeons

With regard to veterinary structures, the administrative situation has been continuously improving for a number of years now. At the end of 2015, ASN counted some 3,817 notified or licensed structures out of the 5,000 structures using ionising radiation in France.

Of the veterinary activities, those performed on large animals (primarily horses) and outside specialised veterinary facilities (in so-called "worksite" conditions), are considered to be those with the highest potential radiation protection implications, more specifically for persons from outside the veterinary facility taking part in these interventions.

The inspections carried out by ASN on more than 30% of these veterinary structures as part of a national priority in the inspection programme revealed areas for improvement in which ASN remains vigilant when examining licensing applications and performing inspections:
- shortcomings in the application of worker monitoring by active dosimetry and in the internal radiation protection controls;
- deficient and sometimes inexistent implementation of radiological zoning;
- the necessity to reinforce the radiation protection of persons external to the veterinary practice who participate in the diagnostic radiology procedures;
- an unsatisfactory administrative situation.

The result of the efforts made by the veterinary bodies in the last few years to ensure conformity with the regulations have been confirmed by the inspectors who have noted good field practices in the inspected structures, and more specifically:
- the presence of in-house PCRs in the majority of structures;
- the use of Personal Protective Equipment (PPE) almost systematically;
- an approach to optimise the conditions of diagnosis in nearly all the structures.


ASN inspection in an equine veterinary clinic, November 2015.

The extensive nationwide commitment of the profession to harmonising practices, raising awareness, training student veterinary surgeons and drafting framework documents and guides is seen in a very positive light by ASN, which every year takes part in meetings with the profession's national bodies (more particularly the veterinary radiation protection commission) jointly with the General Directorate for Labour.

The conventional radiology activities performed on pets (called "canine activities" in France) involve lesser radiation protection implications but represent a very large number of veterinary clinics. As part of its graded approach which consists in adapting the control methods to the radiation protection implications, ASN conducted an experimental control campaign which called upon new dematerialised control methods based on an on-line self-assessment questionnaire. The campaign was carried out in seven *départements* (Aisne, Allier, Aube, Cantal, Haute-Loire, Pas-de-Calais and Puy-de-Dôme). It will be pursued by addressing requests for justificatory documents to a limited number of veterinary structures and by carrying out inspections.

The aim is to obtain a representative picture of radiation protection in the numerous veterinary structures that practise such conventional radiology activities and to identify those structures on which ASN must focus its efforts.

This inspection campaign, carried out in close collaboration with the Higher Council of the Order of Veterinarians, started at the end of June 2015 and will continue until 2016.

Suppliers of ionising radiation sources

ASN considers that the regulatory oversight of suppliers of electrical ionising radiation generators is still insufficient, even though putting such devices on the market is of prime importance for optimising the future exposure protection of the users of these devices (see point 4.4). The work conducted by ASN in this area led to the publication of ASN resolution 2013-DC-0349 of 4th June 2013 and will be continued to propose a draft resolution setting the technical requirements for the devices distributed in France.

Cyclotrons

ASN has been exercising its oversight duty in this field since early 2010; each new facility or major modification of an existing facility is the subject of a complete examination by ASN. The main radiation protection issues on these facilities must be considered as of the design stage. Application of the standards, in particular standard NF M 62-105 *"Industrial accelerators: installations"*, ISO 10648-2 *"Containment enclosures"* and ISO 17873 *"Nuclear facilities – Criteria for the design and operation of ventilation systems for nuclear installations other than nuclear reactors"*, guarantees safe use of the equipment and a significant reduction in risks.

The establishments that hold a cyclotron and use it to produce radionuclides and products containing radionuclides are subject to gaseous effluent discharge limits specified in their license. The discharge levels depend on the frequency and types of production involved.

In order to minimise the activity discharged at the stack outlet, systems for filtering and trapping the gaseous effluents are installed in the production enclosures and in the facilities' extraction systems. Consequently, the very low activities discharged and the short half-life of the radionuclides discharged in gaseous form means there is no impact on the public or the environment.

Some licensees have also installed, beside the shielded enclosures, systems for recovering the gases to allow their decay before their discharge, allowing a substantial reduction in the activities discharged into the environment.

ASN performs about a dozen inspections on these facilities every year. Aspects related to radiation protection, user safety and the correct operation of cyclotrons and production platforms receive particular attention during the inspections. The scope of the inspections performed includes – apart from the aspects relating to radiation protection – the monitoring and maintenance of the production equipment, the inspection of the surveillance and control systems and the gaseous discharge results. The radiation protection organisation of these facilities is satisfactory and they are fully familiar with the regulations. National action plans have been put in place by the licensees and are monitored by ASN in order to ensure continuous improvement of radiation protection and safety in these facilities.

There are disparities in the technical and organisational means implemented by the licensees according to the age of the facilities and the type of activities performed (research or industrial production). Experience feedback in this area has led ASN to ask IRSN to establish recommendations and requirements necessary for the control of the radiological risks applicable to establishments using a cyclotron and producing radionuclides and products containing radionuclides. A draft resolution on the minimum technical design, operating and maintenance rules for this type of facility is currently being prepared by ASN and should be subject to consultations in 2016.

ASN inspection of the Arronax cyclotron, July 2015. Irradiated capsule receiving station.

Monitoring the protection of radioactive sources against malicious acts

In 2014 and 2015, ASN brought the subject of monitoring the protection of radioactive sources against malicious acts to the attention of Parliament through the review of the Energy Transition for Green Growth Bill. The legislative process started in 2008 by the Government with the assistance of ASN was recently concluded with the publication of Ordinance 2016-128 of 10th February 2016 which includes the protection of radioactive sources against malicious acts.

At the same time, in 2015 ASN – along with its institutional partners – continued the preparation of the implementing texts necessary for the effective implementation of monitoring and the steps undertaken since 2011 to produce an inventory of the existing facilities and anticipate staff training and the development of appropriate tools for rapid and effective implementation of this new duty.

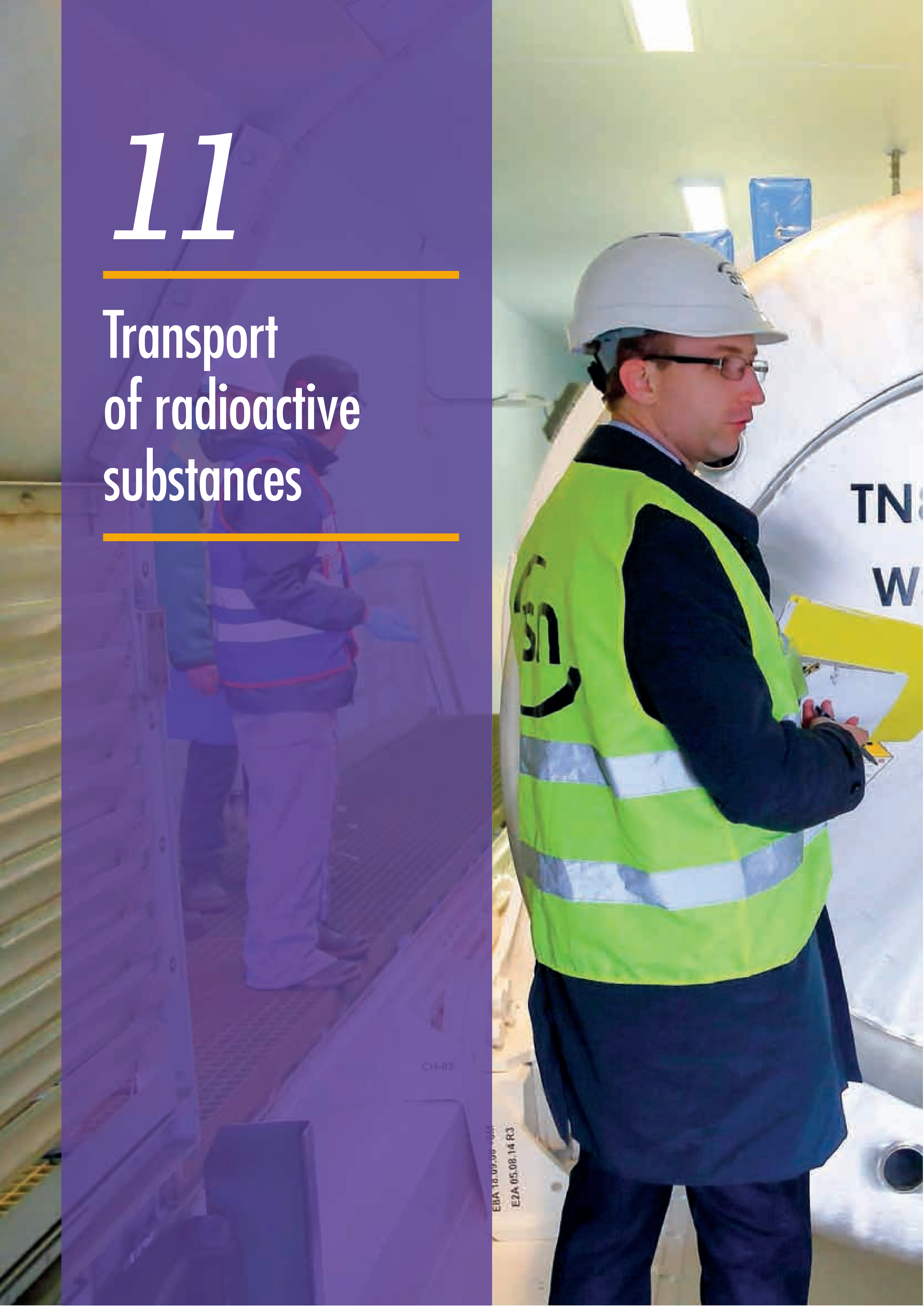
In 2016 ASN will endeavour, with these same partners, to continue the preparation of regulatory texts enabling:
- the safety of the sources to be taken into account when examining licensing applications;
- the technical and organisational requirements for protecting the most hazardous sources against malicious acts to be defined;
- the verification of the safety of sources to be organised.

These texts should come into effect as of July 2017.

To this end, ASN will adapt the tools it already uses to monitor radiation protection, continue to train its inspectors accordingly and communicate widely to the entities concerned.

11

Transport of radioactive substances

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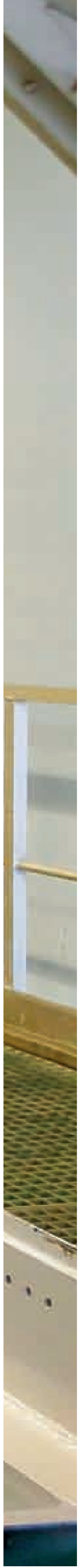


The transport of radioactive substances is a specific sector of dangerous goods transport characterised by the risks associated with radioactivity.

The scope of regulation of the safety of radioactive substance transport covers various fields of activity in the industrial, medical and research sectors. It is based on stringent and restrictive international regulations.

1. MOVEMENTS AND RISKS IN THE TRANSPORT SECTOR

1.1 The diversity of radioactive substance transport movements

The regulations place these packages in different risk "classes". Class 1, for example, represents explosive materials and objects, class 3 flammable liquids, and class 6 toxic and infectious materials. Class 7 covers hazardous radioactive material. About 770,000 shipments of radioactive substances are transported each year in France. This represents about 980,000 packages of radioactive substances, or just a few percent of the total number of dangerous goods packages transported each year in France.

The fuel cycle necessitates an estimated annual total of 19,000 shipments involving 114,000 packages. These include approximately:
- 2,000 shipments from or to foreign countries or transiting via France, representing about 58,000 packages shipped;
- 389 shipments of new uranium-based fuel and some 50 shipments of new uranium and plutonium-based "MOX" fuel;
- 220 shipments transporting spent fuel from the nuclear power plants operated by EDF to the La Hague reprocessing plant operated by Areva;
- about 100 shipments of plutonium in oxide form transported from the La Hague reprocessing plant to the MELOX fuel production plant in the Gard département;
- 250 shipments of uranium (UF_6) hexafluoride necessary for the fuel manufacturing cycle.

1.2 Risks associated with the transport of radioactive substances

The content of the packages is highly diverse: their level of radioactivity varies over more than fifteen orders of magnitude, that is to say from a few thousand becquerels for low-level pharmaceutical packages, to quadrillions (billions of billions) of becquerels for spent fuel. The weight of the packages also varies from a few kilogrammes to about a hundred tonnes.

The major risks involved in the transport of radioactive substances are:
- the risk of external irradiation of persons in the event of damage to the "biological protection" of the packages, a technical material that reduces the radiation received through contact with the package;
- the risk of inhalation or ingestion of radioactive particles in the event of release of radioactive substances;
- contamination of the environment in the event of release of radioactive substances;
- the starting of an uncontrolled nuclear chain reaction ("criticality safety" risk) that can cause serious irradiation of persons if water is present and the safety of fissile radioactive substances is not controlled.

Moreover, the radioactive substances can also be toxic and corrosive. This, for example, is the case with shipments of natural uranium with low radioactivity, for which the major risk for man is the chemical nature of the compound, especially if it is ingested. Similarly, uranium hexafluoride, used in the manufacture of fuels for nuclear power plants can, in the case of release and contact with water, form hydrofluoric acid, a powerful corrosive and decalcifying agent.

Catering for these risks implies having full control over the behaviour of the packages to avoid any release of material and deterioration of the package protection in the event of:
- fire;
- physical impact further to a transport accident;
- ingress of water into the packaging, as water facilitates nuclear chain reactions in the presence of fissile substances;
- chemical interaction between the various constituents of the package;
- substantial release of heat from the transported substances, to avoid possible heat damage to the package constituent materials.

This approach means that safety principles must be defined for the transport of radioactive substances:
- safety is based first and foremost on the robustness of the package: regulatory tests and safety demonstrations are required by the regulations to prove that the packages can withstand reference accidents;

TRANSPORT operations relating to the fuel cycle in France

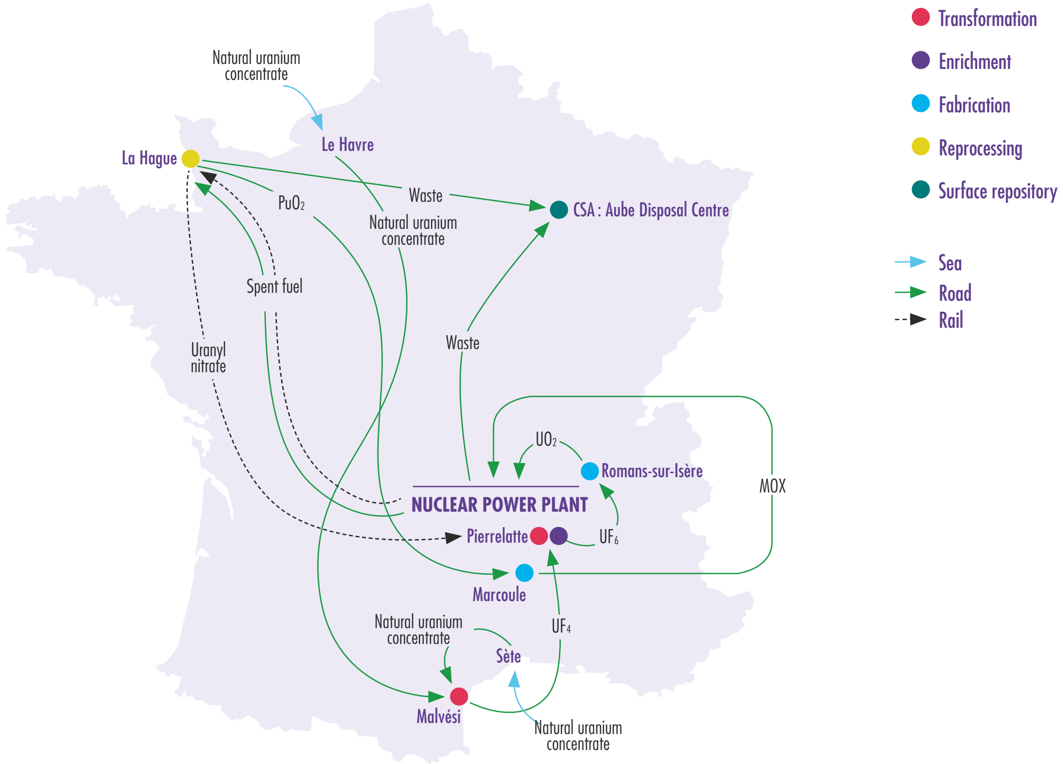


TABLE 1: Breakdown per mode of transport

APPROXIMATE NUMBER OF PACKAGES AND SHIPMENTS		ROAD	ROAD AND AIR	ROAD AND RAIL	ROAD AND SEA	ROAD, SEA AND RAIL	ROAD, SEA AND AIR
Packages approved by ASN	Number of packages	17,875	1,315	455	1,916	0	0
	Number of shipments	12,356	1,249	382	385	0	0
Packages not requiring approval by ASN	Number of packages	866,052	46,942	2,894	6,803	34,364	5,316
	Number of shipments	735,492	21,008	533	905	81	5,316

- the required level, particularly with regard to the reference accidents that the package must withstand, depends on the degree of risk presented by the package.

The statistical data presented in this chapter come from a study conducted by ASN in 2012. It is based on information collected in 2011 from all the consignors of radioactive substances (BNIs, laboratories, hospitals, source suppliers and users, etc.), as well as on reports from the transport safety advisers. A summary is available on the ASN website[1].

1. *www.asn.fr/Informer/Actualites/Enquete-de-l-ASN-sur-les-flux-de-transport-de-substances-radioactives*

Wagon used to transport vitrified waste packages.

2. ROLES AND RESPONSIBILITIES IN REGULATING THE TRANSPORT OF RADIOACTIVE SUBSTANCES

2.1 Regulation of nuclear safety and radiation protection

The objective of ensuring the safety of shipments of radioactive substances is to prevent nuclear accidents and their radiological consequences for people by implementing organisational and technical measures.

In France, ASN has been responsible since 1997 for regulating the safety of transport of shipments for civil uses, while ASND (the Defence Nuclear Safety Authority) fulfils this role for the shipments relating to national defence. ASN's action in the field of transport comprises:
- checking, from the safety standpoint, all the stages in the life of a package, from design and manufacture through to maintenance;
- checking compliance with the safety regulations during the shipment and transportation of the packages.

Section 4 of this chapter gives more details on these inspections.

2.2 Protection against malicious acts

The prevention of malicious acts consists in preventing sabotage, losses, disappearances, theft and misappropriation of nuclear materials that could be used to manufacture weapons. The Defence and Security High Officials (HFDS), under the Ministers responsible for Energy and Defence, are the regulatory authority responsible for preventing malicious acts targeting nuclear materials. In practice, it is the HFDS of the ministry in charge of ecology that is delegated this role by the two abovementioned HFDS.

2.3 Regulation of the transport of dangerous goods

Regulation of the transport of dangerous goods is monitored by the MTMD (Hazardous Materials Transport Mission) of the Ministry of Ecology. This entity is tasked with ensuring the measures relative to the safe transport of dangerous goods other than class 7 (radioactive) by road, rail and inland waterways. It has a consultative body (CITMD – Interministerial Hazardous Materials Transport Committee) that is consulted for its opinion on any draft regulations relative to the transport of dangerous goods by rail, road or inland waterway.

TABLE 2: Administrations responsible for regulating the mode of transport and the package

MODE OF TRANSPORT	REGULATION OF MODE OF TRANSPORT	PACKAGE REGULATION
Sea	General Directorate for Infrastructures, Transports and the Sea (DGITM) at the Ministry for the Environment, Energy and the Sea (MEEM). ASN provides its assistance in regulating compliance with the prescriptions contained in the International Code for the Safe Carriage of Irradiated Nuclear Fuel, Plutonium and High-level Radioactive Wastes on Board Ships ("Irradiated Nuclear Fuel" Code). General Directorate for Energy and Climate (DGEC) of the Ministry of Ecology, Energy and the Sea ("Irradiated Nuclear Fuel" Code).	The DGITM has competence for regulation of dangerous goods packages in general. ASN is tasked with the regulation of packages of radioactive substances
Road, rail, inland waterways	General Directorate for Energy and Climate (DGEC) of the Ministry of Ecology, Energy and the Sea (MEEM).	The General Directorate for the Prevention of Risks (DGPR) is responsible for regulating packages of dangerous goods in general. ASN is tasked with the regulation of radioactive substances
Air	General Directorate of Civil Aviation (DGAC) of the MEEM	The DGAC has competence for regulation of dangerous goods packages in general. ASN is tasked with the regulation of packages of radioactive substances

Inspections in the field are carried out by land transport inspectors attached to the DREALs (Regional Directorates for the Environment, Planning and Housing).

For regulation to be as consistent as possible, ASN collaborates regularly with the administrations responsible for applying the regulations in their particular sector of activity. For example, in 2015 ASN took part in the training of DGAC (General Directorate for Civil Aviation) inspectors responsible for monitoring the air transport of hazardous goods in order to teach them about the specific aspects of class 7 and present experience feedback from ASN's inspections on these subjects.

The breakdown of the various regulatory missions is summarised in table 2.

3. THE DRAFTING OF INTERNATIONAL AND EUROPEAN REGULATIONS RELATIVE TO THE TRANSPORT OF RADIOACTIVE SUBSTANCES

The international nature of radioactive substance transport has given rise to regulations, drafted under the supervision of IAEA (International Atomic Energy Agency), that ensure a high level of safety.

3.1 The different types of package

The degree of safety of the packages of radioactive substances is adapted to the potential danger of the material transported. There are five main package types: excepted packages, industrial packages, type A packages, type B packages and type C packages. These package types are determined according to the characteristics of the material transported, such as total radiological activity, specific activity, corresponding to the degree of concentration of the material, its physicochemical form or the possible presence of fissile radioactive substances, which could lead to a nuclear chain reaction.

3.1.1 Excepted packages

Excepted packages are used to transport very small quantities of radioactive substances, such as very low activity radiopharmaceuticals. These packages are not subject to any qualification tests. They must nevertheless comply with a number of general specifications, notably with regard to radiation protection, to guarantee that the radiation around the excepted packages remains very low.

3.1.2 Non-fissile industrial or type A packages

Industrial packages are used to transport material with low-level activity. Uranium-containing materials extracted from foreign uranium mines are, for example, transported in France in industrial drums with a capacity of 200 litres loaded into 20-foot containers or conventional rail wagons.

Type A packages can, for example, be used to transport radioisotopes for medical purposes commonly used in nuclear medicine departments, such as technetium generators.

3.1.3 Fissile and type B packages

Type B packages are used to transport quantities of the most radioactive substances such as spent fuels, vitrified high level, long-lived nuclear waste, or fresh fuels. Given the level of risk associated with these packages, they are subject to approval delivered by ASN based on the examination of a safety file. These packages are essentially for the nuclear industry and for industrial technical inspections, including industrial radiology.

Type A packages and industrial packages containing fissile radioactive substances are also subject to ASN approval.

3.1.4 Type C packages

Type C packages are designed for the transport of highly radioactive substances by air. In France there is no approval for type C packages for civil uses.

TABLE 3: Breakdown of transported packages by type

	TYPE OF PACKAGE	APPROXIMATE SHARE OF PACKAGES TRANSPORTED ANNUALLY
Packages approved by ASN	Type B packages	2%
	Other packages approved by ASN	1%
Packages not requiring approval by ASN	Type A packages not containing fissile radioactive substances	31%
	Industrial packages not containing fissile radioactive substances	8%
	Excepted packages	58%

3.2 Requirements applicable to each type of package

The regulations define safety requirements for each type of package, including tests to assess their robustness.

The regulations thus require that type A packages that contain no fissile substances (such as enriched uranium), be designed to withstand incidents that can occur during handling or storage operations. They must therefore be subjected to the following tests:
- exposure to a severe storm (rainfall reaching 5 cm/hour for at least 1 hour);
- drop test onto an unyielding surface from a height varying according to the mass of the package (maximum 1.20 m);
- compression equivalent to 5 times the weight of the package;
- penetration by dropping a standard bar onto the package from a height of 1 m.

Additional tests are required if the content of the package is in liquid or gaseous form.

Type A transport package.

Type A packages are not subject to ASN approval: the design of the package and performance of the tests are the responsibility of the manufacturer. These packages and their safety demonstration files are inspected by the ASN inspectors.

Type B packages, which are used to transport the most dangerous substances, must be designed such that safety is guaranteed, including in the event of a transport accident. These accidents are represented by the following tests:
- three consecutive tests:
  - a 9 m drop test onto an unyielding surface;
  - a 1 m drop onto a spike;
  - encircling fire of at least 800°C for 30 minutes;
- immersion in 15 m deep water (200 m water depth for spent fuel) for 8 h.

These tests, which are similar to the automotive industry's crash-tests, were recommended by IAEA. They have been designed, firstly to cover 95% of the most severe accidents, and secondly with the aim of being readily reproducible from one country to another. These tests are thus recognised and applied very widely by the IAEA member countries. Their performance is obligatory within the European Union.

3.3 Defining responsibilities in the transport of radioactive substances

The main participants in transport arrangements are the consignor and the carrier.

The consignor is responsible for package safety and accepts its responsibility by way of the dispatch note accompanying the package remitted to the carrier. The carrier is responsible for carriage of the shipment to its destination. Other participants are also involved: the package designer, manufacturer and owner and the carriage commission agent (authorised by the consignor to organise the transport operation).

For a radioactive substance shipment to be carried out in satisfactory conditions of safety, a rigorous chain of responsibility has to be set up. Therefore:
- The corresponding packaging must be designed and sized in accordance with the conditions of use and the current regulations. The designer must have submitted an application for ASN approval and obtained it.
- The manufacturer must produce packaging in accordance with the description given in the approval.
- The consignor must check that the material is authorised for transport and only use approved, correctly maintained packagings that are suitable for the goods in question and comply with requirements concerning the mode of transport and the shipment restrictions. The consignor must more particularly carry out the leaktightness, dose rate, temperature and contamination inspections and

mark and label the packages. It must also provide the carrier with all the required documents and information.
- The actual transport is organised by the carriage commission agent. The carriage commission agent is responsible for obtaining all the necessary authorisations on behalf of the consignor, and for sending the various notices. He also selects the means of transport, the carrier and the itinerary, in compliance with the regulatory requirements.
- The carrier, usually a specialised company with the necessary authorisations, appropriate vehicles and duly trained drivers, must verify the completeness and availability of the information provided by the consignor, and the good overall condition and correct labelling of the vehicles and packages. It must also verify that the materials to be transported are authorised for transport.
- The consignee is under the obligation not to postpone acceptance of the goods, without vital reason and, after unloading, to verify that the requirements of the corresponding ADR[2] have been satisfied.
- Finally, the container owner must set up a maintenance system in conformity with that described in the safety documents and the authorisation certificate.

The transport of some radioactive substances (including packages containing fissile material) is subject to prior notification to ASN and the Ministry of the Interior by the consignor. This notification stipulates the materials carried, the packagings used, the transport conditions and the details of the persons involved. In 2015, 1,343 notifications were sent to ASN.

3.4 The regulation of radiation protection for transports of radioactive substances

The radiation protection of workers and the public around shipments of radioactive substances must be a constant concern.

The regulations applicable to the transport of radioactive substances make provision for the radiation protection of the public and workers: the public and non-specialised workers must not be exposed to a dose exceeding 1 millisievert (mSv) per year. However, this limit is not intended to be an authorisation to expose the public to up to 1mSv. Moreover, the justification and optimisation principles applicable to all nuclear activities also apply to the transport of radioactive substances (see chapter 2).

Radiation protection is the subject of specific requirements in the regulations applicable to the transport of radioactive substances. Thus, for transport by road, the regulations stipulate that the radiation at the surface of the package must not exceed 2 mSv/h (this limit can be increased to 10 mSv/h in the case of exclusive use, where actions near the package are limited). The radiation should not exceed 2 mSv/h in contact with the vehicle and should be less than 0.1 mSv/h at a distance of 2 m from the vehicle.

Assuming that a transport vehicle reaches the limit of 0.1 mSv/h at 2 metres, a person would have to spend 10 hours without interruption at a distance of 2 metres from the vehicle for the dose received to reach the annual public exposure limit.

These limits are supplemented by requirements relative to the organisation of radiation protection within companies. The transport stakeholders must establish a radiological protection programme that integrates the measures taken to optimise human exposure. It may be necessary to implement dose monitoring of the exposed person according to the foreseeable dose evaluation for certain operations (loading, stowing, unloading, etc.). Training is also one of the pillars of the radiological protection programmes. This training is also provided for in the regulations. All the stakeholders in the transport chain must thus be trained and made aware of the nature of the risks associated with radiation so that they can protect themselves and others against these risks.

3.5 Regulation of the safety of transport operations within the perimeter of nuclear facilities

Dangerous goods transport operations can take place on the private roads of nuclear sites, in what are referred to as “on-site transport operations”. Such operations are not subject to the regulations governing the transport of dangerous goods, which only apply on public highways.

Since 1st July 2013, these transport operations have been subject to the requirements of the “BNI Order”, published on 7th February 2012 (see chapter 3). This Order requires that on-site transport operations be incorporated into the safety baseline requirements for BNIs. The on-site transport of dangerous goods presents the same risks and inconveniences as the transport of dangerous goods on the public highway. The safety of transport must be overseen with the same rigour as for any other risk or inconvenience present within the perimeter of the BNI.

In 2015, ASN continued to receive notification from most BNIs that they were modifying their general operating rules in order to incorporate on-site transport operations into their baseline safety requirements. These notifications were systematically examined by ASN. However, ASN notes that not all the BNIs have as yet incorporated on-site transport operations into their general operating rules.

2. European agreement on the international carriage of dangerous goods by road.

In 2015, ASN more particularly began the review of the notification of modification of the baseline safety requirements applicable to all the EDF nuclear power plants, with a view to incorporating on-site transport operations. ASN also began its examination of the notification submitted by Areva La Hague for the creation of a chapter in the general operating rules describing on-site transport operations. During this examination, ASN will take account of the conclusions of the 14th January 2015 joint review by the Advisory Committees for "Transport" (GPT) and "Plants" (GPU) of the safety of certain on-site transport operations.

3.6 Public information in the field of transport

Order 2012-6 of 5th January 2012 extends the public information obligations to persons responsible for nuclear activities. It is Article L. 125-10 of the Environment Code that sets the threshold beyond which the person responsible for transport must communicate the information requested by a citizen, by reclassification of the provisions of Decree 2011-1844 of 9th December 2011. The thresholds are defined as being those *"above which, in application of the international conventions and regulations governing the transport of dangerous goods, of the Code of Transport and of the texts taken for their application, the transport of radioactive substances is subject to the delivery – by ASN or by a foreign Authority competent in the field of radioactive substance transport - of an approval of the transport package design or a shipment approval, including under special arrangement"*. Any citizen can therefore now ask the persons in charge of transport for information on the risks presented by the transport operations referred to in the Decree.

A person to whom a nuclear licensee or transport supervisor has refused to communicate information, can refer the matter to the CADA (Administrative Documents Access Commission), for its opinion. The matter must be referred to the CADA prior to any legal action. Disputes relative to communication refusals can then be brought before the administrative jurisdictions, even if they are between two private individuals.

In 2014, ASN also drew up an information sheet on the transport of radioactive substances, intended for the general public and available on *www.asn.fr* (information sheet No. 8). This sheet answers questions frequently asked by the public, notably concerning the risks inherent in these transport operations, the organisation of the response by the public authorities to an emergency or the routes followed for these transport operations.

4. ASN ACTION IN THE TRANSPORT OF RADIOACTIVE SUBSTANCES

4.1 Delivery of approval certificates and shipment approvals

The type B and C packages, as well as the packages containing fissile materials and those containing more than 0.1 kg of uranium hexafluoride (UF_6) must be covered by an ASN transport approval. The designers of the package models who request approval from ASN must support their application with a safety file demonstrating the compliance of their package model with all the regulatory prescriptions. Before deciding whether or not to issue approval, ASN examines this file, drawing on the expertise of the Institute for Radiation Protection and Nuclear Safety (IRSN), in order to ensure that the safety cases are pertinent and sufficient. If necessary, the approval is issued with requests for additional information in order to improve the safety cases.

In some cases, IRSN's appraisal is supplemented by a meeting of the Advisory Committee for Transport (GPT). The opinions of the Advisory Committees are always published on *www.asn.fr*. The GPT, for example, met twice in 2011 to examine a new package concept, DE 25, developed by CEA for the transport of waste.

TO BE NOTED

Update of volume 1 of ASN Guide No. 7, known as the *"Applicant's guide"*

In May 2009, ASN published an applicant's guide for requests for approval of shipments of package models or radioactive substances for civil purposes transported on the public highway. This guide contains recommendations concerning the content and format of the application files, to make them easier to examine. It in particular presents the structure of the safety file to be submitted by the applicant in support of its request, the provisions in the event of a modification to an existing package model, the ASN's positions regarding the safety cases, experience feedback from previous technical examinations as well as points concerning the right of access to information and concerning penalties This guide was translated into English in 2010 for distribution to some of the European Union authorities with competence for transport issues. In order to take account of the latest changes to the regulations and lessons learned, ASN initiated an update of this guide. The project was opened to public consultation from 13th October to 13th November 2015 on the ASN website. The comments received are currently being analysed and will be taken into consideration in updating the guide.
The updated guide will be published in 2016.

These approval certificates are usually issued for a period of five years. In 2015, about fifty approval applications were submitted to ASN by the manufacturers.

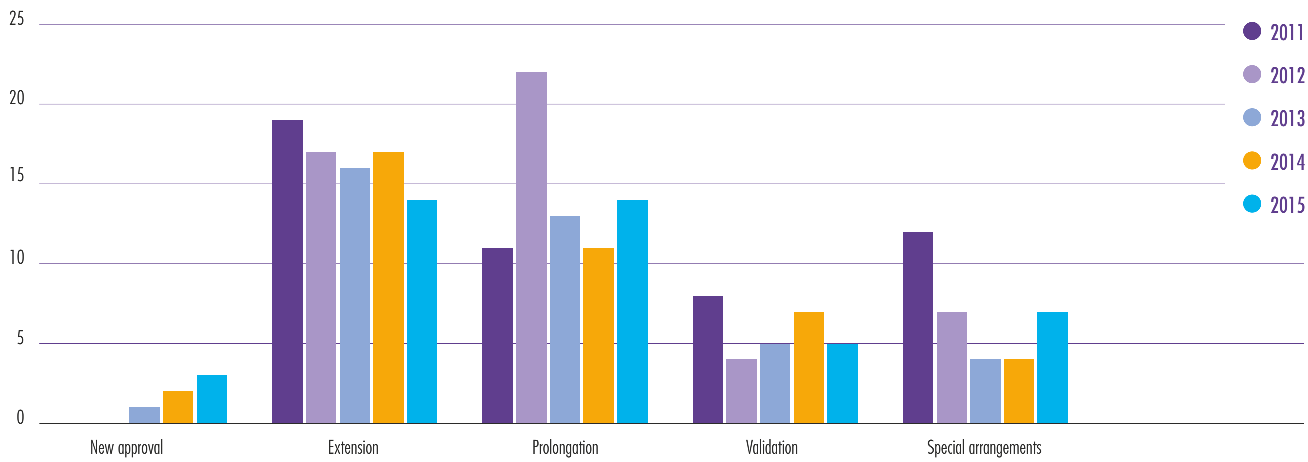
The approval specifies the conditions for manufacture, utilisation and maintenance of the transport package. It is issued for a package model independently of the actual transport operation itself, for which no prior ASN opinion is generally required, but which may be subject to security checks (physical protection of materials against malicious acts under the supervision of the Defence and Security High Official from the Ministry of the Environment, Energy and the Sea).

If a package is unable to meet all the regulatory prescriptions, the regulations nonetheless allow for its transport by means of a shipment under special arrangement. The consignor must then define compensatory measures to ensure a level of safety equivalent to that which would have been obtained had the regulatory prescriptions been met. For example, if it cannot be completely demonstrated that a package is able to withstand the 9-m drop, a compensatory measure may be to reduce the speed of the vehicle and have it escorted. The probability of an accident (and thus of a violent shock on the package) is thus considerably reduced. A shipment under special arrangement is only possible with the approval of the competent authority, which then issues approval for shipment under special arrangement, describing the compensatory measures to be applied.

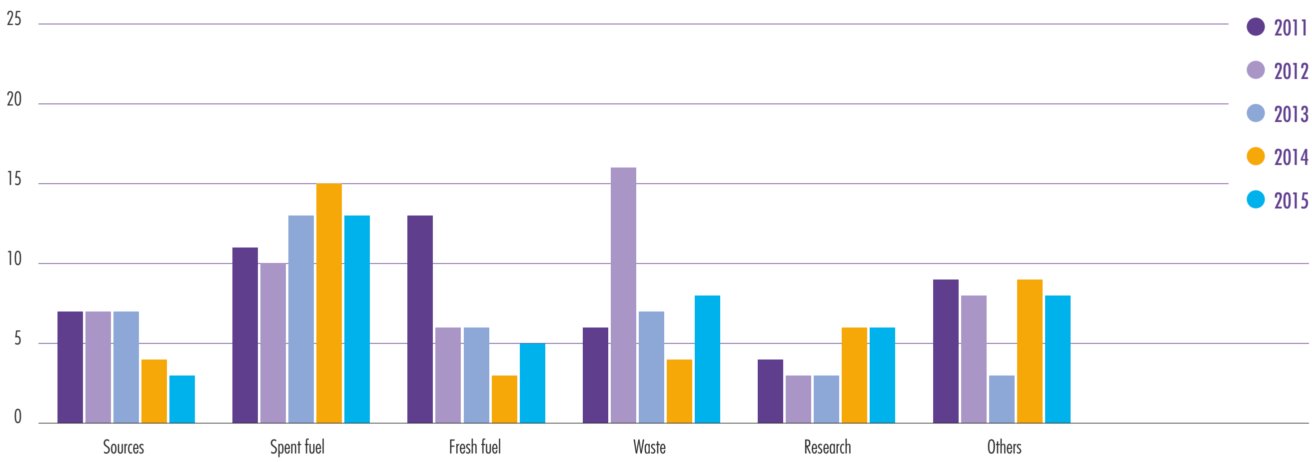
In the case of certificates issued abroad, the international regulations provide for their recognition by ASN. In certain cases, this recognition is automatic and the foreign certificate is directly valid in France. In other cases, the foreign certificate is only valid if validated by ASN, which then issues a new certificate.

ASN delivered 43 approval certificates in 2015, for which the breakdown by type is shown in graph 1. The nature of the transport operations concerned by these certificates is shown in graph 2.

GRAPH 1: Breakdown of the number of approvals according to type



GRAPH 2: Breakdown of the number of approvals according to their content



4.2 Monitoring all the stages in the life of a package and its shipment conditions

ASN performs inspections at all stages in the life of a package, from manufacture and maintenance through to package preparation, carriage and reception.

In 2015, ASN carried out 98 radioactive substance transport inspections (all sectors considered).

4.2.1 Package manufacturing inspections

The manufacture of transport packaging is subject to the regulations applicable to the transport of radioactive substances. In accordance with the regulatory requirements, each manufacturer of an approved package model must be able to provide ASN with all information needed to demonstrate the conformity of the manufacture of the packaging with the package model specifications. These specifications are defined in the safety file specific to each packaging, which contains the safety case for the package model. The safety file also sets packaging design goals. It contains everything relating to the prescriptions concerning the packaging and its content and to the tests required for the package model's safety case.

ASN manufacturing inspection on the CN2700 packaging in 2014.

The role of ASN is to check that the manufacturing specifications and the inspection procedures match up to the design requirements defined in the safety file and that they are correctly implemented.

The quality assurance system is applied and conformity with the safety file specifications is ensured in all the operations from procurement through to final inspection.

In 2015, ASN inspected the manufacture of forged parts for the first TN G3 packaging (package model currently being approved for the transport of spent fuels from NPPs) and the end of manufacturing tightness checks on the Manon overpack (package model approved for transport of sources). ASN also inspected the organisation set up for the manufacture of TN Gemini packagings, designed for the transport of alpha emitting operating waste, and that set up for the manufacture of the R73 and R75 packagings (package models approved for the transport of decommissioning waste and the transport of fuel rod cluster guides respectively).

The follow-up letters to these inspections are available on *www.asn.fr.*

During these inspections, ASN checks the quality assurance procedures implemented for the production of a package on the basis of the design data, and ensures that the inspections and any manufacturing deviations are traceable.

It also visits the manufacturing shops to check the package component storage conditions and the conformity of the various manufacturing operations (welding, assembly, etc.).

When subcontractors are used, ASN checks the monitoring of manufacturing by the manufacturer in charge and intervenes directly on the manufacturing sites, which are sometimes located in other countries. The manufacturing inspections on the TN G3 forged parts thus took place in Italy.

In parallel with these package manufacturing inspections, ASN inspects the manufacture of the specimens used for the regulatory drop tests and fire tests. The objectives are the same as for the series production model, because the specimens must be representative and comply with the maximum requirements indicated in the mock-up manufacturing file, which will determine the minimum characteristics of the actual packaging to be manufactured.

4.2.2 Packaging maintenance inspections

The consignor or user of a packaging filled with radioactive substances must be able to prove to ASN that this packaging is periodically inspected and, if necessary, repaired and maintained in good condition such that it continues to satisfy all the relevant requirements and specifications of its safety file and its approval certificate,

even after repeated use. For approved packagings, the ASN inspections concern the following maintenance activities, for example:
- the periodic inspections of the components of the containment system (screws, bolts, welds, seals, etc.);
- the periodic inspections of the securing and handling components;
- the frequency of replacement of the package components which must take account of any reduction in performance due to wear, corrosion, aging, etc.

In 2015, ASN carried out several inspections on the conformity of maintenance operations, in particular on the FS 47 packagings (package model approved for the transport of plutonium powder), TN MTR (package model approved for the transport of research fuel) and GMA 2 500 (industrial radiography device, approved as a package transporting a source).

4.2.3 Inspections of packages not requiring approval

For the packages that do not require ASN approval (see table 3), the consignor must, at the request of ASN, be able to provide the documents proving that the package design complies with the applicable prescriptions. More specifically, for each package, a certificate delivered by the manufacturer attesting full compliance with the design specifications must be held at the disposal of ASN.

The various inspections carried out in recent years confirm the improvements to the documents presented to ASN and the integration of the recommendations in ASN Guide No.7, volume 3, concerning packages which are not subject to approval.

In 2015, ASN completed its updating of this guide, which was published on 16th November. The manufacturers were asked to submit their comments concerning this update, which was opened for public consultation on the ASN website, from 1st to 30th June. The guide proposes a structure and a minimum content for the safety files demonstrating that packages which are not subject to approval do comply with all the applicable prescriptions, along with the minimum content of a declaration or a certificate of conformity of a package design with the regulations.

ASN thus noted improvements in the content of the certificate of conformity and the safety file drawn up by the participants concerned, more specifically for the industrial package models. However, the designers of type A package models must continue to make efforts, notably on the representative nature of the tests performed and the associated safety case.

Furthermore, ASN still finds that some of the entities concerned (designers, manufacturers, distributors, owners, consignors, companies performing the regulatory drop tests, package maintenance, etc.) display shortcomings in the demonstration of package conformity with the regulations. The areas for improvement remain in particular the following:
- the description of the authorised contents per type of package;
- demonstration that there has been no loss or dispersion of the radioactive content under normal transport conditions;
- compliance with the regulatory radiation protection requirements;
- the representativeness of the tests performed.

4.2.4 Inspections of the shipment of packages of radioactive substances

ASN devotes more than half of its transport inspections to checking shipments and carriers, at both regional and national levels.

During these inspections, the checks concern all regulatory requirements binding on each of the transport stakeholders, that is compliance with the requirements of the approval certificate or declaration of conformity, training of the personnel involved, implementation of a quality assurance programme, satisfactory stowage of packages, dose rate and contamination measurements, documentary conformity, etc.

Among the observations or findings formulated further to the inspections, the most frequent discrepancies concern quality assurance and documentation, or compliance with procedures as indicated in the approval certificates, safety files, or the regulatory texts in general.

ASN's inspections reveal deficiencies in the knowledge of the regulations and responsibilities on the part of the transport stakeholders in small-scale nuclear activities.

Knowledge of the regulations applicable to the transport of radioactive substances seems to be substandard in the medical sector in particular, where the measures taken by some hospitals or nuclear medicine units when returning radionuclide packages after use and shipping sources for maintenance need to be tightened.

ASN has moreover observed that an increasing number of BNIs are using outside contractors to prepare and ship packages of radioactive substances. ASN is particularly attentive to the monitoring of these contractors.

TO BE NOTED

Inspection of the transport of Swiss vitrified waste

A consignment of vitrified nuclear waste was shipped from the Sellafield plant in England to Switzerland, passing through France, which it entered via the port of Cherbourg on 14th September 2015. This consignment was taken by road to the rail terminal in Valognes where the packages were loaded onto rail wagons. The consignment left the country on 18th September. It comprised three TN 81 packages, each containing 28 CSD-V containers of vitrified waste. These containers contain fission products in a glass matrix, inside a metal container. The fission products are the chemical bodies resulting from the fission of uranium in nuclear reactors. They are extracted during reprocessing of the spent nuclear fuel and constitute the ultimate waste from the production of electricity using nuclear energy. These wastes are high level, long-lived. The total activity of the consignment is about 1.15×10^{18} Bq, or an average of 3.83×10^{17} Bq per TN 81 package. These activity levels are comparable to those of the packages containing spent fuels taken from the French NPPs for shipment to the reprocessing plant at La Hague. The TN 81 package model, designed by the Areva TN company, has been approved by ASN.

ASN carried out an inspection on the safety of the consignment on 15th September, at package transhipment in the Valognes rail terminal. The inspectors were accompanied by an inspector from the Swiss safety regulator, as well as a team from IRSN, which took measurements on the packages and then on the loaded wagons, in order to verify compliance with the regulation limits for dose equivalent rate and contamination. Two members of associations represented on the High Committee for Transparency and Information on Nuclear Security (HCTISN) attended a part of the inspection They were able to observe the handling operations on the third package, as well as the radioactivity and contamination measurements taken on this package and on the wagon containing it.

The ASN inspection gave rise to a follow-up letter, which is available on the ASN website. The inspectors considered that the safety level of the transport operation was satisfactory, but they nonetheless made three requests for corrective measures. The measurements taken by IRSN produced values below the regulation limits for the contamination levels and dose equivalent rates.

ASN transport inspection in Valognes - TN 81 type B fissile package, used to transport vitrified waste, September 2015.

4.2.5 Management of transport safety

At the end of 2012, ASN conducted three technical visits to the major players in radioactive substance transport for the fuel cycle, namely Areva, EDF and CEA, in order to assess the management of safety in this area. Analysis of these visits led to the follow-up letters published on *www.asn.fr* in 2013. ASN continued its efforts on this topic, by carrying out a specific inspection at Areva TN in 2015. Among the main recommendations, ASN asks that the general transport organisation take account of subcontracting, that the individual and collective expertise of the participants in the transport of radioactive substances be put to best use and that operations that are important for safety be clearly identified. Finally, ASN considers that in certain cases, consideration should be given to a method for recording and analysing experience feedback from all transport activities, involving the packaging users.

4.2.6 Preparedness for emergency management

Emergency management is the final barrier in the defence in depth system. In the event of an accident involving transport, it should be able to minimise the consequences for the public and the environment. In order to reinforce the preparedness of the industry (consignors and carriers) for emergency management, ASN published a guide in December 2014 on the content of accident and incident management plans concerning the transport of radioactive substances. This guide recommends the drafting of plans to prepare for emergency management and stipulates the minimum content of these plans.

In order to check correct application of this guide, ASN carried out two inspections in 2015 on the topic of preparedness for emergency situations. The inspectors in particular looked at the organisation in place, the material and human resources available, the personnel training and the emergency exercises held. ASN also asked the industrial firms involved in transport operations with the highest potential consequences to send it their plans so that they could be analysed in detail.

The public authorities are also preparing for the possibility of an accident involving the transport of radioactive substances. On 1st October 2015, ASN thus took part in an emergency exercise involving the Prefecture and emergency services, simulating an accident in the Saône-et-Loire *département*.

4.2.7 Analysis of incidents

By listing and analysing the various transport incidents, ASN can identify the problems encountered by the transport operators and the possible safety risks, in order to improve current practices and identify any need for changes to the regulations.

ASN must be notified of any deviation from the regulations or the safety files applicable to the transport of radioactive substances; this notification should conform to the events notification guide, as required by Article 7 of the Order of 29th May 2009 concerning the transport of dangerous goods by road (TMD Order). This events notification guide was communicated by letter to the various stakeholders in the transport of radioactive substances on 24th October 2005 and can be consulted on *www.asn.fr*. It defines the various conditions of notification and rating of transport events on the INES scale. In addition to the notification, a detailed incident report must be sent to ASN within two months.

Events declared in 2015

In 2015, ASN was notified of fifty-six level 0 events, nine level 1 events and one level 2 event in the field of radioactive substances transport. Graph 3 shows the trend for the number of events notified since 2000.

Areas of activity concerned by these events

More than half of the events are notified by the industrial stakeholders in the nuclear cycle (EDF and Areva in particular). About one fifth of the significant events concern radioactive pharmaceutical products. The other events concern transport related to non-nuclear industrial activities (gamma radiography for example).

Very few transport-related events are linked to the non-nuclear industry sectors, when compared with the corresponding traffic levels. This small number of events is probably due to small-scale nuclear activity professionals failing to submit notifications, which can be explained by unfamiliarity with the events notification process.

TO BE NOTED

Level 2 event: non-compliance with safety prescriptions during transport of a gamma ray projector

On 16th March 2015, ASN was informed by the ECW company that a gamma ray projector from the ECW agency at Courcelles-les-Lens (Pas-de-Calais) had been carried on the public highway on 2nd March 20155 in breach of a number of the requirements set out in the transport approval issued by ASN: the device was not in the closed and locked position and was equipped with its worksite accessories, which prevented it from being fully inserted into its transport casing.

Gamma ray projectors are devices used in industrial radiography to detect defects in materials. They contain a high-level radioactive source in a shielded compartment, from which it is only deployed when actually carrying out radiographic examinations (see diagram in chapter 10, p. 342). This compartment, which provides radiological protection, must be secured by a closure system during transport of the gamma ray projector (closed and locked position). Given the activity level of their source, gamma ray projectors must be transported in packages approved by ASN.

The deviations notified to ASN increased the risk of ejection of the radioactive source from its shielding in the event of an accident. The consequences of such a scenario could be significant irradiation of persons in the immediate vicinity of the site of the accident.

The presence of a collimator on the device and the measurements taken after transport by the ECW company indicate that no abnormal beam emerged from the device during transport. However, as the device was not in the locked and closed position, this cannot be absolutely guaranteed.

Following notification of this event, ASN carried out two reactive inspections in the premises of the ECW agency in Courcelles-les-Lens on 26th March and 14th April. A number of deviations were noted by the inspectors, indicating a lack of safety culture within the agency. The ECW company was thus asked to take corrective measures. The inspection follow-up letters can be consulted on the ASN website.

Given the potential consequences in terms of public and worker exposure, ASN rated the transport part of this event at level 2 on the 8-level (0 to 7) international nuclear and radiological events scale (INES).

The contents concerned by the event notifications are extremely varied: radionuclides for medical uses, contaminated material, fuel, empty packaging, etc. Graph 4 shows the distribution of notified transport events according to content and mode of transport.

Causes of events

The most frequent causes of notified significant events are the regulation contamination limits on the package or conveyance being exceeded. Steps have been taken by the industry to reduce the number of these events.

The other causes of significant events recorded include:
- documentary, package labelling and vehicle placarding errors;
- defective stowage or handling accidents, which can lead to package damage;
- theft or loss of radiopharmaceutical packages.

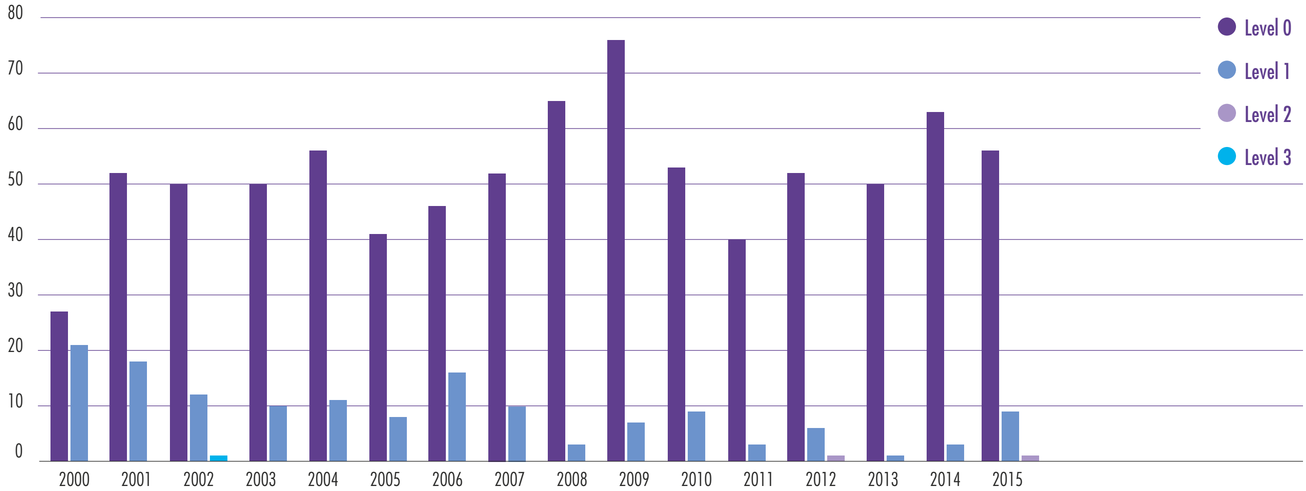
The breakdown of notified transport events according to package content and mode of transport is illustrated in graph 4.

4.3 Participation in drawing up the regulations applicable to the transport of radioactive substances

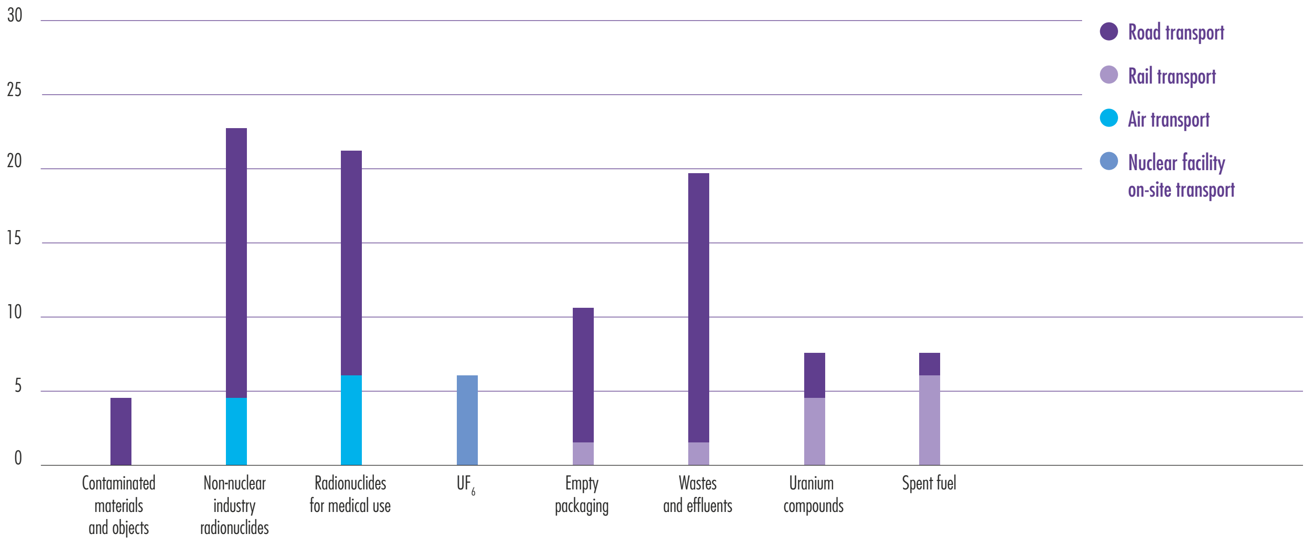
4.3.1 Participation in the work of IAEA

ASN represents France on the Transport Safety Standards Committee (TRANSSC) which, under IAEA supervision, brings together experts from all countries in order to draw up the source document for regulations concerning the transport of radioactive substances. The current edition of this document dates from 2012 and carries

GRAPH 3: Trend in the number of radioactive substance transport incidents or accidents notified between 2000 and 2015



GRAPH 4: Breakdown of notified transport events by content and mode of transport in 2015



number SSR-6. The most important changes with respect to the 2009 edition concern criticality safety, with the modification of the configurations of substances classified as excepted fissile substances, materials for which no demonstration of criticality safety is required at present, subject to compliance with the weight limits per package and per consignment. These modifications could more particularly have an impact on the transport of waste containing fissile radionuclides, which will become subject to safety demonstration constraints.

In 2015, a new revision cycle for the SSR-6 was initiated. ASN thus submitted SSR-6 modification proposals to the TRANSSC, after having them validated by the GPT. At the November meeting of the TRANSSC, the committee voted in favour of a revision of the SSR-6. The revision cycle is not however over and at least another three years will be needed before a new edition can be produced.

4.3.2 Participation in drafting of national regulations

ASN takes part in the drafting of French regulations relative to the transport of radioactive materials. These regulations mainly consist of the TMD Order and the Orders of 23rd November 1987 concerning the safety of ships and of 18th July 2000 concerning the transport and handling of dangerous materials in sea ports. In this respect, ASN sits on the CITMD (Interministerial Hazardous Materials Transport Committee) that is consulted for its opinion on any draft regulations concerning the transport of dangerous goods by rail, road or inland waterway. ASN is also consulted by the Ministry responsible for the Environment when a modification of the three Orders mentioned above can have an impact on the transports of radioactive substances.

Signage attached to packages of radioactive substances.

TO BE NOTED

ASN resolution on the notification system for companies transporting radioactive substances on French territory

On 12th March 2015, the ASN Commission adopted a resolution creating an ASN notification obligation for all companies transporting radioactive substances in full or in part on French territory. This notification concerns the carriers, but also the companies loading, unloading and handling the packages. In the event of an emergency in which human safety is at stake, Article 5 of the resolution enables ASN to suspend the activities which require notification.

The information obtained will be made available to the ASN regional divisions. It will in particular provide a means of contacting the company, including in an emergency, of estimating the nature and volume of the activity and identifying the places of loading, unloading and transit storage of the packages. It will also allow improved targeting of the ASN inspections.

This resolution is issued pursuant to Article R. 1333-44 of the Public Health Code, which makes provision for an ASN resolution to define transport activities subject to an authorisation system and those subject to a notification system. As a result of this resolution, the provisions of the Labour Code concerning the prevention of risks linked to ionising radiation will apply in full to transport companies which are subject to the notification obligation.

This resolution was approved by the Minister responsible for Nuclear Safety and Transports on 24th July 2015. The resolution came into effect on 1st January 2016.

4.4 Participation in international relations in the transport sector

International regulations were drafted and are implemented as a result of fruitful exchanges between countries. ASN includes these exchanges as part of a process of continuous progress in the level of safety of radioactive substance transports, and encourages exchanges with its counterparts in other States.

4.4.1 Participation in the work of the European Association of Competent Authorities on transport

The European Association of Competent Authorities on the Transport of Radioactive Material (EACA) was created in December 2008. Its purpose is to promote the harmonisation of practices in the regulation of the safety of transport of radioactive substances, and to encourage exchanges and experience feedback between the various Authorities. The plenary meeting of May 2015 was for example an opportunity to discuss the lessons learned from certain incidents, the implementation of the new regulatory measures and the contents of a guide designed to harmonise the practices of the various authorities when examining the package model safety files.

4.4.2 Bilateral relations with ASN's foreign counterparts

ASN devotes considerable efforts to maintaining close ties with the competent authorities of the countries concerned by the numerous shipments to and from France. Prominent among these are Belgium, the United Kingdom, Ireland, Germany and Switzerland.

Germany

The French and German Authorities have decided to meet regularly to discuss a range of technical subjects. Numerous shipments cross the Franco-German border. ASN participates in the Franco-German technical committees concerning the schedule for returning the waste resulting from the reprocessing of German spent nuclear fuel. A new package is currently being designed in Germany for the transport of compacted waste. In this context, ASN is involved in the definition of the packaging specifications, equivalent to the safety option file in France, and it will participate in the technical meetings concerning the drop tests when the time comes.

Belgium

For its production of electricity from nuclear power, Belgium uses French-designed containers for fuel cycle shipment. In order to harmonise practices and achieve progress in the safety of these shipments, ASN and the competent Belgian Authority (Belgian Federal Nuclear Regulating Agency - AFCN) regularly exchange know-how and experience.

Since 2005, an annual exchange meeting has been held by ASN and AFCN in order to make a closer examination of the safety files for the French package designs validated in Belgium and to discuss inspection practices in each country. In 2014, an AFCN inspector observed an emergency exercise organised by ASN, together with the Prefecture of the Vaucluse département, involving a shipment of radioactive substances.

United Kingdom

Over the last few years ASN and the United Kingdom's Office for Nuclear Regulation (ONR) have developed close ties. Both countries underwent a review coordinated by IAEA, demonstrating the high level of competence of the two authorities with regard to radioactive substances transport, thus enhancing their mutual trust and confidence.

Against this backdrop, ASN and the ONR signed a memorandum of understanding on 24th February 2006, for the mutual recognition of the approval certificates confirming the safety of radioactive substances transport.

Having successfully cooperated on the Memorandum of Understanding signed in February 2006, ASN and the ONR extended their cooperation on the following subjects, through an agreement concluded on 27th February 2008:
- licensing procedures;
- inspections;
- emergency procedures;
- guides for domestic and international transport of radioactive substances;
- radioactive substance transport standards;
- quality assurance systems.

Since 2006, annual discussion meetings have been held by ASN and ONR, more specifically concerning the examination of safety files for the package models used in the United Kingdom and France.

Switzerland

ASN began bilateral exchanges with the Swiss Federal Nuclear Safety Inspectorate (IFSN) in 2012.

ASN and IFSN meet regularly to discuss the packaging model safety files and the checks on the prescriptions associated with the correct utilization of these transport packages. A joint ASN-IFSN inspection was carried out to check the conformity of the transport of Swiss vitrified waste in September 2015 (see box p. 360). An IFSN inspector took part as an observer in the transport emergency exercise of 1st October 2015.

5. ASN OPINION ON THE SAFETY OF TRANSPORT OF RADIOACTIVE SUBSTANCES AND PROSPECTS

Reinforced safety requirements relating to on-site transport operations performed within the perimeter of BNIs

The requirements concerning on-site transport operations performed within the perimeter of BNIs were reinforced on 1st July 2013 with the entry into force of the main provisions of the BNI Order. The vast majority of the nuclear sites concerned did not make sufficient efforts to ensure that the necessary changes were made to the existing safety baseline requirements in order to guarantee conformity with the regulations in 2013.

Compliance with the regulatory requirements will be closely monitored by ASN in 2016, more particularly with regard to transport operations on EDF NPP sites and on the La Hague site, for which the general operating rules are currently being examined. In addition, the correct working of the internal authorisations system granted in 2013 (for CEA's BNIs) and 2014 (for the Melox BNI and for the BNIs on the Tricastin, Romans-sur-Isère and Malvési sites) will be checked with respect to the procedures adopted by the licensees on the one hand and with respect to the resolutions issued by ASN on the other.

Taking account of notification by carriers of radioactive substances

In 2015, ASN issued a resolution creating a notification system for companies transporting radioactive substances (see box p. 363). This notification system, which came into force on 1st January 2016, will make it possible to draw up an exhaustive list of the carriers of radioactive substances, in order to facilitate their monitoring by means of ASN inspections. On this occasion, ASN will conduct a survey of these companies, in order to gain a clearer understanding of their practices and make them more fully aware of safety and radiation protection rules.

Continuation of inspections of packages that are not subject to ASN approval

When taken individually, the packages not subject to approval represent little danger and accidents involving them have so far had limited radiological health consequences. ASN must however remain vigilant given the very large number of these packages and the sometimes inadequate safety culture of those involved in the transport operations.

Regulatory compliance for packages not subject to approval has on the whole improved with regard to industrial type packages, but ASN considers that this situation is not yet satisfactory for type A packages. Inspections more particularly targeting the verification of the safety files (definition of content, stowage, etc.) and on the certificates associated with type A packages will therefore be carried out again in 2016.

Continuation of inspections in the manufacture and maintenance of transport packages subject to ASN approval

The design of transport packages requiring ASN approval is inspected in depth during the examination of the approval request. Once it has been ascertained that the package design complies with the regulatory requirements, its manufacture and subsequent routine maintenance in accordance with the requirements of its safety file must be verified. ASN has planned to maintain a large number of inspections in this area in 2016, particularly with regard to the maintenance of the oldest packagings.

Improved emergency situation preparedness

In December 2014, ASN published a guide for drafting emergency plans by those involved in transport operations, more specifically the carriers and consignors. In 2016, ASN will continue its inspections to ensure that the recommendations of this guide are implemented satisfactorily.

ASN will also continue to work towards achieving a satisfactory level of preparedness by the public authorities for emergency situations involving a transport operation, in particular by carrying out more exercises and distributing emergency management tools.

Transparency in the area of transport

Growing public and media interest in the transport of radioactive substances was observed for several international shipments organised in 2011. Consequently, ASN has made it a priority to develop the information made available to the public concerning the regulation of the safety of transport of radioactive substances. After devoting an issue of *Contrôle* magazine to this topic in 2012, ASN completed the educational file on its website with an analysis of radioactive substances traffic volumes and published an information brochure intended for the public in 2014. On the occasion of the transport of Swiss vitrified waste, which crossed France in September 2015, ASN published an information notice on its website presenting this transport operation and the checks it carried out.

In 2016, ASN will take part in the National Association of local information committees and commissions (Anccli) seminar on the topic of transport.

12

EDF nuclear power plants (NPPs)

Regulation of NPPs is a traditional duty of ASN. Nuclear power reactors are at the heart of the nuclear industry in France. Many other installations described in the other chapters of this report produce the fuel intended for NPPs or reprocess it, are used for disposal of the waste produced by NPPs, or are used to study the physical phenomena related to the operation and safety of these reactors. The French reactors are technologically similar to each other and form a standardised fleet operated by *Électricité de France* (EDF). Although this standardisation enables the licensee and ASN to acquire extensive experience of the operation of the French nuclear power generating reactors, it does entail an increased risk in the event a design or maintenance fault is detected on one of these facilities. ASN thus requires a high degree of responsiveness on the part of EDF when analysing the generic nature of these faults and their consequences for the protection of people and the environment.

ASN requires the highest level of safety standards for regulating NPPs and adapts the standards continuously in the light of new knowledge. Monitoring the safety of the reactors in service, under construction and planned for the future, is the daily task of around 200 members of ASN staff working in the Nuclear Power Plant Department (DCN) and the Nuclear Pressure Equipment Department (DEP), and of the staff of the regional divisions. It also requires the support of some 200 experts from the Institute for Radiation Protection and Nuclear Safety (IRSN).

ASN is developing an integrated approach to regulation that covers not only the design of new facilities, their construction, modification, integration of feedback on events or maintenance problems but also the fields of human and organisational factors, radiation protection, environmental protection, worker safety and the application of labour legislation. This integrated approach allows ASN to develop a finer appreciation and decide on its position each year with regard to the current status of nuclear safety, radiation protection and the environment with respect to NPPs.

1. OVERVIEW OF NUCLEAR POWER PLANTS

1.1 General presentation of a pressurised water reactor

In routing heat from a heat source to a heat sink, all thermal electric power plants produce mechanical energy, which they then transform into electricity. Conventional power plants use the heat given off by the combustion of fossil fuels (fuel oil, coal, gas). Nuclear plants use the heat resulting from the fission of uranium or plutonium atoms. The heat produced is used to vaporise water. The steam is then expanded in a turbine which drives a generator producing a 3-phase electric current with a voltage of 400,000 V. After expansion, the steam passes through a condenser where it is cooled on contact with tubes circulating cold water from the sea, a river or an atmospheric cooling circuit.

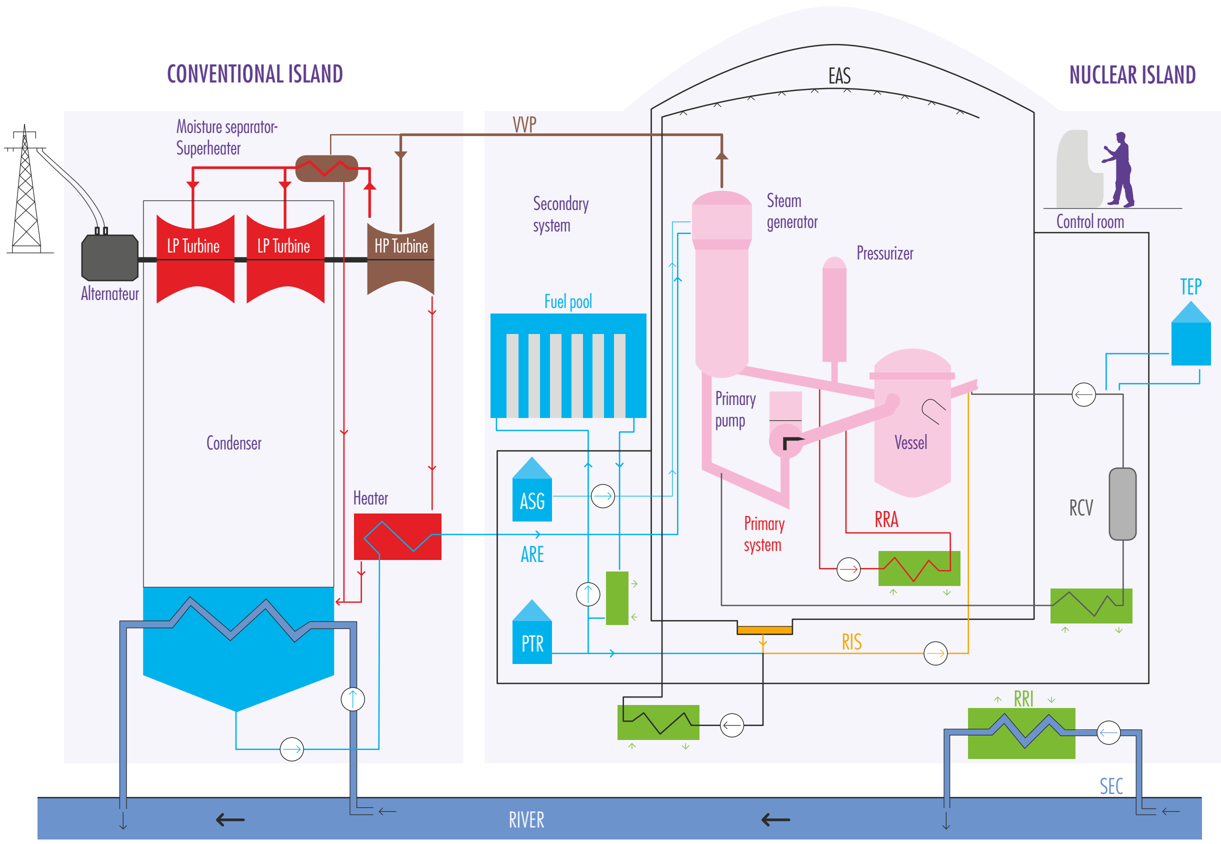
Each reactor comprises a nuclear island, a conventional island, water intake and discharge infrastructures and possibly a cooling tower.

The nuclear island mainly consists of the reactor vessel, the reactor coolant system, the steam generators and the circuits and systems ensuring reactor operation and safety: the chemical and volume control, residual heat removal, safety injection, containment spray, steam generator feedwater, electrical, I&C and reactor protection systems. Various support function systems are also associated with these elements: primary effluent treatment, boron recovery, feedwater, ventilation and air-conditioning, and backup electrical power (diesel generating sets).

The nuclear island also comprises the systems removing steam to the conventional island (Steam Shutoff Valve on the VVP) as well as the building housing the Fuel Storage pool (BK). This building, which adjoins the reactor building, is used to store new and spent fuel assemblies (one third or one quarter of the fuel is replaced every 12 to 18 months depending on the reactor operating modes). The fuel is kept submerged in cells in the pool. The pool water, mixed with boric acid, on the one hand absorbs the neutrons emitted by the nuclei of the fissile elements to avoid sustaining a nuclear fission reaction and, on the other, acts as a radiological barrier.

The conventional island equipment includes the turbine, the AC generator and the condenser. Some components of

THE PRINCIPLE of pressurised water reactor operation



this equipment contribute to reactor safety. The secondary systems belong partly to the nuclear island and partly to the conventional island.

The PWR reactor safety case is based on the application of the principle of defence in depth (see chapter 2, point 1.2.2).

1.2 Core, fuel and fuel management

The reactor's core consists of fuel assemblies in the form of "rods" comprising "pellets" of uranium oxide or oxides of depleted uranium and plutonium (known as MOX fuel) contained in closed metal tubes, referred to as the "cladding". As a result of fission, the uranium or plutonium nuclei, referred to as «fissile», emit neutrons which, in turn, produce further fissions: this is known as the chain reaction. These nuclear fissions release a large amount of energy in the form of heat. The primary system water enters the core from below at a temperature of about 285°C, heats up as it flows up along the fuel rods and exits through the top at a temperature close to 320°C.

At the beginning of the operating cycle, the core has a considerable energy reserve. This gradually falls during the cycle, as the fissile nuclei disappear. The chain reaction, and hence reactor power, is controlled by:
- inserting control rod cluster assemblies, which contain elements that absorb neutrons, to varying depths in the core. These enable the reactor to be started and stopped and its power level to be adjusted to the electrical power to be produced. Dropping the control rod assemblies under the effects of gravity enables the reactor to be shut down in an emergency;
- adjusting the level of boron (which absorbs neutrons) in the primary system water during the cycle as the fissile material in the fuel gradually becomes depleted.

At the end of the cycle, the reactor core is unloaded for renewal of part of the fuel.

EDF uses two types of fuels in its pressurised water reactors:
- uranium oxide based fuels (UO_2) with uranium-235 enrichment to a maximum of 4.5%. These fuels are fabricated in several plants in France and abroad, which belong to the fuel manufacturers Areva NP and Westinghouse;
- fuels consisting of a mixture of depleted uranium oxides and plutonium (MOX). The MOX fuel is produced by the Areva NC Melox plant. The initial plutonium content is currently limited to 8.65% (average per fuel assembly) and provides an energy performance equivalent to UO_2

fuel enriched to 3.7% with uranium-235. This fuel can be used in the twenty-eight 900 MWe reactors for which the Creation Authorisation Decrees (DAC) provide for the use of MOX fuel.

The way in which the fuel is used in the reactors, known as "fuel management", is specific to each reactor plant series. It is, in particular, characterised by:
- the nature of the fuel used and its initial fissile content;
- the maximum degree of fuel depletion at removal from the reactor, characterising the quantity of energy extracted per ton of material (expressed in GWd/t);
- the duration of a reactor operating cycle;
- the number of new fuel assemblies loaded at each reactor refuelling outage (generally 1/3 or 1/4 of the total number of assemblies);
- the reactor operating mode (at constant power or by varying the power to match demand), which determines the loads to which the fuel is subjected.

1.3 Primary system and secondary systems

The primary system and the secondary systems transport the energy given off by the core in the form of heat to a turbo-generator set which produces electricity.

The primary system consists of cooling loops (three loops for a 900 MWe reactor and four for a 1,300 MWe, 1,450 MWe or 1,650 MWe type EPR reactor). The role of the primary system is to extract the heat given off in the core by circulating pressurised water, referred to as the primary or reactor coolant water. Each loop, connected to the reactor vessel containing the core, comprises a circulating pump (known as the primary or reactor coolant pump) and a Steam Generator (SG). The primary water, heated to more than 300°C, is kept at a pressure of 155 bar by the pressuriser, to prevent it from boiling. The entire primary system is located inside the containment.

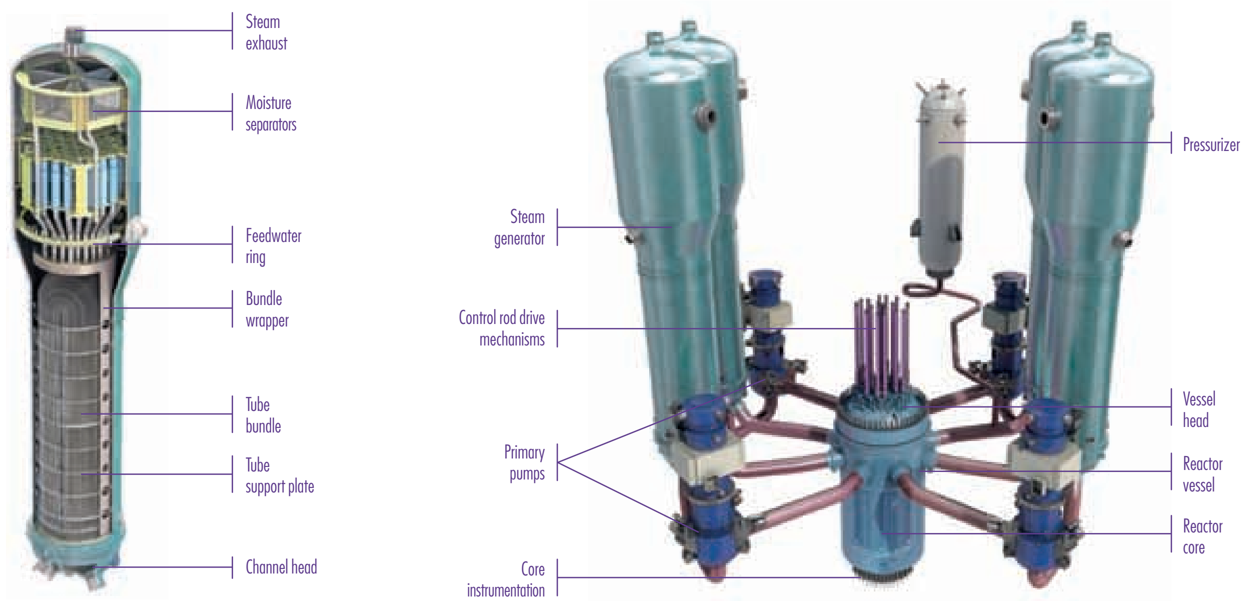
The primary system water transfers the heat to the secondary system water via the steam generators. The steam generators are exchangers that contain 3,500 to 5,600 tubes, depending on the model, through which the primary reactor coolant water circulates. These tubes are immersed in the water of the secondary system and boil it, without ever coming into contact with the primary water.

Each secondary system principally consists of a closed loop through which water runs in liquid form in one part and as steam in the other part. The steam produced in the steam generators is partly expanded in a high-pressure turbine and then passes through moisture separators before final expansion in the low-pressure turbines, from which it is then routed to the condenser. The condensed water is then heated by reheaters and sent back to the steam generators by the condensate extraction pumps and the feedwater pumps.

1.4 The secondary system cooling system

The function of the secondary system cooling system is to condense the steam exiting the turbine. This is achieved by a condenser comprising a heat exchanger containing thousands of tubes through which cold water from outside (sea or river) circulates. When the steam comes into contact with the tubes it condenses and can be returned in liquid form to the steam generators (see point 1.3). The cooling system water that is heated in the condenser

A STEAM GENERATOR and a main primary system of a 1,300 MWe reactor



is then discharged to the natural environment (open circuit) or, when the river flow is too low or heating too great in relation to the sensitivity of the environment, it is cooled in a cooling tower (closed or semi-closed circuit).

The cooling systems are environments favourable to the development of pathogenic micro-organisms. Replacing brass by titanium or stainless steel in the construction of riverside reactor condensers, in order to reduce metal discharges into the natural environment, requires the use of disinfectants, mainly by means of biocidal treatment. Cooling towers can contribute to the atmospheric dispersal of legionella bacteria, whose proliferation can be prevented by reinforced treatment of the structures (descaling, implementation of biocidal treatment, etc.) and monitoring.

1.5 Reactor containment building

The PWR containment building has two functions:
- confine radioactive products likely to be dispersed in the event of an accident. The containments are therefore designed to withstand the pressures and temperatures that could result from the most severe reactor loss of coolant accident and offer sufficient leaktightness in such conditions.
- protect the reactor against external hazards.

Two different containment models have been designed:
- the 900 MWe reactor containments, consisting of a single wall of pre-stressed concrete (concrete containing steel cables tensioned to ensure compression of the structure). This wall offers mechanical resistance to pressure, as well as structural integrity with regard to an external hazard. Leaktightness is provided by a metal liner covering the entire inner face of the concrete wall;
- the 1,300 MWe and 1,450 MWe reactor containments consisting of two walls: an inner wall made of pre-stressed concrete and an outer wall made of reinforced concrete. Leaktightness is provided by the inner wall and the ventilation system which collects and filters residual leaks from the inner wall before discharge. Resistance to external hazards is mainly ensured by the outer wall.

1.6 The main auxiliary and safeguard systems

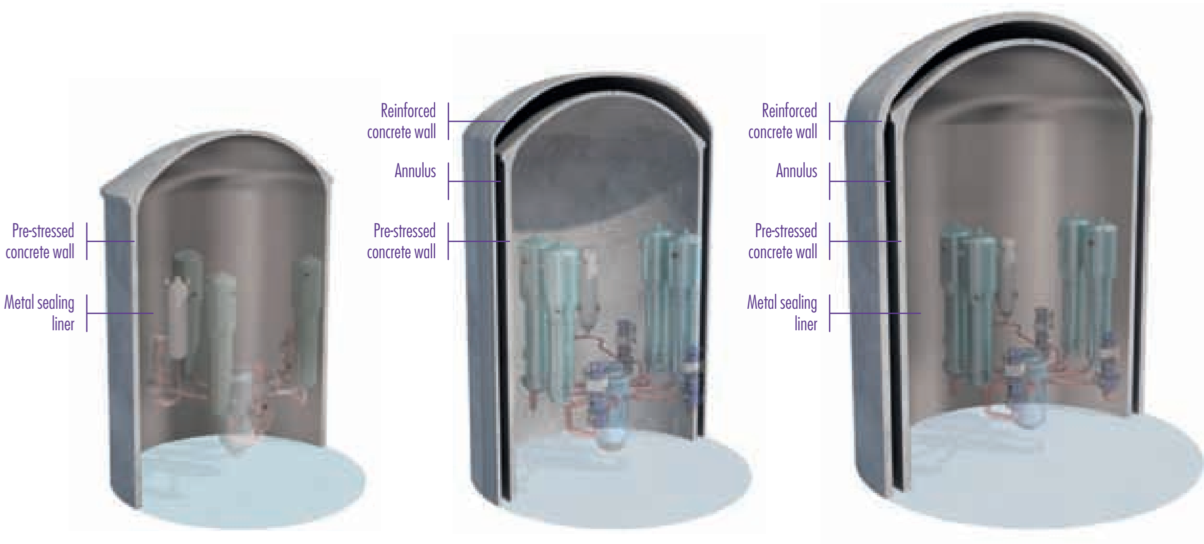
In normal operating conditions, at power, or in reactor outage states, the auxiliary systems control nuclear reactions, remove heat from the primary system and residual heat from the fuel and provide containment of radioactive substances. This chiefly involves the Chemical and Volume Control System (RCV) and the Residual Heat Removal System (RRA).

The purpose of the safeguard systems is to control incidents and accidents and mitigate their consequences. This chiefly concerns the following systems:

ASN inspection in Dampierre-en-Burly NPP, July 2015.

- the Safety Injection System (RIS), the role of which is to inject water into the primary system in the event of its leaking;
- the reactor building Containment Spray System (EAS), the role of which is to reduce the pressure and temperature in the containment in the event of a primary system leak accident;
- the Steam Generators Auxiliary feedwater system (ASG), which supplies water to the SGs if the normal feedwater system is lost, thus enabling heat to be removed from the primary system.

REACTOR containments



900 MWe reactor containments

1,300 MWe/ 1,450 MWe reactor containments

1,650 MWe reactor containments

1.7 Other systems important for safety

The other main systems or circuits important for safety and required for reactor operation are:

- the Component Cooling System (RRI), which cools a number of nuclear equipment items; this system operates in a closed loop between the auxiliary and safeguard systems on the one hand, and between the systems carrying water from the river or the sea (heat sink) on the other;
- the Essential Service Water System (SEC), which uses the heat sink to cool the Component Cooling System;
- the Reactor Cavity and Spent Fuel Pool Cooling and Treatment System (PTR), used notably to remove residual heat from fuel elements stored in the fuel building pool;
- the ventilation systems, which confine radioactive materials by depressurising the premises and filtering all discharges;
- the fire protection water systems;
- the instrumentation and control system;
- the electrical systems.

2. NUCLEAR SAFETY

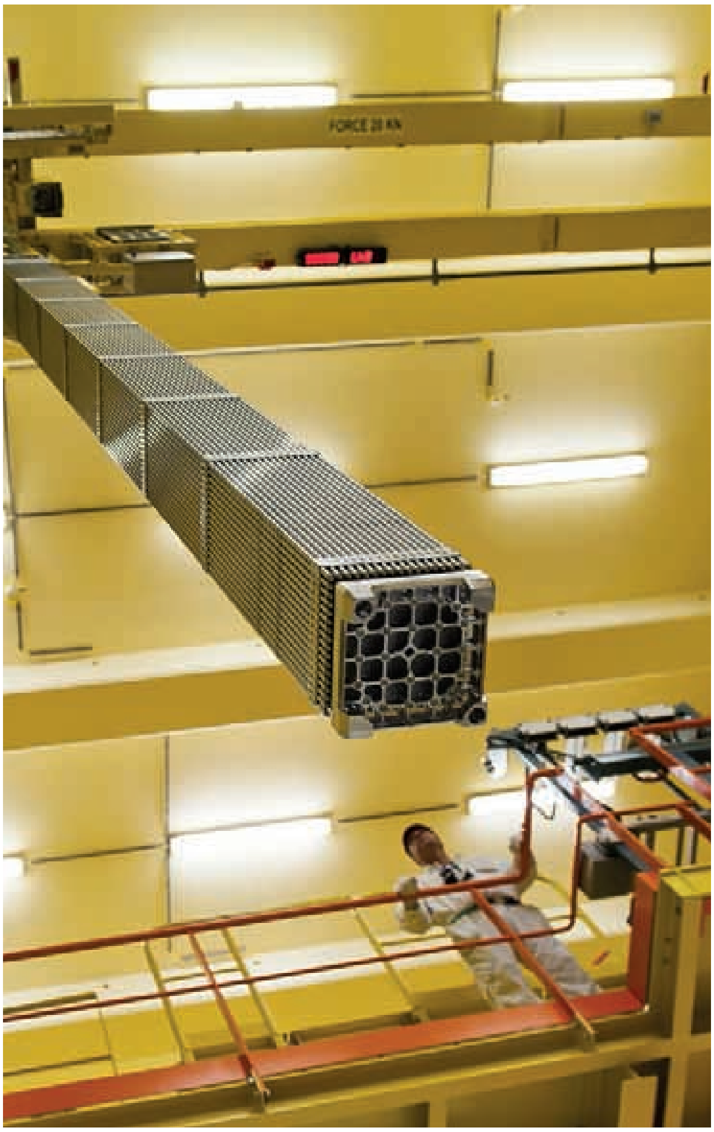
2.1 Social, organisational and human factors

The contribution of people and organisations to the safety of NPPs is a decisive factor in all steps of the plant lifecycle (design, construction, commissioning, operation, decommissioning). ASN therefore focuses on the conditions which are favourable or prejudicial to a positive contribution to NPP safety by the operators and worker groups. ASN defines Social, Organisational and Human Factors (SOHF) as being all the aspects of working situations and of the organisation that will have an influence on the work done by the operators.

The Order of 7th February 2012 setting the general rules for Basic Nuclear Installations (BNIs), requires that the licensee define and implement an Integrated Management System (IMS) designed to ensure that the safety, radiation protection and environmental protection requirements are systematically taken into account in all decisions concerning the facility. The IMS specifies the steps taken with regard to all types of organisation and resources, in particular those adopted to manage important activities. ASN thus asks the licensee to set up an IMS able to maintain and continuously improve safety, notably through the development of safety culture. The Order of 7th February 2012 also requires that the subsequent analysis of significant events determine organisational and human causes in addition to technical causes through an in-depth assessment.

ASN's oversight of organisational and human aspects is in particular based on inspections which concern the measures taken by the licensee to take account of SOHF in all phases of the lifecycle of an NPP. ASN thus regulates engineering activities during the design of a new facility or the modification of an existing one. ASN in particular ensures that the design approach used by the licensee is "focused on the human operator". In addition, the inspections carried out by ASN concern the activities performed for the operation of existing NPPs, the conditions in which these activities are performed (accessibility of premises, noise, heat and light environment, etc.) and the means made available to those concerned (tools, operating documents, etc.). ASN also checks the organisation put into place by EDF to manage the skills and staffing needed to perform these activities. The same applies to the resources, skills and methodology used for implementation of the SOHF approach by EDF. ASN also monitors the EDF safety management system, which must provide a framework and support for the decisions and actions which either directly or indirectly concern safety issues. Finally, ASN monitors EDF's organisation for analysing events, the depth of the analyses carried out to ensure that the root causes are investigated, as well as the preparation and implementation of the follow-up to these analyses.

In addition to the inspections, ASN oversight is based on the evaluations it requests from IRSN and the Advisory Committee for Nuclear Reactors (GPR). For example, the GPR was asked in 2013 to give its opinion on the topic of safety and radiation protection management during reactor outages and, in 2015, on the control of outsourced maintenance activities by EDF in NPPs and on examination of the organisational, human and technical resources used to control the EPR reactor.



MOX fuel assembly in the loading area in the Melox facility (MOX fuel fabrication plant).

2.2 Reactor operation

2.2.1 Operation in normal conditions: ensuring compliance with operating rules and examining changes to documents and hardware

The General Operating Rules (RGE) cover the operation of nuclear power reactors. They constitute the operational implementation of the hypotheses and conclusions of the safety assessments resulting from the safety report and set the limits and conditions for the operation of the facility.

Changing Technical Operating Specifications

Within the RGE, the Technical Operating Specifications (STE) define normal operating conditions, identify the systems necessary for the safety functions implemented in an incident or accident situation (see point 2.2.2) and stipulate which measures are to be adopted if a normal operating limit is exceeded (pressures, temperatures, neutron flux, chemical and radiochemical parameters, etc.) or if a required system becomes unavailable.

The STE change in order to incorporate operating experience feedback from their application and take into account changes made to the facilities. The licensee can also modify them in order to carry out an operation in conditions that are different from those initially considered.

ASN must be notified of any changes to the STE before they are implemented. Among these, certain temporary changes to the STE with minimal impact on safety are exempted from this notification requirement, provided that they can be dealt with by the internal authorisation system implemented by EDF and regulated by an ASN resolution. The working of this system is monitored by ASN in the head office departments of the licensee and in the NPPs.

More broadly, during inspections, ASN verifies that the licensee complies with the STE and, as necessary, checks the compensatory measures associated with any temporary modifications. It also checks the consistency between the normal operating documents, such as instructions and alarm sheets, the STE and the training of the persons responsible for implementing them.

Examination of modifications made to the equipment

To improve the industrial performance of its production facility, process any deviations detected, implement design changes following periodic safety reviews or operating experience feedback, EDF regularly makes changes to its facilities. ASN is notified of those changes liable to affect nuclear safety or environmental protection before their implementation, and they are examined before ASN issues its corresponding position statement. The changes designed to remedy conformity deviations made in response to ASN prescriptions, in particular those resulting from the stress tests, are granted particularly close attention.

ASN checks the ways in which the changes it has approved are implemented, more specifically during reactor refuelling and maintenance outages.

2.2.2 Incident or accident operations

Chapter VI of the RGE comprises all the reactor operating rules for an incident or accident situation and prescribes how the reactor is to be controlled in these situations. ASN must be notified of any changes to Chapter VI of the RGE liable to affect nuclear safety before they are implemented.

Chapter VI of the RGE changes in order to take account of experience feedback from incidents and accidents and to take account of modifications made to the facilities, in particular those resulting from the periodic safety reviews.

ASN also regularly checks the incident or accident operating rules and how they are implemented. To do this, ASN runs simulations with the facility's shift crews. It thus checks that the operating instructions applied are consistent with the rules of Chapter VI of the RGE, the implementation methods for these documents, and the management rules for specific equipment used in accident operating situations.

2.2.3 Operation in a severe accident situation

If the reactor cannot be brought to a stable condition after an incident or accident and if a series of failures leads to core degradation, the reactor is said to be entering a severe accident situation. To deal with this type of unlikely situation, various steps must be taken to enable the operators to safeguard the containment in order to minimise the consequences of the accident (see point 1.3.1 of chapter 5). The operators then draw on the skills of the emergency response teams set up at both the local and national levels. These teams use the On-site Emergency Plan (PUI) plus the severe accident operation guide and the emergency teams action guides in particular.

ASN periodically examines the strategies presented by EDF in these documents, in particular for the reactor periodic safety reviews.

2.3 Fuel

2.3.1 Developments in fuel design and management

In order to enhance the availability and performance of the reactors in operation, EDF, together with the nuclear fuel manufacturers, researches and develops improvements to fuels and their use in the reactor. The latter is known as "fuel management" and is described in point 1.2.

ASN ensures that each change in fuel management is the subject of a specific safety case for the reactors concerned, based on the specific characteristics of the new fuel management. When a change in the fuel or its management model leads to EDF revising an accident study method, this requires prior review and cannot be implemented without ASN approval. When significant changes are made to fuel management, their implementation is dependent on a resolution being issued by the ASN Commission.

2.3.2 Monitoring the condition of fuel in the reactor

Fuel behaviour is an essential element in core safety in normal operation or accident conditions, and its reliability is of prime importance. The leaktightness of the fuel rods, of which there are several tens of thousands in each core and which constitute the first containment barrier, are therefore the subject of particular attention. During normal operation, leaktightness is monitored by EDF by means of continuous measurement of the activity of radioelements in the primary system. Any rise in this activity level beyond predetermined thresholds is the sign of a loss in fuel assembly leaktightness. During shutdown, EDF must look for and identify the assemblies containing leaking rods, which may not then be reloaded. If this activity in the primary system becomes too high, the RGE require reactor shutdown before the end of its normal cycle.

ASN ensures that EDF looks for and analyses the causes of the loss of leaktightness observed, in particular by examining the leaking rods in order to determine the origin of the failures and prevent them from reoccurring. Preventive and remedial actions may therefore affect the design of rods or assemblies, their manufacture, or the reactor operating conditions. Furthermore, the conditions of assembly handling, of core loading and unloading, and the measures taken to exclude foreign material from the systems and pools are also the subject of operating requirements, some of which contribute to the safety case and for which EDF's compliance is verified by ASN. ASN also conducts inspections to ensure that EDF carries out adequate monitoring of its fuel assembly suppliers in order to guarantee that fuel design and manufacture comply with the rules established. Finally, ASN periodically consults the GPR with regard to the lessons learned from fuel operating experience feedback.

2.4 Pressure equipment

2.4.1 Monitoring the manufacture of Nuclear Pressure Equipment (ESPN)

ASN assesses the conformity with the regulatory requirements of the nuclear pressure equipment most important for safety, known as "level N1". This conformity assessment concerns the equipment intended for the new nuclear facilities (EPR Flamanville 3) and the equipment spares intended for nuclear facilities already in operation (replacement steam generators in particular). For the performance of these duties, ASN can rely on the organisations that it approves, which can be tasked by ASN with performing some of the inspections on the level N1 equipment and are responsible for assessing conformity with the regulatory requirements applicable to nuclear pressure equipment that is less important for safety, referred to as "level N2 or N3". Oversight by ASN and its approved organisations comes into play at different stages of design and manufacture of nuclear pressure equipment. It takes the form of examination of the technical documentation for each item of equipment and of inspections in the manufacturers' facilities as well as in those of their suppliers and subcontractors. Five inspection organisations or bodies are currently approved by ASN to assess ESPN conformity: Apave SA, Asap, Bureau Veritas, AIB Vinçotte International and the EDF users inspection entity.

In 2015, ASN and the approved organisations carried out:
• 4,483 inspections to check the manufacture of nuclear pressure equipment intended for the Flamanville 3 EPR reactor, representing 10,133 man-days in the manufacturers' plants, as well as those of their suppliers and subcontractors,
• 1,063 inspections to check the manufacture of the spare steam generators intended for the NPP reactors in operation, which represented 3,936 man-days in the manufacturer's plants, as well as those of their suppliers and subcontractors.

Most of these inspections were performed by the approved organisations, under the supervision of ASN.

2.4.2 Monitoring the main primary and secondary systems

The reactor Main Primary and Secondary Systems (MPS and MSS) operate at high temperature and high pressure and contribute to the containment of radioactive substances, to cooling and to controlling reactivity.

The monitoring of the operation of these systems is regulated by the Order of 10th November 1999 relative to the monitoring of operation of the main primary and the main secondary systems of nuclear pressurised water reactors mentioned in point 3.6 of chapter 3. These systems are thus monitored and periodically maintained by EDF. This monitoring is itself checked by ASN.

These systems are subject to periodic re-qualification every ten years, which comprises a complete inspection of the systems involving non-destructive examinations, pressurised hydrotesting and verification of the good condition and proper operation of the over-pressure protection accessories.

2.4.3 Monitoring of nickel-based alloy areas

Several parts of pressurised water reactors are made with nickel-based alloy. The use of this type of alloy is justified by its resistance to generalised or pitting corrosion. However, in reactor operating conditions, one of the alloys adopted, Inconel 600, proved to be susceptible to stress corrosion. This particular phenomenon occurs when there are high levels of mechanical stress. It can lead to the appearance of cracks, as observed on the SG tubes in the early 1980s or, more recently in 2011, on a vessel bottom head penetration in the Gravelines reactor 1. These cracks require that the licensee repair the zones concerned or isolate them from the rest of the system to prevent any undue risk.

At the request of ASN, EDF adopted an overall monitoring and maintenance approach for the areas concerned. Several parts of the main primary system made of Inconel 600 alloy are thus subject to special monitoring. For each of them, the in-service monitoring programme, defined and updated annually by the licensee, is submitted to ASN, which checks that the performance and frequency of the checks carried out are satisfactory and able to detect the deteriorations in question.

2.4.4 Monitoring the resistance of reactor vessels

The reactor vessel is one of the essential components of a PWR. For a 900 MWe reactor, it is 14 m high, 4 m in diameter and 20 cm thick. It weighs 300 tonnes. It contains the reactor core and its instrumentation. In normal operating conditions, the vessel is entirely filled with water, at a pressure of 155 bar and a temperature of 300°C.

Regular monitoring of the state of the reactor vessel is essential for the following two reasons:
- The vessel is a component for which replacement is not envisaged, owing to both technical feasibility and cost.
- Rupture of this item is not considered in the safety assessments. This is one of the reasons for which all steps must be taken as of the design stage, in order to guarantee its resistance for the operating lifetime of the reactor, including in the event of an accident.

In normal operation, the vessel's metal slowly becomes brittle under the effect of the neutrons from the fission reaction in the core. This embrittlement makes the vessel particularly sensitive to pressurised thermal shocks or to sudden pressure surges when cold. This susceptibility is also aggravated when defects are present, which is the case for some of the reactor vessels that have manufacturing defects under their stainless steel liner.

ASN regularly examines the files related to the vessels transmitted by EDF in order to ensure that the in-service behaviour demonstration for the vessels is sufficiently conservative and complies with the regulations.

The Advisory Committee for Nuclear Pressure Equipment was consulted at the end of 2015 concerning the file transmitted by EDF to substantiate the in-service resistance of the 1,300 MWe reactor vessels.

UNDERSTAND

The principles of demonstrating the in-service resistance of reactor vessels

The regulations in force require in particular that the licensee:
- identify the situations that would result in an impact on the equipment;
- take measures to understand the effect of ageing on the properties of the materials;
- take steps to ensure sufficiently early detection of defects prejudicial to the integrity of the structure;
- eliminate all cracks detected or, if this is impossible, provide appropriate specific justification for retaining such a type of defect as-is.

2.4.5 Monitoring steam generator maintenance and replacement

Steam Generators (SG) comprise two parts, one of which is a part of the primary system and the other a part of the secondary system. The integrity of the main steam generator components is monitored, more specifically the tube bundle, which is particularly important for the safety of the facility. This is because any damage to the tube bundle (corrosion, wear, cracking, etc.) can lead to a primary system leak to the secondary system. Furthermore, a Steam Generator Tube Rupture (SGTR) would lead to the bypassing of the reactor containment, which is the third containment barrier. Steam generators are the subject of a special in-service monitoring programme, established by EDF, reviewed periodically and examined by ASN. After inspection, tubes that are too badly damaged are plugged to remove them from service.

Mechanical and chemical cleaning of steam generators

Over time, the SGs tend to become clogged with corrosion products from the secondary system exchangers. This takes the form of a build-up of soft or hard sludge on the tubesheet, fouling of the walls of the SG tubes and clogging of the foliate channels of the tube support plates. The corrosion products form a layer of magnetite on the surface of the internals. On the tubes, the layer of deposits (fouling) reduces the heat exchange capacity. In the foliate channels, the deposits prevent the free circulation of the water-steam mixture (clogging), which creates a risk of damage to the tubes and the internal structures and which can degrade the overall operation of the steam generator.

To prevent or mitigate such effects, various solutions are used to minimise metal deposits: preventive chemical cleaning or mechanical cleaning (using hydraulic jets), material replacement (brass by stainless steel or titanium alloy, which are more corrosion-resistant) in certain secondary system exchanger tube bundles, along with an increase in the pH of the secondary system.

Replacement of steam generators

Since the 1990s, EDF has been running a Steam Generator Replacement programme (SGR) for those SGs with the most heavily degraded tube bundles, with priority being given to those made from Inconel 600 without heat treatment (600 MA) and then those made from Inconel 600 with heat treatment (600 TT).

The replacement campaign for SGs with a tube bundle made of 600 MA (26 reactors) was completed in 2015 on reactor 3 at the Le Blayais NPP. It is being pursued with the replacement of SGs with heat treated Inconel (600 TT) tube bundles. The operations to replace those of reactor 2 at the Paluel NPP will take place in 2016.

On the occasion of these operations, certain elbows of the primary system piping can also be replaced. These operations are needed in order to anticipate the effects of thermal ageing which affect the mechanical properties of this equipment. The replacement of the steam generators of Paluel NPP reactor 2 should also involve the replacement of 15 elbows on the main primary system.

Incorporation of international operating experience

In 2012, a leak from the primary system to the secondary system occurred on an SG at the San Onofre NPP (United States). Premature wear linked to direct contact between tubes led to this leak. ASN ensured that EDF had analysed the phenomena underlying this deterioration and had provided data to prove that the SGs of the French NPPs were not significantly concerned by this mode of deterioration. Particular monitoring has nonetheless been implemented on the tubes potentially concerned.

2.4.6 Monitoring the other reactor pressure equipment

ASN is also responsible for monitoring EDF's implementation of the regulations applicable to non-nuclear pressure equipment utilised in the NPPs. In this respect, ASN in particular carries out audits and surveillance visits on the site inspection departments. These departments, under the responsibility of the licensee, are responsible for carrying out inspections to ensure the safety of pressure equipment.

2.5 The containments

The containments undergo inspections and tests to check their compliance with the safety requirements. Their mechanical performance in particular must guarantee a good degree of reactor building tightness in the event of its internal pressure exceeding atmospheric pressure, which can happen in certain types of accidents. This is why, at the end of construction and then during the ten-yearly inspections, these tests include an inner containment pressure build-up with leak rate measurement, as specified in Article 8.1.1 of the amended Order of 7th February 2012.

2.6 Protection against natural events, fire and explosions

2.6.1 Prevention of seismic risks

Although the probability of a strong earthquake is low in France, EDF's consideration of this risk is nonetheless closely monitored by ASN. Seismic protection measures are taken into account in the design of the facilities. They are periodically reviewed in line with changing knowledge and changes to the regulations, on the occasion of the periodic safety reviews.

Design rules

Basic Safety Rule (RFS) 2001-01 of 31st May 2001 defines the methodology for determining the seismic risk for surface BNIs (except for radioactive waste long-term repositories).

This RFS is supplemented by a 2006 ASN guide which defines acceptable calculation methods for a study of the seismic behaviour of buildings and particular structures such as embankments, tunnels and underground pipes, supports or tanks.

Buildings and equipment important for the safety of NPPs are designed to withstand earthquakes of an intensity greater than the most severe earthquakes that have ever occurred in the region of the site.

Seismic reassessment

As part of the periodic safety reviews, the seismic reassessment consists of verifying the adequacy of the seismic design of the facility, taking account of advances in knowledge about seismic activity in the region of the site or in the methods for assessing the seismic behaviour of elements of the facility. The lessons learned from international experience feedback concerning earthquakes are also analysed and integrated into this framework.

The studies carried out for the periodic safety review associated with the third ten-yearly outages of the 900 MWe reactors (VD3-900) led to the definition of equipment or structural reinforcements, which are implemented on the occasion of the ten-yearly outage inspections.

Changes in the available knowledge have led EDF to reassess the seismic hazard for the periodic safety review associated with the third ten-yearly outages for the 1,300 MWe reactors (VD3-1,300). ASN considers that EDF's seismic hazards assessment is acceptable, with the exception of that of Saint-Alban, which is inadequate given the current state of knowledge. ASN therefore asked EDF:
- to reassess the seismic spectrum for the Saint-Alban site to take account of uncertainties;
- to define a working programme to verify the strength of the equipment and civil engineering structures and make any necessary seismic reinforcements for the VD3-1,300 periodic safety review.

Extreme earthquakes

Following the Fukushima Daiichi accident, ASN asked EDF to define and install a "hardened safety core" of material and organisational measures to control the fundamental safety functions in extreme situations which, in the French context, are comparable to those which occurred in Japan on 11th March 2011. This hardened safety core shall notably be designed to withstand an earthquake of an exceptional level, exceeding those adopted in the design or periodic safety review of the installations. In order to define this exceptional level earthquake, ASN asked EDF to supplement the deterministic approach to defining the seismic hazard with a probabilistic approach, which would be more closely in line with international best practices (see point 3.1).

2.6.2 Drafting of flooding protection rules

The partial flooding of the Le Blayais NPP in December 1999 led the licensees, under the supervision of ASN, to reassess the safety of the existing BNIs with respect to this risk in more severe conditions than previously and to make a number of safety improvements, with a schedule proportionate to the potential consequences. In accordance with the ASN prescriptions, EDF completed the required work on the entire NPP fleet by the end of 2014.

At the same time, to ensure more exhaustive and more robust integration of the flooding risk, as of the facilities design stage, ASN published Guide No. 13 in 2013 concerning BNI protection against external flooding. For the existing facilities, ASN asked EDF in 2014 to take account of the recommendations of the guide on all its reactors during the course of the coming ten years and no later than the last periodic safety review of the reactors on a given site.

Following the stress tests performed in the wake of the Fukushima Daiichi accident, ASN considered that, with regard to protection against flooding, the requirements arising from the complete reassessment performed after the flooding of the Le Blayais NPP in 1999 provided the nuclear power plants with a high level of protection against the risk of external flooding. However, in June 2012, ASN issued several resolutions to ask the licensees:

- to reinforce NPP protection against certain hazards, such as intense rainfall and earthquake-induced flooding;
- to define and implement a "hardened safety core" of material and organisational measures to control the fundamental safety functions in extreme situations and in particular in the case of flooding beyond the design-basis safety requirements (see point 3.1).

Floor anchoring of a pump.

2.6.3 Prevention of heat wave and drought risks

During the heat waves in recent decades, some of the rivers used to cool NPPs experienced a reduction in their flow rate and significant warming.

Significant temperature rises were also observed in certain NPP premises housing heat-sensitive equipment.

EDF took account of this experience feedback and initiated reassessments of the operation of its facilities in air and water temperature conditions more extreme than those initially included in the design. In parallel with development of these "extreme heat" baseline safety requirements, EDF initiated the deployment of priority modifications (such as an increase in the capacity of certain heat exchangers) and adopted operating practices optimising the cooling capacity of the equipment and improving the resistance of equipment susceptible to high temperatures.

In 2012, ASN approved the application of these baseline requirements to the 900 MWe reactors as well as implementation of the resulting modifications. ASN also asked EDF to take account of the comments it made during this examination process with a view to drafting and implementing baseline requirements applicable to the other plant series.

For the periodic safety review of the 1,300 MWe reactors, EDF has initiated a modifications programme on its facilities designed to provide protection against heat wave situations. The capacity of certain cooling systems for equipment required for the nuclear safety case will in particular be improved.

EDF has also initiated a monitoring programme in order to anticipate climate changes, which could compromise the hypotheses adopted in the "extreme heat" baseline safety standards.

The impact on thermal discharges from the NPPs

NPPs discharge hot effluents into rivers or the sea, either directly, from those NPPs operating with direct or "once-through" cooling, or after cooling of these effluents in cooling towers, enabling some of the heat to be dissipated to the atmosphere. Thermal discharges from NPPs lead to a temperature rise between the points upstream and downstream of the discharge which, depending on the reactors, can range from a few tenths of a degree to several degrees. This warming is regulated by ASN resolutions.

Since 2006, changes have been made to these resolutions for advanced definition of the operations of NPPs during exceptional climatic conditions that would lead to significant warming of the river. These special provisions are however only applicable if the security of the French electricity grid is at stake.

2.6.4 Consideration of fire risk

In the same way as the other BNIs, NPPs are subject to an ASN statutory resolution on the control of fire risks (ASN resolution 2014-DC-0417 of 28th January 2014).

Controlling the fire risk in nuclear power plants is built around the principle of defence in depth, based on three levels: facility design, prevention and fire-fighting.

The design rules should prevent the spread of any fire and limit its consequences. This is primarily built around "fire zoning", that is the principle of dividing the facility into sectors designed to contain the fire within a given perimeter, each sector being bounded by sectoring elements (fire doors, fire-walls, fire dampers, etc.), offering a specified fire resistance duration. The main purpose is to prevent a fire from spreading to two redundant equipment items performing a fundamental safety function.

Prevention primarily consists of the following:
- ensuring that the nature and quantity of combustible material present in the premises remain below that of the scenarios used for zoning;
- identifying and analysing the fire risks in order to take steps to avoid them. In particular, for all work liable to cause a fire, a "fire permit" must be issued and protective measures must be taken.

Finally, fire detection and fire-fighting procedures should enable a fire to be tackled, brought under control, and extinguished within a time compatible with the fire resistance duration of the sectoring elements.

ASN checks that the fire risk is taken into account in the NPPs, notably through an analysis of the licensee's baseline safety requirements, monitoring of significant events notified by the licensee and inspections performed on the sites.

2.6.5 Consideration of explosion risks

An explosion can damage elements that are essential for maintaining safety or may lead to failure of the containment with the release of radioactive materials into the facility, or even into the environment. Steps must therefore be taken by the licensee to protect the sensitive parts of the facility against explosions.

ASN checks these prevention and monitoring measures, paying particular attention to ensuring that the explosion risk is included in EDF's baseline safety requirements and organisation. ASN also ensures compliance with the "Explosive Atmospheres" (ATEX) regulations with respect to worker protection.

2.7 Maintenance and testing

2.7.1 Regulation of maintenance practices

ASN considers that preventive maintenance is an essential line of defence in maintaining the conformity of a facility with its baseline safety requirements.

In order to improve the reliability of the equipment contributing to safety but also to industrial performance, EDF regularly seeks to optimise its maintenance activities in light of best practices used in the industry and by NPP licensees in other countries.

In 2010, EDF thus informed ASN of its intention to deploy a new maintenance methodology developed by the American licensees, called AP-913.

Deployment of AP-913 is based on implementation of the following six processes:
- identification of critical equipment and definition of the associated maintenance and monitoring programmes;
- definition of equipment monitoring and maintenance requirements;
- equipment and systems performance analysis;
- definition and oversight of corrective measures;
- continuous improvement of baseline requirements and oversight of reliability;
- equipment lifecycle management.

The various steps in this methodology and the organisational conditions for its deployment in the NPPs were examined by ASN, which is in favour of its adoption.

The main benefit of this method is to aim for improved equipment reliability through in-service monitoring, in order to improve preventive maintenance and through sharing of maintenance practices among the NPPs. However, ASN considers that proactive steps must be taken with the NPPs to allow correct implementation of this new method and ensure that it is effective. EDF must in particular more closely oversee the implementation of AP-913 in its various NPPs and allocate the necessary manpower to this task. EDF must also ensure that all participants follow the recommended methods for filling out the equipment monitoring indicators, for the preparation, performance and write-up of field visits and for the traceability of maintenance decisions.

UNDERSTAND

Elements Important for Protection (EIP)

Article 1.3 of the BNI Order of 7th February 2012 defines an "Element Important for Protection [EIP]" as being an *"element important for the protection of the interests mentioned in Article L. 593-1 of the Environment Code (public health and safety, protection of nature and the environment), that is structure, equipment, system (programmed or otherwise), hardware, component, or software present in a BNI or placed under the responsibility of the licensee, performing a function necessary for the safety case mentioned in the second paragraph of Article L. 593-7 of the Environment Code or ensuring that this function is performed"*.

Elements known as EIP are the explicit link between the functions to be performed in normal operating conditions or to be performed in an accident situation and the "elements" enabling them to be performed (structure, equipment, system, hardware, component, or software).

For example, to perform a cooling function, a pump (the EIP) with certain flow rate, start-up time and reliability performance requirements is needed.

The EIPs take over from the elements important for safety defined by the 1984 order, but their scope is broader. They also concern the "elements" designed to deal with detrimental effects and drawbacks (environmental protection, etc.).

Some EIP examples: building housing radioactive substances, a fan providing the depressurisation to ensure containment, software used by the reactor protection system, certain components of antibacterial treatment plants.

An EIP can also be an element verifying correct performance of a function, even if it does not directly contribute to the actual performance of this function (radioactivity monitor in a discharge stack, etc.).

2.7.2 Monitoring the test programmes

The elements important for the protection of persons and the environment, identified by the licensee, undergo qualification in order to guarantee their ability to perform the functions assigned to them, in terms of loadings and the ambient conditions associated with the situations in which they are required. The periodic tests help verify that this qualification is maintained and regularly ensure that these elements are available in the conditions in which they are required. The associated rules constitute Chapter IX of the RGE. These rules set the nature of the technical inspections, their frequency and the corresponding criteria, allowing periodic verification of compliance with the qualification requirements.

ASN ensures that the periodic technical checks on the elements important for protection mentioned above are relevant and are continuously improved. It also checks that they are performed in accordance with the general operating rules.

2.7.3 The use of efficient monitoring methods applied to main primary and secondary system pressure equipment

Article 8 of the Order of 10th November 1999 concerning monitoring of the operation of the main primary system and the main secondary systems of pressurised water reactors specifies that the non-destructive testing processes used for in-service monitoring of the pressure equipment of the main primary and secondary systems of nuclear reactors must, before they are used for the first time, be qualified by an entity comprising of experts from inside and outside EDF, whose competence and independence are verified by the French Accreditation Committee (Cofrac).

Qualification is a means of guaranteeing that the examination method actually achieves the level of performance stipulated and is described in a precise set of specifications.

To date, 90 applications have been qualified by the in-service inspection programmes. New applications are currently being developed and qualified in order to meet new needs.

With regard to the Flamanville EPR reactor, 39 processes have been qualified ahead of the pre-service inspection of the main primary system and the main secondary systems. Only four processes, which were belatedly identified as being necessary, are still undergoing development.

Owing to the radiological risks linked to gamma radiography, ultrasound applications are preferred to radiography applications, provided that they can offer equivalent inspection performance.

2.7.4 ASN oversight of reactor outages

Licensees need to periodically shut down their reactors in order to renew the fuel, which becomes gradually depleted during the operating cycle. At each outage, one third or one quarter of the fuel is renewed.

These outages mean that it is possible to access parts of the installation that would not normally be accessible during operation. Outages are therefore an opportunity to verify the condition of the NPP by running checks and performing maintenance work, as well as to implement the modifications scheduled for the NPP.

These refuelling outages can be of several types:
- Simple Refuelling Outage (ASR) and Partial Inspection (VP) outage: these outages last a few weeks and are devoted to renewing part of the fuel and conducting a programme of verification and maintenance that is more extensive during a Partial Inspection (VP) than during a Simple Refuelling Outage (ASR);
- Ten-yearly Outage (VD): this outage entails a wide-ranging verification and maintenance programme. This type of outage, which lasts several months and takes place every 10 years, is also an opportunity for the licensee to carry out major operations such as a complete inspection and hydrotest on the primary system, a containment test or incorporation of design changes decided as part of the periodic safety reviews.

These outages are scheduled and prepared for by the licensee several months in advance. ASN checks the steps taken by the licensee to guarantee safety and radiation protection during the outage, and the safety of operation during the coming cycle(s).

The checks carried out by ASN mainly concern the following aspects:
- during the outage preparation phase, the conformity of the reactor outage programme with the applicable baseline requirements. As necessary, ASN asks for additions to this programme;
- during the outage – through regular briefings and inspections – the implementation of the programme and the handling of any unforeseen circumstances;
- at the end of outage, when the licensee presents its reactor outage report, the condition of the reactor and its readiness for restart. After this inspection, ASN will either approve reactor restart or not;
- after the reactor restarts, the results of all tests carried out during the outage and during the restart phase.

All of these measures are provided for by ASN resolution 2014-DC-0444 of 15th July 2014 concerning pressurised water reactor shutdowns and restarts.

2.8 Maintaining and continuously improving nuclear safety

2.8.1 Management of subcontracted activities

The maintenance of French reactors is to a large extent subcontracted by EDF to outside contractors, with the total workforce representing about 20,000 employees. EDF justifies the use of subcontracting by the need to call on specific or rare expertise, the highly seasonal nature of reactor outages and thus the need to absorb workload peaks.

The nuclear licensee's decision to resort to subcontracting must not compromise the technical skills it must retain in-house, in order to carry out its responsibility for safety and be able to effectively monitor the quality of the work performed by the subcontractors. Poorly managed subcontracting is liable to lead to poor quality of work and have a negative impact on the safety of the facility and the radiation protection of those involved (the subcontractors receive a large share of the dose linked to the work done on all the reactors: see point 4.1.4). These consequences can in particular result from the use of insufficiently qualified personnel, insufficient monitoring of the contractors by the licensee or degraded working conditions.

Therefore, if the decision to outsource certain activities is determined by EDF's industrial policy strategy, the conditions for the use of subcontracting must be such that the licensee retains full responsibility for the safety of its facilities at all times.

In addition, owing to the large number of nuclear reactors operated by EDF, its outsourcing decisions have a direct impact on the industrial fabric specialising in nuclear supplies and maintenance.

A system of prior contractor qualification was put into place by EDF. It is based on an assessment of the technical know-how and the organisation of the subcontracting companies. The principles are described in the "Progress and sustainable development Charter" signed by EDF and its main contractors. In 2013, the French nuclear sector defined "social specifications" applicable to the provision of services and work performed in a nuclear facility. Since July 2013, EDF has transposed these social specifications into its subcontracting contracts for reactors in operation.

Article 124 of Act 2015-992 of 17th August 2015, concerning Energy Transition for Green Growth and owing to the particular importance of certain activities for protection of the interests mentioned in Article L. 593-1 of the Environment Code, a decree of the *Conseil d'État* (Council of State) can regulate or limit the use of service providers or subcontractors for the execution of these activities. In addition, Article 124 states that the licensee must monitor activities important for the protection of the interests mentioned in the same Article L. 593-1 when they are performed by outside contractors and must ensure that these outside contractors have appropriate technical expertise for the performance of said activities. It may not delegate this monitoring action to a service provider.

The Order of 7th February 2012 setting the general rules for BNIs requires that the licensee monitor the activities performed by outside contractors, in order to ensure that the operations they perform comply with the defined requirements and, more generally, that they apply the nuclear safety, radiation protection and environmental protection policy defined by the licensee. The licensee must also ensure the availability of a sufficient number of contractors with the expertise needed to perform the maintenance operations required to ensure the safety of the reactors.

ASN carries out inspections on the conditions in which subcontracting takes place at EDF. ASN in particular checks EDF's implementation of and compliance with a process to ensure the quality of the activities subcontracted: the choice of contractors, monitoring of the work done, integration of experience feedback and adequacy of the resources for the volume of work to be done. For its labour inspectorate duties, ASN also pays close attention to worker protection, notably compliance with health and safety rules and working and rest times, and checks the legality of the service contracts, in particular assessing the independence of the subcontractors carrying out the service from the ordering customer.

2.8.2 Correction of deviations

The checks carried out at the initiative of EDF and the additional verifications requested by ASN can lead to the detection of deviations from the defined requirements[1], which must then be processed. These deviations can have a variety of origins: design problems, construction defects, insufficient control of maintenance work, degradation as a result of ageing, etc.

The measures for detecting and correcting deviations, as prescribed by the Order of 7th February 2012 setting out the general rules for BNIs, play an important role in maintaining the level of safety of the facilities.

"Real time" verification

The performance of periodic tests and preventive maintenance programmes on the equipment and systems helps identify deviations. Routine field inspections are also an effective means of discovering faults.

Verifications during reactor outages

EDF takes advantage of nuclear reactor outages to carry out maintenance work and inspections that cannot be performed when the reactor is in service. These operations are mainly used to remedy anomalies already identified, but also lead to the detection of new anomalies. Before each reactor restart, ASN asks EDF to identify any anomalies not yet remedied, to take appropriate compensatory measures and to demonstrate the acceptability of these anomalies with respect to the protection of persons and the environment for the coming operating cycle.

UNDERSTAND

The defined requirements

The Order of 7th February 2012, amended, states that a defined requirement is a *"requirement assigned to an Element Important for Protection (EIP), so that, with the expected characteristics, it performs the function stipulated in the safety case mentioned in the second paragraph of Article L. 593-7 of the Environment Code, or to an Activity Important for Protection (AIP) so that it meets is objectives with respect to this safety case"*.

For the EIP, these requirements can in particular concern:
- the characteristics of the materials used;
- the manufacturing, assembly, erection and repair processes;
- the physical parameters and criteria characteristic of the performance of the EIP.

For the AIP, these requirements can in particular concern:
- the skills needed to perform the activity;
- any qualifications necessary;
- checks and hold points;
- the equipment and hardware needed to enable the activity to be carried out in accordance with the regulatory or even contractual requirements, such as to guarantee compliance with the safety case.

1. *The Order of 7th February defines the notion of deviation as* "non-compliance with a defined requirement, or non-compliance with a requirement set by the licensee's integrated management system liable to affect the provisions mentioned in the second paragraph of Article L. 593-7 of the Environment Code".

Ten-yearly verifications: conformity checks

EDF carries out periodic safety reviews of the nuclear reactors every ten years, in accordance with the regulations (see point 2.9.4). EDF thus compares the actual condition of the NPPs with their applicable safety requirements and identifies any deviations. These verifications can be supplemented by a programme of additional investigations designed to check the parts of the facility which are not covered by a preventive maintenance programme.

Informing ASN and the public

When a deviation is detected, and in the same way as any BNI licensee, EDF is required to assess the impacts on nuclear safety, radiation protection or protection of the environment. If necessary, EDF sends ASN a significant event notification. As of level 1 on the INES scale, the public is informed on *www.asn.fr* of the events thus notified by the licensees.

ASN's remediation requirements

On 6th January 2015, ASN published Guide No. 21 concerning the handling of non-compliance with a defined requirement for Equipment Important for Protection (EIP). This guide applies to all anomalies affecting an EIP that performs a function necessary for the nuclear safety case with regard to radiological accidents affecting a pressurised water reactor.

It presents ASN's requirements concerning the correction of non-conformities and presents the approach expected of the licensee in accordance with the principle of proportionality. This is based more specifically on an assessment of the potential or actual consequences of any deviation identified and on the licensee's ability to guarantee control of the reactor in the event of an accident, by taking appropriate compensatory measures.

UNDERSTAND

Handling deviations

A deviation is non-compliance with a defined requirement or a requirement set by the licensee's integrated management system. A deviation may thus affect a structure, a system or a component of the facility. It may also concern compliance with an operating document or an organisation. The regulations require that the licensee identify all deviations affecting its facilities and handle them. The activities involved in deviation handling are important for the protection of interests (public health and safety and protection of nature and the environment, as mentioned in Article L. 593-1 of the Environment Code). They are thus subject to oversight and monitoring requirements, the implementation of which is regularly checked by ASN.

2.8.3 Examination of events and operating experience feedback

Operating experience feedback is a source of continuous improvement for the protection of the interests mentioned in Article L. 593-1 of the Environment Code. ASN requires that EDF notify it of the significant events occurring in its NPPs, in accordance with predetermined notification criteria (see point 3.4.2 of chapter 4). Each significant event is therefore rated by ASN on the International Nuclear Events Scale (INES), which comprises eight levels from 0 to 7.

ASN checks how EDF organises and analyses operating experience feedback from significant events and events that have occurred in other countries. At the local and national levels, it examines all significant events notified (a summary of their analysis for 2015 is given in 4.1.6). The significant events considered to be noteworthy owing to their recurrent or generic nature undergo detailed analysis with the support of IRSN. During inspections in the NPPs, ASN also reviews the organisation of the sites and the steps taken to deal with significant events and take account of operating experience. Finally, at the request of ASN, the Advisory Committee for Reactors periodically reviews feedback from PWR operation (see box point 4.1.6).

2.9 NPP operating life extension

Although the regulations governing the operation of the NPPs in France set no time limit for their operating authorisation, Article L.593-18 of the Environment Code states that the licensee must carry out a periodic safety review of each reactor every ten years.

2.9.1 The age of NPPs

The NPPs currently in operation in France were built over a relatively short period of time: forty-five reactors, representing 50,000 MWe, or three quarters of the power output by the French fleet, were commissioned between 1980 and 1990 and seven reactors, representing a further 10,000 MWe, between 1991 and 2000. In December 2015, the average ages of the reactors, calculated from the date of initial reactor criticality, were as follows:
• 34 years for the thirty-four 900 MWe reactors;
• 28 years for the twenty 1,300 MWe reactors;
• 18 years for the four 1,450 MWe reactors.

2.9.2 The main challenges in managing ageing

Like all industrial installations, NPPs are subject to ageing. ASN ensures that, in line with its general operating and maintenance strategy, EDF takes account of ageing-related phenomena in order to maintain a satisfactory level of safety throughout the operating life of the facilities.

To understand the ageing of an NPP, apart from the time elapsed since its commissioning, other factors must be taken into account, in particular physical phenomena that can modify the characteristics of the equipment, depending on its function or conditions of use.

Deterioration of replaceable items

Equipment ageing is the result of phenomena such as the hardening of certain steels under the effect of irradiation or temperature, the swelling of certain concretes, the hardening of polymers, corrosion of metals and so on. These degradations are generally considered at the design and manufacturing stages and then in a monitoring and preventive maintenance programme, or even a repair or replacement programme as necessary.

AGE PYRAMID of the French nuclear power generating reactors (NPP fleet in France as at end of 2015; by date of 1st criticality; power per reactor)

Date of 1st criticality									Global power
1977	Fessenheim 1	Fessenheim 2							1,800 MWe
1978	Bugey 2	Bugey 3							1,800 MWe
1979	Bugey 4	Bugey 5							1,800 MWe
1980	Tricastin 1	Gravelines 1	Tricastin 2	Tricastin 3	Gravelines 2	Dampierre 1	Gravelines 3	Saint-Laurent B1	7,200 MWe
1981	Dampierre 2	Saint-Laurent B2	Blayais 1	Dampierre 3	Tricastin 4	Gravelines 4	Dampierre 4		6,300 MWe
1982	Blayais 2	Chinon B1							1,800 MWe
1983	Cruas 1	Blayais 4	Blayais 3	Chinon B2					3,600 MWe
1984	Cruas 3	Paluel 1	Cruas 2	Paluel 2	Gravelines 5	Cruas 4			6,200 MWe
1985	Saint-Alban 1	Paluel 3	Gravelines 6	Flamanville 1					4,800 MWe
1986	Paluel 4	Saint-Alban 2	Flamanville 2	Chinon B3	Cattenom 1				6,100 MWe
1987	Cattenom 2	Nogent 1	Belleville 1	Chinon B4					4,800 MWe
1988	Belleville 2	Nogent 2							2,600 MWe
1990	Cattenom 3	Penly 1	Golfech 1						3,900 MWe
1991	Cattenom 4								1,300 MWe
1992	Penly 2								1,300 MWe
1993	Golfech 2								1,300 MWe
1996	Chooz B1								1,450 MWe
1997	Chooz B2	Civaux 1							2,900 MWe
1999	Civaux 2								1,450 MWe

● 900 MWe ● 1,300 MWe ● 1,450 MWe

Source: ASN.

The lifetime of non-replaceable items

Non-replaceable items such as the reactor vessel (see point 2.4.4) and the containment (see point 2.5) are closely monitored in order to ensure that they are ageing as anticipated and that their mechanical properties remain within limits that guarantee their correct performance.

Equipment or component obsolescence

Before it is installed in the NPPs, some equipment undergoes a "qualification" process designed to ensure that it is able to perform its functions in the stress and atmosphere conditions corresponding to the accident situations in which it would be required. The availability of spares for this equipment is heavily dependent on the development of the industrial network of suppliers and the cessation of manufacture of certain components or the closure of the manufacturing company, which can lead to supply difficulties. Prior to installing these parts, EDF must check that the new spares that are different from the original parts do not compromise the "qualification" of the equipment on which they are to be installed. Given the incompressible length of this procedure, the licensee must anticipate these needs well in advance.

2.9.3 How EDF manages equipment ageing

The approach adopted by EDF to control the ageing of its facilities is based on three key points:
- Anticipate ageing in the design: during the design and manufacture of components, the choice of materials and the installation arrangements must be tailored to the intended operating conditions and take into account the kinetics of known or presumed deterioration processes.
- Monitor the actual condition of the facility: during operation, degradation phenomena other than those considered in the design can be discovered. The periodic monitoring and preventive maintenance programmes, the additional investigation programmes as well as examination of operating experience feedback (see points 2.7.1, 2.8.2 and 2.8.3) are all designed to detect these phenomena sufficiently early.
- Repair, renovate or replace equipment: given the operating constraints liable to be generated by such routine or exceptional maintenance operations, especially when they can only be performed during reactor outages, EDF must seek to anticipate them, in particular to take account of the time needed to procure new components, the time required to prepare for and carry out the work, the risk of obsolescence of certain components and the loss of technical skills on the part of the workforce.

EDF has established a methodology for controlling the ageing of its reactors after 30 years of operation. Its aim is to demonstrate their ability to continue to function until their fourth ten-yearly outage inspection in satisfactory conditions of safety, on the one hand, in light of the condition of the facilities during their third ten-yearly outage inspections and, on the other, given the knowledge and experience of the mechanisms and kinetics of deterioration linked to ageing.

This methodology comprises a first generic phase, which aims to take account of ageing for an identical reactor series, in order to pool and share the studies. Subsequently, on the occasion of the third ten-yearly outage inspection (VD3) on each reactor, a summary file specific to each reactor is produced in order to demonstrate control of the ageing of the equipment and the reactor's ability to continue to operate for the ten-year period following its VD3. It is drawn up on the basis of the generic file and aims to take account of any specific features of each of these reactors.

Given EDF's envisaged goal of continued reactor operations beyond forty years, the satisfactory control of ageing and the management of equipment obsolescence constitute key safety issues (see point 3.2). ASN considers that the approach adopted by EDF, both generic and for each individual reactor, is on the whole satisfactory but needs to be supplemented with respect to a few points:
- identify the possible vulnerabilities in the components industrial replacement processes, including in the case of an unforeseen operational event on the reactors, and propose steps to improve the robustness of these processes;
- provide a robust demonstration of the mechanical resistance of the vessels beyond their fourth ten-yearly outage inspection.

2.9.4 The periodic safety review

In accordance with the provisions of Article L. 593-18 of the Environment Code, EDF must carry out a periodic safety review of its reactors every ten years, comprising of the following two parts:
- A check on the condition and conformity of the facility: this step aims to verify the situation of the facility with respect to the rules applicable to it. It is based on a range of inspections and tests in addition to those performed in real-time. These verifications can concern checks on the initial design studies as well as field inspections of equipment not addressed by maintenance programmes, or tests conducted every ten years such as the containment pressure tests. Any deviations detected during these investigations are then restored to conformity within a time-frame commensurate with their potential consequences.
- The safety reassessment: this step aims to improve the level of safety in the light of the experience acquired during operation, changing knowledge, the requirements applicable to the more recent facilities and international best practices. Following these reassessments, EDF identifies the modifications it intends to make to its facilities in order to reinforce their safety.

The review process for the EDF reactors

In order to benefit from the standardisation of the reactors operated by EDF, these two parts of the review are first the subject of a generic design programme for a given plant series (900 MWe, 1,300 MWe and 1,450 MWe reactors). The results of this programme are then implemented on each of the reactors of the plant series on the occasion of its ten-yearly outage inspection.

In accordance with the provisions of Article L. 593-19 of the Environment Code, following the ten-yearly outage inspection, the licensee sends ASN a periodic safety review conclusions report. In this report, the licensee states its position on the regulatory conformity of its facility as well as on the modifications made to remedy deviations observed or to improve the safety of the facility. The review report contains information provided for in Article 24 of Decree 2007-1557 of 2nd November 2007.

The ASN analysis

The guidelines of the generic programmes proposed by the licensee to verify the status of the facility and reassess safety are the subject of an ASN position statement issued following consultation of the GPR and possibly of the Advisory Committee for Nuclear Pressure Equipment (GPESPN). On this basis, EDF carries out safety reassessment studies and defines modifications.

Following consultation of the GPR at the end of the periodic safety review generic phase, ASN issues a position statement on the results of the reassessment studies and on the modifications envisaged by EDF that aim to improve safety.

ASN informs the Minister responsible for Nuclear Safety of its analysis of the review conclusions report for each reactor, mentioned in Article L. 593-19 of the Environment Code and can issue new prescriptions regarding its continued operation.

2.10 The Flamanville 3 EPR reactor

The EPR reactor is a pressurised water reactor based on a design which is an evolution of the design of the reactors currently in service in France, enabling it to comply with reinforced safety objectives.

After a period of about ten years during which no nuclear reactors were built in France, EDF submitted an application in May 2006 to the Ministers responsible for Nuclear Safety and Radiation Protection for the creation of a 1,650 MWe EPR type reactor, called Flamanville 3, on the Flamanville site, which already houses two 1,300 MWe reactors.

The Government authorised its creation by Decree 2007-534 of 10th April 2007, following ASN's favourable opinion, subsequent to the inquiry conducted with the assistance of its technical support organisations.

After issue of this Creation Authorisation Decree and the building permit, construction of the Flamanville 3 reactor began in September 2007. The first pouring of concrete for the buildings in the nuclear island began in December 2007. Since then, the civil engineering (structural) work has continued and is now almost completed. In 2015, EDF completed pre-stressing of the inner containment and the civil engineering work on the outer containment. Installation of components (tanks, piping, pumps, cables and electrical and I&C cubicles, etc.) is now well advanced. In 2015, the last components of the primary system were installed and welding of the piping of this system is under way.

According to EDF, fuel loading and start-up of the Flamanville 3 reactor are scheduled for the end of 2018.

2.10.1 The stages up to commissioning of the Flamanville 3 reactor

Pursuant to Decree 2007-1557 of 2nd November 2007 (see point 3.1.3 of chapter 3), ASN authorisation is required to bring nuclear fuel inside the perimeter of the facility and to start up the NPP. Partial commissioning corresponds to the reception of nuclear fuel within the perimeter of the BNI and, for a nuclear reactor, commissioning of the facility corresponds to the insertion of nuclear fuel into the reactor vessel.

In accordance with Article 20 of this same Decree and Article 3 of the Flamanville 3 Creation Authorisation Decree, the licensee must send ASN a file comprising the safety analysis report, the general operating rules, a waste management study for the facility, the on-site emergency plan, the decommissioning plan and an update of the facility's impact assessment, no later than 12 months before the scheduled commissioning date and no later than six months before fuel is introduced within the perimeter of the BNI. These requests were sent by EDF to ASN in March 2015 (see point 3.3) and ASN expressed its comments and requests for additional information in letters dated 12th June and 13th July 2015 (available on *www.asn.fr*).

In parallel with the examination of the commissioning and partial commissioning authorisation requests, ASN also checks the construction, the first facility start-up tests and the preparedness of the teams in charge of operating the facility following its commissioning.

Finally, ASN assesses the conformity of the nuclear pressure equipment that is most important for safety with the requirements set by the regulations. In addition, in accordance with Article 9 of the Order of 10th November 1999 concerning monitoring of the operation of the PWR primary and secondary systems, EDF began the "pre-service inspection" in order to ensure the feasibility of the scheduled operational maintenance, in particular before loading of the fuel. ASN checks the performance

Lifting the steam generators.

of non-destructive tests carried out for this purpose on the Flamanville site.

2.10.2 Monitoring of construction, start-up tests and preparation for operation

ASN is faced by numerous challenges when checking construction, start-up tests and preparation for the operation of Flamanville 3. They concern:

- checking the quality of equipment manufacturing and installation construction in a manner commensurate with the safety, radiation protection and environmental protection issues, in order to be able to rule on the ability of the installation to meet the defined requirements;
- building on the experience acquired by each party concerned during the construction of this new reactor.
- ensuring that the start-up tests programme is satisfactory, correctly performed and that the expected results are obtained;
- ensuring that the teams in charge of operating the installation after commissioning are well-prepared.

To do this, ASN issued prescriptions for the design, construction and commissioning tests of Flamanville 3 and for the operation of the two Flamanville 1 and 2 reactors located close to the construction site. As the subject is a nuclear power reactor, ASN is also responsible for labour inspectorate duties on the construction site. In addition, ASN oversees the manufacture of pressure equipment that will form part of the primary and secondary systems and of the nuclear steam supply system. ASN's main actions in this field in 2015 are described in point 3.3.

2.10.3 Cooperation with foreign nuclear regulators

To be able to share its experience with other nuclear regulators, ASN multiplies technical exchanges with its foreign counterparts on the topic of regulating the design, construction and operation of new reactors.

Bilateral relations

ASN enjoys close relations with foreign nuclear regulators in order to share previous and current experience of authorisation procedures and regulation of the construction of new reactors. These relations started in 2004 with the Finnish Nuclear Safety Regulator (STUK, *Säteilyturvakeskus)* with a view to the construction of EPR type reactors on the sites at Olkiluoto (Finland) and Flamanville (France). Since then, STUK and ASN have worked closely together. In 2015, a technical progress meeting concerning the two projects was held in France and a visit to the Flamanville 3 construction site was organised.

In 2015, ASN and the Chinese Nuclear Safety Regulator (NNSA, National Nuclear Safety Administration) met in China, where two EPR type reactors are under construction. During this meeting, the progress made in the respective reviews of the commissioning authorisation applications were presented and the prospects for cooperation between the two countries were identified for the coming years, in particular with regard to monitoring the results of the start-up tests or the follow-up to the investigation of the Flamanville 3 vessel head anomaly. ASN also met the NNSA in France specifically on this latter subject.

In 2015, ASN welcomed experts from the British Office for Nuclear Regulation (ONR) in order to discuss the monitoring of the manufacture of nuclear pressure equipment intended for the EPR reactors at Flamanville and Hinkley Point C (United Kingdom).

These three safety regulators, STUK, NNSA and ONR, were invited by ASN to attend the debates of the Advisory Committee of experts on the anomaly affecting the Flamanville EPR reactor vessel.

Multinational cooperation

Some international bodies such as NEA and WENRA also provide opportunities for exchanges on practices and lessons learned from overseeing reactor construction.

ASN is a member of the Multinational Design Evaluation Programme (MDEP) which evaluates the design of new reactors (see point 3.3 of chapter 7). In this context, ASN took part in 2015 in the activities of the working group devoted to the detailed design of the EPR. With the support of IRSN, ASN took part in the work dealing with severe accidents, I&C, probabilistic safety assessments and the modelling of accidents and transients. The group also held two plenary sessions. ASN also takes part in the work done by the MDEP's Vendors Inspection Cooperation Working Group, which met twice in 2015, once in China and once at ASN. Within this framework, ASN made a particular contribution to the definition of a list of good inspection practices for suppliers of equipment intended for NPPs and the preparation of a multinational inspection, scheduled for 2016.

ASN also takes part in the Working group on the regulation of new reactors, which is a technical group of the Nuclear Energy Agency (NEA) Committee on Nuclear Regulatory Activities (CNRA) (see chapter 7, point 3.2.). The corresponding work in particular led to the creation of a database of anomalies and deviations observed in recent construction projects. ASN inputs the deviations observed on Flamanville 2 into this database.

For ASN, these international exchanges are one of the driving forces behind the harmonisation of safety requirements and inspection practices.

2.11 Studies on reactors of the future

Since 2000, in partnership with EDF and Areva, CEA has been looking at the development of fourth generation nuclear reactors, notably within the framework of the Generation IV International Forum (GIF). The six technologies covered by the work of this forum are the following:
- SFR: Sodium-cooled Fast Reactor;
- GFR: Gas-cooled Fast Reactor;
- HTR/VHTR: Gas-cooled High Temperature (850°C) and Very High Temperature (1,000°C) fast reactors;
- LFR: Lead-cooled Fast Reactor;
- MSR: Molten Salt Reactor;
- SCWR: Super Critical Water Reactor.

For their promoters, the main challenge for fourth generation reactors is to ensure sustainable development of nuclear energy while improving the use of natural resources, reducing the production of radioactive waste, improving safety (reducing the risk of core melt and improved protection of the population) while offering a greater ability to withstand security, proliferation or terrorism risks. For those promoting them, the industrial deployment of fourth generation reactors is envisaged in France no earlier than the middle of the 21st century. It will require prior creation of a prototype, for which the planned commissioning date is set at 2020 by the Act of 28th June 2006 on the sustainable management of radioactive materials and waste (see point 1.1 of chapter 16).

With this simultaneously medium and long-term view, at a stage much earlier than that required by the regulatory procedure, ASN wishes to monitor the development of fourth generation reactors by French industry, as well as the associated safety concerns – as was the case with development of the EPR so as to be in a position, at the appropriate time, to establish the safety objectives for these future reactors. For ASN, fourth generation reactors will have to meet stricter nuclear safety, radiation protection and environmental protection objectives. ASN in particular considers that fourth generation reactors will require a level of safety significantly higher than that of the third generation reactors, represented in France by the EPR.

ASN underlines the importance it attaches to the safety justification of the plant technology chosen over those adopted by the GIF. In this context, and on the basis of the documents transmitted at its request by CEA, Areva and EDF in 2009 and 2010, ASN asked the Advisory Committees for Nuclear Reactors (GPR), for Plants (GPU) and for Waste (GPD) for their opinion on the range of various reactor technologies envisaged for the fourth generation, with regard to the prospects for more stringent nuclear safety, radiation protection and environmental protection objectives, as well as with respect to the possibility of separation and transmutation of long-lived radioactive elements mentioned by the

Programme Act of 28th June 2006 on the sustainable management of radioactive materials and waste. The Advisory Committees returned an opinion on these subjects in April 2014. ASN will issue a position statement in 2016 on the objectives and orientations of the fourth generation reactors.

At the same time, CEA undertook studies for a prototype Sodium-cooled Fast Reactor (SFR): the Astrid project (Advanced Sodium Technological Reactor for Industrial Demonstration). In mid-2012, CEA sent ASN the Safety Orientations Report (DOrS) for the Astrid prototype. The safety orientations report was the subject of an ASN position statement in April 2014 (see chapter 14).

2.12 Labour Law in the nuclear power plants

ASN carries out labour inspectorate duties in the nineteen nuclear power plants in operation, the seven reactors undergoing decommissioning and the EPR reactor under construction at Flamanville. The number of people working in an NPP varies between 800 and 2,000 EDF and permanent contractor employees, supplemented by a large number of contractors and subcontractors involved in maintenance during reactor outage periods.

The health, safety, working conditions and quality of employment of the employees of EDF or the subcontractors, along with the safety of the facilities, are thus the subject of ASN regulation.

The role of the labour inspectorate is to ensure that the Labour Code as a whole is applied by the employers, whether EDF or its contractors. This oversight applies to the health, safety and working conditions of the employees: exposure to ionising radiation, to conventional risks involved in any industrial activity (risks linked to electrical installations, to pressure equipment, to chemical products, to explosion and asphyxia risks, to work at height or to handling of heavy loads), but also with regard to working hours, the operation of the personnel representative bodies, the conditions concerning the use of subcontracting, etc.

Since 2009, the links between the labour inspection steps taken and the other NPP regulation activities have been consolidated in order to achieve the integrated view of regulation sought by ASN. This is in particular the case for radiation protection, subcontracting, or for Organisational and Human Factors (OHF).

As of 31st December 2015, the ASN resources for its labour inspectorate duties are:
- twelve labour inspectors, including two working on a full-time basis and three undergoing training, assigned to the regional divisions and working directly with the sites;
- a central labour director, responsible for managing and coordinating the network of labour inspectors and acting as the interface with the Ministry responsible for Labour. The agreement with the General Directorate for Labour of the Ministry responsible for Labour, renewed in 2015, is implemented in the regions by agreements between the ASN regional divisions and the Regional Directorates for Enterprises, Competition, Consumption, Labour and Employment (DIRECCTE).

2.13 Personnel radiation protection

Exposure to ionising radiation in a nuclear power reactor comes from activation of corrosion products (primarily) and from fuel fission products. All types of radiation are present (neutrons, α, β and γ) and the risk of exposure is both external and internal. In practice, more than 90% of the doses come from external exposure to β et γ.radiation. Exposure is primarily linked to maintenance operations during reactor outages.

ASN checks compliance with the regulations relative to the protection of workers liable to be exposed to ionising radiation in NPPs. In this respect, ASN concerns itself with all workers active on the sites, whether EDF or contractor personnel.

This oversight is carried out during inspections (specifically on the topic of radiation protection, one to two times per year and per site, during reactor outages, following incidents, or occasionally in the EDF head office departments and engineering centres), and during the review of files concerning occupational radiation protection (significant events, design, maintenance or modification files, EDF documents implementing the regulations, etc.) with the support of IRSN's technical expertise when necessary.

Finally, meetings are held periodically between ASN, IRSN and EDF in order to monitor the progress of the technical or organisational projects or to compare ASN's analysis with that of the licensee, more specifically through annual reviews, and to identify possible areas for improvement.

2.14 The environmental and health impacts of NPPs

2.14.1 Revision of the prescriptions concerning water intake and discharges

The Environment Code empowers ASN to define prescriptions concerning BNI water intake and discharges (see point 4.1.1 of chapter 4).

On the occasion of the renewals or modifications of these prescriptions, ASN sets the limit values for emissions, water intake and discharge of effluents on the basis of the best available technologies in technically and economically acceptable conditions, taking into consideration the characteristics of the installation, its location and the local environmental conditions.

ASN also sets the rules applicable to the management and monitoring of effluent discharges, water intake, environmental monitoring and information of the public and the authorities (see point 4.1 of chapter 4).

In order to set these rules, ASN bases its work on operating experience from all the reactors, while taking account of operational changes (change in conditioning of systems, anti-scaling treatment, biocidal treatments, etc.) and the higher-level regulations.

TO BE NOTED

Radiological impact of discharges

The calculated radiological impact of the maximum discharges given in the EDF files on the most heavily exposed population group, still remains well below the allowable public dosimetric limit (1 mSv/year).

The annual effective dose delivered to the population reference group (group subject to maximum radiological impact) is thus estimated at between a few microsieverts and several tens of microsieverts per year, depending on the particular site. This exposure represents less than 0.1% of the total average dose to which the French population is exposed (see chapter 1).

2.14.2 Oversight of waste management

Management of the radioactive waste produced by NPPs is covered by the general framework for management of waste from all BNIs, presented in chapter 16. For all waste, whether or not radioactive, ASN examines the licensee's baseline requirements as required by the regulations and as described in point 3.5.1 of chapter 3). This document in particular comprises a summary of the waste produced, the quantities involved and the management methods, the "waste zoning" and the status of the existing disposal solutions.

Each site sends ASN annual details of the waste it generates, indicating the disposal routes, a comparison with previous years, a report on any discrepancies observed and on the organisation of the site, as well as any notable occurrences and future prospects. In compliance with the regulations, EDF carries out waste management at source, in particular differentiating between waste from nuclear zones and other waste. EDF's waste management strategy is currently being examined by ASN (see chapter 16). The licensee and ASN hold regular meetings to discuss waste-related matters and waste management, notably through annual reports.

These elements, as well as the inspections during which the inspectors review the site's waste management organisation, constitute the basis of ASN's monitoring of the management of waste produced by EDF's NPPs and compliance with the regulations.

2.14.3 Increased protection against other risks and nuisances

Some cooling systems in NPPs are environments that are favourable to the development of legionella and other amoebas (see point 1.4). ASN therefore sets maximum legionella concentration levels for cooling systems equipped with cooling towers and for Naegleria fowleri amoeba concentration levels downstream of the environmental discharge, along with facility monitoring requirements.

Through file reviews and its field checks, ASN closely monitors the progress of the preventive or remedial measures taken by EDF to reduce the risk of the proliferation of these micro-organisms and the results of these actions, including the chemical discharges resulting from biocidal treatment.

A draft resolution concerning the prevention of microbiological risks linked to the cooling installations of nuclear power reactor secondary systems is currently under preparation, in order to make changes to these regulations that are consistent with those of Installations Classified on Environmental Protection grounds (ICPE). It was opened for public consultation on the ASN website from 2nd March to 4th May 2015. This draft resolution will be presented to the Higher Council for the Prevention of Technological Risks (CSPRT) in 2016 (see chapter 2, point 2.4.3) and submitted for ministerial approval.

Finally, the steps taken by EDF to enable chillers to operate with coolants with a lower overall heating potential are well advanced. Chiller management does not however at present make it possible to eliminate the unwanted discharge of these fluids into the atmosphere.

3. NUCLEAR SAFETY AND RADIATION PROTECTION NEWS

3.1 Experience feedback from the Fukushima Daiichi accident

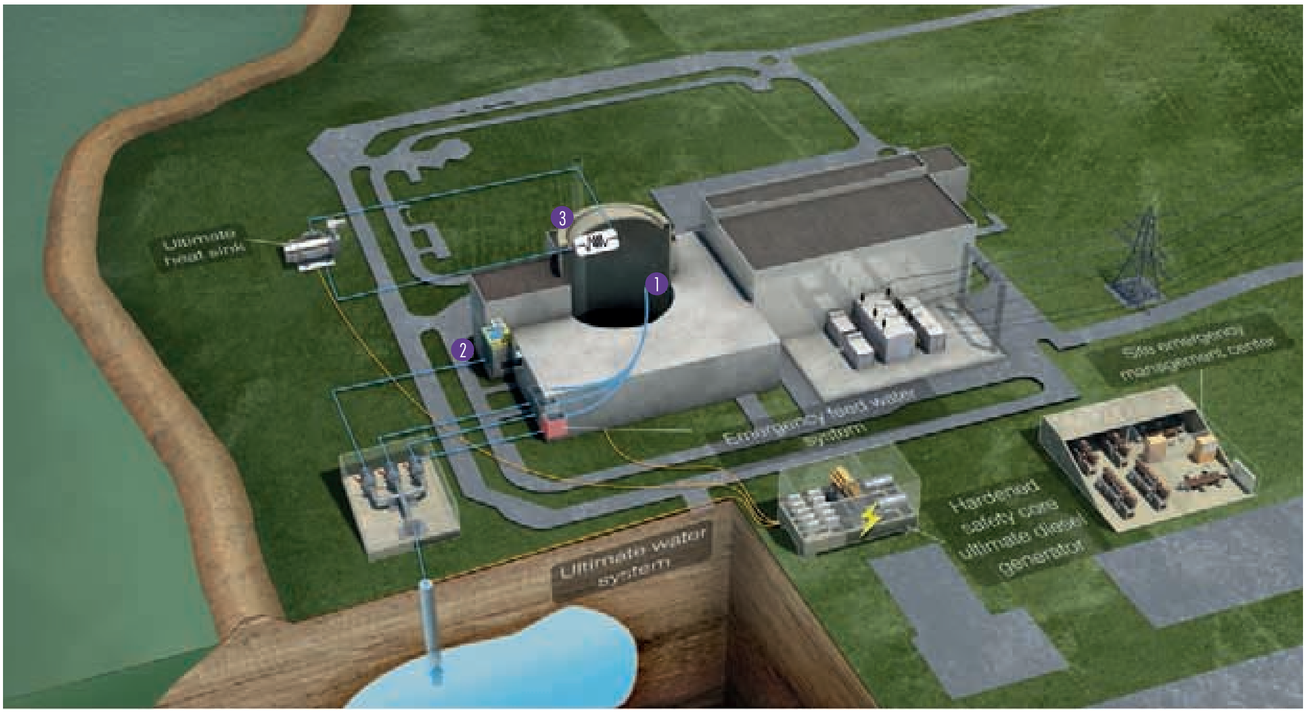
After the Fukushima Daiichi accident, ASN issued a set of resolutions dated 5th May 2011 asking the licensees of major nuclear facilities to perform stress tests in the light of this accident.

The results of these stress tests were presented to the Advisory Committees for Reactors and for Laboratories and Plants which met on 8th, 9th and 10th November 2011, and ASN issued a position statement on them on 3rd January 2012. This position was itself examined within the framework of the European stress tests, which were completed in April 2012.

On the basis of the options of the Advisory Committee and the conclusions of the European stress tests, ASN issued a series of resolutions dated 26th June 2012 requiring EDF to implement:

- •a “hardened safety core” of material and organisational measures which, in the event of an extreme external hazard, are designed to:
  - prevent an accident with fuel melt, or limit its progression,
  - limit large-scale radioactive releases,
  - enable the licensee to carry out its emergency management duties;
- a local emergency centre allowing emergency management of the nuclear site as a whole in the event of an extreme external hazard;
- a Nuclear Rapid Intervention Force (FARN) which, using mobile means external to the site, can intervene on a nuclear site in a pre-accident or accident situation;
- a range of corrective measures or improvements, notably the acquisition of additional communication and radiological protection means, the implementation of additional instrumentation, extensive consideration of internal and external hazard risks, improvement of the way in which emergency situations are taken into account.

THE PRINCIPLE of the hardened safety core



❶ reactor cooling
❷ pool cooling
❸ reactor building cooling

EDF has met all the regulatory deadlines and its commitments.

Nevertheless, ASN has supplemented its demands with a set of resolutions dated 21st January 2014 aiming to clarify certain design provisions of the hardened safety core.

ASN's demands are part of a continuous process to improve safety and aim to be able to cope with situations far beyond those normally considered for this type of installation. They concern measures to prevent and mitigate the consequences of an accident for all the installations on a site, beyond their initial design conditions. They require both additional fixed resources and off-site mobile resources. In the international context, these demands stand out through the scope and scale of the measures adopted in the wake of the Fukushima Daiichi accident.

Given the nature of the required work, the licensee must carry out studies for the design, construction and installation of new equipment, which first require time and then require a schedule to optimise their implementation on each NPP. Insofar as these major works are carried out on nuclear sites which are in service, it is also necessary to ensure that their implementation does not degrade the safety of the power plants.

To take account of both the engineering constraints involved in these major works and the need to introduce the post-Fukushima improvements as soon as possible, their implementation is planned in three phases:

<u>Phase 1 (2012-2015)</u>

Deployment of temporary or mobile measures to enhance protection against the main situations of total loss of the heat sink or electrical power supplies.

At the end of 2015, EDF had deployed the planned measures.

<u>Phase 2 (2015-2020)</u>

Deployment of definitive design and organisational means that are robust to extreme hazards, to deal with the main scenarios of total loss of the heat sink or electrical power supplies beyond the baseline safety requirements in force. The most important measures are:
- installation of a large-capacity ultimate backup diesel-generator set, requiring the construction of a dedicated building to house it;
- setting up of an ultimate water source;
- creation of an ultimate water make-up system for each reactor and each spent fuel pool;
- reinforcement of the earthquake resistance of the containment venting filter;
- construction on each site of a local emergency centre capable of withstanding extreme external hazards (functionally independent in an emergency situation).

EDF had already started most of the studies needed to deploy this equipment. However, discussions are still in progress concerning the schedule to deploy these measures on each of the EDF reactors and ASN will issue a position statement on this subject in 2016.

<u>Phase 3 (as of 2019)</u>

This phase will supplement phase 2, in particular to take account of other potential accident scenarios. The most important measures are:
- removal of the residual power by the steam generators by means of an independent ultimate backup feedwater system supplied by the ultimate heat sink;
- addition of a new makeup pump to the primary system;
- completion of the fixed connection systems for the SG backup feedwater supply, the PTR cooling water tank and the spent fuel pit;
- installation of an ultimate instrumentation & control system and the definitive instrumentation of the "hardened safety core";
- installation of a reactor containment ultimate cooling system that does not require opening of the containment venting-filtration system in the event of a severe accident;
- implementation of a solution for flooding the reactor pit to prevent corium melt-through of the basemat.

EDF still has to conduct feasibility studies on these latter two points. Discussions on the schedule for deployment of the provisions of phase 3 for each of the EDF reactors are in progress and ASN will issue a position statement on this subject in 2016.

3.2 Examination of NPP operating life extensions

The licensee of a nuclear facility must conduct a periodic safety review of its facility every ten years (see point 2.9.4).

The reactors of the 900 MWe plant series

The periodic safety review associated with the third ten-yearly outage inspections

In July 2009, ASN issued a position statement on the generic aspects of an operating life extension for the 900 MWe reactors beyond 30 years. ASN has not identified any generic element that would compromise EDF's ability to manage the safety of the 900 MWe reactors until the next periodic safety review. ASN considers that the new baseline safety requirements presented in the generic safety report for the 900 MWe reactors and the modifications to the installation envisaged by EDF are such as to maintain and improve the overall level of safety of these reactors.

As this generic assessment does not take account of any individual specific features, ASN gives an opinion on the ability of each reactor to continue to function, more specifically based on the results of inspections performed during the reactor conformity check during the third ten-yearly outage and on the assessment of the reactor review report submitted by EDF.

In 2015, 4 reactors incorporated the improvements resulting from the periodic safety review on the occasion of their third ten-yearly outages, thus raising to 27 the number of the 900 MWe plant series reactors (out of 34) which had carried out their third ten-yearly outage inspection.

In 2015, ASN also sent the Minister responsible for Nuclear Safety its analysis of the review conclusions reports for the Tricastin 2 and 3 reactors. On the basis of this analysis, ASN has not identified any element that would compromise EDF's ability to satisfactorily control the safety of these two 900 MWe reactors until the next periodic safety review. Pursuant to Article L.593-19 of the Environment Code, ASN took this opportunity to issue additional prescriptions designed to reinforce the safety of these reactors.

The periodic safety review associated with the fourth ten-yearly outage inspections

The continued operation of the nuclear reactors beyond their fourth ten-yearly outage inspection is of particular importance in a number of respects:

- The period of forty years of operation corresponds to the initial design hypotheses for a certain number of equipment items, in particular with regard to their ability to function in accident operating conditions (qualification). The studies concerning the conformity of the installations and the management of equipment ageing therefore need to be reviewed to take account of the degradation mechanisms actually observed and the maintenance and replacement strategies adopted by the licensee.
- This periodic safety review is then an opportunity to complete the integration on the 900 MWe reactors of the modifications specified following the stress tests carried out in the wake of the Fukushima-Daiichi accident. This concerns the phase 3 work (see point 3.1 on Fukushima).
- Finally, the wish expressed by EDF in 2010 to significantly extend the operating life of the reactors beyond 40 years was examined by ASN. By this time frame, the 900 MWe series of reactors will be operating alongside EPR or equivalent type reactors, which are designed to meet significantly reinforced safety standards. Their safety must therefore be reassessed in the light of these new safety requirements, the state of the art nuclear technologies and the operating life targeted by EDF.

After familiarising itself with ASN's requests of June 2013 concerning the orientations of the generic studies programme carried out by EDF in order to extend the operating life of the reactors beyond 40 years, EDF drafted and, in October 2013, submitted its orientation file for the periodic safety review associated with the fourth ten-yearly outage inspections for the 900 MWe reactors (DOR VD4-900). Further to ASN's requests for additional data in March 2014, EDF updated its file.

ASN examined this file with the assistance of IRSN. In April 2015, it asked the GPR for its opinion on the orientations of the generic studies being envisaged by EDF on the various topics contained in the DOR VD4 900 file.

Following the GPR meeting, EDF completed its generic studies programme in June 2015 with a certain number of measures and clarified a certain number of its proposals.

In 2016, ASN will issue a position statement on the orientation of the generic studies to be carried out in preparation for the fourth periodic safety reviews on the nuclear reactors, after consulting the public on the draft requests for additional information to be sent to EDF concerning its study and verification programme.

The reactors of the 1,300 MWe plant series

The periodic safety review associated with the second ten-yearly outage inspections

In 2006, ASN gave a favourable opinion to the generic aspects of continued operation of the 1,300 MWe reactors up to their third ten-yearly outage inspections, provided that the modifications decided on during this review were effectively implemented.

The twenty 1,300 MWe reactors have now all undergone their second ten-yearly outage inspections and have incorporated the improvements identified by the periodic safety review.

Pursuant to Article L.593-19 of the Environment Code, ASN sent its position statement on the two Saint-Alban reactors, Cattenom reactors 2 and 3, the two Nogent reactors and Penly reactor 1 and took this opportunity to issue additional prescriptions designed to reinforce the safety of these reactors. It is currently preparing its position regarding the continued operation of the other 1,300 MWe reactors.

The periodic safety review associated with the third ten-yearly outage inspections

In early 2015, ASN ruled on the generic aspects of the continued operation of the 1,300 MWe reactors beyond thirty years. ASN considers that the steps taken or being envisaged by EDF to assess the condition of its 1,300 MWe reactors and manage their ageing up until the periodic safety review associated with their fourth ten-yearly outage inspections are acceptable. ASN also considers that the modifications identified by EDF during this study phase will help to significantly improve the safety of these installations. These improvements in particular concern reinforcing protection of the facilities against hazards, reducing releases of radioactive substances in the event of an accident, with or without core melt, and preventing the risk of uncovering of the fuel assemblies stored in the spent fuel pit or during handling.

Paluel reactor 2 is the first 1,300 MWe reactor to undergo a third ten-yearly outage inspection, which started in 2015.

The reactors of the 1,450MWe plant series

The periodic safety review associated with the first ten-yearly outage inspections

The generic studies and modifications associated with the first periodic safety reviews of the 1,450 MWe reactors were the subject of an ASN position statement in 2012, which in particular requested additional work by EDF to demonstrate the adequacy either of the studies conducted, or of the modifications made to the installations during their first ten-yearly outage inspection, in order to comply in full with the objectives set in the periodic safety review.

The first ten-yearly outage inspections took place between 2009 and 2012.

EDF's answers and the periodic safety review conclusions reports for the four 1,450 MWe reactors are currently being assessed and ASN intends to issue its position statement on their continued operation to the Minister in charge of Nuclear Safety in 2016.

The periodic safety review associated with the second ten-yearly outage inspections

In 2011, EDF transmitted its orientation proposals for the generic studies programme for the periodic safety review associated with the second ten-yearly outage inspections of the 1,450 MWe reactors. After consulting the GPR in 2012, EDF supplemented its generic studies programme with a number of measures and clarified some of its proposals. In February 2015, ASN ruled on the orientations of the periodic safety review associated with the second ten-yearly outage inspections of the 1,450 MWe reactors. ASN more specifically considers that the safety objectives to be considered for the VD2 N4 safety review must be defined in the light of the objectives applicable to the new reactors and asked EDF to study the measures liable to comply with this requirement as rapidly as possible, so that they can be implemented as of the second ten-yearly outage inspections on the reactors of the N4 plant series.

The second ten-yearly outage inspections for the 1,450 MWe plant series reactors are scheduled to start in 2018 with the Chooz B2 reactor and will run until 2022.

3.3 Monitoring of the EPR Flamanville 3 reactor

Oversight of the Flamanville 3 engineering activities

In 2015, ASN carried out three inspections in the EDF engineering departments responsible for the detailed design studies for Flamanville 3, for drafting the partial commissioning authorisation application files for Flamanville 3, for defining the start-up tests to be performed or for monitoring manufacturing operations at the suppliers.

Examination of the commissioning authorisation application and the partial commissioning authorisation application for Flamanville 3

On 19th March 2015, ASN received the commissioning authorisation application for Flamanville 3. With IRSN, its technical support organisation, ASN carried out a preliminary review of this application to check that it contains all the documents required by the regulations and the necessary information to allow a full technical examination. Following this preliminary examination, ASN confirmed that all the documents required by the regulations were indeed present, but it considered that additional information was needed to enable ASN to rule on a possible commissioning authorisation for Flamanville 3. The additional information requested in particular concerns the conformity of the as-built installation with the file submitted, the dimensioning of the systems and the accident studies.

ASN did however begin a technical examination of the file on those subjects for which only very little data was still missing. Some subjects, such as the substantiation of the critical heat flux correlation, gave rise to requests from ASN. Two GPR meetings were thus devoted to Flamanville 3 in 2015: one covering technical, organisational and human resources, defined for reactor normal operating conditions and accident operating conditions; the other covering the management of severe accidents, their radiological consequences and the level 2 probabilistic safety assessments. ASN will shortly be issuing its requests resulting from these meetings.

Furthermore, on 19th March 2015, ASN received the partial commissioning authorisation application for Flamanville 3, needed to admit fuel within the perimeter of the facility and carry out certain tests. ASN carried out a preliminary examination of this file, which concluded that a certain amount of additional information was required, more specifically to assess the risks and detrimental effects which could result from tests using radioactive tracer gases to verify the correct operation of certain effluent treatment systems.

Oversight of construction activities on the Flamanville 3 site

In 2015, ASN carried out twenty inspections on the Flamanville 3 construction site to monitor construction, the performance of the first start-up tests and the preparedness of the teams who will be in charge of operating the reactor. These in particular concerned the following technical topics:
- civil engineering, including the activities involved in the pre-stressing of the reactor building inner containment, the concrete sealing of the limonite ring around the reactor vessel at the bottom of the reactor cavity and those involved in the construction of the future local emergency centre;
- the mechanical assembly activities, more specifically concerning the reactor main primary system, the hydraulic part and the motor of a reactor coolant pump, the reactor safeguard systems, the neutron flux measurement system in the reactor vessel and the equipment necessary for operation of the emergency generator sets;
- the electrical systems installation activities, including cable drawing in the buildings;
- the first start-up tests and the associated organisation, in particular for the equipment situated in the reactor pumping station and the premises ventilation equipment;
- non-destructive inspection of welds, in particular during the pre-service inspection of the primary system, and worker radiation protection;
- the organisation of the operating staff for the future Flamanville 3 reactor, for production of the operating documentation, preparations for accepting fuel and integration of organisational and human factors;
- the environmental impact of the construction site;
- the reception and installation of non-nuclear pressure equipment.

In its construction site oversight activities, ASN devoted particular attention to the following subjects in 2015:
- maintaining a strategy to conserve the equipment and structures present on the construction site until the commissioning of Flamanville 3. Owing to the reactor commissioning postponements announced by EDF, ASN ensures that EDF pays particular attention to defining and complying with requirements for conserving the equipment already installed and the structures already built. ASN regularly examines this point during its inspections, in particular ensuring that the risks associated with work being carried out in the buildings simultaneously by several trades are taken into account.
- EDF handling of deviations which occurred during the pre-stressing operations. Pre-stressing determines compliance with the inner containment's ability to withstand an accident situation. The pre-stressing operations gave rise to deviations concerning the tensioning of the cables and the infilling of the sheaths with grout. ASN was attentive to the implementation of the action plan defined by EDF to handle these deviations and prevent them from happening again.
- continuation of the main primary system installation activities and the handling of several deviations. This system contains the reactor core and is thus of primary importance for safety. With regard to EDF's activities, ASN examined the monitoring carried out by EDF on the outside contractors participating in installation of the primary system, in particular its manufacturer Areva NP. In this respect, ASN pays particular attention to compliance with the worksite cleanness requirements and the adequate management by EDF of joint-contractor work in the vicinity of the equipment.
- the preparation for and performance of the first start-up tests on the ventilation equipment and integration of experience feedback for continued testing in the pumping station. The start-up tests must help demonstrate that the reactor's structures, systems and components meet the requirements assigned to them.
- the preparation for operation of the Flamanville 3 reactor by the EDF entity which will be responsible for operation after construction. This entity currently comprises more than 400 staff. With a view to reactor commissioning, EDF is continuing with a process of gradual transfer of responsibility for the operation of the structures, systems and components from the entity in charge of construction and reactor start-up operations to the entity in charge of its future operation. The steps in this process enable future operating personnel to upgrade their skills, familiarise themselves with the reactor equipment, draw up operating documentation and develop the appropriate tools. Through its oversight, ASN verifies whether the future operating staff take advantage of operating experience and best practices employed in EDF's NPPs and whether they correctly assimilate the working of the equipment during reactor construction and systems start-up tests.

Labour inspectorate duties on the Flamanville 3 reactor construction site

The actions carried out by the ASN labour inspectors in 2015 consisted in:
- carrying out safety checks on the construction site;
- answering direct queries from the employees;
- carrying out inquiries following occupational accidents.

In 2015, the ASN labour inspectors also continued with the judicial procedures to deal with illegal work, for which investigations were under way.

Monitoring the manufacture of nuclear pressure equipment for the Flamanville 3 reactor

Over the course of 2015, ASN continued to assess the conformity of the Nuclear Pressure Equipment (ESPN) for the reactor primary and secondary systems. Manufacturing has been completed for the major equipment items and is in progress for cocks, valves and check-valves.

In 2010 and 2011, several non-conformities were detected by Areva NP during the manufacture of the vessel head. More specifically, there were numerous defects in the vessel head adapter welds. These deviations required Areva NP to carry out large-scale repairs, which started in 2013. This repair work continued in 2014 and was closely monitored by ASN. Following ASN requests, Areva NP developed a more effective ultrasound method in 2013 to inspect the vessel head adapter welds. This was deployed in 2015. The vessel head repairs were completed in 2015.

At the end of 2014, Areva NP also informed ASN that the tests carried out on a vessel head representative of that intended for Flamanville 3 revealed the presence of an area with a high carbon concentration leading to mechanical properties that were lower than anticipated. Measurements confirmed the presence of this anomaly in the vessel closure head and bottom head of the Flamanville EPR reactor. In the light of these results, Areva NP sent ASN a file presenting the envisaged approach for demonstrating the sufficient mechanical properties of the material, this approach being based on a new test programme.

On the Flamanville site, the construction of the EPR's nuclear steam supply system is progressing in successive assembly phases, for which ASN, together with the organisations approved for assessment of the conformity of nuclear pressure equipment, ensures compliance with the necessary pre-requisites. These pre-requisites in particular concern adequate consideration of the risks inherent in assembly, the checks to be performed on the site and the organisation put in place by EDF and Areva NP to limit the risks associated with the activities carried out in the vicinity by other contractors

UNDERSTAND

The Flamanville 3 EPR vessel

On 7th April 2015, ASN released information concerning an anomaly in the composition of the steel in the centre of the Flamanville 3 EPR vessel closure head and bottom head. This anomaly is linked to the presence of a high carbon concentration which results in mechanical properties that are not as robust as were expected.

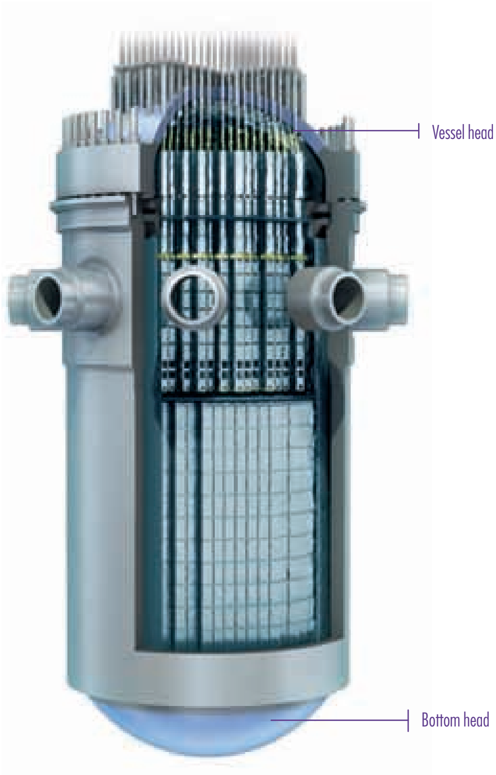
Areva sent ASN a file presenting the approach that it envisages using to demonstrate the sufficiency of the mechanical properties of the material used in the manufacture of the vessel closure head and bottom head for the future Flamanville EPR reactor. This approach will be based in particular on the future results of a new programme of mechanical and chemical tests.

After joint examination of this file with IRSN, ASN convened the Advisory Committee for Nuclear Pressure Equipment (GPESPN) on 30th September 2015. Representatives from the HCTISN, the Anccli and foreign safety regulators concerned by the construction of an EPR reactor attended this session as observers. The GPESPN submitted an opinion and recommendations to ASN.

On this basis, ASN issued a position statement on 12th December 2015 concerning the approach proposed by Areva to demonstrate the mechanical properties of the Flamanville 3 EPR vessel closure head and bottom head.

Subject to its observations and demands being taken into account, ASN considers that the approach proposed by Areva is acceptable in principle and it has no objection to the start of the new planned test programme.

The results of this new test programme will be a crucial factor in ASN's decision on whether or not the Flamanville 3 EPR vessel closure head and bottom head are suitable for service. This test programme will take place over several months in 2016.



and to ensure the cleanness of the working areas and the assembled equipment.

ASN and the approved organisation review the technical documentation concerning assembly operations and the monitoring of the assembly or manufacture of nuclear pressure equipment carried out on the site. ASN and the approved organisations require that Areva NP analyse the feedback from one assembly sequence before initiating the next one. This was in particular the case following the discovery in late 2014 and in 2015 of defects in several primary system welds. These defects occurred during connection of the steam generators to the primary system and during welding of a section of the Pressuriser Expansion Line (LEP). In the first case, investigations are still in progress to look at the origin of the welding defects detected and the corrective measures required. In the second case, the weld affected was repaired and welding of the other LEP sections continued. In 2015, ASN carried out three inspections of Areva NP on the assembly of the NSSS and four inspections of the inspection organisations or bodies approved by ASN to monitor these activities. These inspection organisations and bodies themselves carried out several hundred inspections in 2015.

The NSSS assembly operations will be gradually expanded, after ASN checks that the experience acquired during the activities has been taken into account.

3.4 The other notable findings of 2015

3.4.1 Notable findings relating to oversight of pressure equipment

Replacement of steam generators intended for Le Blayais reactor 3

At the end of 2014, after examining the design and the manufacture of the new steam generators intended for reactor 3 in the Le Blayais NPP, ASN found Areva NP had not provided all the required safety justifications.

On 24th November 2014, ASN therefore asked Areva NP and EDF to provide additional safety justifications. These were the pre-requisites for installation and then commissioning of these steam generators.

Since then, Areva has provided the additional information enabling these preconditions to be lifted. On 24th July 2015, ASN therefore issued the conformity assessment reports for the three replacement steam generators for Le Blayais reactor 3, enabling them to be started up by EDF.

3.4.2 Notable findings relating to labour inspectorate duties

Oversight of occupational health and safety

With regard to occupational health and safety, the ASN inspections more specifically covered the following topics in 2015:
- monitoring of construction site activities, with particular attention being paid to lifting work and risks linked to work being performed by several contractors simultaneously and to work at height;
- the use of Carcinogenic, Mutagenic or Reprotoxic chemical products, asbestos, or welding activities;
- fire protection measures as part of an integrated and coordinated approach to safety and Labour Code requirements;
- operating experience feedback from the viewpoint of occupational safety during steam generator replacement operations;
- risk assessment and prevention during preparations for the operations requiring personnel entry inside the steam generators or reactor buildings at power;
- mandatory checks on polar cranes in reactor buildings and the heavy-lift cranes in the fuel buildings.

Occupational accident inquiries, which are always held in the event of a severe accident, were rare in 2015, and no fatal accident occurred.

Monitoring working hours

In 2015, the ASN labour inspectors continued their checks on compliance with the regulations on working hours and on daily and weekly rest periods, mainly during the reactor outages. They once again observed breaches of maximum working hours and rest periods, for certain populations of technicians and managers required to work intensively during reactor outage periods. Contacts were made with the public prosecutor's offices concerned in order to follow up the procedures initiated.

International subcontracting and provision of services

ASN closely monitors the criminal proceedings instigated in previous years, more specifically through regular contacts with the public prosecutor's offices. The labour inspectors also took part in several inspections jointly with the nuclear safety inspectors, to look at the quality of the work done by the contractors. Inspections were carried out on the conditions for secondment of staff from foreign contractors.

Criminal proceedings

The ASN labour inspectorate sent the various Public Prosecutor's departments concerned four formal notices served on the NPPs in 2015.

3.4.3 Notable findings relating to radiation protection of personnel

Advisory Committee meeting

The Advisory Committee for Nuclear Reactors (GPR) met at the request of ASN in order to rule on the strategy adopted by EDF to limit collective and individual doses of ionising radiation received by workers in its NPPs in operation in France, more specifically for the project to renovate the NPP fleet over the period 2015-2025.

Significant contamination events

Three significant contamination events were notified in 2015 in the NPPs operated by EDF. They concern:
- contamination of the face of a contractor staff member assigned to work on an exchanger on the chemical and volume control system on the primary system of the Le Blayais NPP, leading to exposure in excess of the regulation limit per square centimetre of skin. This event was rated level 2 on the INES scale;
- contamination of the face of a contractor staff member in charge of checking the tag-out padlocks on the valves of the spent fuel pit cooling system in the Gravelines NPP, leading to exposure in excess of one quarter of the regulation limit per square centimetre of skin. This event was rated level 1 on the INES scale;
- contamination of the face of a contractor staff member through contact with a contaminated rope during handling of heat insulation plates in the Nogent NPP, leading to exposure in excess of one quarter of the regulation limit per square centimetre of skin. This event was rated level 1 on the INES scale.

3.4.4 Notable findings relating to the environmental impacts of NPPs and discharges

Revision of the prescriptions concerning water intake and effluent discharges

In 2015, ASN completed its examination of the water intake and effluent discharge files for the Chinon and Saint-Laurent-des-Eaux NPPs and continued its examination of those for Fessenheim, Cruas and Paluel.

The ASN resolutions issued accordingly (see point 2.14.1) deal with the modifications made by EDF to the installations, such as changes to the chemical conditioning of the secondary system and the adoption of anti-scaling or biocidal treatment of the cooling systems (see point 1.4). They also take account of changes to the regulations.

ASN also continued its review of the EDF files concerning implementation on the NPPs of water intake systems designed to guarantee “ultimate makeup” water in the event of an accident, as prescribed by the “post-Fukushima” stress tests (see point 3.1). ASN more specifically temporarily authorised the Chinon and Dampierre-en-Burly NPPs to carry out groundwater pumping tests to determine whether this could be used as the ultimate cooling water make-up source.

Finally, ASN authorised the transfer of non-radioactive warm water from the Gravelines NPP cooling systems to the methane tanker terminal in Dunkerque.

Compliance with discharge limits

In Cattenom NPP, the annual authorised release of copper was found to have been exceeded in 2014. ASN thus served formal notice on EDF in January 2015 to take all steps to ensure compliance with this limit value in 2015. ASN then checked the technical and organisational steps taken, in particular for monitoring of discharges, to ensure compliance with this formal notice.

TO BE NOTED

Level 2 incident in Le Blayais NPP: irradiation of a worker during a scheduled outage of reactor 4

On 21st August ASN was informed by EDF of the exposure of a worker from an EDF contractor to a dose of ionising radiation in excess of the regulation limit.

On 18th August, during the check carried out prior to exiting the controlled area, contamination was detected on the chin of the staff member. He had been assigned to maintenance work in preparation for the hydrotesting of an exchanger on the chemical and volume control system in the reactor 4 safeguard auxiliaries building in the Le Blayais NPP.

The worker was then cared for by the site’s risk prevention service, which carried out decontamination operations. During these operations, the radioactive particle which caused the contamination was found and immediately removed. The occupational physician then assessed the whole body dose received and the dose on the skin of the chin.

For workers liable to be exposed to ionising radiation during their professional activities, the annual regulation dose limits are, for twelve consecutive months, 20 mSv for the whole body and 500 mSv for a skin surface area of 1 cm^2.

The evaluation made by EDF of the dose received by the worker’s chin is higher than the regulation limit for the skin. The whole body dose received by the worker is well below the annual regulation limit.

ASN carried out an inspection on the site on 24th August 2015. The inspectors checked that EDF and the contractor had taken all necessary steps for adequate management of the incident and analysis of its causes.

Owing to the regulation annual dose limit for the skin being exceeded, EDF proposed rating this event level 2 on the eight-level (0-7) INES scale. ASN confirmed the level 2 rating of this incident.

ASN inspection on the topic of water intake and measurement of samples of effluents discharged from the Flamanville NPP, November 2011.

4. ASSESSMENTS

4.1 Assessments of the overall performance of the NPPs in service

4.1.1 Nuclear safety assessment

Reactor operations

Management of reactor operations is on the whole satisfactory. However, in 2015, a number of activities governed by prescriptive documents, such as the performance of periodic tests, were nonetheless the cause of significant events. The root causes of these events are numerous and can sometimes be cumulative. These include inadequate preparation for activities, meaning that the personnel concerned are not sufficiently aware of the risks involved or of the documentation needed to carry them out. It is also necessary to minimise the possible interpretations of these documents and take account of the differing levels of know-how and expertise among the personnel concerned.

This situation is indicative of the insufficient involvement by the head office departments in monitoring the assimilation of the prescriptive documents by the NPPs. It is also indicative of external Operating Experience Feedback (OEF) management that is not yet robust enough, both between the sites and with respect to EDF head office departments. It in particular highlights the need to reinforce the national OEF loop in order to improve the documentary production process. ASN drew the attention of the licensee to these weak points.

EDF's in-house Independent Safety Organisation (FIS) plays its role of verifying the actions and decisions taken by the departments in charge of operating the installations. However, there is a need for improved traceability of the points justifying the need for these verifications and of the resulting positions adopted. The inspections carried out by ASN on the FIS in 2013 and 2014 led EDF to propose an action plan, currently being evaluated by ASN.

With regard to the periodic tests and despite the improvements observed on the sites compared to 2014, efforts are still needed with regard to the scheduling, preparation and performance of these tests. Furthermore, both the prior analysis of the operation and the interpretation of the results obtained need to be strengthened. The process used for a subsequent ruling on the validity of the tests also needs to be reinforced in order to promote a questioning attitude.

UNDERSTAND

The independent safety organisation

The Independent Safety Organisation (FIS) verifies and analyses compliance with the safety requirements by the operational teams. It comprises three levels:

- the General Inspector (IGSNR) reporting to the Chairman of the EDF Group, assisted by three inspectors;
- the director delegate for safety in the Nuclear Operation Division (DPN), assisted by the nuclear inspectorate;
- and the head of the safety-quality delegation in each plant, assisted by the safety-quality department. The safety engineers from the safety-quality department perform daily checks on the safety status of the facility.

Emergency situations

The 2015 emergency management inspections confirmed that the organisation of the NPPs is satisfactory in this field. The teams required to implement the On-site Emergency Plans (PUI) are correctly sized and all the emergency team members take part in an exercise every year. The inspections also showed that the national harmonised baseline requirements of 2014 are correctly implemented and that the new emergency organisation they stipulate for each plant has been correctly taken on board.

Preparedness for management of emergency situations could however be improved in terms of the management and utilisation of mobile resources in an emergency situation and the analysis of the lessons learned from emergency exercises.

Fire and explosion risks

In 2015, ASN carried out 17 inspections on fire and explosion risk management in 15 NPPs. These risks were also identified during the worksite inspections carried out during the reactor outages and during the in-depth inspection on the Bugey NPP.

Exercise involving the rescue of two people on a cooling tower by the GRIMP (Hazardous Environment Reconnaissance and Intervention Group) crews of the Tarn-et-Garonne departmental fire and emergency response service, at a height of 178.50 metres.

Fire

Following these inspections and with regard to the fire risk, ASN notes that the relations between the sites and the departmental fire-fighting and emergency response services are on the whole satisfactory and that the organisation of the response is not generally an issue in the management of actual fires. However, the findings made in previous years are still valid and concern a majority of the sites inspected:
- the sectoring of premises could be improved in order to prevent the spread of fire (in particular poor closure of the doors contributing to fire sectoring and lack of risk assessment with respect to certain sectoring anomalies);
- deviations linked to the management of fire detection inhibitions;
- deviations in the management of stores of equipment representing significant heat potential, in particular during reactor outage phases;
- deviations in the use of fire permits.

Problems with the accessibility of fire-fighting equipment were once again observed.

The number of outbreaks of fire recorded for 2015 exceeds that of 2014. On 2nd July 2015, the lack of identification of the titanium fire risk prior to cutting operations led to a fire which concerned a part of the condenser of the Paluel NPP reactor 2.

Explosion

During its inspections, ASN also assessed the organisation of the sites for dealing with the explosion risk, including nuclear safety and worker protection aspects in the management of this risk.

ASN found that the expertise of the personnel regarding this question is gradually improving, but considers that EDF must ramp-up its efforts concerning training and exercises for the response crews.

Some of the maintenance measures required by the EDF internal doctrine for pipes carrying hydrogenated fluids are not always taken (nitrogen tightness test of the double envelope on certain pipes, daily average estimate of leaks from the alternator, etc.).

ASN also considers that on all the reactors in operation, insufficient consideration is given to the operating experience feedback concerning events which occurred in 2014 on the Dampierre, Tricastin and Le Blayais sites; it found that certain compensatory measures defined in 2014 following these events have still not been implemented.

Finally, an event of interest in terms of operating experience feedback occurred on 16th September 2015 in Civaux: when cutting a pipe, a flame appeared and persisted for approximately fifteen minutes. The risk of hydrogen leaks linked to the cutting of this pipe had not been identified prior to the activity.

Maintenance activities

Concerning the performance of maintenance work, ASN observes that the number of quality defects found is on the whole stable. The workers still have to deal with constraints linked to work organisation, insufficient preparation for certain activities, scheduling changes and problems with worksite coordination, leading to activity delays or postponements. EDF has implemented a specific multi-year action plan designed to reinforce the management of activities scheduled and carried out during maintenance outages of nuclear power generating reactors. Even if this action plan allows unhurried management of the preparation and performance phase by the licensee, ASN considers that EDF must continue with long-term efforts, in particular with a view to the operating life extension of the reactors, the “major overhaul” programme and the lessons learned from the Fukushima-Daiichi accident, leading to an increased volume of maintenance activities, as well as extensive personnel turnover.

With regard to the procurement of spares and equipment repairs, ASN observed that the shortcomings in the satisfactory control of these activities, identified in previous years, are fewer in number but nonetheless persist.

Delays in the inspections or in incorporating new maintenance programmes into the documents mean that deviations or equipment deterioration are detected belatedly.

ASN also observes differences among the sites in how the qualification of the equipment for accident operating conditions is maintained and in the requalification operations for this equipment.

Finally, ASN considers that the NPPs could improve the way in which they implement the AP-913 maintenance method (see point 2.7.1).

Equipment condition

The equipment maintenance and replacement programmes, the periodic safety review approach and the correction of conformity deviations should make it possible to check and ensure the continued ability of the equipment important for safety in an NPP to perform the functions assigned to it for protection of the interests mentioned in Article L.593-1 of the Environment Code.

During the course of its inspections, while still observing shortcomings in the NPPs’ implementation of and compliance with the rules issued by the head office departments for handling conformity deviations, ASN did see significant progress this year on this subject, with regard to organisation and in-house training of the persons involved in this conformity deviations remediation process. ASN considers that the sites must continue their efforts, in particular with regard to the identification and traceability of the deviations detected. The potential seriousness of certain generic conformity deviations demonstrates that EDF needs to improve its control of the operational processes which help to maintain the conformity of the facilities with their design, construction and operating baseline requirements.

In accordance with the ASN resolution on PWR shutdowns and restarts (ASN resolution 2014-DC-0444 of 15th July 2014), EDF performs an analysis of the combination of these deviations for each reactor. ASN considers that these analyses need to be carried out in greater depth.

Finally, in accordance with the ASN resolution on physical modifications to BNIs (ASN resolution 2014-DC-0420 of 13th February 2014), ASN observed that EDF has made progress in demonstrating the qualification of the new equipment installed, whenever necessary.

The first containment barrier

ASN considers that in 2015 the condition of the first containment barrier, which is the fuel cladding, progressed on the whole, despite a few points still to be improved. It in particular noted that the organisation set up to avoid foreign material entering the primary system once again made progress this year.

The number of significant events linked to fuel handling was down. However, during a number of reactor refuelling outages, loose parts were once again detected in the primary system, for example:
- In Golfech 2, 31 pieces of fuel assembly grid springs were removed.
- In Cruas 3, numerous metal brush hairs fell into the pressuriser during a maintenance operation. They were subsequently recovered.

At the end of 2015, the number of reactors with leaking fuel cladding was significantly down, involving only four reactors, instead of the seven one year earlier.

In 2014, the Nogent reactor had been stopped before the normal end of its operating cycle owing to the significant rise in control rod drop time, caused by deformation of fuel assemblies. Dropping the control rod assemblies under the effects of gravity enables the reactor to be shut down in an emergency. In 2015, owing to the significant rise in the drop time of a control rod cluster, EDF interrupted the operating cycle in order to repair two rod assemblies close to this cluster, thus improving the cluster drop time.

In 2014, following an ASN request, EDF adopted measures to reduce the risks of excessive oxidisation of the zircaloy-4 alloy fuel cladding (excessive oxidisation could reduce the strength of the cladding in certain accident situations). These measures limit the oxidisation of the zircaloy-4 alloy cladding and keep control rod movements to the strict minimum necessary once the calculated oxide thickness reaches 80 µm. The number of reactors using assemblies with zircaloy-4 cladding has been reduced from 49 in July 2014 to 31 in July 2015.

Second containment barrier

The requirements of the Order of 10th November 1999, more particularly with regard to maintenance, defect handling, inspections and periodic requalification of the main primary and secondary systems, were on the whole met. Preparation for the hydrotesting of these systems was however inadequate in at least three plants (lack of appropriate tooling, steam generator saturation, etc.).

Compliance with the provisions regarding restart of the reactors after a maintenance outage was also improved in 2015. ASN however observed the persistence of shortcomings in the drafting of the significant maintenance summary files and delays in transmission of the reactor outage results summary documents. A number of the regulation checks required following replacement of main primary and secondary system components had not been performed on several reactors. Corrective measures were taken on this point in 2015. The absence of these checks indicates a lack of stringency in implementation of the requirements applicable to the second barrier.

Similarly, management of the procurement of main primary and secondary system equipment manufactured in accordance with the Order of 12th December 2005 is improving but still requires particular vigilance.

The most sensitive equipment constituting the second containment barrier includes the SGs and more particularly their tube bundles.

ASN considers that the condition of the SG tube bundles has improved owing to the replacement of the last SGs equipped with 600 MA alloy tube bundles (susceptible to external corrosion). The SG replacement campaign will continue in 2016 on the tube bundles made of heat treated Inconel (600 TT). This will be the case of the Gravelines 5 and Paluel 2 reactors in 2016.

ASN considers that EDF's operating and maintenance strategy with regard to SG tube support plate clogging (use of high pH conditioning, monitoring of chemical parameters and preventive SG cleaning) is appropriate. This approach aims to keep the secondary system at an acceptable level of cleanness at all times.

Third containment barrier

Overall management of the containment function

The organisation adopted by the NPPs for monitoring the activities and systems liable to have an impact on the static and dynamic containment of the facilities remains on the whole satisfactory. However, improvements are still expected with regard to the condition of the containment, of the third barrier and its components, in particular concerning maintenance of the floor drains and the doors participating in static containment.

Single wall containments with an internal metal liner

The ageing of the 900 MWe reactor containments was examined in 2005 during the periodic safety review associated with their third ten-yearly outage inspection, in order to assess their leaktightness and mechanical strength. The reactor containment tests performed during the ten-yearly outage inspections on these reactors since 2009 have brought to light no particular problems liable to compromise their operation for a further ten years, with the exception of Bugey reactor 5. Even though its results were in conformity with the test criteria, a test carried out in 2011 showed an unfavourable trend in the tightness of the containment. In prescription [BNI 89-36] of its resolution 2014-DC-0474 of 23rd December 2014, ASN asked the Bugey NPP to schedule a further test no later than September 2016. Pressure testing performed during the partial inspection of reactor 5, which began on 27th August 2015, showed that this containment needs to be repaired. For the rest of the 900 MWe reactor containments, the results of the ten-yearly reactor containment tests have hitherto shown leak rates in compliance with the regulatory criteria (27 of the 34 reactors have undergone this test).

Double-wall containments

The test results for the double-wall containments performed during the first ten-yearly outages of the 1,300 MWe reactors detected a rise in the leak rate from the inner wall of some of them, under the combined effect of concrete deformation and loss of pre-stressing of certain cables that was higher than expected in the design.

EDF then initiated significant work consisting in using a resin sealant locally to cover the interior surface of the inner wall of the most severely affected 1,300 MWe reactors, but also reactors of the N4 plant series. The tests performed since this work, during the second ten-yearly outages of the 1,300 MWe reactors and the first ten-yearly outages on the N4 series of reactors, showed that they all complied with their regulation leak rate criteria. In order to guarantee that these criteria are met during the next ten-yearly outage inspections, EDF is considering supplementing these inner wall sealant coatings with a coating of the same type applied to the outer surface of the reactor building inner containments.

ASN is remaining vigilant with regard to the development of the leaktightness of these containments for which the design makes no provision for an integral metal liner. The issues linked to the double-wall reactor containments were thus analysed by the GPR on 26th June 2013, in the run-up to the third ten-yearly outage inspections for the 1,300 MWe reactors. ASN issued a ruling on this subject in June 2014 and will be attentive to compliance with the undertakings that EDF made on this occasion.

ASN's main conclusions are:
- In addition to EDF's satisfactory monitoring of the condition of the concrete, additional measures to prevent or mitigate the ingress of water from outside must also be envisaged because, given the current state of knowledge, this is the primary means of protecting containments from concrete swelling pathologies.
- EDF must reinforce in-service monitoring and visual inspection of certain containment singularities (sleeves, equipment hatch).
- ASN considers that EDF must give a safety classification to the instrumentation system providing continuous monitoring of the containment leak rate (Sexten) along with in-service monitoring of its correct operation.

4.1.2 Evaluating human and organisational measures

The steps taken by the NPPs and the stakeholders to take account of organisational and human factors

It is considered that the organisation of the NPPs designed to take account of Organisational and Human Factors (OHF) could be improved.

EDF has Human Factors (HF) consultants, who contribute to operating experience feedback and personnel training. Their roles could be extended to other OHF fields, such as taking account of the organisation and the needs of the personnel when making changes to systems or modifications to certain equipment. In 2015, ASN found that several HF consultant positions on several sites were vacant. However, some sites are now beginning to deploy a network of local HF correspondents within the technical departments, coordinated by the HF consultant.

The managers are on the whole strengthening their presence in the field, even if the purpose of these field visits is sometimes lacking in clarity; they can be performed to check behavioural nonconformities by the workers or indeed the condition of the facilities, rather than to observe working situations which would allow the detection of possible improvements or areas in which worker training might be needed.

Major efforts are being made by EDF to develop the use of error reduction practices. ASN considers that this might be insufficient and site-specific measures to improve organisation, safety management or working conditions must also be developed.

Organisation of work and working conditions

In 2015, ASN still observed numerous shortcomings with regard to working conditions. ASN thus noted equipment inappropriate for the tasks in question, owing to its unavailability or poor design, cramped or inaccessible work spaces, errors in signage, or instructions that are hard to read.

On all the sites, documents placed at the disposal of the workers by EDF are sometimes missing and are regularly inappropriate, incomplete, overly complex or unsuitable. ASN has repeatedly observed this situation for several years now, thus calling into question the efficiency of the documentary drafting and revision process in use at EDF, in particular given that these inadequacies can make for difficult working conditions for the personnel and thus degrade performance, possibly leading to the occurrence of significant events. The difficulties linked to documentation are increasingly spotlighted in the assessments carried out by EDF following significant events.

In addition, accessibility and the physical working environment (light, heat, noise) is continuing to create difficult working conditions. On several sites, ASN thus observed inefficient public address and lighting systems in the reactor building. ASN did however note that certain sites were making efforts in this field.

Staff members are also faced with constraints relating to the organisation of work, in particular during reactor outages, such as inadequate preparation for certain activities, scheduling changes and problems of joint contractor work and coordination between those involved. These constraints can lead to degraded working conditions.

Provisions concerning staff and organisations in operational reactor modification activities

At the national level, EDF has developed the "Social, Organisational and Human – SOH" approach, the aim of which is to transform engineering practices at EDF, to take greater account of people and organisations in the changes made to the systems and in modifications to hardware and organisations, as of the design stage. ASN considers the philosophy of the SOH approach to be pertinent and important in guaranteeing the security of the facilities and the safety of the workers. However, the efforts made by EDF to deploy the SOH approach - in particular in all the engineering centres - must be continued in order to achieve the intended effects.

Hardware and documentation modifications are mainly managed at the national level, so the sites do not always have the ability to implement changes necessary to improve the working environment when a difficulty is identified locally. The improvements made by the sites therefore generally consist in implementing mitigation measures rather than actually solving the problem itself.

Skills management, training and qualifications

The skills management, qualification and training organisation in place on the sites is on the whole satisfactory and the management processes well documented and coherent. Most of the sites have set up local training committees involving the executive level, the management and the workers. One of these committees rapidly detects staff training requirements and, with the help of the production engineering training unit, creates short and specifically targeted training programmes according to the identified needs.

Generally speaking, the training programmes are implemented satisfactorily and the establishment of «academies» for the different professional disciplines is highlighted as a strong point for the training of newcomers to the sites. However, the training proposed by some sites is not always adapted rapidly enough. Moreover, the staff do not always receive the scheduled training.

Inadequacies on certain sites are however still being found by ASN during the inspections, concerning succession planning (GPEC). In several NPPs, certain departments had still not produced a skills map in 2015, even though this is the GPEC tool that enables the site to obtain a dynamic, forward-looking picture of the professional skills available over a five-year period. However, EDF is on the whole making major investments in hiring and training, in order to anticipate the renewal of the skills threatened by staff retirements. Failure to anticipate large-scale retirements in certain disciplines is still being observed on a number of sites, leading to insufficient headcounts and potentially leading to difficulties in having more experienced personnel available for mentoring the young recruits.

Given the level of retirements expected in the coming years and the considerable work to be accomplished by EDF subsequent to the stress tests or for the periodic safety reviews, ASN considers that EDF's recruiting and training efforts must be maintained.

4.1.3 Health and safety assessment, professional relations and quality of employment in the NPPs

On the whole, there is satisfactory compliance with daily and weekly rest periods, although EDF could further improve its compliance with ASN's requests concerning working hours, in particular owing to the absence of a system for counting the time worked by the management.

Greater consideration is being given to certain occupational risks, such as those linked to welding fumes. In addition, EDF's announced expansion of the duties of the «zone managers" to all aspects of conventional occupational safety is a positive point. However, constant attention to health and safety risks is required at all times. Moreover, the presence of asbestos in equipment if often identified belatedly, meaning that the organisation of the work then needs to be adapted accordingly.

Progress is still required in the management of multiple contractors working simultaneously (quality of prevention plans in particular) and the use of subcontracting (combatting the illegal loaning of labour). ASN also asked EDF to improve the distribution of operating experience and best practices between the sites.

4.1.4 Evaluation of radiation protection

In 2015, ASN carried out 28 radiation protection inspections. In 2015, ASN focused particular attention on compliance with the prescriptions for occupational radiation protection during work in controlled zones and this was checked in most of the NPPs operated by EDF.

The collective dose on all the reactors fell slightly in 2015 by comparison with 2014 (graph 2). The average dose received by the workers for one hour of work in a controlled zone has been falling since 2013. The doses received by the workers are broken down as shown below in graphs 1, and 3.

Graph 1 shows the breakdown of the population in terms of whole body external dosimetry. It can be seen that the dosimetry for 76% of the exposed workers is less than 1 mSv for the year 2015, which corresponds to the annual regulation limit for the public. The annual regulation limit for whole body external dosimetry (20 mSv) was exceeded on no occasion in 2015

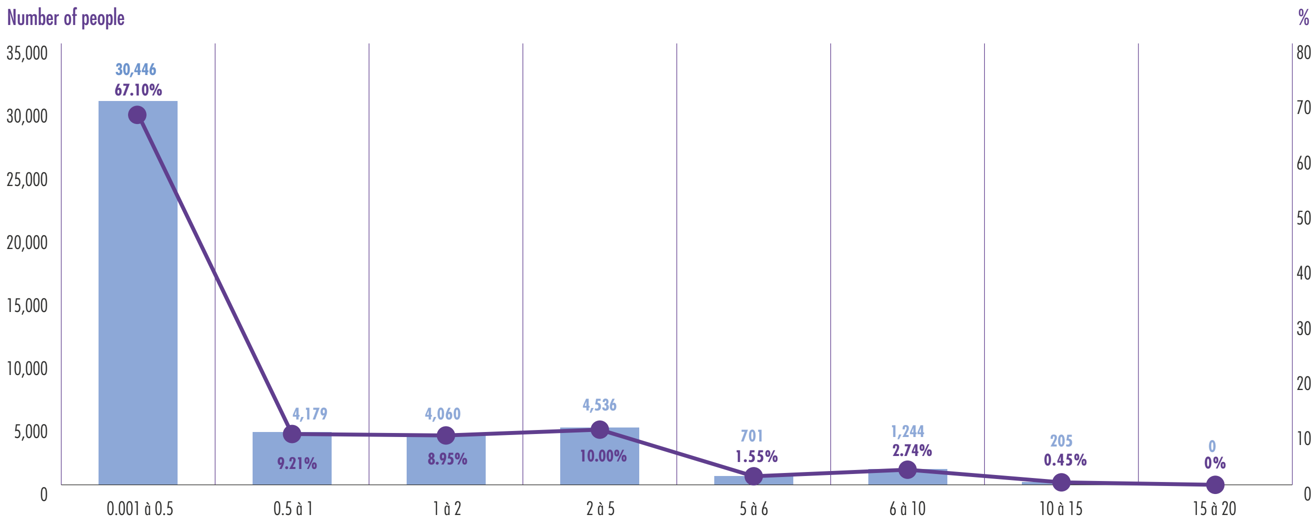
Graph 2 shows the long-term trend in the collective dose received by NPP workers. It shows that, following a period of significant progress in dose reduction (1996-2005), the period 2005-2015 shows a stabilisation in these doses, with contrasting results between the sites, and an upward trend in the volume of maintenance work in controlled zones in recent years, combined with continued optimisation efforts.

Graph 3 shows the trend in whole body average individual dosimetry according to the worker categories involved in reactor maintenance. The most exposed worker categories in 2015 are those in charge of installing and removing heat installation and welders.

ASN considers that the radiation protection situation of the NPPs in 2015 could be improved on a certain number of points:
- The management of industrial radiography worksites could be improved. ASN in particular observed two events in which the signs barring entry to operations areas were ignored. Progress is expected in the preparation of the worksites, more specifically the involvement of all stakeholders and the quality of the installation visits carried out when preparing these worksites.
- Management of contamination dispersal inside the reactor building is still insufficient, owing to inadequate worksite containment or contamination level signage errors. ASN repeatedly observed non-compliance with instructions for contamination checks on personnel exiting worksites, the lack of contamination inspection devices or devices that are unserviceable. In addition, on several sites, the inspectors found a lack of radiation protection culture on the part of certain workers.

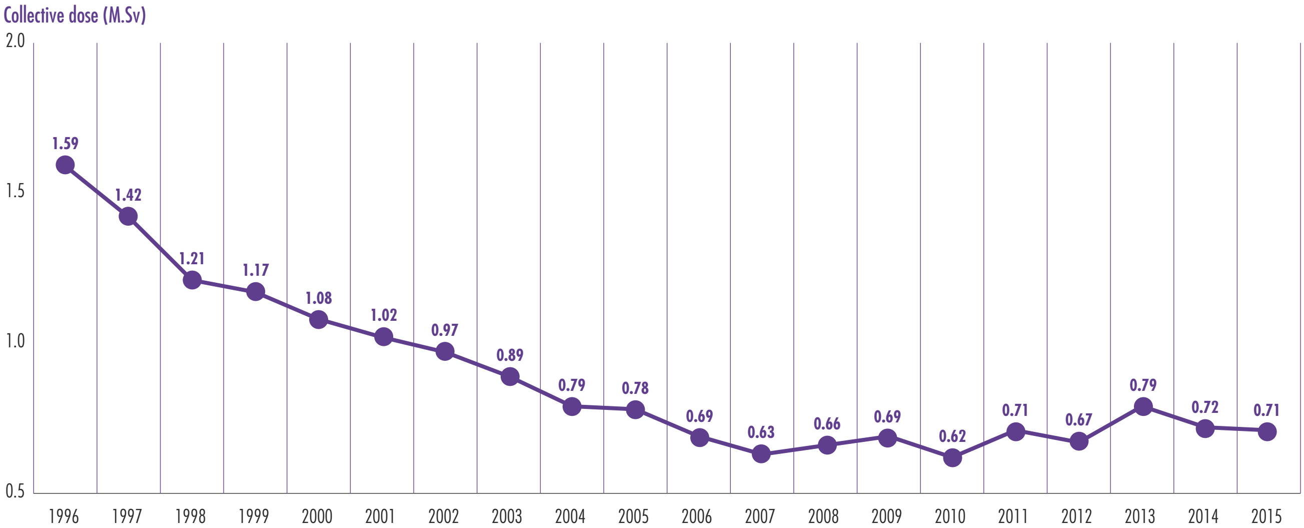
These inadequacies can contribute to delaying the detection of bodily contamination of the workers (see point 3.4.3):
- With regard to exposure monitoring, ASN has observed numerous events relating to the failure of workers to wear individual dosimeters. Improvements were however observed in terms of the optimisation of exposed worker classification and improvements in remote-dosimetry.
- EDF has taken steps to reinforce control of personnel access to limited stay areas, although further improvements are still required. ASN observes inadequacies in the identification and signposting of these areas.

GRAPH 1: Breakdown of the population per dose range over the year 2015



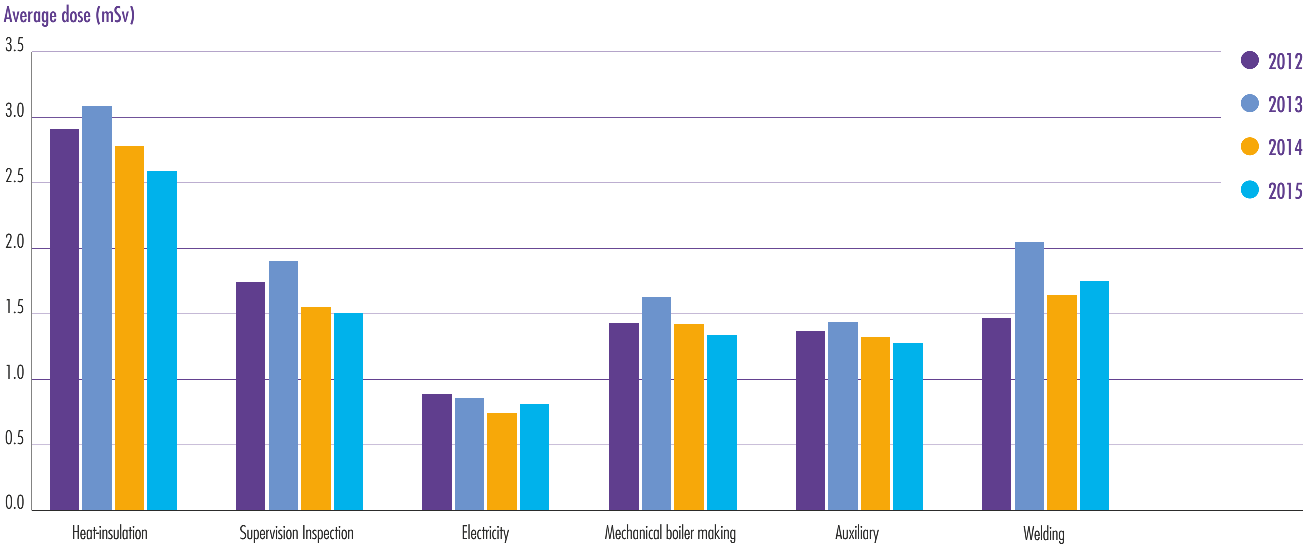
Source: EDF.

GRAPH 2: Mean collective dose per reactor



Source: EDF.

GRAPH 3: Evolution of mean individual dose according to categories of workers involved in reactor maintenance



Source: EDF.

4.1.5 Control of detrimental effects and impact on the environment

In 2015, ASN carried out 40 inspections on the control of the detrimental effects and environmental impact of NPPs, mainly concerning the prevention of detrimental effects, management of environmental discharges and waste management.

On most sites, the way in which detrimental effects and the environmental impact of NPPs are managed is considered to be satisfactory, in particular through the continued use of structures enabling new regulatory requirements to be implemented and the creation on several sites of independent environment organisations similar to the independent safety organisation (see box page 400). There are however considerable differences among the sites with regard to the oversight and coordination measures adopted to define and monitor the discharge objectives. Learning lessons from experience feedback is also an area in which progress could still be made.

Deviations are still being observed in the operation and monitoring of the facilities. In particular, on the majority of sites, the detection and handling of deviations concerning the conformity of the facilities could be improved, or are sometimes even completely inadequate. Liquid containment anomalies observed on several sites also show that a number of operating and maintenance provisions are not given sufficient attention by EDF. Finally, waste management is on the whole better, but could often be improved, with deviations from the operational baseline requirements being observed.

ASN considers that the quality of the documentation on conventional risks and on the operation of the installations could be improved, in particular with regard to the display of certain instructions inside the installations and the labelling of hazardous substances.

ASN notes that progress has been made in applying and assimilating the prescriptions regulating discharges set out in the waste and the detrimental effects prevention and mitigation provisions of the Order of 7th February 2012 and in resolution 2013-DC-0360 of 16th July 2013.

Finally, ASN considers that EDF's approach for integrating the items and activities concerning the control of detrimental effects and environmental impact, from among the equipment important for protection of the interests defined by the Order of 7th February 2012, is insufficient and must be significantly reinforced.

4.1.6 Analysis of operating experience

The operating experience feedback process

Operating Experience Feedback (OEF) relies mainly on the process to identify and handle deviations ("OEF loop"). This process mobilises all the players involved in reactor operations, including outside contractors. The steps taken by EDF since 2012, in particular as part of its "corrective measures programme", mean that it is better able to detect deviations from the specified requirements, with greater involvement in this process by its contractors and subcontractors. The result is a significant rise in notifications, requiring adaptation of the licensee's organisation. However, in 2015, ASN noted that the OEF loop is still not effective enough and considers that improved subsequent assessment of the remedial, corrective and preventive measures taken is required.

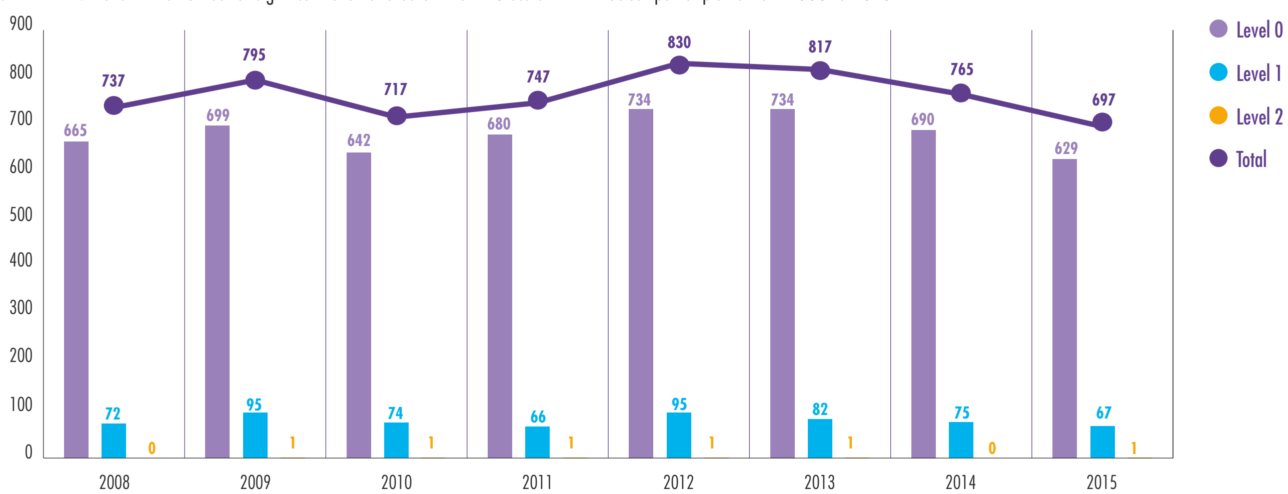
There are also differences in the way in which the NPPs take account of operating experience feedback. Some plants focus on their local OEF while others extensively integrate the national OEF sent out by the head office departments.

Greater EDF vigilance in disseminating OEF to its contractors and subcontractors is also required, because these latter generally work on several NPPs.

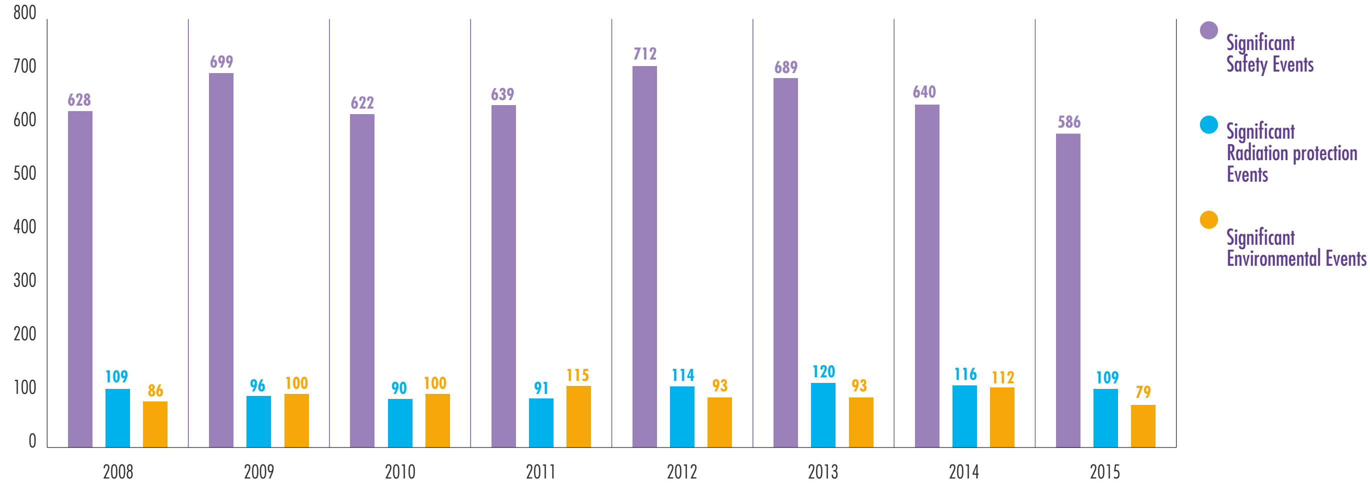
With regard to reactive operating experience feedback – in other words following a significant event (see chapter 4, point 3.3) – the NPPs are using a new significant events analysis method proposed by the EDF head office departments. ASN notes differences between the sites in the quality of the significant event reports: the analyses made by some sites go beyond the apparent causes and highlight organisational malfunctions, while the analyses performed on others simply focus on the apparent causes, despite the presence of "human factors" consultants. Reactive operating experience feedback, which mainly comprises an analysis of the often organisational root causes and the identification, implementation and follow-up of corrective measures, all too often remains superficial. A frequent ASN observation is that the corrective measures adopted by the sites are not always able to address the organisational malfunctions highlighted in the analyses.

The deviations leading to significant events are analysed by the EDF head office departments in order to assess to what extent they are generic. 2015 was marked by an increase in the number of generic events. Although the cause of this increase could be the completion of the complex characterisation work done on the deviations behind these events, the potentially serious nature of certain generic significant events confirms the importance of the

GRAPH 4: Trend in the number of significant events rated on the INES scale in EDF nuclear power plants from 2008 to 2015

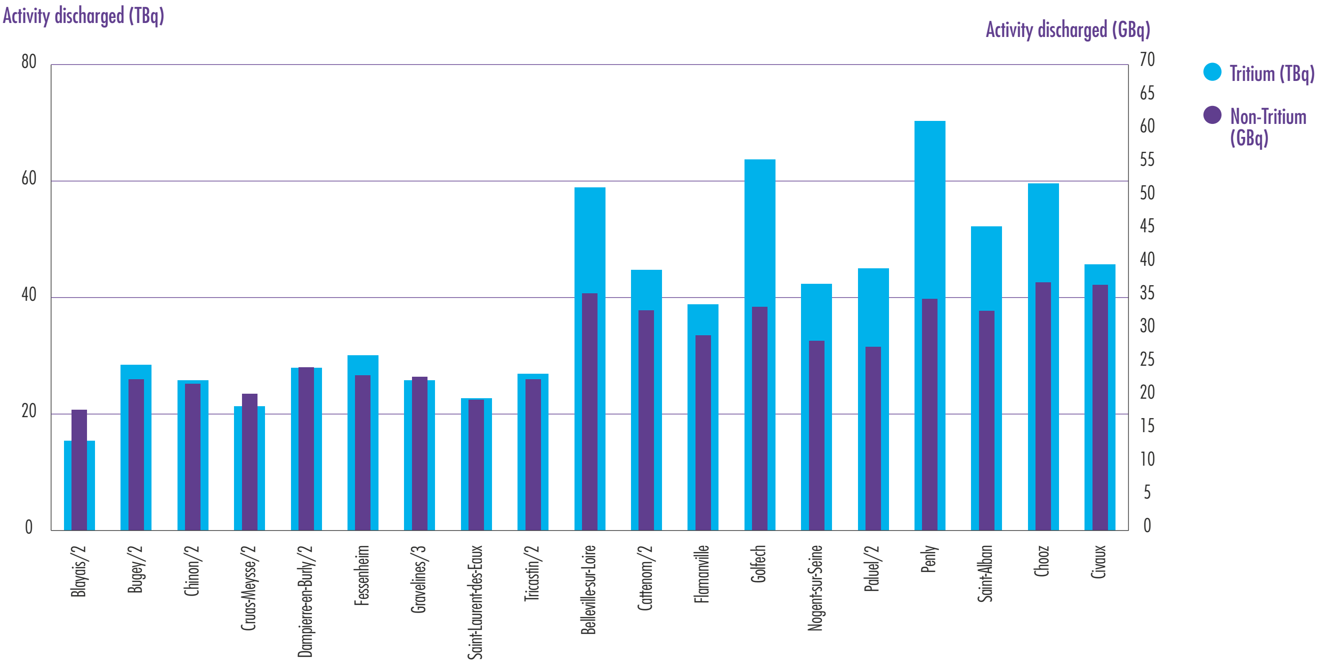


GRAPH 5: Trend in the number of significant events per domain in EDF nuclear power plants from 2008 to 2015



Events off the INES scale are also taken into account.

GRAPH 6: Liquid radioactive discharges for the NPPs in 2015



As there can be a different number of reactors on each site, the results are given "per pair of reactors", to enable a comparison to be made from one site to another. This for example entails:
- *keeping the results as-are for the Golfech site, which has two reactors;*
- *dividing by two those of Chinon, which has four reactors (Chinon/2);*
- *dividing by three those of Gravelines, which has six reactors (Gravelines/3).*

processes which help to maintain the conformity of the installations with their design, construction and operating baseline requirements.

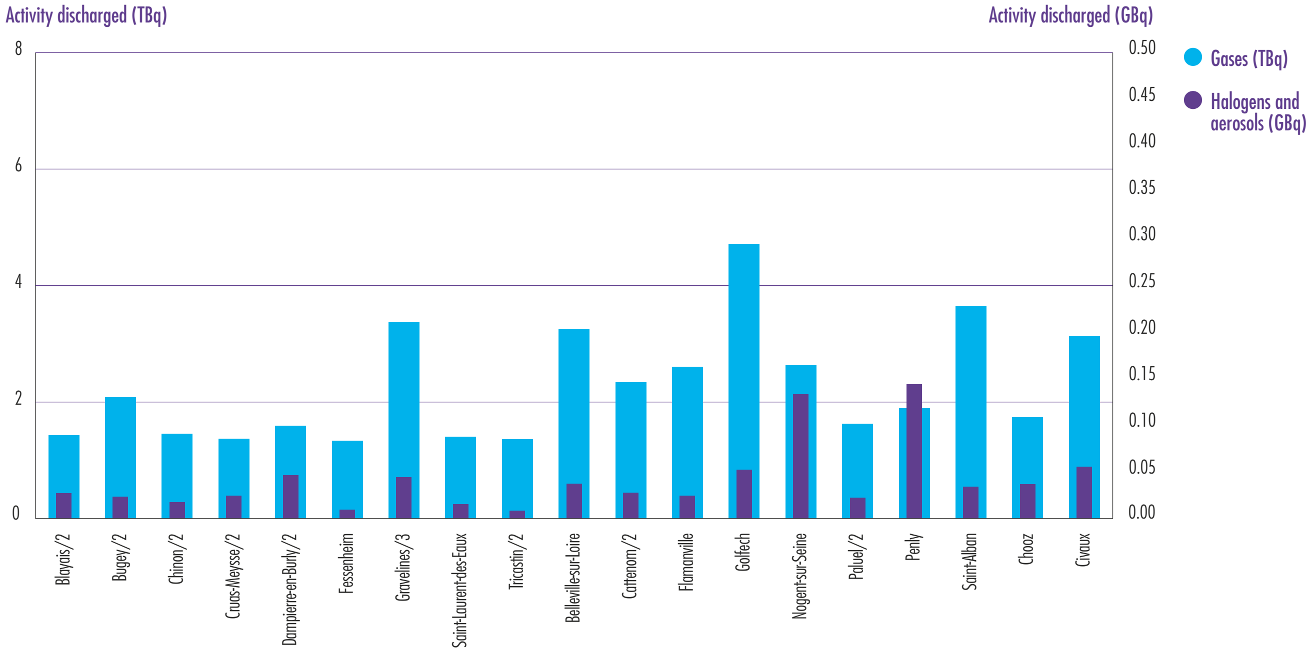
Analysis of significant events statistics

In accordance with the rules concerning the notification of significant events (see point 3.3 of chapter 4), EDF notified 586 significant safety events in 2015, 109 radiation protection events and 79 environmental protection events.

Graph 4 shows how the number of significant events notified by EDF and classified on the INES scale has evolved since 2008.

Graph 5 shows the trends in the number of significant events per area concerned by notification since 2008: Significant Safety Events (ESS), Significant Radiation protection Events (ESR) and Significant Environmental Events (ESE).

GRAPH 7: Gaseous radioactive discharges for the NPPs in 2015



As there can be a different number of reactors on each site, the results are given "per pair of reactors", to enable a comparison to be made from one site to another. This for example entails:
- *keeping the results as-are for the Golfech site, which has two reactors;*
- *dividing by two those of Chinon, which has four reactors (Chinon/2);*
- *dividing by three those of Gravelines, which has six reactors (Gravelines/3).*

Whatever the notification area, several of these events, which are similar in the NPPs or are the result of common causes, are together referred to as Generic Significant Events (ESG), 15 of which were notified in 2015.

The number of ESS notified is slightly down by comparison with 2014 (- 8%).

The number of ESR also fell by about 7% by comparison with 2014. A level 2 ESR on the INES scale was however notified (see box page 398).

The number of ESE fell significantly compared to 2014, by nearly 30%. This reduction is partly explained by the exceptionally high number last year, owing to problems with management of devices containing coolant fluids. EDF is in the process of carrying out modification work on the chillers in all the reactors in service, in order to minimise these emissions, which could be the reason for this improvement.

The details of the significant events for each site are presented in chapter 8.

4.2 Evaluation of the manufacture of nuclear pressure equipment

Advancing industrial practices

ASN observes that the justifications and demonstrations provided by the manufacturers with regard to the regulations applicable to nuclear pressure equipment are still regularly unsatisfactory. As of the first half of 2015, EDF and Areva therefore took fundamental measures to change their practices and bring them into line with the regulatory requirements. ASN monitored these measures, most of which were carried out within the framework of the French Association for NSSS design, construction and monitoring rules (Afcen) and involved the majority of the profession. ASN considers this approach to be a positive one, but will be attentive to ensuring that it is seen through to completion.

The Areva NP plant in Le Creusot

In 2014 and 2015, ASN was also informed of several manufacturing anomalies in the Areva NP plant in Le Creusot. ASN asked Areva NP to conduct a general quality review of past and present nuclear activities in this plant in order to obtain an overall picture of the pertinence of the organisation and practices at Creusot Forge, the quality of the parts produced since manufacturing started for the Flamanville 3 EPR and the safety culture within the facility. The audit work carried out by Areva so far has proven to be insufficient.

5. OUTLOOK

In 2016, ASN actions in the field of the oversight of NPPs will more specifically concern the following topics.

The periodic safety reviews

In 2016, ASN will issue a position statement on the orientations of the fourth periodic safety review for the 900 MWe reactors. In 2016, this step will enable the examination of the generic phase of this review to start, in parallel with the second periodic safety review of the 1,450 MWe reactors.

Monitoring the implementation of the material and documentary modifications resulting from this third ten-yearly outage inspection on the 1,300 MWe reactors, more particularly during the ten-yearly inspection of the Paluel 2 reactor, which should be completed in 2016, remains a particular challenge, given their scope and their nature, at a time of significant turnover between generations of staff.

Experience feedback from the Fukushima Daiichi accident

Monitoring the implementation of the prescribed material and organisational measures enabling EDF to justify satisfactory control of the basic safety functions in extreme situations remains a priority for ASN.

In 2016, ASN will pay particular attention to examining the design, construction and operating provisions adopted by EDF to address the prescriptions concerning the "hardened safety core". This will be an opportunity to examine the natural hazard levels used in the design of the "hardened safety core". The modification notification files for the facilities, concerning the installation of an additional electricity generating set on each reactor and a new emergency centre for each site will also be examined and the initial site deployment work will be inspected.

Oversight of the EPR reactor

In addition to the review of the detailed design of the Flamanville 3 EPR reactor, ASN is actively involved in checking the construction work and preparation for the start-up tests of this reactor on the site, in the engineering centres and at the EDF suppliers. The nuclear safety inspectors will continue with inspections at a sustained rate. 2016 will also see the continued review of the commissioning authorisation application for this reactor. The review of this application will entail an ASN verification that the requirements of the Flamanville 3 Creation Authorisation Decree and the additional prescriptions it has issued are taken into account. ASN will also continue with the conformity assessments of the nuclear pressure equipment most important for safety.

Deviation handling

Operating experience feedback from the NPP reactors reveals that there are still inadequacies in the processes employed by the licensee to obtain conformity of the facilities with their design and operating baseline requirements and then maintain this compliance over the long term. It also highlights weaknesses in the design of modifications and of their operating documents. Some of the conformity deviations are discovered during equipment verifications as part of the periodic checks or spot checks. On the occasion of the fourth periodic safety review of the 900 MWe reactors, ASN will ensure that design reviews are developed to complete the latent conformity deviations detection process.

Adaptation to the provisions of the Energy Transition for Green Growth Act

The TECV Act introduces new public consultation obligations on the occasion of the periodic safety reviews after the 35th year of operation of an NPP reactor. ASN will adapt its processes to take account of these new provisions in its preparations for the fourth periodic safety review of the 900 MWe reactors.

Experience feedback concerning nuclear pressure equipment regulations

In 2016, ASN will continue with the in-depth work it has begun with the manufacturers, operators and organisations it approves, with regard to the drafting of professional baseline requirements and conformity assessment baseline requirements. These baseline requirements will make it easier to demonstrate and assess nuclear pressure equipment conformity with the regulations.

ASN will also continue its operating experience feedback approach with regard to nuclear pressure equipment regulations as part of the process to codify in the Environment Code the provisions concerning in-service monitoring of products and equipment with a potential risk.

The organisation of the nuclear sector stakeholders

In 2015, EDF reorganised its departments in charge of engineering and the production of electricity generated by nuclear power. ASN will ensure that this new organisation is able to address safety issues correctly and promotes communication and cooperation between all the EDF departments concerned by these issues.

2015 was also marked by the beginning of discussions concerning the future of the Areva group. Areva's contribution to the NPPs is mainly engineering, provision of maintenance services and design and manufacture of equipment. ASN will ensure that the new organisations adopted take account of safety issues and that the safety improvement processes already under way are continued. As in 2015, it will convene hearings with EDF and Areva senior management to ensure that this is the case.

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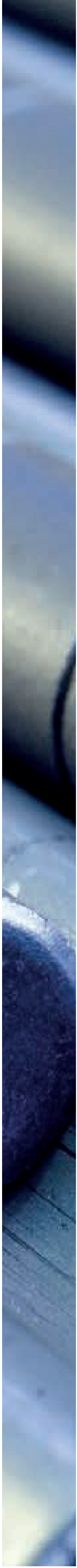
Nuclear fuel cycle installations



The fuel cycle begins with the extraction of uranium ore and ends with packaging of the various radioactive wastes from the spent fuels so that they can be sent for disposal. In France, all the uranium mines have been closed since 2000, so the fuel cycle concerns the steps involved in the fabrication of the fuel and then its reprocessing once it has been used in nuclear reactors.

Fuel cycle plants comprise all the facilities performing conversion, uranium enrichment, design and fabrication of fuels for nuclear reactors, that is the front-end part of the cycle – in other words before irradiation – as well as facilities for reprocessing spent fuel, that is the back-end part of the cycle. These facilities utilise nuclear material, transformed into fuel, based on uranium oxide or a mixture of uranium and plutonium oxides (called MOX), the plutonium having been generated by burn-up of the enriched natural uranium fuel in power reactors and then extracted from the irradiated fuels during the reprocessing operations.

The main plants operating in the fuel cycle – Areva NC Tricastin (Comurhex and TU5/W), Eurodif, Georges Besse II (GB II), Areva NP Romans-sur-Isère (ex-FBFC and ex-Cerca), Mélox, Areva NC La Hague and Areva NC Malvési (which is an Installation Classified on Environmental Protection grounds – ICPE) – are part of the Areva group (of which Areva NC and Areva NP are subsidiaries). ASN regulates these industrial facilities and considers that steps must be taken for all of the Group's facilities in order to promote safety and radiation protection coherently and allow the use of international best practices. ASN also monitors the overall consistency of the fuel cycle in terms of safety and regulatory compliance. Areva and EDF must in particular demonstrate that their industrial fuel management choices do not compromise the safety of the facilities.

1. THE FUEL CYCLE

The uranium ore is extracted, then purified and concentrated into "yellow cake" on the mining sites. The solid yellow cake is then converted into uranium hexafluoride gas (UF_6). This raw material, which will be subsequently enriched, is made at the Areva NC Comurhex plants in Malvési (which converts to UF_4) and Tricastin (which converts to UF_6). The facilities in question – most of which are regulated under the legislation for Installations Classified on Environmental Protection grounds (ICPEs) – use natural uranium in which the uranium-235 content is around 0.7%.

Most of the world's NPPs use uranium which is slightly enriched in uranium-235. For example, the fleet of Pressurised Water Reactors (PWR) requires uranium enriched to between 3% and 5% with the U-235 isotope. The gas centrifuge process used by the GB II plant replaced the gaseous diffusion process, employed by the Eurodif plant until June 2012.

The process used in the FBFC plant at Romans-sur-Isère transforms the enriched UF_6 into uranium oxide powder. The fuel pellets manufactured with this oxide are clad to make fuel rods, which are then combined to form fuel assemblies. These assemblies are then placed in the reactor core where they release power by the fission of uranium-235 nuclei.

After a period of use of about three to five years, the spent fuel is removed from the reactor and cooled in a pool, firstly on the site of the plant in which it was used and then in the Areva NC reprocessing plant at La Hague.

At this plant, the uranium and plutonium from the spent fuels are separated from the fission products and actinides[1]. The uranium and plutonium are packaged and then stored for subsequent re-use. However, at present, the uranium obtained from reprocessing is no longer used to produce new fuels. The radioactive waste produced by these operations is disposed of in a surface repository if it is low-level waste, otherwise it is placed in storage[2] pending a final disposal solution.

The plutonium resulting from the reprocessing of these uranium oxide fuels is used in the Areva NC plant in Marcoule, called Mélox, to fabricate MOX fuel (Mixture of uranium and plutonium OXides) which is mainly used in certain 900 MWe nuclear power reactors in France.

1. Actinides are chemical elements heavier than uranium.
2. Storage is temporary, while disposal is final.

TABLE 1: Fuel cycle industry movements in 2015

	MATERIAL PROCESSED			PRODUCT OBTAINED (1)		PRODUCT SHIPPED (2)	
INSTALLATION	ORIGIN	PRODUCT	TONNAGE (unless otherwise specified)	PRODUCT	TONNAGE (unless otherwise specified)	DESTINATION	TONNAGE (unless otherwise specified)
Comurhex Pierrelatte	SBNI Marcoule	Uranyl Nitrate	-	U_3O_8	-	SBNI Pierrelatte	-
	ICPE Malvési	UF_4	16,530 t	UF_6	18,535 t	Areva NC Tricastin	18,535 t
Areva NC Pierrelatte TU5 facility	Areva NC La Hague	Uranyl Nitrate	4,976 t	U_3O_8	1,501 t	Areva NC Tricastin	1,501 t
Areva NC Pierrelatte W plant	URENCO	UF_6 (depleted)	7,883 t	U_3O_8	6,332 t	Areva NC Tricastin	6,332 t
	SET		11,678 t		9,270 t		9,270 t
Eurodif Pierrelatte (3)	Eurodif	UF_6 (derived from natural and depleted uranium)	12.09 t	UF_6 (depleted)	48.66 t	Eurodif	
		UF_6 (based on enriched uranium)		UF_6 (enriched uranium)	138.87 t		
FBFC Romans-sur-Isère	CER Ensam, CNRS, IES, RX solutions, CEN MOL, United States	Uranium (depleted or natural)	1.52 kgU	Fuel elements and targets for research reactors, scrap		CER Ensam, CNRS, IRE, RX solutions	952 gU
	CER Ensam, CNRS, United States	Uranium LEU	138.17 kgU			Institut REZ, ANSTO, CEN BR2, CER Ensam, CNRS, Petten, IRE, Maria	201.86 kgU
	CEA, United States	Uranium HEU	12.31 kgU			Andra, CEA, CEN BR2, Institut REZ, Petten, ILL, Maria	28.36 kgU
				Fuel elements based on depleted uranium	0.954 tU (4)	CEA	0.532 tU
				UO_2 (based on depleted uranium)		Mélox Marcoule	0.882 kgU
	SET	UF_6 (based on enriched uranium)	596.12 tU	UO_2 (based on enriched uranium)	5.486 tU	Areva NP Richland	2.478 tU
						CEA	3.008 tU
	Urenco			Fuel elements based on enriched uranium	617.06 tU	EDF	482.18 tU
	UEIP					Electrabel	11.11 tU
Mélox Marcoule	Areva NC Tricastin	Depleted UO_2	144.05 tHM	Fuel elements MOX	127.71 tHM (5)	EDF	120.11 tHM
						FBFC	12.81 tHM
	Areva NC La Hague	PuO_2	13.51 tHM			EPZ	7.72 tHM
Areva NC La Hague	**Fuels reprocessed in the La Hague plant**						
	EDF, Borssele	UOX, MOX	673.99 t(U+Pu)	Uranyl Nitrate	1,204.77 tU	Areva NC Tricastin	1,228.05 tU
	Orphée, BR2 MOL	RTR	0.16 t(U+Pu)				
	EDF, Sogin	UOX, MOX	531.43 t(U+Pu)	PuO_2	15.39 $tPuO_2$	Mélox Marcoule	13.41 $tPuPO_2$
	Fuels stored in the la hague plant pools						
	EDF, Borssele, Sogin, Phénix, RNR, BR2 MOL, Orphée, Osiris	Spent fuel elements	1,222.86 t(U+Pu)	-	-	-	-
GB II Pierrelatte	Converters and Eurodif	UF_6	10,823 t	UF_6 (depleted)	9,156 t	Defluorination	9,156 t
				UF_6 (enriched)	1,457 t	Fuel manufacturers	1,457 t

(1) The products obtained may be shipped or stored in the facility concerned
(2) The shipped products may have been obtained during the year 2013 or during previous years
(3) The facilities have been shut down since 2008. In 2013, they reprocessed, produced or shipped no products
(4) tU : metric ton of uranium
(5) tHM: ton equivalent heavy metal

Once they have been used in the nuclear reactors, MOX fuels are not reprocessed in the current fleet of nuclear facilities. They would only be reprocessed if future fast neutron reactors were to be commissioned. Since the shutdown of the Superphenix reactor in 1996, no company has as yet initiated the official process to build such a reactor (see chapter 12). CEA is studying a prototype called Astrid (see chapter 14). Pending reprocessing or disposal, the spent MOX fuels are stored at the La Hague plant.

The main material flows are presented in table 1.

The existence of nuclear facilities which are necessary for the operation of the BNIs mentioned above must also be noted, in particular Socatri, which handles the maintenance and decommissioning of nuclear equipment and the processing of nuclear and industrial effluents from the Areva Group's companies in Tricastin, or from Somanu in Maubeuge, which provides off-site servicing and repairs for certain nuclear components.

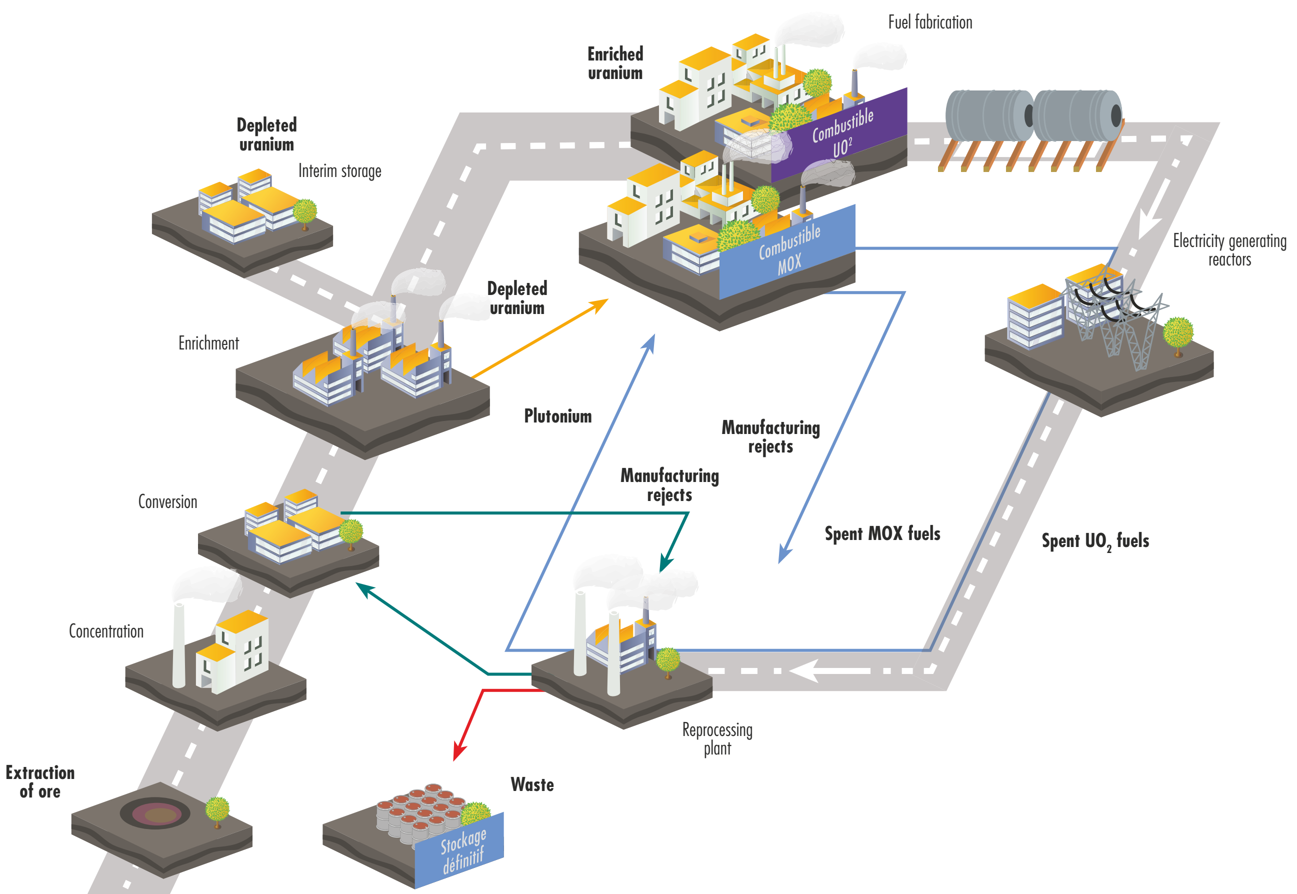
1.1 The front-end fuel cycle

To produce fuels that can be used in the reactors, the uranium ore must undergo a number of chemical transformations, from the preparation of the "yellow cake" through to conversion into uranium hexafluoride (UF_6), the form required for enrichment. These operations take place primarily on the Tricastin site, in the Drôme and Vaucluse *départements,* also known as the Pierrelatte site.

1.1.1 The facilities on the Tricastin site

In order to simplify the legal organisation of Areva's Tricastin platform, a process was initiated by Areva NC in 2012 to merge the Areva subsidiaries on the Tricastin site. This process was completed for the Comurhex BNI in 2013. The change in licensee at Socatri initiated in 2013 was suspended at the request of Areva NC in 2014. On the Romans-sur-Isère site, Areva NP took over responsibility for operating FBFC in 2014.

THE FUEL CYCLE



Furthermore, the management of the Tricastin site submitted an authorisation application to ASN on 13th July 2012 for implementation of an internal authorisation process, comparable to that already in place on Areva's La Hague site. After a two-year review process, ASN approved this system in resolution 2014-DC-0460 of 23rd September 2014. This relieves the licensees of BNIs 93, 105, 138, 155 and 168 of the need to submit prior notification of modifications and operations considered to be "minor", as they comply with the criteria set by the above-mentioned ASN resolution. This resolution requires that the licensees inform ASN of the anticipated programme of operations concerned, at least once a year, and send it an annual summary of the system. This resolution entered into force on 1st January 2015.

Areva NC TU5 facility and W plant - BNI 155

On the Tricastin site, Areva NC operates:
- the TU5 facility (BNI 155) for conversion of uranyl nitrate $UO_2(NO_3)2$ produced by reprocessing spent fuel into uranium sesquioxide U_3O_8;
- the W plant (ICPE within the BNI perimeter) for conversion of depleted uranium hexafluoride (UF_6) into uranium sesquioxide (U_3O_8).

U_3O_8 is a stable solid compound able to guarantee safer uranium storage conditions than in liquid or gaseous form. BNI 155, called TU5, can handle up to 2,000 tonnes of uranium per year, enabling it to reprocess all the uranyl nitrate produced by the Areva plant at La Hague. Once converted, the uranium from reprocessing is placed in storage on the Areva NC Tricastin site.

The review report was transmitted on 28th November 2014. This file is currently being reviewed by ASN. The conclusions of this review will be released at the end of 2016.

ASN considers that the facilities located within the perimeter of Areva NC's BNI 155 are operated with a satisfactory level of safety.

The new hydrofluoric acid storage area entered service satisfactorily at the beginning of 2015. This work is improving risk prevention during the transfer operations involving this product. The technical prescriptions for operation of the facility were also updated.

The licensee is also required to create a new emission area in which the depleted UF_6 is heated so that it can be emitted in the process used in the W plant (EM3), the commissioning of which is planned for 2018, as part of the safety improvements specified by ASN. This new area must ensure a higher level of protection thanks to the creation of a concrete building (in place of the existing building made of cladding), in order to improve seismic resistance, prevent the fire risk, the explosion risk, the dispersion risk and improve the containment and purification of gaseous effluents. Examination of the file began in 2015, as did preparations for the construction site.

Comhurex uranium hexafluoride preparation plant - BNI 105

On 1st January 2014, Areva NC took charge of operating the BNI 105 on the Tricastin platform, in place of the former licensee, Comurhex.

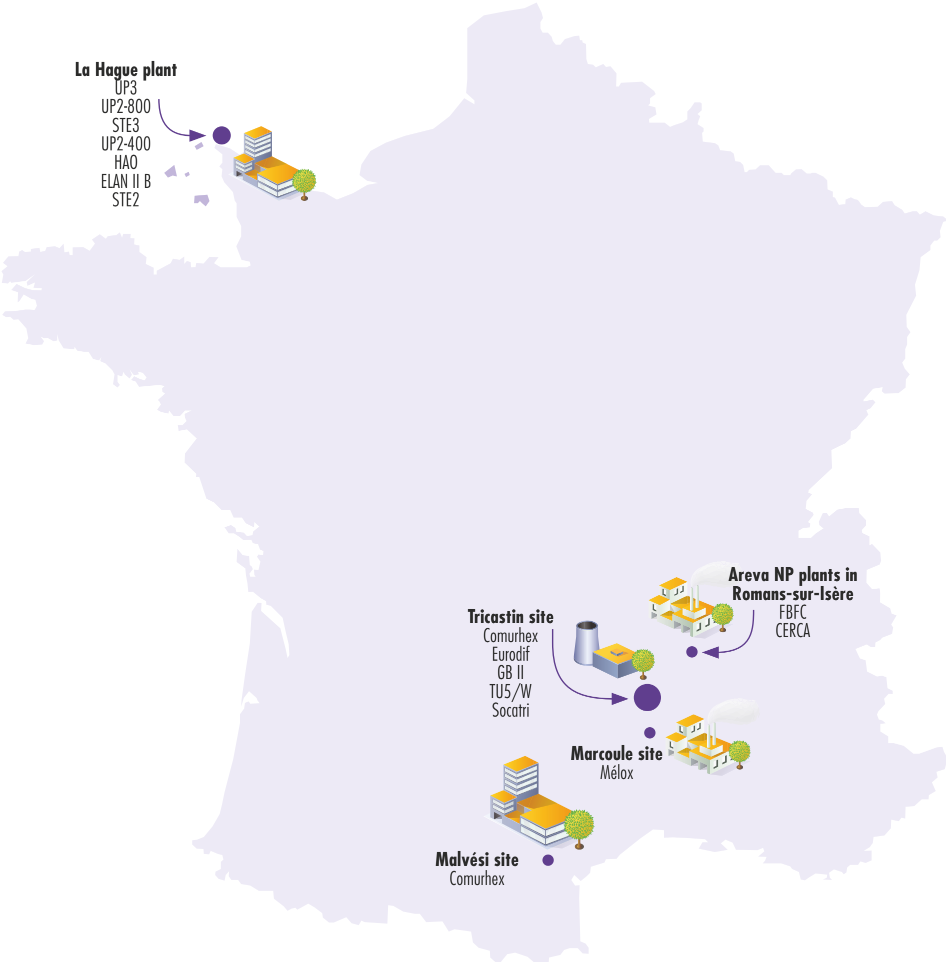
The ICPEs not needed for operation of the BNI are included in the perimeter of BNI 105 operated by Areva NC owing to the related risks, that is the risks created by these ICPEs to the safety of the BNI, which is also undergoing decommissioning (see chapter 15). These ICPEs are primarily devoted to the fluorination of uranium, in the form of uranium tetrafluoride (UF_4) into uranium hexafluoride (UF_6) so that it can be subsequently enriched. Each year, they produce about 14,000 tonnes of UF_6 from the UF_4 coming from the Areva NC Comurhex facility in Malvési. Until 2015, they also produced chlorine trifluoride (ClF_3) used for rinsing the diffusion cascade in the Georges Besse plant as part of the operations to prepare for decommissioning. This production is today stopped, which eliminates all the risks linked to this activity. This ICPE is one that requires authorisation and comprises institutional controls (Seveso) and is subject to the financial guarantees arrangement for making the facilities safe and, finally, is subject to the industrial emissions directive.

The plant's production tool will be modernised through the construction and then commissioning of the Comurhex II installations, initially scheduled for 2015 and currently planned for 2018, while the existing plant, Comurhex I, will close by the end of 2017. Unit 61 in Comurhex I was commissioned in October 2013 but delays in the new plant project led Areva NC to ask ASN to authorise continued operation of the old ICPE plants. This operating extension of the Comurhex I plants from July 2015 up to the end of 2017 was accepted in 2015.

This extension was covered by ASN resolution CODEP-LYO-2015-024792 of 30th June 2015 which prescribed the main reinforcement work required on these plants. This work in particular concerns the implementation of mitigation means to limit the consequences of a major hazardous gas leak in the process buildings, the anticipated shutdown of the installations (storage of propane and ammonia, recycling of the hydrofluoric acid), connection of the gauges room to the gas pressure reduction control system and improvement of the safety system to make it independent of the control system. On 11th August 2015, ASN carried out a dedicated inspection on the actual implementation of these main improvements.

Areva NC also continued its work to improve the containment of the 400 structure. A number of significant loss of containment events in this structure nonetheless occurred in 2015. ASN is thus remaining particularly vigilant to ensuring that sufficient stringency is maintained

THE INSTALLATIONS of the fuel cycle in operation or undergoing decommissioning



in the operation and maintenance of these plants. This latter point must also be considered in the context of the ongoing staff turnover, which is a subject of particular attention for ASN, in particular in the light of the start-up of new plants in the coming years.

With regard to the environmental aspects, the discharge resolutions for BNI 105 were revised in 2015. ASN also notes repeated events entailing hydrofluoric acid discharge limits being exceeded at the 200 structure stack. With a view to the continued operation of the plants, ASN prescribed automatic shutdown of the electrolysis process when an exceedance is detected, as well as an additional discharge counting system. ASN also observed an unsatisfactory situation in the management of the conventional waste areas in BNI 105. The licensee reacted rapidly and implemented a conformity action plan.

Finally, ASN is calling on the licensee to remain vigilant with regard to the stringency required in the management of anomalies detected by the periodic checks and tests and in the management of modifications.

ASN considers that the facilities located within the perimeter of BNI 105 are operated with a level of safety that is on the whole satisfactory.

The Eurodif gaseous diffusion enrichment plant – BNI 93

This installation is dealt with in section 15.

The Georges Besse II gas centrifuge enrichment plant – BNI 168

BNI 168, called Georges Besse II (GB II), licensed in 2007 and operated by the Société d'enrichissement du Tricastin (SET), is a plant enriching uranium by means of gas centrifugation. The principle of this process involves injecting UF_6 into a cylindrical vessel rotating at very high speed. The centrifugal force concentrates the heavier molecules (containing uranium-238) on the periphery, while the lighter ones (containing uranium-235) are recovered in the centre. By combining several centrifuges, creating what is known as a cascade, it is then possible to recover a stream enriched with fissile U-235 isotope and a depleted stream. This process has two key advantages over the gaseous diffusion process used in the old Eurodif plant: it consumes less electrical energy (75 MWe as against 3,000 MWe for equivalent production) and is safer, because the quantities of material present in the centrifuge cascades are far smaller (6 tonnes in GB II instead of 3,000 tonnes in Eurodif) and are utilised in gas form at below atmospheric pressure.

The GB II plant comprises two separate enrichment units (South and North units) and a support unit, the REC II. In early 2009, ASN authorised commissioning of the South enrichment facility. Today, all the cascades in the South unit are in service.

The North unit is built along the same lines as the South unit but only contains six rather than eight modules and differs in that it is authorised to enrich the uranium resulting from reprocessing of spent fuel in the first pair of modules. The start-up authorisation for this facility was given by ASN on 31st January 2013. Enrichment of the uranium resulting from reprocessing has never been implemented in the facility and requires prior authorisation from ASN. The gradual start-up of the enrichment cascades was virtually completed in 2015 under the supervision of the cascades start-up internal authorisation committee, which functions satisfactorily.

The conclusions of the criticality risk inspection carried out by ASN in 2014 were unsatisfactory and in 2015 ASN checked that the SET had taken steps to improve its management of this risk.

ASN also authorised the commissioning of the unit dedicated to the transfer, sampling and inspection of nuclear material (REC II) in its resolution 2014-DC-0461 of 7th October 2014. This unit contains the main nuclear safety and chemical issues of the GB II facility. In 2015, ASN checked the conditions for the commissioning of this facility. ASN considers that the reliability of the facility's operation needs to be improved.

The Georges Besse II plant displayed a satisfactory standard of safety in 2015. The technologies utilised in the facility enable high standards of safety, radiation protection and environmental protection to be reached.

The Atlas facility

Decree 2015-1210 of 30th November 2015 authorised Areva NC to create the Atlas BNI (Areva Tricastin analysis laboratories). The purpose of this facility is to group the activities currently performed by the industrial analysis laboratories specific to the various Areva facilities on the Tricastin and Romans-sur-Isère sites. The licensee then submitted a commissioning authorisation application for this BNI. This application is currently being examined and the result should be made known in late 2016 – early 2017.

Grouping of the Tricastin site storage areas within the same BNI

In 2012, Areva submitted a safety options file for the Écureuil project for the creation on the Tricastin site of an extension to the storage capacity for U_3O_8 from reprocessing, using existing and previously delicensed buildings. ASN issued an opinion on the options file in October 2013. This project was then abandoned by the licensee.

In February 2015, Areva informed ASN that it wanted to create a new BNI intended for management of the stock of uranium-bearing materials on the Tricastin site. After carrying out work to optimise the existing storage facilities on the site, which enables the storage saturation date to be pushed back from 2019 to 2021, Areva sent ASN a safety options file in April 2015 concerning the creation of new storage buildings to replace the *Écureuil* project. ASN issued a negative opinion on this safety options file, which failed to take account of the changes made to the regulations since 2012 and which was based on obsolete natural hazards. Areva envisages submitting a creation authorisation application for a new BNI in late 2016.

FBFC nuclear fuel fabrication plant in Romans-sur-Isère.

TO BE NOTED

ASN maintains reinforced monitoring of the Areva plants in Romans-sur-Isère

Areva on the whole complied with the deadlines of the action plan transmitted in 2014 and designed to reorganise how it meets its commitments and improve safety management. This work led the site to extensively revise the safety baseline requirements of the two BNIs, which are now in conformity with the state of the art of the nuclear sector.

Given the number and scale of the projects initiated in the facility to improve the robustness of the equipment and processes, ASN carried out reinforced monitoring of the site in 2015.

On 8th January 2015, ASN issued a resolution setting additional prescriptions for Areva NP concerning the «hardened safety core» and management of emergency situations, based on the lessons learned from the Fukushima-Daiichi accident. This regulatory text also sets deadlines for compliance with the main commitments in the two BNIs. The conclusions of the ten-yearly reviews of BNIs 98 (FBFC) and 63 (Cerca), planned for 2016 and 2017 respectively, will enable ASN to issue a position statement on the adequacy of the steps taken since the previous reviews.

ASN inspection on the FBFC site, Romans-sur-Isère plant, October 2015.

1.1.2 Nuclear fuel fabrication plants in Romans-sur-Isère

On completion of the uranium enrichment process, the actual nuclear fuel is fabricated in various installations, depending on the type of reactors for which it is intended. The fabrication of fuels for electricity generating reactors involves the transformation of UF_6 into uranium oxide powder. The pellets fabricated from this powder in the Areva NP plant in Romans-sur-Isère (BNI 98), are placed in metal tubes to constitute the fuel rods, which will in turn be grouped together to form fuel assemblies. The fuels used in experimental reactors are more varied and some of the for example, use highly-enriched uranium in metal form. These fuels are fabricated the Areva NP plant at Romans-sur-Isère (BNI 63).

The two BNIs located on the Romans-sur-Isère site, previously operated by the FBFC company, have been operated by the Areva NP company since 1st January 2015.

The FBFC nuclear fuel fabrication plant – BNI 98

In recent years, the licensee has modified the organisation of the units and begun the renovation of its industrial tool. This renovation has in particular reduced the exposure of the workers through improved containment of the uranium powders used.

ASN is remaining vigilant with regard to the time taken to complete the renovation projects for the uranium-bearing material scrap recycling unit (R1) and the relocation of the activities from the waste treatment unit (AX2). These units entail major safety issues, in particular with respect to the criticality risk and the risk of dissemination of radioactive and chemical substances in the event of an earthquake. This is why, in a resolution of 8th January 2015, ASN required that work be carried out in order to ensure the conformity of these facilities or, failing which, the removal of all radioactive materials.

The report on the periodic safety review of this facility, submitted to ASN on 30th December 2014, is currently being examined.

The Cerca nuclear fuel fabrication plant – BNI 63

This plant is one of the oldest French nuclear facilities still in service. There are major nonconformities in the structures of the buildings and equipment by comparison with current safety standards, in particular in terms of the ability to withstand earthquakes, extreme climatic events and stability in the event of fire. Despite ASN's repeated reminders since the 2006 periodic safety review, Areva NP is struggling to begin the necessary renovation work and has even mentioned the possibility of closing the facility within the next few years owing to its obsolescence and the cost involved in upgrading it. This is why, in a resolution of 8th January 2015, ASN required that work be carried out to ensure the conformity of these facilities or, failing which, that all radioactive materials be removed. Areva stated that at the end of 2015 it had taken the decision to construct an extension to the building meeting current safety standards.

On 25th August 2015, ASN also issued a resolution to upgrade the regulatory oversight of the activities carried out in the facility and of the scope of its operations. As this installation is ageing and has not undergone any substantial modifications, the technical prescriptions issued concerning it were contained in widely scattered and sometimes obsolete texts, which were complex and hard to interpret. ASN's resolution lists the activities authorised in the facility and the types and quantities of radioactive substances used in it. It also specifies a number of provisions, in particular linked to the prevention of accident risks, the control of detrimental effects and environmental impact, to informing ASN and to managing emergency situations, along with particular provisions concerning the possession and utilisation of radioactive sources.

The report on the periodic safety review of this facility, submitted by Areva NP on 31st December 2015, is currently being examined. This review comprises an assessment of the conformity of this facility with its initial authorisation and the safety reassessment with respect to current safety standards.

1.2 The back-end fuel cycle – reprocessing

1.2.1 Areva NC reprocessing plants in operation at La Hague

The La Hague plants, intended for reprocessing of spent fuel assemblies from nuclear power reactors, are operated by Areva NC.

The various facilities of the UP3-A and UP2-800 plants and of the STE3 effluent treatment station were commissioned from 1986 (reception and storage of spent fuel assemblies) to 1994 (vitrification facility), with most of the process facilities entering service in 1989-1990.

The Decrees of 10th January 2003 set the individual reprocessing capacity of each of the two plants at 1,000 tonnes per year, in terms of the quantities of uranium and plutonium contained in the fuel assemblies before burn-up (in the reactor), and limit the total capacity of the two plants to 1,700 tonnes per year.

The limits and conditions for discharges and for water intake by the site are defined by two ASN resolutions of 22nd December 2015. A new update is planned.

Operations carried out in the plant

The reprocessing plants comprise several industrial units, each of which performs a specific operation. There are thus the reception and storage installations for spent fuel, facilities for shearing and dissolving it, for chemical separation of fission products, uranium and plutonium, for purification of the uranium and plutonium and for treatment of effluents and conditioning of waste.

When they arrive in the plants, the spent fuel assemblies in their transport casks are unloaded either under water in the spent fuel pool, or in a dry, leaktight, shielded cell. The assemblies are then stored in pools for cooling.

Afterwards, the assemblies are sheared and dissolved in nitric acid to separate the pieces of metal cladding from the spent fuel itself. The pieces of cladding, which are insoluble in nitric acid, are removed from the dissolver, rinsed in acid and then water, and transferred to a compacting and drumming unit.

The nitric acid solution comprising the dissolved radioactive substances is then processed in order to separate the uranium and plutonium from the fission products and other transuranic elements (in other words the chemical elements heavier than uranium).

After purification, the uranium is concentrated and stored in the form of uranyl nitrate $UO_2(NO_3)_2$. It is intended for conversion into a solid compound (U_3O_8) in the Tricastin TU5 facility, referred to as Reprocessed Uranium (URT).

After purification and concentration, the plutonium is precipitated by oxalic acid, dried, calcined into plutonium oxide, packaged in sealed containers and placed in storage. The plutonium is then intended for the fabrication of MOX fuels in the Areva NC plant in Marcoule (Mélox).

The effluents and waste generated by the operation of the plants

The fission products and other transuranic elements resulting from reprocessing are concentrated, vitrified and packaged in Standard Vitrified Waste Packages (CSD-V). The pieces of assembly cladding are compacted and packaged in Standard Compacted Waste Packages (CSD-C).

The reprocessing operations described in the previous paragraph also use chemical and mechanical processes, the operation of which generates gases and liquid effluents as well as solid waste.

The solid waste is also packaged on-site, either by compacting, or by encapsulation in cement. The solid radioactive waste from the reprocessing of spent fuel assemblies from French reactors is, depending on its composition, either sent to the low- and intermediate-level, short-lived waste repository at Soulaines (see chapter 16) or stored on the Areva NC site at La Hague, pending a final disposal solution (in particular the CSD-V and CSD-C).

In accordance with Article L. 542-2 of the Environment Code concerning radioactive waste management, radioactive waste from the reprocessing of spent fuels of foreign origin is shipped back to its owners. It is however impossible to physically separate the waste according to the fuel from which it comes. In order to guarantee fair distribution of the waste resulting from the reprocessing of the fuels from its various customers, the licensee proposed an accounting system to track items entering and leaving the La Hague plant. This system, called Exper, was approved by Order of the Minister responsible for Energy on 2nd October 2008.

The gaseous effluents are given off mainly during fuel assembly shearing and during the dissolving operation. These gaseous effluents are processed by scrubbing in a gas treatment unit. Residual radioactive gases, in particular krypton and tritium, are checked before being released into the atmosphere.

UNDERSTAND

The installations at La Hague

Shutdown installations undergoing decommissioning:

- **BNI 80:** Oxide High Activity facility (HAO)
  - HAO/North: Facility for underwater unloading and spent fuel storage
  - HAO/South: Facility for shearing and dissolving of spent fuel elements
- **BNI 33:** UP2-400 facility, first reprocessing unit
  - HA/DE: Facility for separation of uranium and plutonium from fission products
  - HAPF/SPF (1 to 3): Facility for fission product concentration and storage
  - MAU: Facility for uranium and plutonium separation, uranium purification and storage in the form of uranyl nitrate
  - MAPu: Facility for purification, conversion to oxide and initial packaging of plutonium oxide
  - LCC: Central product quality control laboratory
  - ACR: Resins packaging facility
- **BNI 38:** STE2 facility: collection, treatment of effluents and storage of precipitation sludge, and AT1 facility, prototype installation currently being decommissioned
- **BNI 47:** ELAN II B facility, CEA research installation currently being decommissioned

Installations in operation:

- **BNI 116:** UP3-A facility
  - T0: Facility for dry unloading of spent fuel elements
  - D and E pools: Pools for storage of spent fuel elements
  - T1: Facility for shearing of fuel elements, dissolving and clarification of solutions obtained
  - T2: Facility for separation of uranium, plutonium and fission products, and concentration/storage of fission product solutions
  - T3/T5: Facilities for purification and storage of uranyl nitrate
  - T4: Facility for purification, conversion to oxide and packaging of plutonium
  - T7: Facility for vitrification of fission products
  - BSI: Facility for plutonium oxide storage
  - BC: Plant control room, reagent distribution facility and process control laboratories
  - ACC: Hull and end-piece compaction facilities
  - AD2: Technological waste packaging facility
  - ADT: Waste transit area
  - EDS: Solid waste storage area
  - D/E EDS: Storage/removal from storage of solid waste
  - ECC: Facilities for storage and recovery of technological waste and packaged structures
  - E/EV South-East: Vitrified waste storage facility
  - E/EV/LH and E/EV/LH 2: extension of vitrified residues storage capacity
- **BNI 117:** UP2-800 facility
  - NPH: Facility for underwater unloading and storage of spent fuel elements in pool
  - C pool: Pool for storage of spent fuel elements
  - R1: Fuel elements shearing, dissolving and resulting solutions clarification facility (including the URP: plutonium re-dissolution facility)
  - R2: Uranium, plutonium and fission product separation, and fission product solution concentration facility (including the UCD: alpha waste centralised processing unit)
  - R4: Facility for purification, conversion to oxide and initial packaging of plutonium oxide
  - SPF (4, 5, 6): Facilities for storage of fission products
  - BST1: Facility for secondary packaging and storage of plutonium oxide
  - R7: Facility for vitrification of fission products
  - AML - AMEC: Packaging reception and maintenance facilities
- **BNI 118:** STE3 facility: effluent recovery and treatment and storage of bituminised waste packages
  - D/E EB: storage of alpha waste
  - MDS/b: mineralisation of solvent waste

The liquid effluents are processed and generally recycled. After verification and in accordance with the discharge limits, certain radionuclides, such as iodine and tritium, are sent to the marine outfall pipe. The others are sent to on-site conditioning units (solid glass or bitumen matrix).

1.2.2 Operation of the La Hague plants

Examination and follow-up of the periodic safety review files

In 2008, ASN examined the conclusions of the periodic safety review for BNI 118, which includes the Effluent Treatment Station (STE3), the solvent mineralization facility (MDS/B) and the sea discharge outfall pipe. ASN is particularly attentive to licensee compliance with the undertakings made during this periodic safety review. ASN observed that, on the whole, Areva NC is late in meeting its initial undertakings, in particular concerning the performance of conformity examinations on the facility and the processing of legacy waste.

In 2010, the licensee transmitted the periodic safety review report for BNI 116 (UP3-A plant). At the request of ASN, the Institute for Radiation Protection and Nuclear Safety (IRSN) assessed the report submitted by Areva and presented the results of its assessment to the Advisory Committee for Laboratories and Plants (GPU) during six meetings from mid-2012 to March 2015.

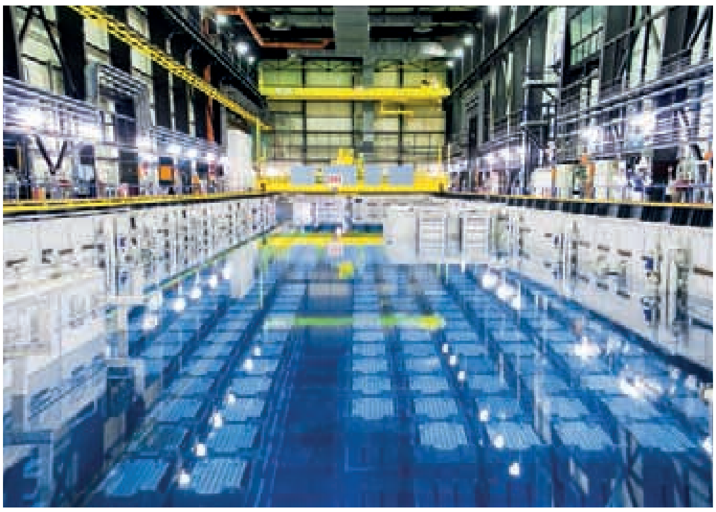
- The first GPU meeting took place on 27th June 2012. It examined the method and the data used by Areva NC for the performance of this review, as well as the approach used to identify the Elements Important for Safety and how it was applied to BNI 116.
- The second GPU meeting was held on 12th June 2013 and examined operating experience feedback, more specifically concerning the incidents that had occurred.
- The third GPU meeting took place on 14th January 2014 and was devoted to reviewing the safety of on-site transport operations carried out with the Hermes-Mercure and Navettes package models.
- The fourth GPU meeting on 26th March 2014 was devoted to reviewing the conformity of BNI 116 with its baseline safety requirements, the satisfactory control of the ageing of this facility and the safety of maintenance operations.
- The fifth GPU meeting of 18th March 2015 was devoted to the safety reassessment conducted by the licensee, in particular in the light of changing regulations and best practices in the field of safety and radiation protection as well as the lessons learned from operating experience feedback from the facility.
- The sixth GPU meeting of 25th March 2015 was devoted to the programme of measures defined by the licensee to improve the safety of its facility, in order to rule on the level of safety of the UP3-A plant both now and for the next ten years.

Following this assessment, ASN will be sending Areva NC prescriptions for the safety improvements needed further to the review. This review showed the need for a significant improvement in the protection of the installation against the risk of fire and against the lightning risk. ASN is also considering requiring greater checks on equipment used to concentrate the fission products in the facility (the «evaporators») as this equipment, which concentrates particularly radioactive substances, is corroding more rapidly than anticipated at the design stage.

ASN asked Areva NC to take account of operating experience feedback from the examination of the BNI 116 safety review file (plant UP3-A) when examining the review orientation file for BNI 117 (plant UP2-800) submitted by Areva at the beginning of January 2016.

Internal authorisation systems for minor modifications

ASN approved the implementation of a system of internal authorisations for minor operations on the La Hague site in its 14th December 2010 resolution. This system provides for two internal authorisation levels, depending on the extent of the operations and the associated radiation protection and safety implications. Before a planned operation or modification is authorised, it is assessed – depending on its assigned level – by either a safety specialist independent of the requesting operating unit, or, for the most significant operations, an Internal Authorisations Assessment Committee (CEDAI). In 2014, ASN received the analysis of the operating experience feedback about the working of the internal authorisations system, which Areva was supposed to have transmitted after it had been in use for three years. This information is being used to examine the application for revision of the internal authorisations system that Areva intends to submit in 2016, to integrate on the one hand the changes made following the ASN inspections and the Areva general inspection and, on the other, the new procedures in particular concerning the composition of the CEDAI and the criteria for identifying minor operations.



Spent fuel pool D. Areva spent fuel reprocessing plant at La Hague.

Areva NC monitoring of the status of evaporator capacity

In 2011, Areva NC brought to light several holes in the shell of an evaporator used to concentrate fission product solutions in the R7 unit. This evaporator could not be returned to service and needs to be replaced. In mid-2012, the licensee sent ASN a file presenting the safety options it had selected for the design of the new evaporator, to replace the old one. Examination of this file continued in 2014. The installation of this new evaporator is today scheduled for about 2017.

Furthermore, in October 2014, high corrosion rates were observed on the fission product solutions concentration evaporators in the R2 unit. These rates are higher than those of the equipment design and higher than those observed on the same equipment in the T2 unit. ASN asked the licensee to explain this difference between the R2 and T2 units and to analyse the impact of this accelerated corrosion mechanism on the security of the plant's evaporator capacity for the coming years. Moreover, given the safety issues associated with these evaporators, ASN is considering prescribing an annual inspection of the condition of this equipment in order to preclude any possibility of an accident. The situation of this equipment is the subject of particularly high vigilance on the part of ASN, which considers that this is a priority issue for 2016 in terms of safety on this site.

Radiation protection

In 2015, as in previous years, ASN considers that worker radiation protection in the La Hague plant is on the whole satisfactory. The staff of outside contractors, in particular those working on the decommissioning of the UP2-400 plant, are the most exposed workers in the facility.

1.2.3 Ongoing and future plant modifications

Authorisation applications for processing of new types of fuels

The operating range of the plants is defined in the 12th May 1981 Creation Authorisation Decrees for the plants on the La Hague site, updated in 2003 for each type of fuel assembly.

In 2011, Areva NC asked for authorisation to receive, store and reprocess spent MOX fuels from the Italian Trino reactor, in the UP3-A and UP2-800 plants on the La Hague site. ASN authorised these operations in its resolution of 31st March 2015.

In 2013, Areva NC applied for authorisation to extend the operating range of its facilities so that on the one hand it could receive and store fuel pins irradiated in the Phenix reactor, prior to reprocessing and, on the other, so that it could reprocess fuels based on Enriched Reprocessed Uranium (URE), while remaining within the operating range specified by the Decrees of 12th May 1981. ASN issued these authorisations in its resolutions of 11th March 2014 and 24th April 2014 respectively.

In 2014, Areva NC also applied for ASN authorisation to extend the operating range of its plants to reprocess Enriched Natural Uranium based fuels (UNE) resulting from "Galice" fuel management in EDF's reactors. ASN authorised these operations in its resolution of 15th July 2015.

In 2015, Areva NC requested authorisation to receive, store and reprocess spent fuels comprising MOX and enriched natural uranium pins from the Italian Garigliano reactor, in the UP3-A and UP2-800 plants. These fuels (assemblies comprising both MOX pins and uranium oxide pins) do not fall within the operating range of the plants defined by the Decrees of 12th May 1981. The modification of these Decrees is currently being reviewed.

Also in 2015, Areva NC requested authorisation to receive and reprocess low-enrichment uranium-silicide test and research reactor fuels from the Osiris reactor, in the UP3-A plant. This file is currently being reviewed by ASN.

Implementation of new storage capacity for vitrified waste packages

The construction of the first vitrified waste storage extension on the La Hague site (EEVLH) in order to anticipate saturation of storage capacity for vitrified waste packages (R7, T7 and EEVSE) which began in 2007, was completed in 2013. This extension comprises two pits, known as pits 30 and 40, each able to increase the existing facility's storage capacity by 4,199 packages.

Initially, only pit 30 was equipped with its storage shafts. This pit was partially commissioned following the ASN resolution of 12th September 2013, with a storage capacity limited to six packages of vitrified waste per shaft. ASN considered that the safety case did not allow it to go any further than this, in particular in terms of heat removal from the waste packages at full capacity. Once the licensee completed its safety assessment and ASN had reviewed it, ASN issued the authorisation for complete commissioning of pit 30 on 11th June 2015.

The forecasts of the storage capacity for standard vitrified waste packages (CSD-V) on the La Hague site show the need for a doubling of current capacity by 2017. On 4th June 2013, Areva NC thus sent the Minister in charge of Nuclear Safety a file requesting authorisation to modify the UP3-A plant (BNI 116) in order to increase this storage capacity:
- 4,199 additional spaces with the outfitting of pit 40 of the EEVLH extension;
- 8,398 additional spaces with the construction of the EEVLH 2 extension, an installation equivalent to EEVLH and comprising two new pits (pits 50 and 60).

This file is currently being reviewed by ASN. The environmental authority issued an opinion in September 2014 and a public inquiry was held from 13th April to 18th May 2015.

Implementation of new process in STE3

On 4th May 2012, Areva NC submitted a modification authorisation application file for BNI 118 to the Minister responsible for Nuclear Safety. The purpose of this modification application is to allow processing and packaging of the sludges stored in the STE2 facility, by means of a new process to be utilised within an existing building of the STE3 facility, in place of one of the two bituminisation lines (line A).

This process will consist of the following:
- drying of the STE2 treatment sludges;
- compacting of the powder resulting from drying, in the form of pellets;
- packaging of the pellets in a package filled with an inert material (C5 package);
- storage of the C5 packages, pending opening of a long-term management solution.

This authorisation application was examined by ASN and is the subject of a draft decree by the Minister responsible for Nuclear Safety, for which ASN issued a favourable opinion on 3rd December 2015. The Decree authorising the modification was signed on 29th January 2016.

The special fuels reprocessing unit project

In 2014, Areva presented ASN with a project to install a new special Fuels Reprocessing Unit (TCP). This unit would comprise new shearing and dissolving equipment, in particular for the spent fuels from test and research reactors and the Phenix reactor. The R&D studies concerning this project are ongoing.

With regard to the authorisation to receive and reprocess spent fuels from the Phenix reactor, Areva transmitted a safety options file for this new reprocessing unit at the beginning of 2016. This undertaking was taken up in the ASN resolution of 11th March 2014 which also prescribes the submission of an application for authorisation to modify the facility before 31st December 2018. This will also be the subject of a public inquiry.

1.2.4 Recovery and packaging of legacy waste

The former UP2-400 plant has been finally shut down since 1st January 2004. The final shutdown and decommissioning operations for the UP2-400, HAO and STE2 facilities and the ELAN II B unit are described in detail in chapter 15.

Unlike the waste packaged directly on-line produced by the new UP2-800 and UP3-A plants at La Hague, most of the waste produced by the first UP2-400 plant was stored in bulk without any final packaging. The operations involved in recovering this waste are technically difficult and require the use of considerable resources. The difficulties associated with the age of the waste, in particular the need for characterisation prior to any recovery and processing, confirm ASN's approach which, for any project, requires the licensees to assess the corresponding production of waste and make provision for processing and packaging as and when the waste is produced. The recovery of the waste contained in the old storage facilities on the La Hague site is also a precondition for the decommissioning and clean-out of these storage facilities.

The recovery of legacy wastes from the La Hague site is thus monitored particularly closely by ASN, mainly because of the major safety and radiation protection implications associated with it. Furthermore, recovery of the site's legacy waste is one of the Areva group's major commitments, made within the framework of the ministerial authorisations to start up new spent fuel reprocessing plants (UP3-A and UP2-800) in the 1990s.

The initial schedule for the recovery of these wastes slipped significantly and has continued to slip in recent years. ASN considers that the deadlines must no longer be pushed back, because the buildings in which this legacy waste is stored are ageing and no longer comply with current safety standards. ASN in particular considers that Areva NC must as rapidly as possible recover the legacy waste produced by operation of the UP2-400 facility, more specifically the sludges stored in the STE2 silos, the waste from the HAO and 130 silos and the fission products solutions stored in the SPF2 unit.

A final decision must be reached concerning disposal routes or new intermediate storage facilities, because their implementation involves large-scale projects: further postponement would jeopardise compliance with the deadlines set by the Environment Code, which states that the owners of intermediate level long-lived waste produced before 2015 must package it by 2030 at the latest (see video on *www.asn.fr,* rules for recovery and packaging of legacy waste at La Hague).

STE2 sludges

Since 2010, the scenario for the recovery and packaging of STE2 sludges has been stabilised and consists in transfer of the sludges to BNI 118 (STE3) for processing and packaging via a new process as yet to be built (see point 1.2.3). The recovery of these sludges should be completed no later than 31st December 2030 in accordance with the provisions of the Environment Code. The envisaged corresponding waste packages are called C5 packages.

In its resolution 2011-DC-0206 of 4th January 2011, ASN stipulated that it must first approve the production of this type of package, for which the design must take account of the risk of radiolysis leading to the production of hydrogen (see chapter 16).

In 2015, ASN authorised the first phase of the STE2 sludges recovery work.

TO BE NOTED

ASN oversees the recovery of legacy waste at La Hague

In the light of the points mentioned in the box opposite, ASN has since 2012 been drafting a resolution on the Waste Recovery and Packaging programme (RCD) aiming more specifically to regulate the progress and performance of this programme according to the safety implications of the operations. The preparation of this draft resolution entailed Areva NC being called to a hearing by the ASN Commission on 17th June 2014, during which ASN recalled that it would be particularly attentive to compliance with the deadlines concerning the RCD programme. The resolution concerning the legacy waste recovery and packaging operations was signed by the ASN Commission on 9th December 2014 following consultation of the public and the local information committee.

At ASN's request, Areva NC defined the safety priorities for these RCD operations:

- Priority 1 storage (highest priority):
  - in BNI 33: tanks 2720-10, 2720-20 and 2720-30 in the SPF2 unit;
  - in BNI 38: silo 130, silos 550-10 to 15 in the STE2-A unit and 550-17 in the STE-V unit;
  - in BNI 80: the HAO Silo;
- Priority 2 storage:
  - in BNI 33: settling tanks 1 to 5 in the "cladding removal" unit and 6 to 9 in the HA/DE unit, pits 217.01 and 217.02 of the "cladding removal" unit and the Organised Disposal Pool (SOD) for gas-cooled reactor structural waste;
  - in BNI 38: silo 115;
  - in BNI 80: pools S1, S2 and S3 for Organised Hulls Disposal (SOC);
- Priority 3 storage :
  - in BNI 33: area 791 in the plutonium intermediate level facility (MAPu);
  - in BNI 38: pits 2 and 26 in the North-West zone, the pit in building 128, building 119, the *Parc aux Ajoncs* and the trenches in the North-West zone;
  - in BNI 47: the elution columns and strontium titanate capsules;
  - in BNI 118: tanks 6523-50 and 6610-20 in the STE3 and MDSA units.

Silo 130

Further to the licensee's postponement of waste recovery from Silo 130 because of its outdated design and uncertainties as to the resistance of its civil engineering structure over time, ASN issued prescriptions on 29th June 2010 requiring that the licensee take compensatory safety measures, to be implemented before mid-2012. As these measures had not been taken by Areva NC before mid-2012, ASN served formal notice on the licensee to perform these operations before 9th December 2013 in a resolution of 26th March 2013. Following an inspection of silo 130, ASN lifted the formal notice in 2014. An exercise simulating a leak from silo 130 was also carried out by the licensee in 2014, at the request of ASN, and confirmed the ability of the licensee's organisation to manage such a situation.

Old fission product solutions stored in the SPF2 unit in the UP2-400 plant

To package fission products from reprocessing of gas-cooled reactor fuel, in particular that containing molybdenum (UMo FP), the licensee has opted for cold crucible vitrification. The package thus produced is called CSD-U (UMo standard waste package).

The use of the cold crucible with legacy solutions was authorised by an ASN resolution of 20th June 2011. In 2013, the first CSD-Us were produced but the cold crucible then became unavailable owing to a technical problem. It was restarted in 2015.

Other legacy waste recovery and packaging projects

For the other lower-priority legacy waste recovery and packaging projects, the following events in 2015 are worthy of note:

- continued R&D studies on the packaging processes for GCR and low granulometry type wastes;
- end of operations to recover drums from building 119;
- the application for authorisation to transfer the elution columns and strontium titanate capsules to improve the safety of the storage conditions and perform investigations;
- lifting of the hold point for recovery of non-fixed contamination waste from the Parc aux Ajoncs in the ASN resolution of 28th September 2015.

TO BE NOTED

The RCD operations for silo 130

Silo 130 is situated within the perimeter of the site's old effluent treatment station. The silo 130 containment is underground. It is made of reinforced concrete and designed for dry storage of the solid waste generated by reprocessing of spent fuel from the Gas-Cooled Reactor (GCR) plant series. As of 1973, the silo received waste of this type, until the 1981 fire which forced the licensee to flood the waste. The tightness of the silo thus filled with water is ensured by means of a containment barrier consisting of a steel liner.

Should its single containment barrier fail, silo 130 represents a risk of environmental contamination with radioactive substances. In its resolution of 29th June 2010, ASN thus required Areva NC to implement means of monitoring the tightness and mitigating the consequences of a possible leak from silo 130.

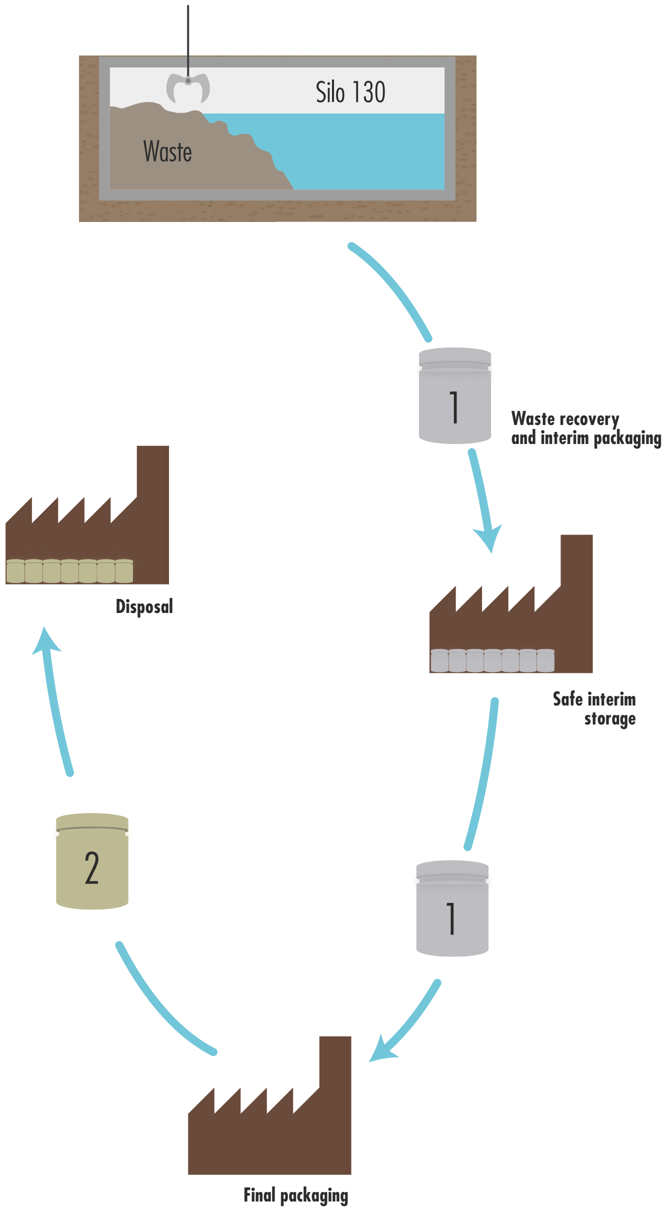
The RCD operations for silo 130 can be divided into two distinct phases (see diagram opposite):

- first step: waste recovery and safe interim storage; this first step, which will be spread over several years, is designed to ensure rapid improvement of the safety of the current silo 130 by emptying it of its waste and storing it safely, pending the development of final disposal solutions; the package intended for interim packaging of the waste from silo 130 has not yet been finally determined;
- second step: final packaging and disposal of the waste; this second step intends to carry out final packaging of the waste from silo 130 in an appropriate disposal package and to dispose of this waste in a dedicated facility. If this disposal facility is not available at the time of final packaging of the waste, additional interim storage could prove necessary.

These recovery operations entail risks of disseminating radioactive substances and exposing workers to ionising radiation. These risks are however lower and more easily managed than those represented by the current situation of silo 130.

Areva NC is today focusing on the construction of the recovery unit and an authorisation application is currently being reviewed. ASN set 1st July 2016 and 31st December 2022 as the latest dates for the beginning and end of the recovery operations for all the waste.

DIAGRAM of recovery and packaging operations



1. Interim package - 2. Final package

1.3 The back-end fuel cycle: fabrication of MOX fuel

The Mélox uranium and plutonium-based fuel fabrication plant

BNI 151 Mélox, situated on the Marcoule nuclear site, operated by Areva NC, is today the world's only nuclear installation producing MOX fuel, which consists of a mixture of uranium and plutonium oxides.

The facility's periodic safety review file was sent by the licensee on 21st September2011. One of main issues which came out of the review was controlling worker exposure to ionising radiation and adaptation of the facility and its organisation to changes in the composition of the materials used. In its resolution of 15th July 2014, ASN stipulates that continued operation of the plant is dependent on compliance with the prescriptions for controlling the risk of worker exposure to ionising radiation, the criticality risk and the risk of fire. It in particular prescribes the oversight of the measures identified during the review and the undertakings made by the licensee.

In 2012, Mélox submitted an application for authorisation to implement an internal authorisations process. This authorisation was granted by the ASN resolution of 23rd September 2014.

In 2015, ASN observed that the safety situation in the facility is on the whole satisfactory. The containment barriers remain effective, the radiation protection and criticality risk control issues are dealt with rigorously.

However, ASN did observe that monitoring of subcontracted operations needs to be significantly improved. ASN also observed that the management of equipment subject to pressure equipment regulations was inadequate, which led Areva NC to implement a programme to guarantee compliance.

The licensee has expressed its aim of producing a limited quantity of experimental fuels in the coming years, to qualify new types of fuels for the possible construction of fast neutron reactors. This operation is not authorised by the Mélox Creation Authorisation Decree and would need to be the subject of a modification of the authorisation decree covering this facility.

2. INTEGRATION OF EXPERIENCE FEEDBACK FROM THE FUKUSHIMA-DAIICHI ACCIDENT

All of the fuel cycle facilities were dealt with as a priority in the light of the experience feedback from the Fukushima-Daiichi accident. The licensees supplied stress test reports in September 2011 for all facilities and sites, with the exception of BNI 63 (Cerca), for which the report was submitted in September 2012.

In its resolutions of 26th June 2012, ASN set additional prescriptions for the Areva Group facilities assessed in 2011, in the light of the conclusions of the stress tests. These prescriptions more specifically require the implementation of a "hardened safety core" of material and organisational provisions designed to prevent a severe accident or limit its spread, mitigate large-scale releases and enable the licensee to fulfil its emergency management duties. The licensee is more specifically required to propose the level characterising the extreme natural hazards to be considered in the design and sizing of the "hardened safety core" equipment.

ASN reviewed the proposals from the Areva group to define the "hardened safety core" and its functions, including for the Areva NP BNI 63 in Romans-sur-Isère.

The ASN resolutions of 9th January 2015 prescribe the hazard levels and associated requirements for the "hardened safety core" and the deadlines for deployment of this "hardened safety core" for all cycle installations. The reference earthquake was in particular defined in it, based on an earthquake liable to occur every twenty thousand years. The current state of knowledge in seismology makes it particularly difficult to characterise such events, whereas the design of industrial facilities presupposes a precise definition of the loadings the facility must be able to withstand. Even if a reference earthquake has today been characterised for the "hardened safety core" at La Hague, technical discussions are continuing for the other Areva sites at Romans-sur-Isère, Marcoule and Tricastin. With the aim of ensuring consistency and stringency, ASN thus allowed more time for the technical debate and will rule in 2015 on the levels to be adopted by all the licensees.

Similarly, ASN will decide on the definition of the tornado risks to be considered for the components of the "hardened safety cores" of all French nuclear facilities in 2016.

3. REGULATING THE NUCLEAR FUEL CYCLE FACILITIES

ASN regulates the fuel cycle facilities at different levels:
- the safety cases produced by the licensee during the various steps in the operation of the nuclear facilities;
- the organisation of the licensees through inspections conducted in the field;
- fuel cycle consistency;
- operating experience feedback within the fuel cycle BNIs.

This part specifies how the steps taken by ASN apply to the fuel cycle facilities.

3.1 The main steps in the life of nuclear facilities

When the facilities undergo a significant modification or make the transition to decommissioning, ASN is responsible for reviewing these modifications and proposes the relevant decrees for these changes to the Government. ASN thus establishes prescriptions for these main steps. Finally, ASN also reviews the safety files specific to each BNI, paying attention to their integration into the broader framework of laboratory and plant safety.

The Areva group has not yet carried out the first periodic safety reviews on all its facilities. The series of initial periodic safety reviews to be completed before the end of 2017 is a major challenge for the Areva facilities. The review of the methodology and the conclusions of the review of the UP3-A facility on the La Hague site presented by the licensee should be an opportunity for Areva to improve its process for the future periodic safety reviews. When examining each new file, ASN will be attentive to ensuring that experience feedback from the previous reviews has been correctly taken into account. ASN will in particular ensure that lessons are learned from the UP3-A safety review with regard to identifying Elements Important for Protection (EIP) and the associated defined requirements, in compliance with the “BNI” Order.

3.2 Particular regulatory actions conducted in consultation with the Defence Nuclear Safety Authority

Given the probable declassification of the Tricastin secret BNI (SBNI) and ASN’s takeover of responsibility for oversight of these facilities, ASN and the Defence Nuclear Safety Authority (ASND) are attempting to maintain a degree of consistency in the application of the safety and radiation protection requirements for the facilities under their respective responsibility on the Tricastin site.

Most of the facilities regulated by the ASND have in fact been shut down or are being decommissioned and no longer play a role in national defence. In this respect, they no longer need to be subject to secrecy measures and will thus be gradually “declassified” in the coming years.

The facilities which are currently reprocessing the effluents and wastes from the entire site are scheduled for decommissioning and their activities will be taken over by the Trident unit in the Socatri facility (see chapter 14). Some of the uranium storage facilities will be dismantled and the others will be incorporated into the project to group the storage areas on the Tricastin site within the same BNI (see point 1.1.1).

ASN and ASND have set up a working group to clarify the steps involved in ASN’s takeover of the regulation of the safety of activities on this site. The decision was made that this take-over would be gradual, comprise as few steps as possible and be an opportunity to reorganise the oversight of the Tricastin site, so that no zones are outside the control of a safety regulator. Jointly with the ASND and the Ministry for the Environment, Energy and the Sea (MMEM), ASN will define the final breakdown into BNIs resulting from the ongoing process to declassify the INBS on the site. The BNI and INBS systems are in fact different and even if an INBS can house several nuclear facilities with different purposes and safety issues, the same does not apply to a BNI. The Tricastin INBS, which houses a wide variety of facilities, will thus need to be broken down into coherent BNIs as part of the declassification process. Their safety baseline requirements will then need to be brought into line with the BNI system.

The first step of the declassification process has been initiated, which should lead to ASN registering a first BNI radioactive materials storage area as a BNI in 2016. This process should end by the year 2018.

3.3 The licensee’s organization and management structure for fuel cycle nuclear installations

For each facility, ASN regulates the organisation and means chosen by the licensee to enable it to assume its responsibilities in terms of nuclear safety, radiation protection, emergency management in the event of an accident and protection of nature, the environment and public health and safety. ASN issues an opinion or recommendations regarding the chosen organisations and may issue prescriptions on specific identified points if it considers that these organisations present shortcomings in terms of internal oversight of safety and radiation protection, or that they are inappropriate.

ASN observes the working of the organisations put into place by the licensees mainly through inspections, more specifically those devoted to safety management.

During the various periodic safety reviews of the Areva plants, ASN examines the management processes which it was not possible to deal with during the overall safety management review, the conclusions of which were sent to Areva on 21st September 2012. A final opinion will be issued on all the national and local management processes following all of these reviews, which will be completed in 2018.

For 2016, ASN will be particularly vigilant in ensuring that the wide-ranging reorganisation announced by the Areva group does not compromise the progress made in safety management across the group. The group announces that on the one hand its nuclear fuel conversion, enrichment and reprocessing activities should be brought together within a new unit and that, on the other, the nuclear fuel fabrication and nuclear equipment manufacturing activities should be brought together within an entity jointly-owned by several industrial groups. In accordance with the law, the entities which, as a result of this split-up, will become licensees of existing BNIs within the Areva group, will need to prove to ASN that they do in fact have the technical and financial capacity to assume their nuclear safety responsibilities.

Examining the measures taken by the Areva group head office departments in terms of safety

ASN's regulatory actions also cover the Areva head office departments, which are responsible for the group's safety, radiation protection and environmental protection policy. ASN looks at how they draft and ensure the implementation of this policy in the various establishments within the group. In 2015, ASN continued with the actions taken in 2013 concerning on the one hand the identification of the systems, structures and components of the "hardened safety core" as part of the post-Fukushima process and, on the other, integration into the BNI baseline safety requirements of the new provisions of the Order of 7th February 2012, more specifically with regard to the identification of the elements important for protection and their associated safety requirements, on-site transport operations and controlling the impact of nuisances generated by the facilities. The 2015 inspection of the head office departments found that the group had made significant progress in formally defining its safety policy and how it is implemented. Areva is however significantly behind schedule in integrating EIP regulations (these regulations aim to ensure that each element of a BNI on which the licensee has built this BNI's safety case does actually meet the requirements stipulated in this safety case).

3.3.1 Taking account of social, organizational and human factors

Formalisation of the way Social, Organisational and Human Factors (SOHF) are taken into account really began in 2005-2006 for the fuel cycle installations, with the drafting of internal policies specific to each licensee. This approach began to be centralised within the Areva Group as of 2008, which is when the Group's head office departments started employing SOHF specialists. Since then, a national policy has been developed and is being gradually deployed among the group's licensees. The GPU meeting held in 2011 on safety management at Areva also enabled development and follow-up of the SOHF measures adopted. ASN considers that this approach must be continued for it to fully bear fruit. Most of the various licensees within the Areva Group are now staffed with persons competent in SOHF.

During the course of 2015, Areva developed its action plan for implementation of the objectives defined in its nuclear safety policy.

At the same time, ASN began to examine the deployment in the BNIs of the safety management tools created by Areva in response to the group's undertakings to the Advisory Committee in 2011. This approach aims in particular to assess the effectiveness of implementation in the field of the directives and guides produced by the group's head office departments.

With regard to the emergency organisation in an extreme situation, the Areva head office departments satisfactorily assisted the sites with the initial deployment of the SOHF methodology defined within the context of the stress tests. However, in 2014 and 2015, the head office departments delegated deployment of these methodologies to the sites, but did not retain sufficient coordination and oversight capability for these deployments. In 2016, ASN will therefore pay particular attention to consistency between emergency organisations in the event of extreme situations, on Areva's different nuclear sites.

3.4 Fuel cycle consistency

ASN monitors the overall consistency of the industrial choices made with regard to fuel management, from both the safety and the regulatory viewpoints. To do this, on the basis of the "Cycle impact" file transmitted by EDF and drafted every ten years with the fuel cycle stakeholders, Areva and Andra, ASN reviews the consequences for the various steps of the fuel cycle of EDF's strategy to use new fuel products in its reactors and new fuel management processes.

The issue of long-term management of spent fuel, mining residues and depleted uranium is examined taking account of the unforeseen variables and uncertainties attached to these industrial choices. In the short and medium terms, ASN intends to ensure that saturation of the spent fuel storage capacities in the NPPs or in the Areva La Hague pools – as has been observed in other countries – is anticipated and prevented by the licensees. The aim is to avoid the licensees using old facilities with a lower level of safety as an interim measure. ASN is assisted in this approach by the Ministry in charge of Energy, which it consults in particular to obtain information relative to materials traffic, industrial constraints that could affect safety, or energy policy guidelines. In order to maintain an overall and constantly appropriate view of the fuel cycle, these data must be periodically updated. ASN therefore periodically asks that together with the fuel cycle companies, EDF provide elements to demonstrate compatibility between changes in fuel characteristics and fuel management and developments in fuel cycle installations. Moreover, for any new utilisation of fuel, EDF must demonstrate that it has no unacceptable effect on the fuel cycle installations.

In 2015, ASN therefore asked EDF to conduct an overall review of the "Cycle impact" file be carried out for 2016. The aim is to *"obtain a robust long-term overview of the developments which could affect all fuel cycle activities and the consequences of these developments on facilities and transports."* The period covered by the study will be from January 2016 to December 2030 and it will need to identify the limit thresholds (capacity saturation, fuel isotope limit reached, etc.) foreseeable up until 2040.

This file will be required to show that the changes in fuel characteristics or in irradiated fuel management and the developments to the fuel cycle facilities envisaged by the industrial players concerned will in no respect be unacceptable, over the coming fifteen years, whether with regard to the operation of the NPPs, the operation of the front-end and back-end plants in the cycle or the medium and long-term management of the waste. It shall also demonstrate long-term management of traffic and stocks of materials, fuels and waste and anticipate difficulties or contingencies in the operation of the fuel cycle.

EDF considers that available capacity can guarantee storage of spent fuels for at least the next ten years, but cannot make any commitment thereafter, stating that this problem of spent fuel storage capacity saturation is being examined in another context, that of the "Cycle impact" file, which will be transmitted by EDF in 2016 at the request of ASN. Given the anticipated time-frame for saturation of spent fuel storage capacity and given the time needed to design and build such a facility, ASN draws *"the attention [of EDF] to the prospect of saturation of French spent fuel storage capacity"* and asks EDF *"in the next update of the file to present [its] strategy concerning this subject and the various contingencies associated with the creation of new storage capacity"*. In the light of the information at its disposal, ASN stated that *"transmission of a Safety Options File (DOS) by EDF within a period of 12 to 18 months is necessary"* in order to create such capacity.

The overall revision of the "Cycle impact" file currently being drafted comprises a number of innovations with respect to the previous approaches initiated in 1999 and 2006:
- The study period, which habitually covered ten years, is increased to fifteen years, in order to take account of the time actually observed in the nuclear industry to design and build any new facilities identified as being necessary further to the assessment carried out.
- Radioactive substances transport contingencies are explicitly incorporated into the assessment.
- Nuclear reactor closures are studied for the period of time considered, in particular assuming stable electricity demand until 2025, to take account of the planning provisions included in the Energy Transition for Green Growth Act.
- The strategy for managing and storing spent fuels pending reprocessing or disposal is part of the scope of the assessment. Saturation of existing capacity is in fact highly probable during the period in question.

4. ASN INTERNATIONAL ACTIONS

ASN enjoys regular discussions with its foreign counterparts to share best practices for regulating the nuclear safety of fuel cycle facilities.

Bilateral relations with the British safety regulator, the ONR (Office for Nuclear Regulation), were less frequent in 2015 but discussions should be held in 2016 concerning the recovery and packaging of legacy waste on the La Hague and Sellafield sites. Discussions on criticality control practices could also be held in 2016.

ASN also took part in a workshop by the International Atomic Energy Agency (IAEA) concerning the monitoring of the ageing of fuel cycle facilities, involving a comparison of international practices in this field.

ASN also held discussions with the American safety regulator, the NRC (Nuclear Regulatory Commission), on monitoring the commissioning of MOX production facilities, on monitoring fuel reprocessing facilities and, more particularly, preventing the explosion risk linked to "red oils" in these facilities.

On other matters, ASN had preliminary contacts with its Chinese counterpart with a view to the construction in China of a facility comparable to that of La Hague.

5. OUTLOOK

Cross-disciplinary aspects

ASN will be continuing its review of several of the Areva Group's BNIs and will initiate this process on new facilities at La Hague and Romans-sur-Isère in particular, but also on EDF's inter-regional fuel stores (in Chinon and Bugey).

ASN will be initiating a new process for examining safety and radiation protection management in the Areva group on the basis of the answers to the first review phase which ended in 2011 and on the basis of the reviews of the group's various facilities.

ASN will continue to monitor the implementation of the additional safety measures required following the stress tests, more specifically the Areva proposals concerning the definition of systems, structures and components robust to extreme hazards and the management of emergency situations, in particular compliance with the new prescriptions issued at the end of 2014 and in early 2015. In 2016, ASN should in particular be validating the reference hazards to be considered for the "hardened safety core" (especially the earthquake and tornado aspects).

With regard to the Areva group, ASN will be particularly vigilant in ensuring that the BNI licensees to be created as a result of the ongoing split-up of the group, are in full possession of the capabilities needed to meet their responsibilities as licensees. In particular, the engineering capabilities of the two groups resulting from Areva as it currently stands must be credible enough to make any changes to the facilities concerned and manage any emergencies in them.

Fuel cycle consistency

In 2016, ASN will begin to examine the new "Cycle impact" file, covering the period 2016-2030 and aimed at anticipating the various emerging needs in order to manage the nuclear fuel cycle in France. ASN focuses in particular on monitoring the level of occupancy of the spent fuel underwater storage facilities (Areva and EDF). It asked EDF to examine the impact on the anticipated saturation dates for these storage facilities of the shutdown of a reactor, of a possible modification in the spent fuel reprocessing traffic, as well as the solutions envisaged for delaying these dates. ASN considers that the saturation of the storage facilities must be anticipated (pools at La Hague and fuel building pools for the EDF reactors) and that Areva and EDF must very rapidly define a management strategy going beyond 2030.

ASN will also continue to monitor the files associated with fuel cycle consistency, notably the creation of a BNI dedicated to the storage of uranium from reprocessing on the Tricastin site and UP3-A in La Hague for the storage of compacted waste packages from spent fuel reprocessing.

Tricastin site

In 2016, ASN will examine the Atlas BNI commissioning authorisation application and will continue its review of the modification of the Socatri facility as part of the Trident project (see chapter 14). ASN will pay particular attention to the reorganisation of nuclear waste management on the site, pending the construction of the Trident unit.

ASN will continue to monitor the reorganisation of the Tricastin platform to ensure that these major organisational changes within the group have no impact on the safety of the various BNIs on the site. It will also require that the licensees of the platform assume their responsibilities so that they complete the unification process scheduled for 2012 or abandon the pooling of the equipment which should be at the disposal of each of them.

Jointly with the ASND and the Ministry for the Environment, Energy and the Sea (MMEM), ASN will define the final breakdown into BNIs resulting from the ongoing process to declassify the INBS on the site. In this respect, ASN will register the first BNI resulting from this process in 2016.

Romans-sur-Isère site

Areva NP still needs to carry out major conformity work on several buildings.

Given the malfunctions observed in recent years, ASN will pursue its heightened surveillance of the facility in 2016 in order to ensure that this licensee's nuclear safety performance is improved. It will be attentive to compliance with the deadlines for performance of the work defined in the facility's safety improvement plan and the revision of its safety baseline requirements. It will also be attentive to ensuring the implementation of the improvements planned as part of the stress tests.

The reports presenting the conclusions of the ten-yearly safety reviews carried out on the two facilities on the site and submitted in late 2014 for BNI 98 and late 2015 for BNI 63, will be reviewed to enable ASN to reach a conclusion with regard to the conditions for authorisation of possible continued operation of these facilities for the next ten years.

Mélox plant

Further to the conclusions of the periodic safety review on the facility and the ASN position statement of July 2014 regarding the continued operation of the Mélox plant, the licensee is required to implement its action plans, more specifically with regard to controlling the criticality risk and radiation protection measures, in particular in terms of dosimetry. ASN will monitor the licensee's compliance with its undertakings and the ASN prescriptions.

In addition, the changes to fuel management for power reactors requiring adaptation of the characteristics of the MOX fuel, will be a subject of interest for ASN. Areva NC will be required to demonstrate that these changes have no consequences for the safety of the facility and, as necessary, will submit the necessary modification files.

La Hague site

For the La Hague plants, ASN considers that efforts must be continued for the recovery and packaging of legacy waste on the site in order to meet the prescribed deadlines. Within the framework of the periodic safety reviews of the facilities, 2016 should see the continued implementation of the process to identify the operational Elements Important for Protection (EIP) and to improve the general operating rules of these plants.

The UP2-800 plant periodic safety review report submitted by Areva NC at the end of 2015 will be completed during the course of 2016.

The review of the UP3-A plant revealed a phenomenon of corrosion on the six R2 and T2 evaporators used to concentrate the fission products remaining after extraction of the plutonium and uranium from spent nuclear fuels that was much faster than had been anticipated by the licensee. The effects of this phenomenon on this equipment are only partially understood by Areva. The data transmitted to ASN on this subject at the end of 2015 led it to ask the licensee to present very rapidly the measures it intends to take to limit the development of the corrosion phenomenon, to obtain a reliable picture of the condition of its equipment and to operate the facility safely in the event of a containment breach. In any case, ASN will issue a statutory resolution concerning the operation of this equipment, which will need to be replaced. ASN considers that replacement of this equipment must be a priority for the licensee.

With regard to the forthcoming process changes in the La Hague facility, ASN attaches particular importance to two modifications: On the one hand, the TCP project which will allow reprocessing of several particular fuel assemblies and thus postpone saturation of the spent fuel storage pools and, on the other, the replacement of the R7 evaporator, for which the particularly corrosive solutions are currently being concentrated in other equipment in the plant and are liable to damage it.

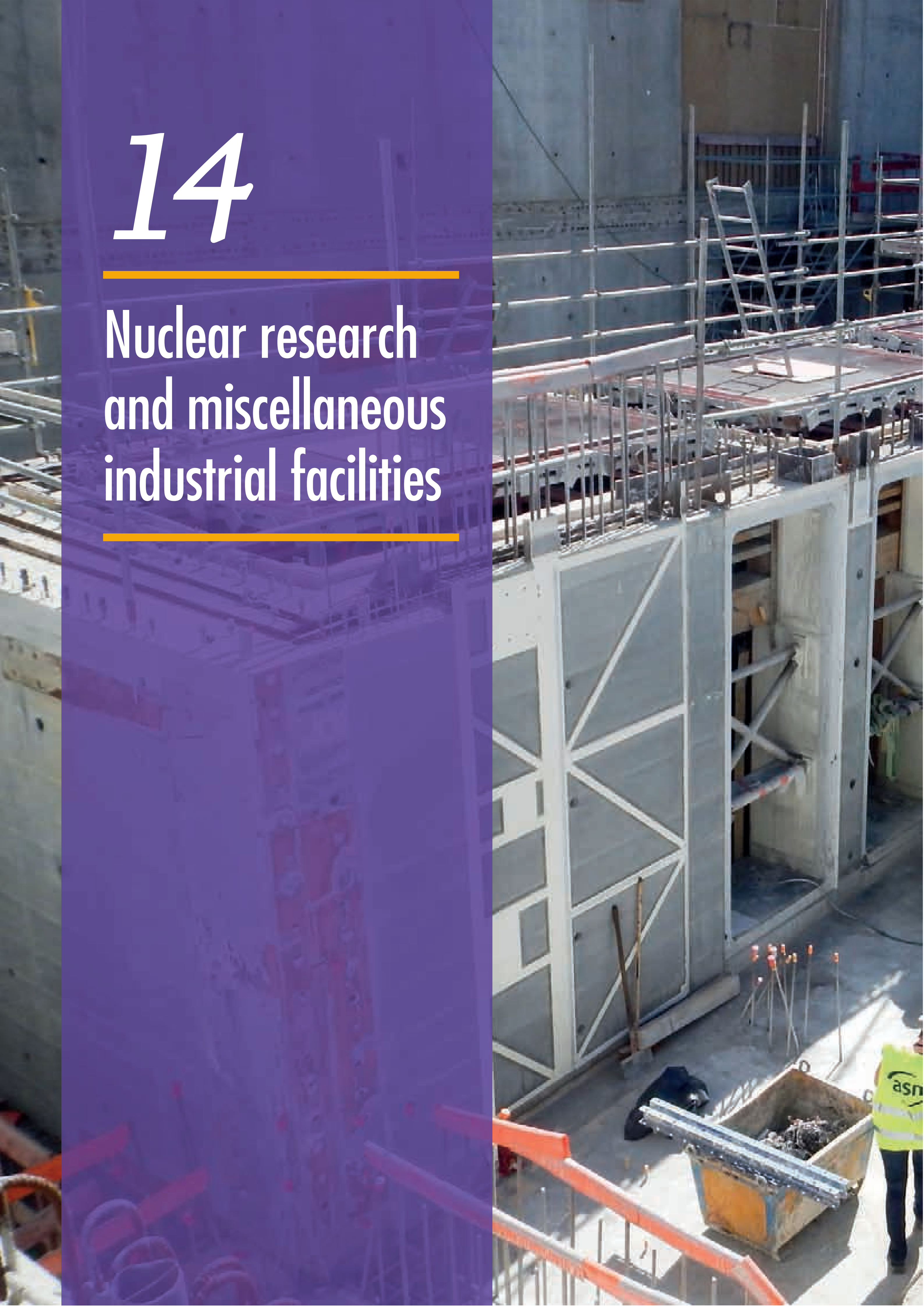
ASN will also be vigilant in ensuring that all the fuels received in the Areva NC plant are intended for reprocessing in accordance with the plant's authorization decrees.

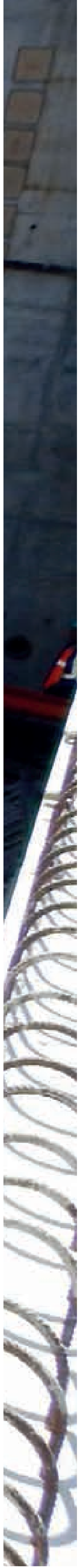
With regard to the recovery of legacy waste, ASN will be attentive to ensuring that any changes in Areva's industrial strategy do not lead to non-compliance with the ASN prescriptions concerning the recovery and removal of waste from silo 130 and the STE2 and HAO sludges.

ASN already issued prescriptions to this effect in 2010 for silo 130 and in 2014 for the RCD programme as a whole. 2016 will thus be marked by ASN's verification of the licensee's implementation of the above-mentioned regulatory provisions.

14

Nuclear research and miscellaneous industrial facilities





This chapter presents ASN's assessment of the safety of civil research and industrial BNIs. These facilities are different from the BNIs involved directly in the generation of electricity (reactors and fuel cycle facilities). These BNIs are operated by the Alternative Energies and Atomic Energy Commission (CEA), by other research organisations (for example the Laue-Langevin Institute (ILL), the ITER international organisation and the Ganil) or by industrial firms (for instance CIS bio international, Synergy Health and Ionisos, which operate facilities producing radiopharmaceuticals, or industrial irradiators).

These activities, which range from fundamental research to applied developments, started in the late 1940's in France. They support medical and industrial activities, more specifically the fuel cycle, nuclear power generation, reprocessing and waste disposal. The variety of the activities covered and their past history explains the wide diversity of facilities concerned.

The safety principles applied to these facilities are identical to those adopted for power reactors and nuclear fuel cycle facilities, while taking account of their specificities with regard to risks and drawbacks. In order to reinforce how these risks and drawbacks are dealt with, ASN defined three categories for the facilities it regulates in its resolution of 29th September 2015 (see chapter 3).

1. CEA INSTALLATIONS

The CEA centres comprise facilities devoted to research (experimental reactors, laboratories, etc.) and their support facilities (waste storage facilities, effluent treatment stations, etc.). Research at CEA focuses on areas such as the lifetime of power plants, future reactors, nuclear fuel performance, or the reprocessing and packaging of nuclear waste.

Point 1.1 below lists the generic subjects which marked the year 2015. Point 1.2 describes topical events in the various CEA installations currently operating. The CEA facilities undergoing clean-out or decommissioning are covered in chapter 15 and those devoted to the management of waste and spent fuel are covered in chapter 16.

1.1 Generic subjects

Through inspection campaigns, analysis of the lessons learned from operation of the facilities, or the review of files, ASN identifies generic topics on which it questions and monitors CEA. Generic subjects on which ASN focused in 2015 were:
- monitoring of periodic safety reviews, more specifically to ensure that aspects common to the BNIs on a given site are taken into account, along with experience feedback from the additional information during examination of the files for the CEA facilities with the lowest risks;
- waste management (see chapter 16) and the decommissioning of CEA facilities (see chapter 15) for which numerous projects are significantly behind schedule owing to changes in strategy.

During the course of 2015, the ASN commission called the CEA Chairman to a hearing concerning:
- CEA's post-operational clean-out, decommissioning and waste management strategy (see chapter 15);
- the future of the Saclay centre;
- the Jules Horowitz and Astrid reactor projects (see point 1.2.2).

1.1.1 Experience feedback from the Fukushima Daiichi accident

Further to the Fukushima Daiichi accident, ASN undertook stress tests of nuclear facilities. The approach consists in assessing the safety margins in the facilities with regard to the loss of electrical power, or cooling, and with regard to extreme natural hazards.

In May 2011, ASN instructed CEA to carry out stress tests on the BNIs with the highest risks in the light of the Fukushima Daiichi accident (batch 1). For the highest-priority experimental reactors, and in the light of the conclusions of the stress tests, in June 2012 ASN prescribed the installation of "hardened safety cores" of organisational and material provisions.

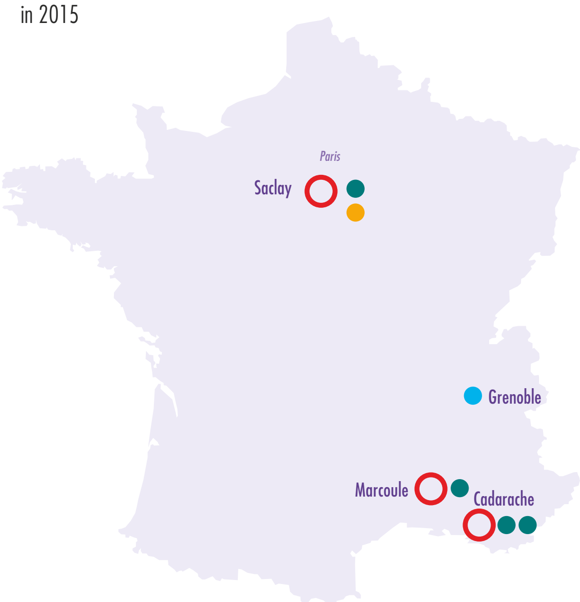
The stress tests approach continued for a second group (batch 2) of 22 lower-priority facilities. These include CEA's research facilities such as Chicade, LECA, MCMF, Cabri, Orphee, Atalante, as well as the emergency management resources on the Cadarache and Marcoule sites. CEA only identified the need to define a "hardened safety core" for Orphée, which was prescribed by ASN.

On 8th January 2015, ASN set requirements for CEA associated with the equipment and provisions of the "hardened safety core" for the facilities and centres which so require, along with the deadlines for their implementation, which should continue until 2018 (see figure 1). For the Saclay centre, CEA released its stress tests report on 30th June 2013. It was reviewed until 2015; ASN prescribed the requirements associated with the equipment and provisions constituting the centre's "hardened safety core" on 12th January 2016.

Finally, for the thirty or so other facilities of lesser importance (batch 3), ASN set out a calendar on 21st November 2013 for CEA to submit the stress test reports, a process which will run until 2020 (see figure 2).

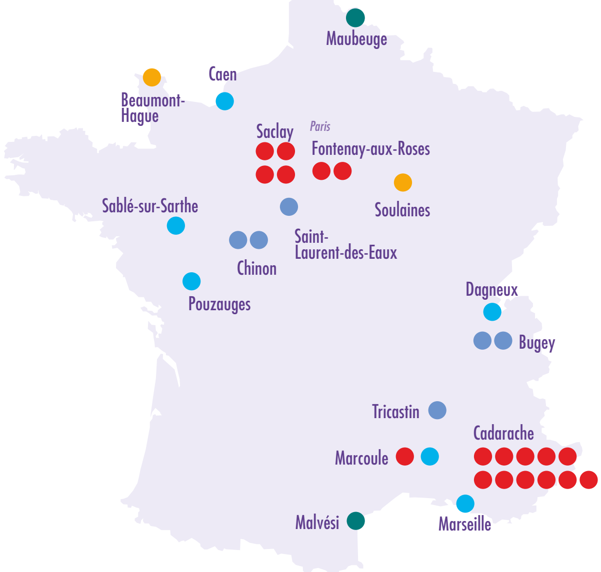
Given the available resources, it was not possible to review the files submitted by CEA and Areva in 2015 within a time-frame compatible with the prescriptions of January 2015, which could lead to delays in the implementation of the provisions of the "hardened safety core".

FIGURE 1: CEA centres and facilities, ILL and CIS bio international concerned by the "hardened safety core" additional prescriptions in 2015



- **CEA centre**
  - CEA Cadarache centre
  - CEA Marcoule centre
  - CEA Saclay centre
- **Research facilities operated by CEA**
  - Cadarache Site: Cabri, Jules Horowitz Reactor
  - Marcoule Site: Phénix
  - Saclay Site: Orphée
- **Facility operated by the Institut Laue-Langevin**
  - Grenoble: High-Flux Reactor
- **Facility operated by CIS bio international (project)**
  - Saclay: Radiopharmaceuticals production plant

FIGURE 2: research facilities concerned by the stress tests prescribed in november 2013 (batch 3)



- **18 CEA facilities**
  - 11 BNIs at Cadarache
  - 4 BNIs at Saclay
  - 2 BNIs at Fontenay-aux-Roses
  - Diadem (Marcoule)
- **6 EDF facilities**
  - MIR (Chinon and Bugey)
  - BCOT (Tricastin)
  - AMI (Chinon)
  - The Saint-Laurent-des-Eaux silos
- **6 accelerators and irradiators**
  - Ganil (Caen)
  - Ionisos (Dagneux, Sablé-sur-Sarthe, Pouzauges)
  - Synergy Health (Chusclan, Marseille)
- **2 LLW/ILW waste storage facilities (Andra)**
  - Aube Disposal Centre (CSA) (Soulaines)
  - Manche Disposal Centre - CSM (Beaumont-Hague)
- **2 AREVA group facilities**
  - Écrin (Comurhex Malvési)
  - Somanu (Maubeuge)

1.1.2 Management of nuclear safety and radiation protection at CEA

ASN monitors management of safety at CEA at several levels:
- together with the Chairman, ASN checks CEA's "major commitments" concerning the upgrading of old facilities, the final shutdown and decommissioning of facilities which cannot be upgraded and the management of waste, in particular with regard to compliance with the scheduled deadlines and consideration of the safety and radiation protection issues;
- with respect to the general and nuclear Inspectorate, ASN asks CEA to increase exchanges and transparency with regard to the authority, so that it can better evaluate the internal monitoring measures;
- concerning the Protection and Nuclear Safety Division (DPSN), ASN examines how CEA's nuclear safety and radiation protection policy is drafted and to what extent it is developing an overall approach to generic subjects;
- with regard to the centres, ASN reviews the files specific to each BNI, paying particular attention to their consistency with CEA's policy; in this respect, it in particular reviews the conditions in which safety management measures are carried out.

In 2009, CEA also submitted a report on the management of nuclear safety and radiation protection, supplemented in 2010, which was the subject of an ASN review, followed by additional requests in 2011. This review more particularly focused on the organisation of decision-making and internal oversight, the integration of safety issues into project management, the consideration given to social, organisational and human factors, skills management, subcontracting, operating experience feedback and safety in routine operations. The progress made in CEA's commitments and its answers to ASN's requests are the subject of three-yearly reports. In 2015, ASN asked CEA to supplement these reports and specified the framework for the forthcoming review on this subject planned for 2020 or 2021. In addition, ASN intends to inspect two centres in 2016 to verify the effective implementation of the CEA measures it has approved.

1.1.3 Monitoring of CEA's "major commitments" with its main nuclear safety and radiation protection commitments

In 2006, ASN stated that it wanted to see rigorous monitoring of the CEA safety issues with the highest potential consequences, by means of a high-level oversight tool, in particular for the decision-making process. In 2007, CEA therefore presented ASN with a list of "major commitments".

Despite the delays in meeting certain commitments, the results of this arrangement are on the whole positive. It allows targeted tracking of priority actions, which have a clearly set deadline. Any extension must therefore be duly justified and discussed with ASN. In 2015, the commitments relating to the use of the new Tirade packaging were met and the issue was closed out..

In 2015, at ASN's request, CEA defined nine new "major commitments" staggered between 2016 and 2022.

To date, 22 of the 35 "major commitments" defined since 2007 have been met.

TABLE 1: New CEA "major commitments"

SITE	BNI	ACTION	DEADLINE
Cadarache	42-95	Remove radioactive materials from ÉOLE-Minerve to achieve a 95% reduction in the radiological impact	1st half 2016
	55	Deploy the resources linked to the STAR STEP project	1st half 2016
	37	Transmit the file defining structural reinforcements of the renovated STD	2nd half 2017
	35	Removal all radioactive materials from the MCMF, subject to consolidation of the inventory	2nd half 2017
	56	Complete recovery of waste from trench T2, excluding earth	2nd half 2017
Marcoule	72	Transmit the NOAH commissioning file for decommissioning of Phenix	2nd half 2021
		Transmit the Diadem commissioning file	1st half 2019
Saclay	35	Recovery of effluents from tank MA500	2nd half 2018
Fontenay-aux-Roses	165-166	Decommissioning of the facilities	To be defined in connection with the BNI decommissioning decrees modification application files

1.1.4 The periodic safety reviews

Commissioning of the CEA installations began in the early 1960s. The equipment in these installations is ageing. Furthermore, it has been subject to modification, sometimes with no overall review of its safety. Since 2006, the Environment Code has required a safety review of each installation every ten years. The periodic safety reviews for CEA's facilities have been scheduled. Fourteen CEA facilities in service will therefore be required to submit a safety review file in 2016 and 2017, representing a significant workload.

In general, the periodic safety reviews can lead the licensee or ASN to define extensive upgrading work in areas where safety regulations and requirements have changed, in particular regarding resistance to earthquakes, fire protection and containment. ASN oversees all the work and requalification procedures, in accordance with principles and a schedule that it itself approves. Following the periodic safety reviews, ASN may define prescriptions to govern continued operation. Finally, for some facilities, ASN may determine a final shutdown date. This decision by the licensee to shut down the installation at the end of operations is the result either of the excessive difficulty involved in performing the safety improvements needed to bring it into line with the safety requirements applicable to the more recent installations, or the disproportionate cost of these improvements. ASN is then attentive to compliance with the associated deadlines.

In 2015 ASN asked CEA to specify its terms of application in the periodic safety reviews of aspects common to several BNIs on the same site, which can be found in common chapters of the safety analysis reports and impact assessments.

1.1.5 Revision of the prescriptions concerning water intake and effluent discharges

With regard to the revisions of the prescriptions applicable to the Cadarache and Fontenay-aux-Roses centres, there has been little change since 2014. The files submitted still do not meet the regulation requirements and need to be supplemented. ASN asked CEA to clarify and reinforce its organisation in order to take greater account of environmental aspects at the various stages in the life of these facilities (ten-yearly safety reviews, hardware modifications, etc.).

In 2015, ASN completed its review of the applications for updating the prescriptions regulating water intake and effluent discharges for the Marcoule BNIs and in 2016 will set limit values and define procedures for the discharge of effluents and consumption of water.

1.2 Operation of the facilities

1.2.1 CEA centres

Cadarache Centre

The Cadarache Centre is located at Saint-Paul-lez-Durance, in the Bouches-du-Rhone département. It employs about 5,000 people and occupies a surface area of 1,600 hectares. As part of CEA's strategy of specialising its centres, the Cadarache site deals mainly with nuclear energy. Twenty BNIs are situated on it. The purpose of these Cadarache centre installations is R&D to support and optimise existing reactors and to design new generation systems. The Cadarache centre also takes part in the launch of a number of new projects, in particular the construction of the Jules Horowitz Reactor (RJH).

Although there is a slight rise in the proportion of inspections with results that warrant corrective measures, the BNIs in CEA's Cadarache centre are operated in safety conditions that are on the whole satisfactory. With regard to the centre's ability to produce the regulatory files, while those concerning the more routine subjects are produced properly, CEA must nevertheless reinforce its organisation so that files on waste studies, discharge and water intake license applications or subjects with parallel impacts on safety and the environment are submitted in compliance with regulatory requirements.

With regard to the handling of deviations from the facilities' baseline safety requirements, CEA's priorities must be their detection and the steps taken to ensure that they do not happen again. From this standpoint, ASN considers that CEA needs to improve its early warning signs monitoring process.

The centre is also struggling to anticipate changes to the regulations and assess their impacts on its facilities, more specifically with regard to ASN fire and environmental resolutions.

Saclay Centre

The Saclay centre is located about 20 km from Paris in the Essonne *département*. This centre occupies an area of 223 hectares and employs about 6,000 staff. Since 2006, it has been home to CEA headquarters.

This centre has focused mainly on material sciences since 2005, from fundamental to applied research in a wide variety of fields and disciplines, such as physics, metallurgy, electronics, biology, climatology, simulation, chemistry and the environment. The purpose of applied nuclear research is to optimise the operation and safety of the French nuclear power plants and to develop future nuclear systems.

The centre houses eight BNIs as well as an office of the French National Institute for Nuclear Science and Technology (INSTN), a training Institute, and two Industrial companies: Technicatome, which designs nuclear reactors for naval propulsion, and CIS bio international (see point 3.2).

ASN considers that the BNIs are operated in conditions of safety that are on the whole satisfactory. CEA must however remain vigilant to compliance with the operations baseline requirements for the facilities and with the regulatory texts. A number of deviations from the baseline requirements have been detected by inspections or were notified by CEA as significant events.

For the Saclay site, CEA released its stress tests report on 30th June 2013. The review of this report continued through to 2015 and ASN prescribed the requirements associated with the equipment and measures constituting the centre's "hardened safety core" on 12th January 2016.

ASN observed progress in the management of waste storage, in particular in BNI 35, with the definition of operating instructions. Improvements are however still needed for BNI 101, with regard to the management of facility waste zoning and the issue of formal operating instructions for the storage areas. BNI 49 must also be vigilant with regard to managing the traffic and storage of decommissioning waste, which gave rise to the notification of two significant events.

The organisation for the management of the centre's on-site and off-site transport operations appeared to be satisfactory, apart from management of deviations, for which analysis and follow-up need to be strengthened.

The ASN inspections carried out in 2015 also revealed a number of deviations concerning the application of regulatory procedures for the management of BNI modifications. ASN calls on the licensee to conduct a review of its organisation and define an improvement action plan to prevent these deviations from reoccurring.

CEA again notified events concerning the monitoring of gaseous discharges from the facilities. One event in particular revealed that the steps taken by CEA to ensure compliance with the resolutions regulating the discharges from the centre were not exhaustive and were not carried out with the necessary rigour.

Finally, ASN is particularly critical of how the replacement of very high level sources is managed in BNI 77, which led to several weeks of incorrect storage in the centre's installations, a fact that was only notified belatedly. At ASN's request, CEA examined the internal causes of this situation and this lack of transparency.

Marcoule centre

The Marcoule centre is the CEA centre for the back-end nuclear fuel cycle and in particular for radioactive waste. It plays a major role in the research being conducted pursuant to the Programme Act of 28th June 2006 on the sustainable management of radioactive materials and waste. Defence nuclear facilities are installed on it, along with three CEA BNIs – Atalante, Phenix (see chapter 15) and Diadem – for which ASN issued a favourable creation authorisation opinion on 12th November 2015 (see chapter 16).

The site also comprises three other BNIs, not operated by CEA: the Gammatec irradiator, Melox (see chapter 13) and Centraco (see chapter 16).

In 2015, as in previous years, ASN considered that the safety management of the BNIs in the Marcoule centre operated by CEA was on the whole satisfactory. The inspections carried out on the centre's management and on the civil BNIs revealed no significant deviation.

Fontenay-aux-Roses centre

The two BNIs in this centre are currently being decommissioned (see chapter 15).

Grenoble centre

The CEA BNIs in this centre are currently being decommissioned (see chapter 15).

1.2.2 Research reactors

The purpose of experimental nuclear reactors is to contribute to scientific and technological research and to support operation of the nuclear power plants. Each reactor is a special case for which ASN has to adapt its monitoring while ensuring that safety practices and rules are applied and implemented. In this respect, the last few years have seen the development of a more generic approach to the safety of these facilities, inspired by the rules applicable to power reactors. This approach in particular concerns the safety assessment based on "operating conditions" (postulated initiating events) and the safety classification of the associated equipment. It has led to significant progress in terms of safety. This approach is also used for the periodic safety reviews of the facilities as well as for the design of new reactors.

Critical mock-ups

Masurca reactor (Cadarache)

The Masurca reactor (BNI 39), whose creation was authorised by a Decree dated 14th December 1966, is intended for neutron studies – chiefly on the cores of fast neutron reactors – and the development of neutron measurement techniques. This installation has been shut down since 2007 for compliance work, in particular with regard to seismic resistance. The reactor core has been completely unloaded and the fuel has been stored since then in the fissile materials Storage and Handling Building (BSM). The stress tests performed, more specifically in the seismic field, confirmed the need to build a new BSM and, in the meantime, to transfer the fissile material to the Magenta facility (BNI 169), which is built to earthquake design standards.

Although removal of the fissile materials was completed in October 2014, the renovation project (modernisation of the existing buildings and construction of the new storage building designed to meet reference earthquake standards) was once again delayed by CEA: the substantial modification application file is now being announced by CEA for the first quarter of 2016. Even if the organisation currently in place in the facility for monitoring outside contractors is satisfactory, it will need to be significantly strengthened in the light of the renovation operations.

Despite the delays in the facility's renovation project, CEA submitted its periodic safety review file in April 2015. ASN considered it to be unsatisfactory and requested that it be supplemented, in particular with regard to the conformity of the equipment necessary in the short term in the light of the requirements defined by CEA.

ÉOLE and Minerve reactors (Cadarache)

The ÉOLE and Minerve critical mock-ups are very low power reactors (less than 1 kW) used for neutron studies, in particular to qualify calculation systems, evaluate gamma or neutron attenuation in materials and acquire basic nuclear data.

The ÉOLE reactor (BNI 42), whose construction was authorised by the Decree of 23rd June 1965, is intended for neutron studies of light water reactor cores. It is able to reproduce a neutron flux representative of that of the power reactor cores, on a very small scale. The Minerve reactor (BNI 95), whose transfer from the Fontenay-aux-Roses research centre to the Cadarache research centre was authorised by the Decree of 21st September 1977, is situated in the same hall as the ÉOLE reactor. It is primarily devoted to effective cross-section measurements.

In 2015, ÉOLE and Minerve continued their teaching and research activities, in particular with the "FLUOLE 2" programme, for which ÉOLE was authorised to operate at 1 kW.

The examination of the second periodic safety review led ASN to issue its resolution of 30th October 2014, making continued operation conditional on the removal of most of the nuclear materials from storage in the near future, along with a limited improvement in its seismic resistance, no later than the end of 2017 and then its compliance with current seismic resistance requirements before the end of 2019. In 2015, CEA thus transferred a significant part of the radioactive substances stored in the facility to the Magenta installation on the Cadarache site, nine months ahead of the schedule set by ASN, thus achieving a 95% reduction in the radiological impact of a possible accident. With regard to the limited seismic resistance reinforcements, the studies have reached the detailed design stage and will enable CEA to clarify how it will be carrying out the reinforcement work before the end of 2017.

Given the cost of the reinforcements to the buildings that would be needed in order to meet current seismic resistance requirements, CEA will shut down the facility at the end of 2019 to comply with the ASN resolution of 30th October 2014.

ASN inspection in the core of the shutdown Masurca reactor, April 2015.

Irradiation reactors

The Osiris reactor and its ISIS critical mock-up (Saclay)

The Osiris pool-type reactor (BNI 40) has an authorised power of 70 megawatts thermal (MWth). It is primarily intended for technological irradiation of structural materials and fuels for various power reactor technologies. It is also used for a few industrial applications, in particular the production of radionuclides for medical uses, including molybdenum-99 (99Mo). Its critical mock-up, the ISIS reactor, with a power of 700 kWth, is essentially used for training purposes today. These two reactors were authorised by a Decree dated 8th June 1965.

Owing to the significant design differences between this older facility and the best techniques currently available for protection against external hazards and the containment of materials in the event of an accident, 2015 was the last year of operation for the Osiris reactor. The ISIS reactor will be able to continue to operate until 2019.

The various inspections showed that the facility is operated in satisfactory conditions. Application of the regulatory provisions concerning nuclear pressure equipment was improved.

The main cause of most of the significant events in 2014 was hardware failures, in particular in instrumentation and control. They had no major safety impact. A number of residual studies from the 2009 periodic safety review underwent complementary analyses, in particular with regard to the handling conditions for the Orphée spent fuel stored in the facility. The handling conditions for these fuels were made more robust in order to improve control of the criticality risk.

With a view to the shutdown of the Osiris reactor, CEA updated the decommissioning plan, proposed extensive decommissioning preparation work, which is to begin in 2016, and undertook to submit the decommissioning file by the end of 2016. ASN asked CEA to provide additional substantiation information in order to assess whether these preparation operations are indeed in conformity with the ASN Guide on BNI final shutdown and decommissioning (Guide No. 6) (see chapter 15) and recalled that any significant modification to the facility must be substantiated.

Jules Horowitz Reactor (RJH) (Cadarache)

With the support of several foreign partners, CEA is building a new research reactor owing to the ageing of the European irradiation reactors currently in service, which are scheduled for shutdown in the short to medium term. The RJH (BNI 172) will be able to carry out work similar to that done by the Osiris reactor. It does however comprise a number of significant changes with regard to both the possible experiments and the level of safety.

The construction work on the facility, which started in 2009, continued in 2015. According to CEA, commissioning of the RJH will be significantly behind schedule, in fact more than four years late.

TO BE NOTED

Shutdown of the Osiris reactor (Saclay)

While the ASN resolution of 2008 duly noted CEA's undertaking to cease all activities at Osiris by the end of 2015, CEA has since 2011 repeatedly expressed its desire to continue operations, given that reactor core melt is a design basis scenario for the various intervention and response plans for the Saclay plateau, where urban development is accelerating. In its opinion of 25th July 2014, ASN restated that that *"it was not in favour of continued operation of the Osiris facility beyond 2015 owing to the current level of safety of this reactor"*. However, considering the fact that the CEA application was based on the possible risk of a shortage of medical radionuclides, ASN could have *"for the period 2016-2018, examined an approach which would minimise operation of the Osiris reactor, reserving it solely for the purpose of countering the shortage of 99Mo"*. The shutdown of the reactor in late 2015 was confirmed by the Government in August 2014 and CEA carried out this shutdown In December 2015. The latest assessments by the Nuclear Energy Agency, which take account of the Osiris shutdown, show no major risks linked to the production of 99Mo by irradiation in European research reactors.

CEA transmitted the updated decommissioning plan for the facility at the end of 2014 and should then submit a decommissioning authorisation application file. ASN will be attentive to the definition and monitoring of the decommissioning preparation operations, which can involve risks In terms of radiation protection and dispersal of materials.

The civil engineering work on the reactor building was completed with pre-stressing of the building. The operations involved in the lining of the reactor cavity continued with the installation of the anchors and of the first stainless steel liners. The nuclear auxiliaries building is still under construction, in particular the installation of the shielded experimentation cells. Installation of the lining on the storage channel and pools also continued. The manufacture of the first elements of the reactor itself also began in 2015. ASN considers that CEA is demonstrating sufficient rigour and efficiency with regard to the risks and drawbacks of the project.

The inspections in 2015 mainly concerned the pre-stressing work on the reactor building and the organisation of the construction site, with regard to both procedures and follow-up of anomalies. ASN is also continuing regular discussions with CEA in order to check the measures requested following analysis of the preliminary safety report and in preparation for the review of the future commissioning authorisation application.

Neutron source reactors

Orphée reactor (Saclay)

The Orphée reactor (BNI 101) is a pool-type research reactor with an authorised power of 14 MWth, using heavy water as the moderator. It was authorised by the Decree of 8th March 1978 and its first divergence dates from 1980. It is equipped with nine horizontal channels, tangential to the core, enabling nineteen neutron beams to be used. These beams are used to conduct experiments in fields such as physics, biology and physical chemistry. The reactor also has ten vertical channels for the introduction of samples to be irradiated in order to produce radioisotopes or special materials and to carry out analysis by activation. The neutron radiography installation is used for non-destructive testing of certain components.

ASN considers that the level of safety of the Orphée reactor is on the whole satisfactory. During an inspection in 2015, ASN in particular noted compliance with the planned measures and restart conditions following the two significant fuel handling events which occurred at the end of 2014. However, improvements are necessary with regard to radioactive waste management, especially concerning the management of waste zoning in the installation and the formal definition of storage area operating instructions. The licensee must also reinforce its organisation for planning and following up the performance of periodic checks and tests.

The causes of the significant events notified in 2015 are split equally between hardware failures and organisational shortcomings. The analysis of one of these events has shown that the licensee needs to be vigilant in the analysis and traceability of deviations from the safety requirements with regard to the supply of equipment important for the protection of interests.

UNDERSTAND

Jules Horowitz Reactor, risks and prevention systems

Just like all reactors, the RJH presents four main risks:

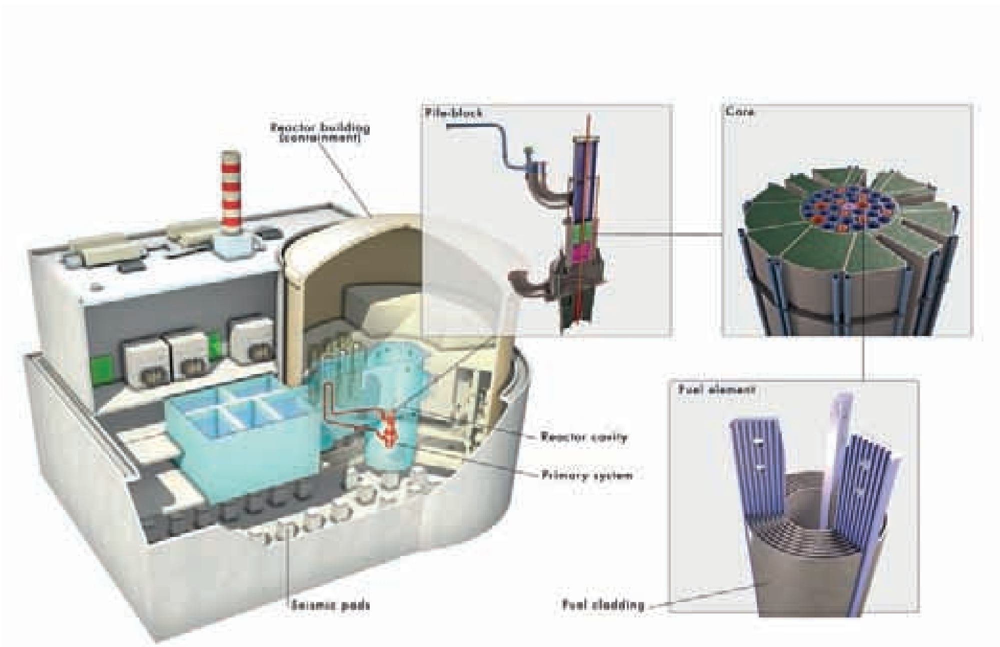
- **Core melt:** resulting from overheating of the irradiated fuel. To prevent this, the core is cooled by a closed circuit of circulating water (primary system), itself cooled by a secondary system. Finally, the water from the Provence canal, which is then directed to the EDF canal, cools this latter (tertiary system). At the same time, the reactor (the core and part of the primary system) is immersed in the water-filled reactor cavity.
- **Criticality:** runaway fission reaction of the uranium atoms contained in the reactor core (fuel). To prevent this, a specific fuel elements geometry must be maintained. To do this, and over and above the numerous retaining systems in the reactor, protection is provided by the "reactor building" (pre-stressed concrete).
- **Dispersal of radioactivity:** in an accident situation, radioactivity can be dispersed in liquid, gaseous or dust form. Three barriers are designed to prevent this:
  - 1st barrier: the fuel cladding: which will prevent the fuel from coming into contact with the water in the primary system;
  - 2nd barrier: the primary system: if the 1st barrier fails, the primary system will contain the radioactivity dispersed into the water;
  - 3rd barrier: the containment: if the 2nd barrier fails, the pre-stressed concrete reactor building acts as the containment for the radioactive substances.
- **Irradiation:** emission of particles that are harmful to the organism. To prevent this, screens can be installed, or materials such as water, concrete, etc. can be used. The water in the reactor cavity for example also acts a protective shield. Steps are also presented to deal with hazards that can stem from the installation itself or even from its environment: extreme climatic conditions, flooding, earthquake, airplane crash, internal fire or explosion, projectile or falling load inside the installation. Seismic pads are for instance present underneath the installation

In addition, the assessments carried out following the Fukushima Daiichi accident led CEA to identify a «hardened safety core» of equipment, the operation of which must be guaranteed in extreme situations.

This equipment must enable the following to take place:

- cooling of the core to prevent an accident: equipment designed to maintain convection in the primary system and pool make-up system from outside the facility;
- in the event of an accident, limit discharges into the environment: equipment designed to isolate and depressurise the containment, radiological activity and pressure sensors;
- in the event of an accident, monitor the facility and manage the emergency: in the fall-back centre, indicators of the temperature and water level in the reactor cavity and of maintained convection in the primary system, with installation of mobile resources (portable lighting, radiation protection monitors, communication devices, etc.).

In order to obtain commissioning authorisation for the RJH, CEA shall demonstrate that the steps it has taken can guarantee the operational safety of the reactor and meet the ASN demands and prescriptions issued at the time of the creation of the facility.



Jules Horowitz Reactor.

In addition, even though ASN notes that a large share of the undertakings made for the periodic safety review of the facility in 2009 have been met, a number of particular technical justifications have yet to be produced.

In the follow-up to the Fukushima Daiichi accident, the ASN resolution of 8th January 2015 set the requirements for the facility's "hardened safety core", which is the only one of the CEA batch 2 facilities for which the need to deploy such a hardened safety core was identified by the licensee.

Test reactors

Cabri reactor (Cadarache)

The Cabri reactor (BNI 24), created on 27th May 1964, is used for experimental programmes aimed at better understanding nuclear fuel behaviour in the event of a reactivity accident. The reactor is operated by CEA. Modifications to the facility were authorised in a Decree of 20th March 2006, in order to run new research programmes. The reactor's sodium loop was replaced by a water loop in order to study the behaviour of high burn-up fraction fuels in accident situations representative of those that could be encountered in a pressurised water reactor.

Installation of biological shielding in the Cabri research reactor containment, 2012.

2015 was marked by the first criticality of the modified reactor, authorised for start-up tests by ASN on 13th October 2015. In order to authorise this criticality, ASN in particular examined:
- the implementation of the prescriptions of the ASN resolution of 8th January 2015 concerning integration of the lessons learned from the Fukushima Daiichi accident;
- the completion of CEA's 2004 commitments prior to criticality, as part of the facility's safety reassessment and the modification project authorised in 2006;
- the completion of CEA's 2008 and 2009 commitments for refuelling of the driver core;
- updating of the facility's baseline requirements, in particular the safety analysis reports and the general operating rules transmitted in February 2015;
- implementation of compensatory measures following the significant event of 15th December 2014 concerning a fault in the core system.

The three inspections carried out by ASN in 2015, devoted to the start-up tests and the periodic checks and tests, did not reveal any significant deviation with respect to the facility's baseline safety requirements. CEA will be required to conduct a more detailed analysis of the numerous events which occurred at first criticality.

On 13th October 2015, ASN also prescribed the transmission of additional files, including a report summarising the commissioning tests prior to the first experimental test. In it, ASN also notifies the deadline for the next periodic safety review of the facility in 2017.

Phébus reactor (Cadarache)

The Phébus reactor (BNI 92), the creation of which was authorised by the Decree of 5th July 1977, enabled tests to be performed concerning the severe accidents that could affect pressurised water reactors. It was finally shut down in 2010 following the "fission products" experimentation programme which started in 1988. CEA informed ASN in 2013 that it intended to shut down this BNI once and for all and in 2014 transmitted an updated file presenting the decommissioning preparation operations and the decommissioning plan. In 2015, CEA was authorised to begin the first operations to prepare for decommissioning, in this case the disassembly of cooling equipment outside the reactor building. CEA undertook to submit the decommissioning file for the facility no later than 2017. It will also submit the facility's periodic safety review file. ASN asked CEA to supplement its decommissioning plan and its safety review orientations file with respect to the management of radioactive substances.

Teaching reactor

ISIS reactor (Saclay)

With Osiris, this is one of the two reactors in BNI 40 (see "Osiris reactor"). ASN authorised the operation of this mock-up until 2019.

1.2.3 Laboratories

The irradiated materials and spent fuel assessment laboratories

These laboratories are investigative tools available to the nuclear licensees. From the safety viewpoint, these installations must meet the same standards and rules as the fuel cycle nuclear installations, but the safety approach also has to be proportionate to the specific risks presented. In this context, ASN categorised these installations in its resolution of 29th September 2015.

Active Fuel Examination Laboratory (LECA) (Cadarache)

The LECA (BNI 55) was commissioned in 1964 and is a laboratory for both destructive and non-destructive examination of spent fuels from various types of nuclear power plants or research reactors, and of irradiated structures or instruments. It is an ageing facility whose seismic resistance was reinforced beginning in 2010, with a view to shutdown in 2015.

In 2014, CEA transmitted the file presenting the conclusions of the periodic safety review for the installation which it wishes to continue to operate on a long-term basis. The complexity of the analysis of the reinforcements envisaged for seismic resistance of the civil engineering structures and the limited resources available for examination of the file meant that ASN pushed the end of the examination back to 2016.

The LECA extension Treatment, Clean-out and Reconditioning Station (STAR) (Cadarache)

The STAR facility (BNI 55) is a high-activity laboratory comprising shielded cells. It was designed for the stabilisation and reconditioning of irradiated fuel rods surplus to requirements with a view to storing them in the CASCAD facility (see chapter 16). It also carries out destructive and non-destructive examinations on irradiated fuels. Its creation was authorised by the Decree of 4th September 1989 and its definitive commissioning was declared in 1999.

ASN regularly checks CEA's compliance with the commitments made after the periodic safety review completed in June 2009. Following this review, CEA in particular made a commitment to implement a project for redevelopment and the installation of new equipment, in particular for handling purposes. On 13th May 2014 ASN prescribed the operating procedures associated with this project. Work has been started by CEA and ASN will remain vigilant in ensuring that it is completed on time, in 2016.

Laboratory for Research and Experimental Fabrication of Advanced Nuclear Fuels (LEFCA) (Cadarache)

The LEFCA (BNI 123), commissioned in 1983, is a laboratory in charge of conducting studies on plutonium, uranium, actinides and their compounds in a variety of forms (alloys, ceramics, composites, metal, etc.) with a view to their applications in nuclear reactors. The LEFCA carries out studies aimed at understanding the behaviour of these materials in the reactor and at various stages in the fuel cycle. It also produces devices for experimental irradiation designed to test the behaviour of these materials, as well as carrying out stabilisation and reconditioning of uranium and plutonium bearing materials.

ASN is currently examining the facility's periodic safety review report, transmitted in December 2013. The first part of this examination took place in a specific context: in 2014, CEA announced that it would be transferring the LEFCA R&D activities in 2017 to the Atalante facility and finally shutting it down by 2020. Following the assessment of the review file, ASN will issue a ruling on the continued operation of the facility.

Elsewhere, following a previous review, ASN issued a prescription for CEA on 29th June 2010 requiring it to ensure that a groundwater drainage system was operational before 30th September 2015 in order to prevent the risk of soil liquefaction in the event of an earthquake. Following the late transmission of the file in July 2015, CEA did not at first correctly assess the environmental impact of the system and commissioning could not be carried out in good time. During an inspection, ASN nonetheless checked that it was technically ready and postponed commissioning to the end of 2016 without initiating any sanctions or enforcement measures.

ASN asked CEA to take greater account in the future of environmental protection and the regulation deadlines for review of the prescribed modifications.

Finally, the obsolescence of the LEFCA nuclear ventilation PLCs is considered by ASN to be a point meriting vigilance and will be the subject of particular attention during inspections and in the follow-up of the periodic safety review examination.

Spent Fuel Testing Laboratory (LECI) (Saclay)

The LECI (BNI 50) was notified by CEA on 8th January 1968. An extension was authorised by decree in 2000. The role of the LECI is to study the properties of nuclear materials, whether or not irradiated. The LECI also has a role to provide support for the delicensing of the Saclay centre.

ASN considers that the level of safety of the facility is satisfactory. Follow-up of the commitments made following inspections and significant events is in particular of high quality. However, ASN is waiting for clarification of the response if the radiation protection monitors are triggered and in the event of an alert on the gaseous discharge vent.

This facility also accommodates a shielded cell (Célimène, building 619) which has not been used since 1993. For the time being, CEA envisages that its decommissioning will be completed in 2024. The examination of the periodic safety review, which began in December, was on the whole satisfactory and gave rise to an improvement action plan that CEA has undertaken to implement. In 2016, ASN will prescribe some of these improvements considered to be the most important, in particular the demonstration of the seismic design of the facility and the decommissioning of the Célimène unit.

Research and development laboratories

Alpha facility and Laboratory for Transuranian Elements Analysis and Reprocessing Studies (Atalante) (Marcoule)

The main purpose of the Atalante facility (BNI 148), created in the 1980s, is to conduct research and development on the recycling of nuclear fuels, the management of ultimate waste and the exploration of new concepts for fourth generation nuclear systems.

In 2015, the safety level in Atalante was on the whole stable by comparison with the previous years. Given the variety and numerous changes in the activities carried out in the facility, this level of safety is based on operation conforming to the baseline requirements. In 2016, the start-up of new processes and the transfer of R&D activities from Cadarache will be decisive factors in the safety of the facility and ASN will be vigilant in ensuring that account is taken of organisational and human factors, the organisation and management of safety and the hardware modifications made to the facility.

Following three significant events in 2014 and 2015 concerning the electrical power supply and I&C, in particular Elements Important for Protection (EIP), ASN carried out reinforced investigations in 2015. It will be maintaining particular vigilance during the inspections scheduled for 2016 as well as during the examination of the next periodic safety review. The licensee sent ASN the file presenting the orientation of the forthcoming safety review in April 2015. ASN issued its opinion, stressing the importance of the conformity of Activities Important for Protection (AIP) and of the EIP in the facility with their requirements defined by CEA, and the regulation review deadlines.

1.2.4 Fissile material stores

The Central Fissile Material Warehouse (MCMF) (Cadarache)

Built in the 1960s, the MCMF (BNI 53) is a storage warehouse for enriched uranium and plutonium. Its main duties are reception, storage and shipment of non-irradiated fissile materials pending reprocessing, whether intended for use in the fuel cycle or temporarily without any specific purpose surplus to requirements.

Given the inadequate seismic design of the facility, ASN asked CEA to remove the nuclear materials stored in it before 31st December 2017, the date on which the facility will be finally shut down. The commissioning of the Magenta facility meant that removal of materials from MCMF could continue. The removal from storage operations continued in 2015, within a time-frame compatible with the ASN request.

In 2015, the licensee transmitted the orientations file for the safety review scheduled for 2017. In the next few years, CEA must submit the decommissioning file for the facility.

The Magenta facility (Cadarache)

The Magenta facility (BNI 169), which replaces the MCMF, is dedicated to the storage of non-irradiated fissile material and the non-destructive characterisation of the nuclear materials received. Its creation was authorised in 2008 and its commissioning on 27th January 2011. The increase in activity in the facility, owing to the transfer of storage from Masurca, the MCMF, and ÉOLE-Minerve to Magenta, is taking place with a satisfactory level of safety, with the organisation of operations being efficient in the light of the current risks.

The activities authorised in Magenta restrict the risks to the storage of materials, as CEA has not transmitted authorisation applications for commissioning of glove boxes. In this respect, ASN notes that the transmission of safety baseline requirements conforming to the actual condition of the facility is behind schedule.

1.2.5 The Poseidon irradiator

The Poseidon facility (BNI 77) at Saclay, created by the Decree of 7th August 1972, is an irradiator consisting of a cobalt-60 source storage pool, partially topped by an irradiation bunker. The facility also features a submersible chamber and a test cell. R&D into the behaviour of materials under radiation is carried out in Poséidon. The main risk in the facility is that of exposure to ionising radiation owing to the presence of very high level sealed sources.

The safety of the facility is considered to be satisfactory, the operating conditions are correct and the follow-up of the periodic inspections and tests is appropriate. The bunkers do however show signs of cracking, which requires very strict monitoring.

Examination of the periodic safety review, for which the complete file was transmitted in June 2013, and of the stress tests, is continuing. In 2016, ASN will specify the preconditions for continued operation.

1.2.6 Waste and effluent storage and treatment facilities

The CEA waste and effluent storage and treatment facilities are addressed in chapter 16.

1.2.7 Installations undergoing decommissioning

The CEA facilities undergoing decommissioning, as well as the CEA decommissioning strategy, are covered in chapter 15.

1.3 Planned facilities

The purpose of the ASTRID project (Advanced Sodium Technological Reactor for Industrial Demonstration), currently at the design phase, is to produce a technological demonstrator for which the technical options can be extrapolated to a possible Generation IV electricity generating reactor by about 2050. This project is supported by CEA, in association with EDF and Areva. Astrid is a Sodium-Cooled fast neutron Reactor (SCR), one of the six identified Generation IV reactor series. The first orientations envisaged for the design of Astrid were presented in a Safety Guidelines Document (DOrS) which was submitted to ASN in 2012 in advance of the regulatory procedures. This DOrS precedes the optional transmission of a Safety Options File (DOS) which was not transmitted before the end of 2015, as had been initially planned by CEA. This DOrS is also well upstream of the BNI creation authorisation application procedure. Concerning this DOrS, in a letter dated 10th April 2014, ASN informed CEA of the demonstrations that would need to be provided in the next stage of the procedure, so that it could issue a position statement on the safety of the Astrid project. For ASN, this reactor must offer a level of safety at least equivalent to that of the third generation reactors (the EPR in France), incorporate the improvements resulting from the lessons learned from the Fukushima Daiichi accident and, as a prototype of a fourth generation plant series designed to provide significant safety gains, enable reinforced safety options to be prepared and tested.

1.4 ASN's general assessment of CEA actions

The results of 2015 and ASN's assessment of each facility are detailed per region in chapter 8, in chapter 15 for the facilities being decommissioned and in chapter 16 for the waste processing and storage facilities.

2015 was marked by CEA being required to implement post-Fukushima "hardened safety cores" in some of its centres and facilities. This implementation will significantly improve safety and enable CEA to acquire robust diagnosis and emergency management resources.

ASN underlined that the performance of these numerous reviews associated with the preparation of the final shutdown and decommissioning authorisation application files represents a major safety issue, which will require significant resources on the part of CEA. CEA's compliance with the deadlines set for its "major commitments" has improved. It also agreed to give fresh impetus to this approach in order to share the main nuclear safety issues to be dealt with over the coming decade.

ASN will also be vigilant with regard to the actual initiation of the decommissioning operations on the facilities finally shut down, in accordance with French regulations (see chapter 15) and the updating of CEA's decommissioning, post-operational clean-out and waste management strategy.

ASN considers that the level of safety in the facilities operated by CEA is on the whole satisfactory, in particular the operation of its experimental reactors. ASN considers that CEA must reinforce its surveillance and its oversight of external contractors in a context of large-scale subcontracting.

2. NON-CEA NUCLEAR RESEARCH INSTALLATIONS

2.1 Large National Heavy Ion Accelerator

The Ganil (National Large Heavy Ion Accelerator) economic interest group, was authorised by the Decree of 29th December 1980 to create an accelerator in Caen (BNI 113). This research facility produces, accelerates and distributes ion beams with various energy levels to study the structure of the atom. The intense, high-energy beams produce strong fields of ionising radiation, activating the materials in contact, which then emit radiation even after the beams have stopped. Irradiation thus constitutes the main risk at the Ganil.

Elements of the RHF "hardened safety core": reinforcement of a door to withstand extreme flooding.

In order to be able to produce exotic nuclei[1], the Ganil was authorised in 2012 to build phase 1 of the Spiral 2 project. ASN issued a partial commissioning license for phase 1 of this project on 30th October 2014. ASN examined the commissioning application for phase 1 of the Spiral 2 project and notes that the additional information requested, more specifically concerning the seismic resistance of the facility, was submitted late, meaning that it was impossible to conduct a complete examination in 2015.

ASN has completed the examination of the first periodic safety review of the installation since it was commissioned in 1983. This review was on the whole satisfactory and led ASN to issue several prescriptions on the conformity of the installation with its safety baseline requirements and the regulations currently in force, in order to allow continued operation.

1. The "exotic nuclei" are nuclei which do not exist naturally on Earth. They are created arti cially in the Ganil for nuclear physics experiments on the origins and structure of matter.

Finally, ASN issued a resolution on 7th July 2015 concerning effluent discharges and transfers at the Ganil.

ASN considers that the licensee must improve how it organises waste management and in particular its monitoring of the outside contractor responsible for packaging the Very Low Level Waste (VLLW) and the Low-Level Waste (LLW) produced on the site. ASN also regrets the absence of advance planning for the removal of the waste stored since 2012.

2.2 The High Flux Reactor (RHF) at the Laue-Langevin Institute

The RHF (BNI 67) in Grenoble, operated by the Laue-Langevin Institute (ILL), provides neutrons used for experiments in the fields of physics and biology. This reactor was authorised by the Decree of 19th June 1969, modified by the Decree of 5th December 1994, and has a maximum power of 58.3 MWth, operating continuously in 50-day cycles. The reactor core is cooled by heavy water contained in a reflective tank, which is itself immersed in a light water pool.

ASN considers that those aspects of RHF safety identified by ILL as priorities are managed both proactively and reactively. In the light of the experience feedback from the Fukushima Daiichi accident, the ILL thus rapidly carried out major reinforcement work, which continued satisfactorily in 2015. However, ASN did find that, despite these improvements, the expected rigour in the traceability of the activities and updating of the baseline safety requirements was not always present. The planning and quality of the files were not always sufficient. The post-Fukushima work should continue in 2016 with the same level of proactive commitment, but with more rigour in document transmissions and updates. ASN does however consider that the licensee needs to improve its organisation in order to comply with the requirements of the regulations. It must in particular improve and clarify the facility's baseline safety requirements and then ensure that the facility actually complies with these requirements.

The licensee must also make progress in the traceability and monitoring of its activities important for protection, in particular works, maintenance and periodic checks and tests. In 2015, ASN thus asked the ILL to significantly improve its monitoring of the regulatory inspections on electrical and lifting equipment and its lock-out if the equipment is not up to date with these regulatory inspections. ASN also requires ILL to analyse and make greater use of operating experience feedback in order to improve its own organisation, in particular on the basis of notified significant events and the observations and requests expressed by ASN further to inspections. In 2015, in reply to several requests from ASN, the ILL proposed implementing an integrated management system meeting the requirements of the regulations, along with a reorganisation of its safety system in order to improve its independence.

Implementation of these changes will be submitted to ASN for approval.

In response to a formal notice service by ASN, the ILL submitted applications for special conditions regarding the implementation of Title III of the Decree of 13th December 1999 concerning nuclear pressure equipment, for the 21 equipment items non-compliant with the regulations. Each of these files describes the measures proposed to compensate for the verifications which cannot be performed owing to the specific nature of the RHF equipment. After analysing the proposals, ASN defined these special conditions.

Finally, the ILL must be the subject of a periodic safety review in 2017. ASN hopes that already in 2016 the licensee will make a serious commitment to updating and re-assessing the facility's baseline safety requirements from both the technical and documentary viewpoints.

2.3 European Organization for Nuclear Research (CERN) installations

The European Organization for Nuclear Research (CERN) is an international organisation whose role is to carry out purely scientific and fundamental research programmes concerning high energy particles. A tripartite agreement signed by France, Switzerland and CERN came into effect on 16th September 2011. The oversight of nuclear safety and radiation protection was previously managed through bilateral agreements.

For the CERN, 2015 was marked by the extension of a lengthy outage, to allow higher power operation by the LHC accelerator, which was restarted in 2015.

In 2014, ASN and the Swiss Federal Office for Public Health (OFSP) approved the site's nuclear waste management study and the safety file for a new linear accelerator, built in the CERN and called Linac 4. This accelerator was inspected jointly with the Swiss Authorities in 2015.

The CERN notified the Swiss, French and German authorities of its first significant event in 2015, which is positive in terms of transparency.

2.4 The ITER project

ITER (BNI 174) is an experimental installation, the purpose of which is scientific and technical demonstration of controlled thermonuclear fusion energy obtained with magnetic confinement of a deuterium-tritium plasma, during long-duration experiments with a significant power level (500 MWe for 400 s). This international project enjoys financial support from China, South Korea, India, Japan, Russia, the European Union and the United States, who make in-kind contributions by providing equipment for the

ASN inspection of monitoring of the outside contractors in charge of manufacturing ITER vacuum chamber sectors in South Korea, April 2015.

project *via* the domestic agencies. The headquarters agreement between ITER and the French state was signed on 7th November 2007 and the creation of the BNI was authorised by the Decree of 9th November 2012. The ASN resolution of 12th November 2013 sets prescriptions more specifically concerning the design and construction of the facility, in order to implement and supplement the requirements already defined by the authorisation decree.

2015 was marked by the appointment of a new Director General for ITER and by organisational changes, more particularly with the creation of project teams, incorporating the domestic agencies, for the supply of the vacuum chamber and buildings. The impact of these changes will be assessed in 2016, in particular by comparison with the improvements expected by ASN with regard to monitoring of the chain of outside contractors, which includes the domestic agencies. Initial improvement requests have already been sent out to ITER.

Despite significant delays, building work on the facility continued in 2015, more specifically with the construction of level B2 (2nd basement) of the tokamak complex and the construction of the metal framework for the assembly hall. Manufacturing of equipment for the facility also progressed. In April 2105, ASN carried out an inspection in South Korea on the monitoring of outside contractors in charge of manufacturing sectors of the vacuum chamber and observed that the requirements defined for this work package had been correctly addressed. An inspection also concerned the supply by the American domestic agency of drainage tanks, which were delivered to the ITER site in 2015. On this subject, ASN considers that efforts are still needed to formally define and substantiate the inspections confirming equipment compliance with the requirements defined by ITER, the handling and follow-up of deviations and the archival and accessibility of documents.

Significant efforts in project organisation and the adoption of a safety culture have on the whole been made since the beginning of construction, but ASN remains vigilant on these subjects, given the complex international organisation of the project, as well as on the requirements defined and their assimilation by the outside contractors.

Owing to the fact that the project is on the whole behind schedule (slippage in the design and construction calendar) and to the experimental nature of the facility (certain important demonstrations are based on the results of innovative research, for which it is hard to determine and anticipate the schedule), the licensee announced significant delays in the transmission of files and in particular for important elements such as the detritiation system, the transfer casks, the tritium, waste and hot cell buildings. These delays had no impact on the safety of the facility and on 22nd October 2015, ASN therefore modified the 12th November 2013 prescriptions regulating the design and construction of the facility. ASN nonetheless expects the licensee to make improvements concerning compliance with the deadlines to which it is committed and will remain particularly attentive to the quality of the demonstrations and justifications produced.

3. THE OTHER NUCLEAR INSTALLATIONS

3.1 Industrial ionisation installations

Irradiators sterilise medical devices, foodstuffs, pharmaceutical raw materials, etc., by irradiating them with gamma rays emitted from sealed cobalt-60 sources. The irradiation cells are made from reinforced concrete, designed to protect the environment. The sealed sources are either placed in the lowered position, stored in a pool under a thickness of water which protects the workers in the cell, or are placed in the raised position to irradiate the items to be sterilised. The main risk in these facilities is irradiation of the personnel.

The Ionisos group operates three industrial ionisation facilities located in Dagneux (BNI 68), Pouzauges (BNI 146) and Sablé-sur-Sarthe (BNI 154). ASN considers that the licensee must continue its efforts to detect deviations and ensure compliance with the deadlines set for the handover of files or requests for additional data. The three periodic safety reviews for the Ionisos facilities must be carried out no later than November 2017 and the licensee must also submit a stress tests report by this same deadline. The file for the first periodic safety review concerning the Sablé-sur-Sarthe facility was transmitted on 30th June 2015 and is being examined by ASN. In October 2015, ASN asked Ionisos to update its decommissioning strategy for the parts of the Dagneux facility that had been shut down for several years.

Synergy Health operates the Gammaster (BNI 147) irradiator in Marseille and the Gammatec (BNI 170) on the Marcoule site, for which commissioning was authorised on 17th December 2013. Improvements are still needed in terms of radiation protection and the results of internal inspections must be written up in a more clearly defined format. A modification file for commissioning of an internal laboratory was submitted to ASN in August 2015 and is currently being examined. ASN considers that Gammaster operations have been improved. The licensee has requalified the sources present on the site and has revised its emergency response organisation, which is satisfactory. It must continue efforts with regard to the regulatory watch and assimilation of the regulations and must pay particular attention to the deadlines for performance of its periodic inspections, especially those required by the regulations.

UNDERSTAND

ITER, risks and prevention system

The ITER project, devoted to research on thermonuclear fusion, is based on a "tokamak" type machine.

The principle consists in introducing gaseous fuel [1] into a vacuum chamber [2] and then heating it to a temperature of about 100 million degrees to obtain a deuterium-tritium plasma which, through fusion, produces neutrons and particles. Heating is mainly by means of an electric current created by the windings of a central solenoid [4] and additional heating systems [3] injecting electrically neutral, highly energetic particles.

The plasma is controlled and confined inside the vacuum chamber by magnetic fields, about 200,000 times stronger than that of the Earth, generated by superconducting coils [5 and 6] and by the central solenoid [4]. There can be considerable mechanical stresses in the event of a plasma malfunction, such as vertical displacement or disruption. The plasma diagnostic system [7] measures its behaviour and performance by means of devices installed on the inner walls of the vacuum chamber and in the penetration cells [8].

The vacuum chamber is protected from heat and from neutrons by blanket modules [9] covered with beryllium, the toxicity of which requires personnel protection and waste management measures. Steps are taken to prevent the risks of internal explosion in the vacuum chamber, which could disperse hydrogen isotopes or dust. The divertor [10], placed at the base of the vacuum chamber, is used to extract the impurities and residues generated by fusion, along with some of the power produced.

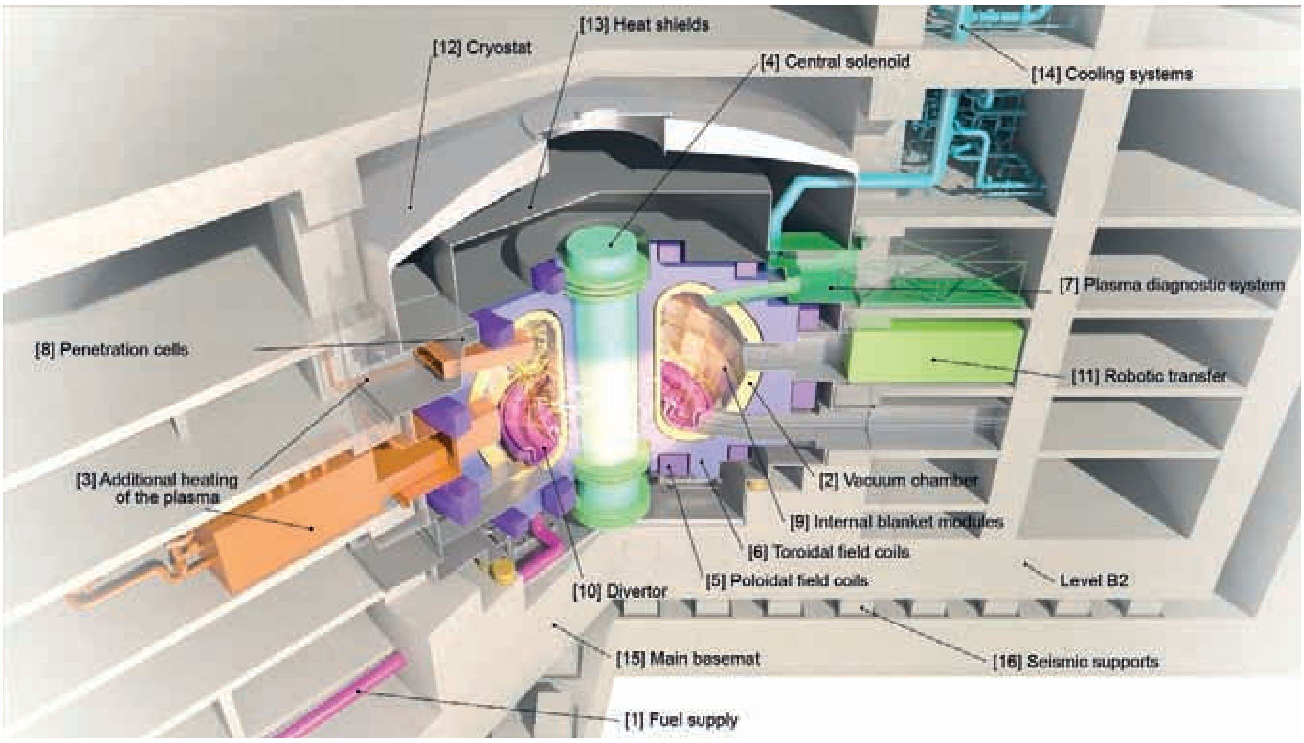
For maintenance, the highly Irradiating internal components of the vacuum chamber are extracted and transferred to another building by means of robotic equipment and casks [11].

The tokamak is enclosed in a cryostat [12] comprising heat shields [13] enabling the coils, which are at very low temperature, to be separated from the high-temperature components. Heat is transferred outside by means of a water cooling system [14] consisting of two loops leading to cooling towers.

The walls of the vacuum chamber and the buildings, plus the ventilation system, allow containment of the tritium, an isotope of hydrogen which gives off low levels of radioactivity but which is present in large quantities in the ITER facility, preventing it from being released into the environment. A detritiation system, Installed In the "tritium" building next to the tokamak, extracts the tritium from the gases and liquids so that it can be returned to the fuel cycle. It comprises recombiners, molecular sieves and scrubbing columns (offering 99% efficiency in a normal operating situation and 90% in the event of a fire).

The complex of buildings housing the tokamak and the tritium building is built on a main basemat [15] which itself rests on seismic pads [16], themselves built on an isolating seismic lower basemat.

The main safety issues in the facility are thus the containment of radioactive substances, tritium in particular, in normal and accident situations, as well as radiation protection, more specifically during maintenance of highly irradiating components.



3.2 The radio-pharmaceutical production facility operated by CIS bio international

CIS bio international is a key player on the French market for radiopharmaceutical products used for both diagnosis and therapy. Most of these radionuclides are produced in BNI 29 (UPRA) at Saclay. This facility also recovers used sealed sources which had been used for radiotherapy and for industrial irradiation. By Decree on 15th December 2008, CIS bio international was authorised to succeed CEA as operator of BNI 29.

The reorganisation efforts made in 2015 have not yet given tangible results, in particular for simultaneous management of large-scale projects, operational rigour, compliance with deadlines and monitoring operating compliance with the requirements defined by the licensee and the regulations. ASN still observes considerable slippage in the deadlines for transmission of significant event reports and in the performance of the actions identified by the inspections. The deviations observed during inspections and in the causes of events are indicative of persistent shortcomings in operational rigour, the intervention process and the assessment of the importance of the deviations. Equipment maintenance in particular needs to be improved.

3.3 Maintenance facilities

Two Basic Nuclear Installations, operated by Areva and EDF, handle nuclear maintenance activities in France.

The facility of the *Société de maintenance nucléaire* (Somanu) in Maubeuge

Authorised by the Decree of 18th October 1985, BNI 143, a subsidiary of Areva, specialises in the maintenance and appraisal of equipment coming from the primary cooling systems of EDF reactors.

ASN considers that even if operation of the facility and the transparency of exchanges are on the whole satisfactory, the process to produce safety case studies is a laborious one. The licensee must therefore reorganise in order to better address ASN's requests and the commitments it has made, more specifically with respect to its periodic safety review filed at the end of 2011 and must reinforce corrective measures concerning compliance with the provisions of the Order of 7th February 2012.

TO BE NOTED

The consequences of the last periodic safety review and the stress tests on UPRA (BNI 29)

CIS bio international experienced difficulties with its submission of the reports that would enable ASN to rule on the continued operation of the facility or its ability to withstand extreme hazards. At the request of ASN, it was required to supplement these periodic safety review and stress tests reports, initially submitted in 2008 and 2012. These additions were submitted well behind schedule.

With regard to the periodic safety review, ASN considered that continued operation was acceptable, provided that significant improvements were made, more specifically with regard to control of the fire risk and compliance with the commitments made by the licensee. With regard to the stress tests and despite the licensee being unable to identify any cliff-edge effects, ASN considers that it must be able to manage emergency situations involving extreme hazards, because the consequences of an accident would require population protection measures. This is all the more necessary as the facility is located in Saclay, an area that has seen extensive urban development.

A number of works, which have been under way for several years, are thus needed to improve the safety of the facility and are still not completed. As a rule, the large-scale actions initiated by CIS bio international are never completed within a reasonable time-frame.

In 2013, ASN prescribed the main safety improvements necessary for continued operation of the facility. In 2016, it will prescribe the deadlines for other safety improvements, for which CIS bio international has failed to meet its commitments and the reinforcement of the emergency management measures in the event of an extreme hazard. It will take appropriate enforcement and penalty measures should they prove necessary.

Following a failure to comply with the prescriptions issued in 2013 concerning control of the fire risk, ASN applied enforcement measures and prescribed additional compensatory measures in 2014 and 2015. In 2015, CIS bio international decided to contest these measures before the competent jurisdictions.

The examination of the applications for changes to the creation authorisation decree and the water intake and effluent discharge resolutions has been suspended pending additional information from Somanu, for which ASN observes a significant delay.

The Clean-out and Uranium Recovery Facility (IARU), situated in Bollène

The activities of BNI 138, operated by Socatri, a subsidiary of Areva, can be divided into four sectors:
- repair and decontamination (dismantling/reassembly, decontamination, mechanical work, maintenance for disposal or refurbishment);
- effluent treatment (in particular that from the Eurodif plant) via the STEU (treatment of uranium-bearing effluents for recovery in the form of uranate) and STEF (final treatment with production of metal hydroxide sludges) stations;
- waste treatment and conditioning (sorting, crushing, compacting, disposal, etc.);
- storage and transport.

Socatri receives containers of contaminated equipment and vessel heads on behalf of the EDF Tricastin Operational Hot Unit (BCOT) (building 852). Socatri carries out sorting, reconditioning and crushing of waste from small producers on behalf of the French national agency for radioactive waste management (Andra).

In 2015, ASN found shortcomings in the control of operational safety in the activities carried out by Socatri. Despite reinforced oversight of Socatri's commitments further to the periodic safety review of BNI 138, ASN found in 2015 that the licensee was having trouble complying with the deadlines and the content requirements and then implementing them operationally. These shortcomings in particular concern the commitments made for controlling the criticality risk. In 2015, ASN also found several deviations from the criticality requirements in the operating baseline requirements in force.

ASN also found that the licensee had not carried out a sufficiently complete assessment of compliance with the facility's baseline safety requirements at the time of the BNI periodic safety review, more particularly concerning the EIP. Finally, numerous shortcomings in the control of the fire risk were observed during an unannounced inspection on this topic in 2015.

ASN thus requires far greater operational rigour on the part of Socatri and improved compliance with its baseline safety requirements.

Examination of the file containing significant changes to the BNI creation authorisation decree, in particular concerning the creation of the new Trident waste processing unit, resumed after Socatri transmitted new information in July 2015. The regulatory process will continue in 2016.

Tricastin Operational Hot Unit (BCOT)

BNI 157, operated by EDF, was authorised by Decree on 29th November 1993. This facility, also situated in Bollène, is intended for maintenance and storage of equipment and tools from PWR reactors, except for fuel elements.

Two old reactor vessel heads were still present in the facility at the end of 2015, with their removal to Andra being scheduled for 2016. Finally, ASN is completing its examination of the facility's periodic safety review report, submitted in 2010 and supplemented by EDF in 2011 and 2013 at the request of ASN. This will lead in 2016 to monitoring of the removal of radioactive substances and of the facility's ability to withstand an earthquake. The licensee is envisaging final shutdown of the facility in the next few years and its periodic safety review contains no plans to reinforce the facility's ability to withstand external hazards.

3.4 Inter-regional Fuel Warehouses (MIR)

EDF has two inter-regional fuel warehouses, on the Bugey site in the Ain *département* (BNI 102) and at Chinon in the Indre-et-Loire *département* (BNI 99). These facilities were respectively authorised by the Decrees of 2nd March 1978 amended, and 15th June 1978 amended. EDF uses them to store new nuclear fuel assemblies (only those made of uranium oxide of natural origin) pending loading into the reactor.

ASN observes improved compliance with the commitments made following inspections and significant events. Several physical improvements are thus currently being implemented. The periodic safety review and stress tests files were transmitted on time, in March 2015. However, these files still contain too many gaps and inconsistencies for them to be examined. ASN therefore asked EDF to remedy this situation within six months.

4. OUTLOOK

A wide variety of research and other facilities are monitored by ASN. ASN will continue to oversee the safety and radiation protection of these installations as a whole and compare practices per type of installation in order to choose the best ones and thus encourage operating experience feedback. ASN will also continue to develop a proportionate approach when considering the risks and drawbacks of the facilities, as classified by the resolution of 29th September 2015.

Concerning CEA

ASN considers that the "major commitments" approach, implemented by CEA since 2006, is on the whole satisfactory. It will be attentive to the implementation of the new "major commitments" made in 2015.

Generally speaking, ASN will remain vigilant to ensuring compliance with the commitments made by CEA, both for its facilities in service and those being decommissioned. Should it prove necessary, ASN will issue prescriptions for removal from storage, as was the case on the EOLE and Minerve facilities. Similarly, ASN will remain vigilant to ensuring that CEA performs exhaustive periodic safety reviews of its facilities so that examination can be carried out in satisfactory conditions and so that the safety of the facilities benefits from the necessary improvements. As necessary, it will request additional information for those CEA files it considers to be unacceptable, as was the case for Masurca in 2015.

ASN will be particularly attentive to compliance with the deadlines for transmission of the decommissioning authorisation application files for CEA's old facilities which have been or will shortly be shut down (more specifically Phébus, Osiris, MCMF, Pégase). The Rapsodie reactor, the situation of which is described in chapter 15, is also concerned as are the following waste processing facilities (chapter 16): the storage BNI (BNI 56) in Cadarache, the effluent treatment station (BNI 37) in Cadarache, the solid radioactive waste management zone (BNI 72) in Saclay. The drafting of all these decommissioning files and then performance of these decommissioning operations represent a major challenge for CEA, for which it must make preparations as early as possible. Finally, ASN will oversee the operations to prepare for the decommissioning of the Osiris reactor, which was shut down in 2015.

In 2016, ASN intends to:
- continue with surveillance of the operations on the RJH reactor construction site and prepare for examination of the future commissioning authorisation application by means of advance examinations;
- begin the examination of the significant modification authorisation application for Masurca and examine the safety review file completed by CEA;
- complete its examination of the periodic safety review files for the LECI, Poséidon, LEFCA and LECA facilities and decide on the conditions for their possible continued operation.

Concerning the other licensees

ASN will continue to pay particularly close attention to ongoing projects, that is ITER and commissioning of the Ganil extension.

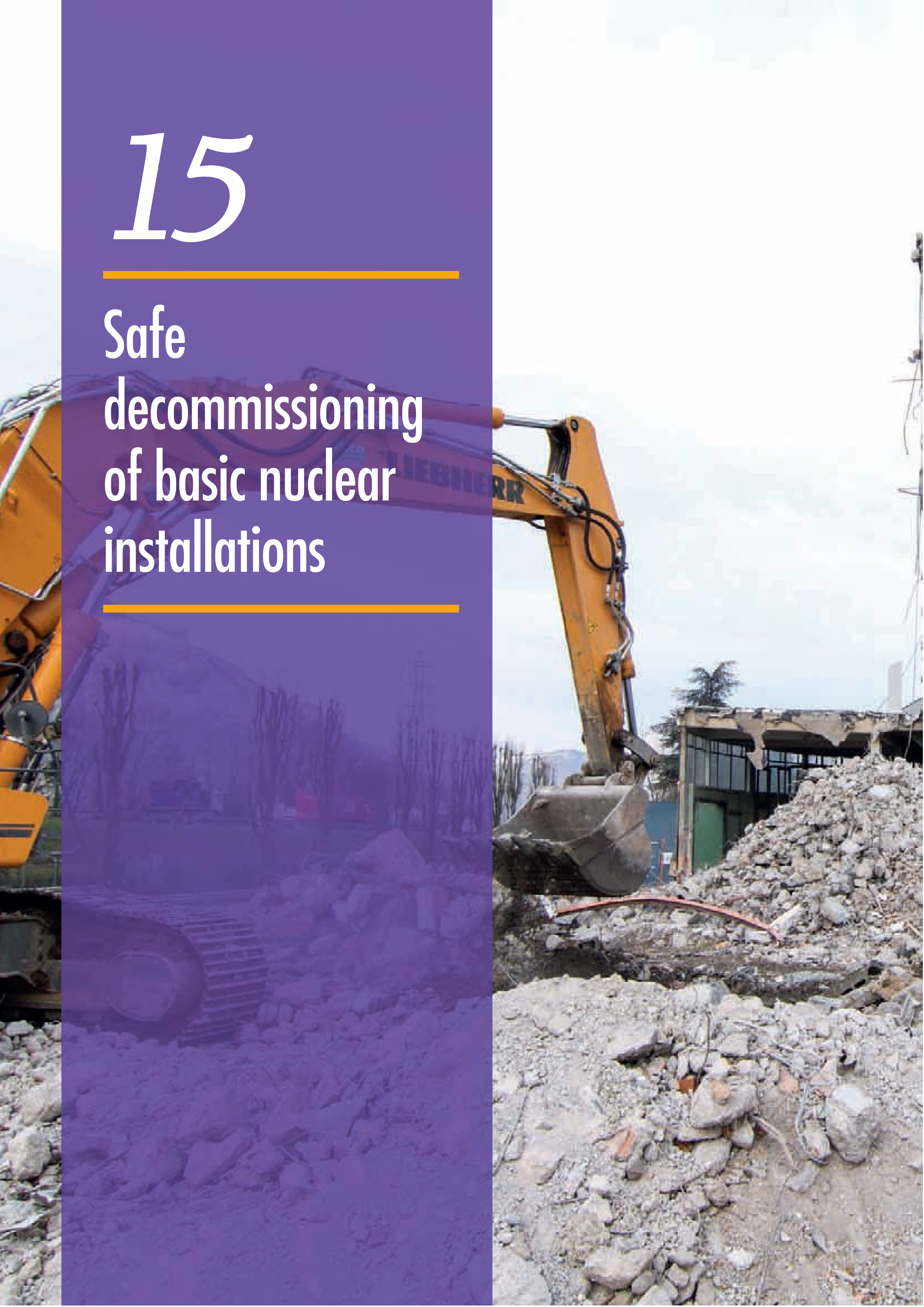
ASN will continue to examine the periodic safety review files for Ionisos.

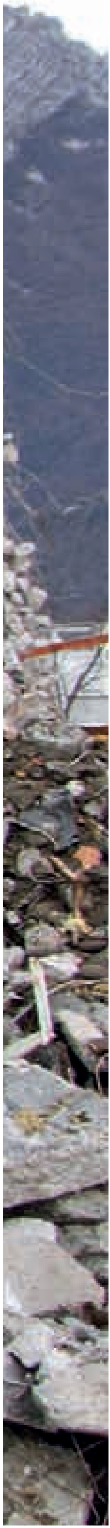
ASN will finalise the examination of complete commissioning of the "hardened safety core" on the RHF operated by the ILL, several years ahead of the other licensees.

Finally, in 2016, ASN will maintain its close surveillance of the radio-pharmaceuticals production plant operated by CIS bio international, with regard to the following points:
- increased operational rigour and safety culture;
- performance of the prescribed work, completed in 2015, for continued operation of the plant following its last periodic safety review;
- post-operational clean-out operations on the very high-level activity units of the facility that have been shut down.

15

Safe decommissioning of basic nuclear installations





The term decommissioning covers all the technical and administrative activities carried out following the final shutdown of a nuclear facility, in order to achieve a final predefined status in which all the hazardous and radioactive substances have been removed from the facility. These activities can include, for example, equipment dismantling operations, post-operational clean-out of premises and ground, destruction of civil engineering structures, treatment, packaging, removal and disposal of waste, whether radioactive or not. This phase in the life cycle of the facilities is characterised by rapid changes in the state of the facilities and changes in the nature of the risks.

In 2015, about thirty nuclear installations of all types (electricity generating or research reactors, laboratories, fuel reprocessing plants, waste treatment facilities, etc.), were shut down or were undergoing decommissioning in France.

Decommissioning operations are usually long-term undertakings that represent a real challenge for the licensees in terms of project management, maintaining skills currency and coordinating the various types of work which often involve many specialised companies. The risks associated with nuclear safety and radiation protection must be considered with the necessary rigour, in the same way as the conventional risks associated with any construction site and the risks linked to the loss of the design and operating memory due to the long duration of this phase, which often lasts more than ten years. The size of the current French nuclear fleet, which will have to be decommissioned at the end of its operating cycle, and the ongoing debates on the energy transition make decommissioning a major challenge for the future, to which all the stakeholders must devote sufficient resources.

The regulations relative to the decommissioning of Basic Nuclear Installations (BNI) were clarified and supplemented as of 2006 through Act 2006-686 of 13th June 2006 relative to Transparency and Security in the Nuclear field, which is now codified, and then through the Decree of 2nd November 2007 and the Order of 7th February 2012. ASN is continuing the development of the regulatory framework and the doctrine applicable to this phase of the BNI life cycle.

The year 2015 saw the delicensing of two installations: the Siloé reactor in Grenoble in January, and the LURE (Electromagnetic Radiation Laboratory) in Orsay in December.

1. TECHNICAL AND LEGAL FRAMEWORK FOR DECOMMISSIONING

1.1 Decommissioning risks

The risks presented by the facility when in operation change as its decommissioning progresses. Even if certain risks, such as criticality, quickly disappear, others, such as those related to radiation protection or conventional safety (numerous contractors working together, falling loads, work at height, and so on) gradually become more significant. The same goes for the fire or explosion risks (due to the cutting up of structures using thermal techniques that generate heat, sparks and flames).

The decommissioning of a facility leads to the production of large volumes of waste which must be properly managed to limit the risks relating to safety and radiation protection.

ASN also believes that management of the waste resulting from decommissioning operations is crucial for the smooth running of the decommissioning programmes (availability of disposal routes, management of waste streams). This subject receives particular attention when evaluating the overall decommissioning strategies and the waste management strategies established up by the licensees at ASN's request.

Decommissioning operations can therefore only begin if appropriate disposal routes are available for all the waste liable to be produced. The example of the decommissioning of EDF's first-generation reactors is a good illustration of this problem (see point 2.1.4).

French policy for the management of very low-level radioactive waste does not include a system of clearance levels for this waste, but requires that it be managed in a specific route so that it remains isolated and traceable. This is why, with regard to the possible recycling of the waste resulting from decommissioning, ASN is attentive to the application of French doctrine for radioactive waste which states that contaminated waste or waste that could have been contaminated in the nuclear sector may not be reused outside this sector (see chapter 16).

Similarly, the risks associated with Social, Human and Organisational Factors (SHOF) (due to changes in organisation with respect to the operating phase, frequent use of outside contractors, and risks associated with loss of memory) must be taken into account.

Lastly, the sometimes rapid changes in the physical state of the installation and the risks it presents raise the question of ensuring that the means of surveillance used are adequate and appropriate at all times.

1.2 The ASN doctrine concerning decommissioning

1.2.1 Immediate dismantling

The International Atomic Energy Agency (IAEA) has defined two possible decommissioning strategies for nuclear facilities following final shutdown:
- deferred dismantling: the parts of the installation containing radioactive materials are maintained or placed in a safe state for several decades before actual decommissioning operations begin (the "conventional" parts of the installation can be decommissioned as soon as the installation is shut down);
- immediate dismantling: decommissioning is started as soon as the installation is shut down, without a waiting period, although the decommissioning operations can extend over a long period of time.

The IAEA considers that safe enclosure (or entombment), which consists in placing the parts of the installation containing radioactive substances in a reinforced containment structure for a period that enables a sufficiently low level of radiological activity to be reached with a view to releasing the site, is no longer a possible decommissioning strategy, but may be justified in exceptional circumstances.

Many factors can influence the choice of one decommissioning strategy rather than another: national regulations, social and economic factors, financing of the operations, availability of waste disposal routes, decommissioning techniques, qualified personnel, personnel present during the operating phase, exposure of the personnel and the public to ionising radiation resulting from the decommissioning operations, etc. Consequently, practices and regulations differ from one country to another.

Today, in accordance with IAEA recommendations, French policy aims to ensure that BNI licensees adopt an immediate dismantling strategy.

This principle currently figures in the regulations applicable to BNIs (Order of 7th February 2012, the "BNI Order"). It has been included in the doctrine established by ASN for BNI decommissioning and delicensing since 2009 and has just been taken up at legislative level in the Energy Transition for Green Growth Act (TECV). This strategy moreover avoids placing the technical and financial burden of decommissioning on future generations. It also provides the benefit of having the knowledge and skills of the teams present during operation of the installation, which are vital during the first decommissioning operations.

ENERGY TRANSITION FOR GREEN GROWTH ACT (TECV)

Changes brought by the TECV:
- When the licensee plans to definitively stop the operation of all or part of its installation, it must notify the Minister responsible for Nuclear Safety and ASN at least two years before the planned shutdown date, or as quickly as possible if the shutdown is implemented with shorter notice for reasons justified by the licensee. This notification is made known to the CLI (Local Information Committee) and made available to the public.
- The licensee is no longer authorised to operate the installation as from final shutdown of the installation.
- The licensee is obliged to submit its decommissioning file no later than two years after giving notification of its intention to definitively shut down its installation.
- Any installation that has been shut down for at least two years is considered to be definitively shut down and must be decommissioned (this period can however be extended to five years under special circumstances).

ASN is contributing to the ongoing updating of the Decree of 2nd November 2007 relative to the BNI decommissioning procedures, and on 28th January 2016 it issued an opinion on the draft decree updating the procedures governing BNI final shutdown and decommissioning.

The aim of the strategy adopted in France is that:
- the licensee prepares the decommissioning of its installation from the design stage;
- the licensee anticipates decommissioning before its installation stops operating and sends the decommissioning authorisation application file before its installation is shut down;
- the decommissioning operations are carried out "in as short a time as possible" after shutting down the installation, a time which can vary from a few years to a few decades, depending on the complexity of the installation.

1.2.2 Complete clean-out

The decommissioning and post-operational clean-out operations for a nuclear installation must progressively lead to elimination of the radioactive substances resulting from the activation phenomena and/or of any contamination deposits or migrations, in both the structures of the installation premises and the ground of the site.

The structure clean-out operations are defined on the basis of the prior updating of the facility's waste zoning plan which identifies the areas in which the waste produced is, or could be, contaminated or activated. As work progresses (for example after cleaning the surfaces of a room using appropriate products), the "possible nuclear waste production areas" are downgraded to "conventional waste areas".

Pursuant to the provisions of Article 8.3.2 of the BNI Order, *"the final state reached on completion of decommissioning must be such that it prevents the risks or inconveniences that the site may represent for the interests mentioned in Article L. 593-1 of the Environment Code, in view more particularly of the projections for reuse of the site or buildings and the best post-operational cleanout and decommissioning methods available under economically acceptable conditions".* In this context, ASN recommends, in accordance with its decommissioning policy developed in 2009, that the licensees deploy clean-out and decommissioning practices taking into account the best scientific and technical knowledge available at the time and under economically acceptable conditions, with the aim of achieving a final status in which all the hazardous and radioactive substances have been removed from the BNI. This is the reference approach according to ASN. Should it be difficult to apply this approach due to the nature of the contamination, ASN considers that the licensee must go as far as reasonably possible in the clean-out process. Whatever the case, the licensee must provide technical or economic elements proving that the reference approach cannot be applied and that the clean-out operations cannot be taken further under acceptable economic conditions using the best technical clean-out and decommissioning methods available.

In accordance with the general principles of radiation protection, the dosimetric impact of the site on the workers and public after decommissioning must be as low as possible. ASN therefore considers that the defining of a priori thresholds cannot be envisaged. More specifically, achieving a threshold with an exposure level leading to an annual dose of 300 µSv for the workers or the public does not, in principle, constitute an acceptable objective.

ASN is working on the updating of its technical guide relative to structure clean-out operations (Guide No.14, available on *www.asn.fr*) with a view to publication in 2016. It had been issued in 2010 in draft form pending publication of the Order of 7th February 2012 and the resolution on the study of management of the waste produced in basic nuclear installations. The provisions of this guide have already been implemented on numerous installations with diverse characteristics, such as research reactors, laboratories, fuel manufacturing plant, etc. In 2015, ASN also produced a draft guide on the management of polluted soil in nuclear installations. It was made available to the stakeholders for consultation in view of publication in the first quarter 2016.

1.3 Decommissioning regulatory framework

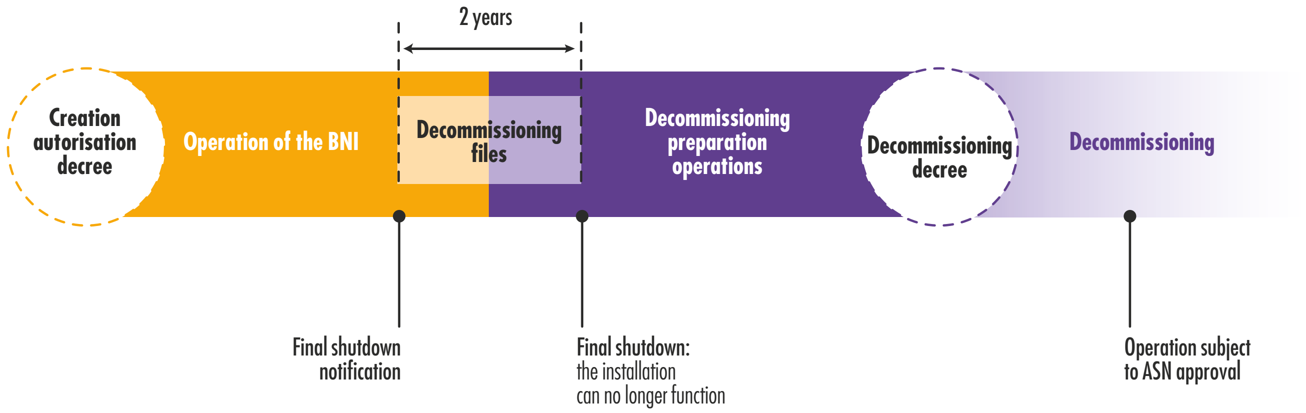
From the moment a BNI is definitively shut down, it must be decommissioned and therefore changes its purpose with respect to that for which its creation was authorised, as the creation authorisation decree specifies, among other things, the operating conditions of the installation. Furthermore, the decommissioning operations imply a change in the risks presented by the installation. Consequently, these operations cannot be carried out within the framework set by the creation authorisation decree. The decommissioning of a nuclear installation is prescribed by a new decree issued after consulting ASN. This decree sets out, among other things, the main decommissioning steps, the decommissioning end date and the final state to be attained.

In order to avoid fragmentation of the decommissioning projects and improve their overall consistency, the decommissioning file must explicitly describe all the planned operations, from final shutdown to attainment of the targeted final state and, for each step, describe the nature and scale of the risks presented by the facility as well as the envisaged means of managing them. This file is subject to a public inquiry.

Given the fact that installation decommissioning operations are often very long, the decommissioning decree can stipulate that a number of steps will, when the time comes, be subject to prior approval of ASN on the basis of specific safety analysis files (previously called "hold points").

The diagram below illustrates the corresponding regulatory procedure.

PHASES in the life of a BNI



The licensee must prove in its decommissioning file that the decommissioning operations are carried out in as short a time as possible.

The decommissioning phase may be preceded by a decommissioning preparation stage, provided for in the initial operating licence. This preparatory phase in particular allows removal of part of the radioactive and chemical substances as well as preparation for the decommissioning operations (readying of premises, preparation of worksites, training of teams, etc.). It is also during this preparatory phase that installation characterisation operations can be carried out: production of radiological maps, collection of pertinent data (operating history) with a view to decommissioning, etc. For example, the fuel of a nuclear reactor can be removed during this phase.

ASN will ensure that no decommissioning operations are carried out during this preparatory phase and that the duration of this phase does not exceed a few years. ASN recommends that the licensee should inform the CLI of the planned operations in the decommissioning preparation phase, regularly inform the CLI of the progress of operations and present the results once they are completed.

As part of its oversight duties, ASN monitors the implementation of the decommissioning operations as prescribed by the decommissioning decree.

The Environment Code provides that – as is the case for all other basic nuclear installations – the safety of a facility undergoing decommissioning be reviewed periodically, usually every 10 years. ASN's objective, through these periodic safety reviews, is to check that the level of safety of the installation remains acceptable until it is delicensed, with the implementation of measures proportionate to the risks presented by the installation during decommissioning.

TO BE NOTED

Guide to the final shutdown and decommissioning of the BNIs

The new version of Guide No.6, whose content has been updated, was published in July 2015. The main modifications introduced by this update are:

- integration of the new requirements of the Order of 7th February 2012 concerning justification of the time frame – which must be as short as possible – between final shutdown of operation of the facility and its decommissioning, the objectives with regard to the final state reached on completion of decommissioning, and the conditions for updating the decommissioning plan during operation of the installation in order to look ahead to its future decommissioning;
- addition of details on the conditions of examination by ASN and the relationships between the technical examination and the external consultations (environmental authority, public inquiry);
- addition of several recommendations concerning "good practices" observed by ASN;
- addition of details on the conditions for maintaining operation of equipment, structures or installations lying within the perimeter of a BNI that is in final shutdown status;
- addition of details concerning the decommissioning preparation operations;
- use of the vocabulary of the Order of 7th February 2012 and of the ASN resolution concerning the study of the management and assessment of the waste produced in the BNIs ("areas where nuclear waste production is possible", "delicensing of waste zoning", etc.).

Guide No.6 will be updated again in 2016 after publication of the TECV implementing texts.

On completion of decommissioning, a nuclear facility can be delicensed by an ASN resolution approved by the Minister responsible for Nuclear Safety. It is then removed from the list of BNIs and is no longer subject to the BNI system. To support its delicensing application, the licensee must provide a dossier demonstrating that the envisaged final state has indeed been reached and describing the state of the site after decommissioning (analysis of the state of the soil and remaining buildings or equipment, etc.). Depending on the final state reached, ASN may make delicensing of a BNI subject to the putting in place of active institutional controls. These may set a certain number of restrictions on the use of the site and buildings (use limited to industrial applications for example) or precautionary measures (radiological measurements to be taken in the event of excavation, etc.).

1.4 The financing of decommissioning and radioactive waste management

1.4.1 The legislative and regulatory provisions

Articles L. 594-1 to L. 594-14 of the Environment Code define the system for ring-fencing funds to meet the costs of decommissioning nuclear facilities and managing the spent fuel and the radioactive waste. This system is clarified by Decree 2007-243 of 23rd February 2007 amended and the Order of 21st March 2007 concerning the securing of financing of nuclear costs.

It aims to secure the funding for nuclear costs in compliance with the "polluter-pays" principle. It is therefore up to the nuclear licensees to take charge of this financing, by setting up a dedicated portfolio of assets capable of meeting the expected costs. They are obliged to submit three-yearly reports and annual update notices to the Government. Provisioning is ensured under direct control of the State, which analyses the situation of the licensees and can prescribe measures should it be found to be insufficient or inappropriate. In any case, the nuclear licensees remain responsible for the satisfactory financing of their long-term costs.

These costs are divided into five categories:
- decommissioning costs, except for long-term management of radioactive waste packages;
- spent fuel management costs, except for long-term management of radioactive waste packages;
- cost of Recovering and Packaging legacy Waste (RCD), except for long-term management of radioactive waste packages;
- costs of long-term management of radioactive waste packages;
- cost of surveillance following disposal facility closure.

The costs involved must be assessed using a method based on an analysis of the options that could be reasonably envisaged for the operation, on a conservative choice of a reference strategy, on consideration of residual technical uncertainties and performance contingencies, and on consideration of operating experience feedback.

An agreement signed between ASN and the General Directorate for Energy and Climate (DGEC) whereby ASN ensures the surveillance of these long-term costs, defines:
- the conditions in which ASN produces the opinions it is required to issue pursuant to Article 12, paragraph 4 of the above-mentioned Decree of 23rd February 2007, on the consistency of the strategies for decommissioning and management of spent fuels and radioactive waste;
- the conditions in which the DGEC can call on ASN expertise pursuant to Article 15, paragraph 2 of the same Decree.

1.4.2 Review of the reports submitted by the licensees

The third three-yearly reports were submitted in 2013 and formed the subject of ASN opinion 2013-AV-0198 of 9th January 2014. In this opinion, ASN recommends as a general rule that the licensees:
- implement harmonised approaches for the declaration of decommissioning costs;
- take into account the costs of remediation of contaminated soil, favouring the complete clean-out of sites;
- assess the impact on the unavailability of waste treatment, packaging and storage facilities on the evaluation of the costs;
- assess the impact of the modifications of their installations induced by the conclusions of the stress tests and the periodic safety reviews on the decommissioning strategy, and hence on the evaluation of the costs;
- re-evaluate the costs of implementing long-term management solutions for high-level waste and intermediate-level, long-lived waste, on the basis of the latest technical design options of the deep geological disposal (see chapter 16).

The opinion also contains specific recommendations concerning each licensee.

In 2014, the licensees transmitted the first discounting notes for the third three-yearly reports on which ASN gave an opinion to the DGEC on 18th December 2014. In addition to the points put forward in its opinion of 9th January 2014, ASN urges the licensees to include the final shutdown preparation operations in their decommissioning costs, as these are an integral part of the decommissioning operations of an installation. ASN has also drawn the attention of the DGEC to the hypothesis considered by CIS bio international of a start of decommissioning in 2078, which is not credible in the light of the conclusions of the last periodic safety review of the installation and its age. Eventual findings on the operating lifetime of CIS bio international's current installations show that it would be prudent to adopt a final shutdown date at the latest within the next ten years for the evaluation of the decommissioning costs. ASN recommends that CIS bio international update without delay the discounting of its costs mentioned in Article L. 594-1 of the Environment Code, taking into account a more realistic operating time.

1.5 Lessons learned from the Fukushima Daiichi accident

To take into account the lessons learned from the nuclear accident that occurred at the Fukushima Daiichi nuclear power plant in Japan, ASN asked the BNI licensees to carry out stress tests, including on installations undergoing decommissioning.

With regard to EDF, at the request of ASN, the stress test reports for the BNIs undergoing decommissioning (Chinon A1, A2 and A3, Saint-Laurent-des-Eaux A1 and A2, Bugey 1, Chooz A, Superphénix, Brennilis) and the Fuel Evacuation Facility (APEC) (Creys-Malville) were submitted on 15th September 2012. ASN gave its conclusions on 10th October 2014. It considered that the procedure followed complied with the specifications and asked for further information relative to the seismic risk in the APEC and the gas-cooled reactors, and the flood risk in the gas-cooled reactors. EDF has already committed itself to taking several of these demands into account.

With regard to the CEA installations, the Plutonium Technology Facility (ATPu) (Cadarache) currently undergoing decommissioning was the subject of resolution No. 296 of 26th June 2012 setting out additional requirements in the light of the conclusions of the stress tests. In addition to the generic requirements, ASN asked CEA to keep up to date the estimated quantities of fissile materials present in each area within the ATPu. ASN did not however consider it necessary to set "hardened safety core" requirements for this BNI.

ASN resolution of 26th June 2012, issued subsequent to the transmission on 15th September 2011 of the stress tests report for the Phénix reactor (Marcoule), sets out additional requirements to reinforce the robustness of the installation against extreme situations, notably by establishing a "hardened safety core". The ASN resolution of 8th January 2015 also sets additional prescriptions specifying the requirements applicable to the "hardened safety core" of the Phénix reactor and the management of emergency situations.

ASN has not issued prescriptions for the Rapsodie reactor (Cadarache), for which the report was issued on 13th September 2012. Nevertheless, CEA has undertaken to review the scenario of a sodium-water reaction induced by rainfall occurring further to an extreme earthquake having caused severe structural failure of the BNI buildings. The corresponding study was submitted at the end of 2014 at the request of ASN.

The report concerning the Irradiated Materials Facility (AMI) operated by EDF at Chinon was submitted on 6th June 2014. ASN considered on 10th July 2015 that the measures adopted by EDF to mitigate the consequences of an accident situation associated with extreme external hazards, such as those taken into consideration for the stress tests, were satisfactory, subject to removal in the short term of the radiological inventory present in the installation.

The experience feedback from the Fukushima Daiichi accident will be taken into account for the facilities of lesser importance later on, notably during the next periodic safety reviews for the Procédé and Support BNIs (Fontenay-aux-Roses).

The installations whose decommissioning work is sufficiently far advanced, or whose potential source term is very low and for which delicensing is very close, are not concerned by the stress tests.

1.6 The international action of ASN in the area of decommissioning

ASN participated in various international actions relating to decommissioning in 2015.

It contributed in particular to the WENRA "Waste and decommissioning" working group which in June 2013 published a report identifying the reference safety levels applicable to the decommissioning of nuclear installations. These reference safety levels must be transposed into the national regulations of each of the WENRA member countries. Publication of the Order of 7th February 2012 allowed a number of these safety levels to be transposed, relating to safety management in particular, but other measures still have to be specified in ASN resolutions, notably the resolutions relative to the studies of waste management in the installations and to decommissioning, currently under preparation.

ASN is also a member of the International Decommissioning Network (IDN) coordinated by the IAEA and as such keeps itself informed of the international projects. It has contributed in particular since 2012 to the CIDER (Constraints to Implementing Decommissioning and Environmental Remediation) Project, which aims to identify and develop aids to overcome the difficulties that member countries can encounter in site decommissioning and rehabilitation projects.

2. SITUATION OF NUCLEAR INSTALLATIONS UNDERGOING DECOMMISSIONING IN 2015

Some thirty installations are currently being decommissioned in France (see map opposite).

2.1 EDF nuclear installations

2.1.1 The decommissioning strategy of EDF

The decommissioning strategy of EDF, the first version of which was submitted to ASN at its request in 2001, presents the decommissioning programme for the first-generation Nuclear Power Plants (NPP) and the state of reflections on the decommissioning strategy for the fleet currently in operation.

As requested by ASN, EDF submitted an update of the decommissioning strategy for its reactors in October 2013. This file was examined by the advisory committee of experts in 2015. ASN had asked EDF beforehand to include a study of the alternative solutions for graphite waste management in order to avoid making decommissioning of the gas-cooled reactor vessels more dependent on the commissioning of the Low-Level Long-Lived Waste (LLW-LL) disposal facility. It nevertheless notes that where decommissioning of gas-cooled reactors is concerned, the question of the disposal route for graphite waste can complicate correct implementation of this immediate dismantling strategy.

The examinations of the safety of the installations, the review of EDF's decommissioning strategy and waste management, and the Andra report on the technical feasibility of a LLW-LL repository were communicated in 2015.

On the basis of these new elements, the ASN Commission will again hear EDF on the decommissioning strategy for the gas-cooled reactors in March 2016. It will adopt a position on the need to prescribe firstly the date for opening the gas-cooled reactor vessels and secondly a feasibility study for the creation of storage facilities for managing the LLW-LL graphite waste.

2.1.2 Internal authorisations

The system of internal authorisations is governed by the Decree of 2nd November 2007 (see chapter 3) and the resolution of 11th July 2008. The aim of implementing a system of internal authorisations in basic nuclear installations is to consolidate the prime responsibility of the operator with regard to nuclear safety and radiation protection, one of the fundamental principles of the safety of activities involving risks being that the person or entity carrying them out is responsible for them. For operations of minor importance it introduces flexibility in the updating of the baseline safety requirements of the facilities, whose state changes rapidly during decommissioning. ASN, having authorised the EDF system of internal authorisations relating essentially to reactors undergoing decommissioning through a resolution of 15th April 2014, conducted an inspection on the subject in 2015 to check application of the resolution.

2.1.3 The Brennilis NPP

The Brennilis NPP on the Monts d'Arrée site, called EL4-D, is an industrial prototype heavy water moderator nuclear power reactor cooled with carbon dioxide which was definitively shut down in 1985. The nuclear operator since 2010 is EDF. Partial decommissioning operations were carried out from 1997 to mid-2007 (plugging systems, dismantling certain heavy water and carbon dioxide systems and electromechanical components, demolition of non-nuclear buildings, etc.). A Decree of 27th July 2011 authorised part of the decommissioning operations with the exception of decommissioning of the reactor unit. In 2015, decommissioning of the installation continued under this Decree (cleaning up of the soil situated around the Effluent Treatment Station (STE), decommissioning of the STE, decommissioning of the heat exchangers. EDF must submit a complete decommissioning file for this installation without delay.

During 2015, the licensee encountered several difficulties in the decommissioning operations:
- the heat exchanger decommissioning worksite was interrupted on 23rd September 2015 when in the clearing up and equipment removal phase, due to a fire and triggering of the on-site emergency plan;
- the clean-up and demolition worksite of the effluent treatment station was interrupted several times, notably by the incident involving the fall of a screening machine which damaged the worksite containment.

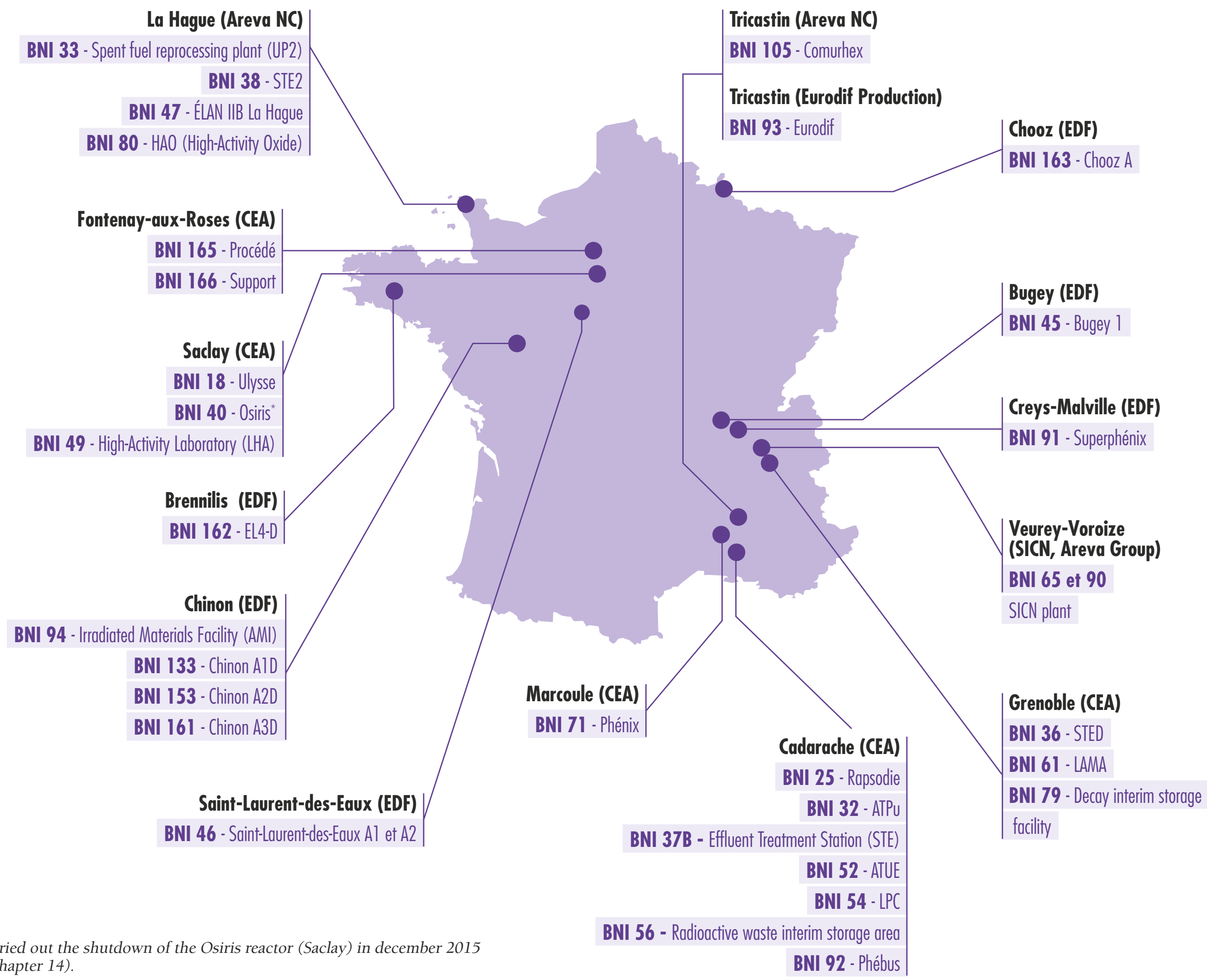
ASN's inspections further to these incidents revealed deficiencies in the preparation of operations and in the risk analyses, particularly with regard to consideration of the fire risk.

ASN has asked EDF to review all the organisational and human measures implemented to control the risks associated with hot work on the decommissioning work sites as soon as possible.

These difficulties led EDF to ask for an extension of the deadline for performing the operations authorised by the decree to that it can complete STE clean-out.

Clean-out of the STE and the subjacent soils should continue in 2016.

INSTALLATIONS definitively shut down or in the process of decommissioning as at 31st December 2015



** CEA carried out the shutdown of the Osiris reactor (Saclay) in december 2015 (see box chapter 14).*

2.1.4 The gas-cooled reactors

These first-generation reactors functioned with natural uranium as the fuel and graphite as the moderator. They were cooled by gas. The last reactor of this type to be shut down was Bugey 1 in 1994.

EDF changed decommissioning strategy in 2001 by switching from a deferred dismantling to an immediate dismantling strategy. However, essentially further to the difficulties Andra encountered in creating a disposal facility for the Low-Level Long-Lived (LL-LL) waste, the time frames given in the EDF's decommissioning strategy file, which was updated in 2013, were pushed back by almost 20 years with respect those given in the 2001 file. ASN is examining this file and will adopt a position on the acceptability of EDF's proposed strategy for decommissioning the gas-cooled reactors (see point 2.1.1).

Moreover, a file concerning the seismic behaviour of the gas-cooled reactor vessels was submitted to ASN by EDF jointly with the update of the reactor decommissioning strategy in 2013. This file is currently being examined.

Bugey 1 reactor

Under EDF's current decommissioning strategy, this reactor is the first gas-cooled reactor that should be decommissioned (first-off). Complete decommissioning of the installation, for which final shutdown became effective in 1994, was authorised by Decree of 18th November 2008. ASN set the prescriptions and limits concerning the Bugey nuclear site's water intake and effluent discharge limits in resolutions of 15th July 2014. The renewal of the prescriptions was necessary more particularly to integrate the Bugey 1 reactor decommissioning operations.

Lastly, in order to implement the work to extract operating waste from the reactor pressure vessel, planned in 2016, EDF submitted a safety file to ASN in 2014, and this file is currently being examined.

ASN considers that the safety of decommissioning of the Bugey reactor 1 is satisfactory on the whole, despite occasional shortcomings in operating rigour.

ASN, which ensures labour inspection on this installation, has also noted deviations or near-accidents with regard to occupational safety which must give rise to corrective actions.

EDF's decommissioning strategy for the gas-cooled reactors (see point 2.1.1) will take into account the issue of decommissioning the Bugey 1 reactor pressure vessel in order to meet the deadline date for filling the Bugey 1 reactor with water is met (see point 2.1.1).

Chinon A1, A2 and A3 reactors

The former Chinon A1, A2 and A3 reactors were shut down in 1973, 1985 and 1990 respectively.

Reactors A1 and A2 were partially decommissioned and transformed into storage facilities for their own equipment (Chinon A1 D and Chinon A2 D). These operations were authorised by the Decrees of 11th October 1982 and 7th February 1991 respectively. Chinon A1 D is currently partially decommissioned and has been set up as a museum since 1986. Chinon A2 D is also partially decommissioned and accommodates the Intra group (robots and machines for intervening on accident-stricken nuclear installations).

The complete decommissioning of the Chinon A3 reactor was authorised by Decree of 18th May 2010. The preparatory work for complete decommissioning was started by the licensee in mid-2011. ASN gave its approval in 2012 for the decommissioning work on the exchangers (first step in decommissioning of the facility) of the Chinon A3 reactor.

ASN updated the prescriptions regulating the water intakes and effluent discharges in 2015.

Decommissioning of the Chinon A3 heat exchangers continued in 2015. Work has also started on Chinon A2. The licensee's monitoring of outside contractors on the worksites remains a major issue in the decommissioning of these installations.

The fire risk is well managed by the licensee, who has put in place a continuous improvement process to control this risk. ASN has nevertheless noted a few deviations from the corresponding new regulations.

ASN considers that the level of safety of the Chinon A nuclear installations is satisfactory.

In 2016, ASN will also continue to monitor the various actions carried out by the licensee concerning the monitoring and implementation of a plan for managing legacy hydrocarbon pollution of the soil.

In 2016 ASN will state its position on the decommissioning schedule for the Chinon A reactors (see point 2.1.1) and especially the decommissioning of Chinon A1 D and A2 D. In the coming years, EDF should submit the conclusions of the periodic safety reviews of the three reactors and the decommissioning files for the Chinon A1D and Chinon A2D reactors.

Saint-Laurent-des-Eaux A1 and A2 reactors

Complete decommissioning of the facility, which comprises two reactors and for which final shutdown was declared in 1994, was authorised by Decree of 18th May 2010. A file concerning the renewal of the prescriptions regulating water intakes and effluent discharges is currently being examined by ASN.

Since 2013, EDF has been carrying out expert appraisals inside the vessel of reactors A2 and A1. The resulting data served to produce a file substantiating the resistance of the reactor structures and whose examination is nearing completion.

The licensee has continued to progress with the installation's legacy waste and effluents treatment work, despite unforeseen events that yet again affected the worksites. A plan of action has been successfully applied to improve operating rigour following several deviations on one of the worksites in 2014 and 2015. ASN has also observed satisfactory presence in the field for the monitoring of outside contractors. The licensee must therefore continue its actions in order to be able to start the decommissioning operations, apart from reactor pressure vessel A2, under satisfactory conditions in 2016.

The fire risk is well managed by the licensee. ASN has nevertheless noted a few deviations from the corresponding new regulations.

ASN considers that on the whole the level of safety of the nuclear installations of the former Saint-Laurent-des-Eaux NPP is satisfactory.

EDF is going to carry out the periodic safety review of the installations in the next few years.

2.1.5 Chooz A reactor

The reactor of the Ardennes NPP was the first pressurised water reactor built in France. It was shut down in 1991. Its decommissioning foreshadowed the future decommissioning of pressurised water reactors, the technology of the French nuclear power reactors currently in operation.

Within the context of partial decommissioning of the reactor, the Decree of 19th March 1999 authorised the modification of the existing facility to convert it into a storage facility – called CNA-D – for its own equipment left on site. Its complete decommissioning was authorised by Decree of 27th September 2007.

After decommissioning the steam generators and the primary system, ASN, through its resolution of 3rd March 2014, authorised decommissioning of the reactor vessel which is planned to start in 2016.

The preparatory work for decommissioning the Chooz A reactor vessel started in 2015. The reactor cavity gates were dismantled and the pressuriser, dismantled in 2013, was removed.

With regard to the environment and nuclear safety, ASN considers that the decommissioning operations are being carried out satisfactorily.

UNDERSTAND

The implications of decommissioning the PWR vessel

The Chooz A reactor is a Pressurised Water Reactor (PWR) like EDF's 58 reactors in operation. It is therefore the first reactor using this technology to be decommissioned in France by EDF and the first shut down reactor to have its vessel dismantled.

Decree 2007-1395 of 27th September 2007 authorising decommissioning of the Chooz A reactor set four hold points: dismantling of the primary system, dismantling of the reactor vessel, start of stages 2 (surveillance phase) and 3 (demolition and redevelopment of the site), considering that the change of stage operations require a specific examination.
ASN thus authorised dismantling of the reactor vessel in 2014.

The main challenges of dismantling the reactor vessel are:

1 - Worker radiation protection is a major issue. This is because the reactor vessel, the metal of which has been activated, cannot be decontaminated beforehand (unlike the already dismantled steam generators) to reduce the dose rate. EDF has therefore planned to carry out the operations to remove the elements from the vessel and cut up of the vessel under water in the reactor cavity, using remotely operated means.

2 - There is a risk associated with the handling of large components (the vessel weighs about 200 tonnes).

3 - New facilities must be built to treat and package the waste.

4 - Waste management represents a major challenge since the activated waste, once characterised and packaged, must be transferred to ICEDA (activated waste packaging and interim storage installation). This facility will therefore have to be put into service within a time frame compatible with the progress of vessel dismantling.

To cope with these challenges, EDF has the benefit of international experience feedback from reactors of identical technology on which this same procedure has been used, particularly the Zorita NPP in Spain.

Regarding radiation protection, in 2015 ASN observed the progress made by EDF under the action plan implemented in 2014. ASN considers that EDF must maintain its training and awareness-raising efforts for its outside contractors in this area.

Several incidents occurred during operations on electrical distribution panels in 2014 and 2015 due to insufficient preparation of the activities concerned and to concomitance of activities.

EDF must have completed the periodic safety review of Chooz A in 2017. ASN examined the orientations of this safety review in 2015.

2.1.6 The Superphénix reactor and the Fuel Evacuation Facility (APEC)

The Superphénix fast neutron reactor, a sodium-cooled industrial prototype, is located at Creys-Malville. It was definitively shut down in 1997. This installation is associated with another BNI, the Fuel Evacuation Facility (APEC), which consists primarily of a storage pool in which the spent fuel removed from the Superphénix reactor vessel is stored, and storage for packages of soda concrete from the Sodium Treatment Installation (TNA).

ASN considers that the safety of the Superphénix reactor decommissioning operations and of APEC operation is satisfactorily ensured. The progress ASN observed in 2014 with regard to operating rigour and monitoring the performance of maintenance operations and periodic tests was maintained in 2015.

In addition, following the detection of anomalies in 2014, the licensee has listed the retention structures on the site and defined corresponding inspection programmes. Nevertheless, in 2015 ASN asked EDF to rapidly set up an organisational structure enabling it to remove and treat, as rapidly as possible, the hazardous substances that could accumulate in the retention structures.

Lastly, ASN has verified that the organisation and provisions with regard to occupational radiation protection and the transport of radioactive substances complied with the regulations.

Examination of the file transmitted for the authorisation to treat the residual sodium from the reactor vessel and its filling with water revealed no blocking points. Preparation and performance of these operations represent the main risk activities for the coming year. The periodic safety review files for the Superphénix reactor and the APEC were submitted in 2016. ASN made a statement in 2014 on the orientations of the then forthcoming periodic safety reviews and will start the technical examination of the files received.

TO BE NOTED

Lifting of the Superphénix stopping point

Decree 2006-321 of 2nd March 2006 authorising decommissioning of the Superphénix reactor stipulates that starting of the residual sodium treatment operations after emptying the main vessel must receive prior authorisation from ASN. On this account, in 2014 EDF transmitted a file in for this operation, which will be carried out in two stages:

- carbonation of the residual sodium,
- filling the reactor vessel with water.

This operation is necessary for the dismantling of the reactor vessel and its internal parts which must be carried out under water.

The main safety issues involved in the treatment of the residual sodium of the main vessel are represented by the risks of an uncontrolled sodium-water reaction and a hydrogen explosion.

These risks are controlled in particular by the systems of the Sodium Treatment Installation (TNA) situated on the reactor vessel, which limit the injection flow rates and control discharges from the vessel into the reactor building.

After examination, ASN authorised starting of these operations through a resolution of 21st December 2015.

2.1.7 Irradiated Material Facility (AMI)

This facility (BNI 94) situated on the nuclear site of Chinon (Indre-et-Loire *département*) was notified and commissioned in 1964, and is operated by EDF. Its main purpose is to carry out reviews and assessments of activated or contaminated materials from PWR reactors.

2015 saw the gradual transfer of the expert appraisal activities to a new facility on the site – the Lidec (Integrated Laboratory of the CEIDRE). Consequently there are no more expert appraisal activities in the AMI. ASN was particularly attentive to the management of this transfer.

During operation of the AMI, a few malfunctions occurred in work management and performance and in the performance of tests. The fire-response provisions must be made more robust. In a context in which the organisation of the facility is due to change significantly in 2016, ASN will be particularly attentive to the licensee's compliance with the facility's baseline requirements and to operating rigour.

The decommissioning authorisation application file submitted by the licensee in June 2013 must, in view of the requests made at the end of 2014, be supplemented to indicate the initial state of the installation at the time of application of the decree authorising shutdown and decommissioning, planned towards the end of 2017. As part of the decommissioning preparation operations, specific provisions will be implemented for the packaging and storage of some of the waste. The waste in question is legacy waste for which appropriate management routes are not yet available. ASN will be attentive to the legacy waste recovery and packaging operations, given the lateness accumulated over the last few years.

With the prospect of a periodic safety review in 2017, ASN has examined the review orientation file and additional requests have been made to the licensee.

2.2 CEA installations

ASN and ASND (Defence Nuclear Safety Authority) have noted that the decommissioning operations and the recovery and packaging of CEA legacy waste are significantly behind schedule, the forecast duration of the decommissioning and legacy waste retrieval operations has been very significantly increased, and there is considerable lateness in the transmission of decommissioning files. Consequently, ASN and ASND have asked CEA to present the new decommissioning strategy envisaged by CEA for all the BNIs and individual installations situated inside the Secret Basic Nuclear Installations (SBNIs), within one year. ASN and ASND have asked CEA to draw up decommissioning programmes for the next fifteen years based on prioritised priorities of safety, radiation protection and environmental protection, particularly taking into account the total potential activity of the radioactive and hazardous substances present in the installation.

ASN and ASND have therefore asked CEA to conduct an overall review of the nuclear installation decommissioning strategy and the management of CEA's radioactive waste; this review more specifically concerns the prioritisation of operations, human resources and the effectiveness of the organisational set-ups to achieve them and the appropriateness of the financial resources allocated to these operations. ASN and ASND have also asked CEA to increase the human resources assigned to the decommissioning operations and to the organisation of its decommissioning and waste management programmes. Lastly, they have asked CEA to review the budget resources assigned to decommissioning operations.

2.2.1 The Fontenay-aux-Roses centre

CEA's first research centre, located in Fontenay-aux-Roses (Hauts-de-Seine *département*) since 1946, is continuing to move away from nuclear activities in order to concentrate on research into the life sciences.

The CEA Fontenay-aux-Roses centre comprises two BNIs, namely Procédé (BNI 165) and Support (BNI 166). BNI 165 accommodated the research and development activities on nuclear fuel reprocessing, transuranium elements, radioactive waste and the examination of irradiated fuels. These activities were stopped in the years 1980-1990. BNI 166 is a facility for the characterisation, treatment, reconditioning and storage of legacy radioactive waste and waste from the decommissioning of BNI 165.

The decommissioning of these two installations was authorised by Decrees of 30th June 2006. The initial planned duration of these decommissioning operations was about ten years. CEA has informed ASN that due to the strong presumptions of radioactive contamination underneath one of the buildings and unforeseen difficulties, the decommissioning operations will be extended at least until 2023 for the Procédé installation and 2029 for the Support installation. CEA submitted an authorisation application file in June 2015 to modify the Decrees of 30th June 2006, particularly with regard to the decommissioning deadlines and the final state. The Minister responsible for Nuclear Safety referred the case to ASN for its decision on the admissibility of the file.

Furthermore, in application of ASN resolution of 2nd February 2012, CEA submitted a file in early 2013 with a view to revising the order regulating discharges in order to update it and incorporate the decommissioning operations. ASN's examination of this file revealed serious shortcomings. The file is still under examination and will have to be supplemented to enable ASN to finalise its decisions. The site's on-site emergency plan is also being examined.

ASN considers that the level of safety of CEA's Fontenay-aux-Roses installations has improved, particularly in the control of the fire risk, but is nevertheless not entirely satisfactory. The BNI licensee made a substantial effort to formalise its organisational arrangements in 2015. Nevertheless, ASN has observed that the interventions carried out under the centre's multi-technique contract are not always controlled by CEA. ASN will be particularly attentive to consideration of human and organisational factors in the progress plan that CEA is to implement in 2016 and in the results of this plan.

2.2.2 The Grenoble centre

The Grenoble centre was inaugurated in January 1959. Activities associated with the development of nuclear reactors were carried out there before being gradually transferred to other CEA centres in the 1980's. Now the Grenoble centre conducts its research and development in the fields of renewable energies, health and microtechnology. In 2002 the CEA centre in Grenoble launched a site delicensing programme.

The site housed six nuclear facilities which were gradually shut down and entered the decommissioning phase with a view to their ultimate delicensing. Delicensing of the Siloette reactor was declared in 2007, that of the Mélusine reactor in 2011 and that of the Siloé reactor in January 2015.

ASN considers that the safety of the decommissioning and post-operational clean-out of the installations in the Grenoble centre was on the whole satisfactory in 2015.

Radioactive effluent and solid waste Treatment Station and Decay Storage facility (STED)

The final shutdown and decommissioning operations of the STED (BNI 36) and the interim radioactive waste decay storage facility (BNI 79) were authorised by the Decree of 18th September 2008 which prescribed a term of 8 years for the completion of decommissioning activities.

All the buildings have been destroyed in compliance with the above-mentioned Decree. The main operations still to be carried out concern the decontamination of the soil.

The technical discussions between ASN and CEA concerning remediation of the soil of the STED (Effluent and Waste Treatment Plant) continued in 2015. ASN asked CEA to continue the remediation operations that can be technically achieved for an economically acceptable cost.

Active Material Analysis Laboratory (LAMA)

This laboratory conducted post-irradiation studies of uranium and plutonium based nuclear fuels, and structural materials from nuclear reactors until 2002. Decommissioning of the LAMA was authorised by Decree on 18th September 2008.

2015 saw completion of the LAMA clean-out and waste zoning delicensing operations. CEA submitted its delicensing application file for the BNI in March 2015.

Siloé reactor

Siloé is an old research reactor used mainly for technological irradiation of structural materials and nuclear fuels.

CEA was authorised to carry out the decommissioning operations by Decree of 26th January 2005. The work was completed in 2013. Delicensing of the waste zoning of the Siloé BNI was declared in 2014. The Siloé BNI 20 was delicensed by resolution of 9th January 2015.

2.2.3 The Cadarache centre installations undergoing decommissioning

Rapsodie reactor and Fuel Assembly Shearing Laboratory (LDAC)

The experimental reactor Rapsodie is the first sodium-cooled fast neutron reactor built in France. It functioned until 1978. A reactor vessel sealing defect led to its final shutdown in 1983.

Decommissioning operations have been undertaken since then but were partly stopped further to a fatal accident (explosion) that occurred in 1994 when washing out a sodium tank. At present, the core has been unloaded, the fuel evacuated from the installation, the fluids and radioactive components have been removed and the reactor vessel contained. The reactor pool has been emptied, partially cleaned out and decommissioned. In addition, 23 tonnes of sodium are stored and must be removed to the CEA Marcoule centre for treatment.

The CEA transmitted its complete decommissioning authorisation application to ASN in December 2014 and the periodic safety review file for the installation in May 2015. In July 2015, ASN informed the Minister responsible for Nuclear Safety, who had referred this file to ASN, that further information was necessary in order to continue the examination.

The work currently being performed by CEA chiefly involves renovation, clean-out and decommissioning operations limited to specific equipment items, along with waste removal operations. ASN considers that the standard operating operations are carried out regularly, that the premises are well kept and that substantial work had been carried out to make the applicable documents consistent with the general operating rules. The measures taken by CEA to ensure removal of the sodium-containing waste still present in the installation by 2018 are also closely monitored by ASN.

The purpose of the LDAC, located within the Rapsodie BNI, was to perform inspections and examinations on irradiated fuels from the fast-neutron reactors. This laboratory has been shut down since 1997 and partially cleaned out. Its decommissioning is included in the decommissioning project for the entire BNI.

Two successive significant events that occurred in the radiochemistry laboratory early in the year highlighted the singular situation of this installation classified on environmental protection grounds within the BNI. The BNI licensee reacted appropriately by making improvements in the organisation of the interfaces with this laboratory and through safety awareness-raising actions with its personnel.

Enriched Uranium Processing Facilities (ATUEs)

Until 1995, the ATUEs converted uranium hexafluoride from the enrichment plants into sinterable oxide, and ensured the chemical reprocessing of waste from the manufacture of fuel elements. The installation was also equipped with a low level organic liquid incinerator. Production in the facilities ended in July 1995 and the incinerator was shut down at the end of 1997.

The installation's final shutdown and decommissioning authorisation Decree of 8th February 2006 prescribed work completion in 2011. After having observed that the decommissioning operations were stopped and that CEA had not followed up its request to submit a new authorisation application file in order to complete the decommissioning, ASN served CEA with a compliance notice on 6th June 2013. In February 2014 CEA submitted a new application for authorisation to complete the decommissioning and clean-out operations. Considering that this file meets the conditions set in the compliance notice resolution, ASN suspended the notice resolution by a resolution on 29th April 2014. However, it turned out that further information was required, which ASN indicated to the Minister responsible for Nuclear Safety who had referred this file to ASN. The additional information was provided in December 2015.

The Plutonium Technology Facility (ATPu) and the Chemical Purification Laboratory (LPC)

The ATPu produced plutonium-based fuel elements initially intended for fast neutron or experimental reactors and then, as of the 1990s, for pressurised water reactors using MOX fuel. The LPC's activities were associated with those of the ATPu: physical-chemical checks and metallurgical examinations, treatment of effluents and contaminated waste. The two facilities were shut down in 2003.

CEA is the nuclear licensee for these facilities. Areva NC has been the industrial operator responsible for operation of the facilities since 1994 and is also responsible for their decommissioning until CEA takes over this latter activity completely, which is planned for the second half of 2016.

Decommissioning of the two facilities, authorised by the Decrees of 6th March 2009 and governed by the resolutions of 26th October 2010, continued in 2015 with a large volume of operations, resulting in a significant reduction in the source term. For some of these operations the licensee made modification declarations, examined by ASN, such as the retrieval of bitumen from the annular tanks of the LPC.

With regard to the cryogenic treatment unit, the decommissioning operations authorised by ASN resolution of 20th October 2011 are in progress.

ASN has kept close track of implementation of the measures taken by CEA further to the compliance notice resolution of 19th February 2013 concerning monitoring of Areva NC and management of the skills associated with decommissioning safety, and the organisation put in place by the operator appears to be effective on the whole.

In 2016 ASN will remain attentive to the situation of these two BNIs with regard to social, organisational and human factors, and will see to the long-term continuation of the progress registered so that the resuming of decommissioning activities by CEA after the departure of the industrial operator takes place under suitably safe conditions.

2.2.4 The Saclay centre installations undergoing decommissioning

The decommissioning operations carried out on the site concern two BNIs in final shutdown state and three BNIs in operation but with sections that have stopped their activity and on which preparatory operations for decommissioning are being carried out. They also concern two ICPEs (Installations Classified on Environmental Protection grounds), EL2 and EL3, which were previously

BNIs but which have not been completely dismantled due to the absence of a disposal route for low-level long-lived waste. Their delicensing in the 1980's from BNI status to ICPE status, in compliance with the regulations of that time, would not be possible today.

High-Activity Laboratory (LHA)

The LHA comprises three buildings housing several laboratories which were intended for research into or the production of various radionuclides. On completion of the decommissioning and clean-out work authorised by Decree of 18th September 2008, only two laboratories currently in operation should ultimately remain under the ICPE system. These two laboratories are the laboratory for the chemical and radiological characterisation of effluents and waste, and the packaging and storage facility for the recovery of sources that are surplus to requirements.

The decommissioning of the cells, tanks and liners present in the intercell yards of the BNI continued in 2014. After a preparatory phase, decommissioning of the TOTEM shielded chain, which was stopped in 2012, started again. The first operations to clean out the civil engineering structures of the decommissioned cells started in 2015.

ASN considers that the safety of BNI 49 undergoing decommissioning remains satisfactory and notes that the decommissioning operations are proceeding according to the schedules. The commitments made further to the inspections and significant events are well met on the whole. Nevertheless, the inspections carried out in 2015 revealed shortcomings in the management of decommissioning waste movements and storage areas, which led to the notification of several significant events.

More generally, the majority of event notifications were made further to an ASN inspection, which tends to show that the deviation detection and analysis process, particularly concerning the results of inspections and periodic tests, is not robust.

The cell clean-out operations will continue in 2016.

The level of subcontracting is particularly high on this BNI. Control of the operations performed by outside contractors is an important issue. In this context and in view of observed deviations, ASN considers that CEA must not simply question the organisation and resources of these contractors, but also question its own organisation and means deployed to control the services of its subcontractors.

Ulysse reactor

Ulysse was the first French university reactor. The facility has been definitively shut down since February 2007. The facility has had no fuel since 2008. The final shutdown and decommissioning authorisation decree for the BNI was published on 18th August 2014 and provides for a five-year decommissioning period.

BNI 18 is an installation whose decommissioning has just started and for which the risks with regard to safety are limited.

The installation is ageing and modifications have been introduced to allow its future decommissioning (appropriate ventilation, specific electrical switchboard, procurement of gantry, etc.). Unnecessary items have been removed (batteries, documentation, etc.). In 2015, CEA prepared the installation for decommissioning by arranging the external areas, receiving the ventilation unit and dismantling and removing the control room.

The decommissioning operations will start in 2016. The level of subcontracting will be particularly high on this BNI. ASN will be attentive to the control of operations performed by outside contractors.

2.2.5 The Marcoule centre installations undergoing decommissioning

The Phénix reactor

The Phénix reactor, built and operated by CEA, is a sodium-cooled fast neutron reactor demonstrator. It was definitively shut down in 2009. The decommissioning authorisation application file was submitted in December 2011. Within the framework of the examination of this decommissioning application, CEA also anticipated the plant's next periodic safety review by submitting its file to ASN at the end of 2012.

The Advisory Committee of Experts for Laboratories and Plants (GPU) met on 12th November 2014 and issued a favourable opinion on the continued operation of the installation with a view to its decommissioning, on the performance of the final shutdown and decommissioning operations, and on the treatment of the sodium and objects containing sodium from the Phénix power plant. ASN sent its conclusions on the technical examination and the consultations to the Minister responsible for Nuclear Safety and issued its opinion on 22nd December 2015.

Preparatory operations for the decommissioning of the Phénix power plant continued in 2015 and essentially involved unloading the fuel storage tank and the vessel, preparing carbonation of the residual films of sodium from the secondary systems, and fitting out the future premises or units necessary for the decommissioning work (NOAH worksite, etc.). CEA nevertheless encountered difficulties during unloading of the fuel storage tanks and the vessel due to problems linked to the ageing of certain items of equipment in the shielded cells for treating irradiated assemblies and experimental objects.

The inspections in 2015 focused on occupational radiation protection, waste management, monitoring outside contractors, operational control of the facilities and compliance with operating documents. Moreover, shortcomings in the monitoring of outside contractors were noted during an inspection conducted jointly with ASND concerning a consignment of waste containers transported between the nuclear power plant and the storage facility of the Marcoule SBNI.

2.3 Areva installations

The situation of the UP2-400 complex is described in chapter 13. This complex comprises the former spent fuel reprocessing plant UP2-400 (BNI 33) and the associated units, shut down since 2004, namely the Effluent Treatment Plant STE2A (BNI 38), the Oxide High Activity Facility HAO (BNI 80), and the ELAN IIB installation (BNI 47), which manufactured caesium-137 and strontium-90 sources until 1973.

Extraction in fume cupboard of a primary component on the CEA Marcoule Phénix installation, April 2009.

2.3.1 The UP2-400 spent fuel reprocessing plant and associated facilities

The HAO (High Activity Oxide) facility (BNI 80)

BNI 80 ensured the first stages of the reprocessing of spent oxide nuclear fuels: reception, storage then shearing and dissolution. The dissolution solutions produced in BNI 80 were then transferred to the UP2-400 industrial plant in which the subsequent reprocessing operations took place.

UNDERSTAND

Decommissioning of the Phénix NPP

CEA plans completing decommissioning of the Phénix NPP by 2045 at the latest. These operations involve the following stages:

- continuation of removal of the fuel elements and various removable components from the reactor core, then transfer of the fuels to the La Hague plant;
- elimination of the sodium risks by treating the sodium and objects having been in contact with this metal: this treatment will necessitate the construction of new units and two new buildings (NOAH and ELA) within the perimeter of BNI 71;
- dismantling of some of the reactor block structures (activated structures present in the reactor vessel), of the reactor vessel and the fuel storage tank, the shielded cells, etc.;
- dismantling of the workshops created for the decommissioning of the NPP and dismantling of the NOAH and ELA buildings;
- cleaning out of the civil engineering structures that CEA wants to keep once decommissioning is completed.

The availability of the NOAH and ELA infrastructures led CEA to also request authorisation to treat - jointly with the sodium-containing waste and the sodium from the Phénix NPP - sodium-containing waste and batches of «legacy» sodium from other CEA facilities (SURA facilities, an experimental loop of CABRI, Rapsodie, LECA, and ICPEs situated at Cadarache).

The major safety issues identified in the decommissioning of the Phénix NPP are:

- control of the criticality associated with the reactivity of the fuel elements during the period when fissile material is present in the installation and during the assembly handling and treatment phases, in the irradiated elements cell for example;
- the risks associated with sodium, as sodium reacts violently with the oxygen in air and with water. The risk is therefore present right through to the end of sodium treatment;
- management of the radioactive waste resulting from the decommissioning and clean-out operations;
- control and limitation of gaseous and liquid effluent discharges associated with the sodium treatment operations.

Safety functions enable these risks to be drastically reduced, thanks in particular to control of the reactivity, to the containment of the radioactive substances, and by maintaining the primary sodium in the reactor vessel in the liquid phase. Numerous commitments from the licensee should also help minimise these risks.

BNI 80 comprises five facilities:
- HAO North, fuel unloading and storage site;
- HAO South, in which the shearing and dissolution operations were carried out;
- the filtration building, which accommodates the filtration system for the pool of the HAO South facility;
- The HAO silo, in which are stored the hulls and end-pieces in bulk, fines coming essentially from shearing, resins and technological waste resulting from operation of the HAO facility from 1976 to 1997;
- the SOC (Organised Storage of Hulls) comprising three pools in which the drums containing the hulls and end-pieces are stored.

The decommissioning of the HAO was authorised by Decree of 31st July 2009. The first stage in the work which aims at carrying out the majority of the HAO South facility decommissioning operations is in progress. The HAO North facility, which is still in operation, will be decommissioned in a second phase.

The Waste Retrieval and Packaging (RCD) project currently under way in the HAO silo and the SOC represents the first hold point in the decommissioning of the installation. The civil engineering works concerning the construction of the waste retrieval and packaging unit authorised by resolution of 10th June 2014 continued in 2015. The licensee also put in place a seal between the R1 unit situated in BNI 117 and the retrieval unit.

ASN is moreover vigilant with regard to the implementation times for these operations, which must be completed before 31st December 2022.

Furthermore, BNI 80 formed the subject of a periodic safety review, the examination of which will be finalised in 2016.

BNIs 33 and 38

In October 2008, Areva NC submitted three final shutdown and decommissioning authorisation applications for BNI 33 (UP2-400), BNI 38 (STE2 and AT1 facility) and BNI 47 (ELAN IIB).

On completion of the technical examination of the files submitted in 2008, ASN considered that the measures defined by Areva NC for the decommissioning of BNIs 33 and 38 showed nothing unacceptable with regard to safety, radiation protection or waste and effluent management. Nevertheless, this examination did reveal the necessity for the licensee to provide a large number of additional studies. Consequently, only those operations for which the information in the safety cases was considered sufficient could be authorised for BNIs 33 and 38.

The three decrees authorising the start of the final shutdown and decommissioning operations for the three BNIs date from 8th November 2013. The decrees concerning BNIs 33 and 38 only authorise partial decommissioning, whereas the decree concerning BNI 47 authorises complete decommissioning of the installation.

The decrees for BNIs 33 and 38 required the licensee to submit new files before 30th June 2015. The licensee therefore submitted new complete decommissioning application files for BNIs 33 and 38 in July 2015. It also submitted the periodic safety review files for BNIs 33, 38 and 47. Concomitant examination of the periodic safety review files and the decommissioning files will allow the compatibility of the ageing control measures with the decommissioning strategy envisaged by the licensee – particularly the projected duration of the decommissioning project as a whole – to be checked.

The operations carried out in 2015 essentially concern the retrieval of the waste from the dissolvers in the High Activity / Dissolution Extraction (HA/DE) facility, continued removal of the glove boxes from the Intermediate-level Plutonium Facility (MAPu), oxalic acid rinsing of the High-Level Fission Products (HAPF) facility and conducting various investigations and radiological mappings.

UNDERSTAND

The legacy waste of La Hague

The legacy waste to be retrieved and packaged on the La Hague site comes from the reprocessing of spent fuel from the gas-cooled reactors and the first spent fuels from the light water reactors in the UP2-400 industrial plant between 1966 and 2004. This waste, which is primarily Intermediate Level Long-Lived Waste (ILW-LL), essentially comprises graphite sleeves, hulls and end-pieces, insoluble fines, saturated resins, magnesium waste, waste contaminated with uranium and plutonium, active effluent treatment sludge, solvents and solutions of uranium-molybdenum fission products (PF UMo). Today this waste is stored in several old-generation facilities displaying varying levels of safety, but which are unsatisfactory on account of their layout (buried or semi-buried), their design (containment barriers), their earthquake design basis and the nature of the waste stored in them. The waste must thus be retrieved from the storage facilities using the retrieval equipment planned for when these facilities were designed, or using equipment to be designed if these facilities do not have any. Once retrieved, the waste must be packaged with a view to final disposal. Retrieval of this waste will also clear the facilities of their waste allowing them to be decommissioned and cleaned out in the context of the UP2-400 industrial plant (BNI 33, 38, 47 and 80) decommissioning operations.

ASN resolution of 9th December 2014 governs the retrieval of this waste.

2.3.2 Comurhex plant in Pierrelatte

Operated by Areva NC, this plant mainly produced uranium hexafluoride (UF_6) for the fabrication of nuclear fuel. Alongside this main activity, the Comurhex plant produced various fluorinated products such as chlorine trifluoride.

The production of UF_6 from natural uranium was carried out in a part of the plant subject to ICPE regulations, while the production of UF_6 from reprocessed uranium was carried out in a part of the plant constituting a BNI. This part, BNI 105, which was definitively shut down in 2008, essentially comprises two units:
- the 2000 unit, which transformed reprocessed uranyl nitrate $UO_2(NO_3)_2$ into uranium tetrafluoride (UF_4) or uranium sesquioxide (U_3O_8);
- the 2450 unit, which transformed the UF_4 from the 2000 unit into UF_6. This UF_6 was intended to enrich the reprocessed uranium for the manufacture of fuel.

In May 2011 the BNI 105 licensee had submitted a first final shutdown and decommissioning application file which had been judged incomplete.

In February 2014 Areva NC submitted a new final shutdown and decommissioning authorisation application. Following the licensee's responses to the requests for additional information necessary for the file, further requests were transmitted to Areva NC relative to the soil remediation strategy in particular.

2.3.3 Eurodif plant at Tricastin

The Eurodif Production facility, licensed in 1977, mainly consisted of a plant for separation of the isotopes of uranium using the gaseous diffusion process, with a nominal annual capacity of 10.8 million separative work units.

Following stoppage of its production in May 2012, Eurodif Production was authorised in May 2013 to implement the operations of the Eurodif project for intensive rinsing followed by venting "Prisme"), which consisted in repeatedly rinsing the gaseous distribution circuits with chlorine trifluoride (ClF_3), a toxic and hazardous substance which allows the extraction of virtually all the residual uranium deposited in the barriers.

In accordance with the Decree of 24th May 2013, the licensee filed its final shutdown and decommissioning application for the installation in March 2015. Examination of its admissibility revealed that further information was required before the examination could

Areva NC, Tricastin site, Comurhex and Comurhex 2 plants.

proceed. These clarification requests concern general aspects in the decommissioning strategy adopted by Eurodif Production, more particularly in the management of radioactive waste and the description of the initial and final states of the installation.

The last rinsing operations were completed in October 2015 under what ASN considers to be satisfactory conditions, apart from the end-of-soaking criteria actually used, which differ from those specified in the safety baseline requirements, which must be taken into account if necessary in the decommissioning input data. Since these operations were completed there is no chlorine trifluoride (ClF_3) in the facility.

Due to technical difficulties, particularly concerning the qualification of new equipment items, the operations to pressurise the cascade with air did not start until 2015 and will continue until mid-2016.

ASN moreover authorised the operations to pressurise the DRP unit with air and the final shutdown of the units of annex U for treating substances extracted from the diffusion cascade. It is currently examining the rinsing authorisation application for the annex U systems. After completion of all these operations, which will have eliminated the majority of the source term, the plant will be in a surveillance phase until the first decommissioning operations are started.

ASN will ensure that in 2016 the last operations of the Prisme project are carried out in strict compliance with the authorisations it has delivered.

2.3.4 SICN plant in Veurey-Voroize

The former nuclear fuel fabrication plant of Veurey-Voroize, operated by the *Société Industrielle de Combustible Nucléaire* (SICN - Areva Group) consists of two nuclear facilities, BNIs 65 and 90. Fuel fabrication activities were definitively stopped in the early 2000's. The Decrees authorising the decommissioning operations date from 15th February 2006. The decommissioning work has now been completed.

The site nevertheless displays residual contamination of the soil and groundwater, the impact of which is acceptable for its envisaged future use (industrial). ASN has therefore asked the licensee to submit, as a prerequisite to delicensing, an application for the implementation of active institutional controls designed to restrict the use of the soil and groundwater and to guarantee that the land usage remains compatible with the state of the site. SICN submitted this file to the Isère *département* Prefecture in March 2014, and the delicensing application file for the two BNIs to ASN. Delicensing will not be able to be declared until these active institutional controls have been effectively put in place by the Prefect of the Isère *département*, at the end of the examination procedure which includes a public inquiry.

Performance of intensive rinsing operations - Monitoring of Eurodif venting (Prisme). Eurodif plant decommissioning worksite on Areva NC's Tricastin site.

2.4 Other installations

The Electromagnetic Radiation Laboratory (LURE)

The LURE, situated in the heart of the Orsay campus, was an installation producing synchrotron radiation (high-power X-rays) for a wide variety of research applications. It comprised six particle accelerators. CNRS (French National Centre for Scientific Research), the LURE licensee, was authorised to proceed with final shutdown and decommissioning by Decree on 14th April 2009.

The decommissioning operations were completed in 2010. As provided for by the above-mentioned decree, the CLIO and PHIL accelerators are kept in activity; moreover, two areas with residual activity linked to the presence of the electron converters subsist. The cleaning out of these areas required the destruction of part of the civil engineering calling into question the mechanical strength of the building as a whole, therefore during the examination it had been planned to put biological protections in place.

The licensee submitted its decommissioning file in spring 2011. Delicensing of the LURE waste zoning, except for the area with residual activity, was declared in 2012. The LURE BNI 106 was delicensed by resolution of 27th October 2015. The Prefect of the Essonne *département* issued an order introducing active institutional controls on 1st October 2015.

3. OUTLOOK

The main actions ASN will carry out in 2016 will firstly concern continuation of the development of the regulatory framework for decommissioning, and secondly close monitoring of certain installations.

ASN thus plans to:
- assist the Ministry of the Environment, Energy and the Sea by finalising the modifications to the Order of 2nd November 2007 made necessary by new legislative provisions relative to decommissioning;
- supplement and finalise the series of guides relative to the decommissioning procedure, the clean-out of structures and the remediation of soils in BNIs by updating Guide No.6, by publishing Guide No.14 and by publishing the contaminated soil management guide;
- implement actions with respect to the decommissioning strategy of EDF and more particularly the decommissioning of the gas-cooled reactors;
- start examining the decommissioning strategies of Areva and CEA;
- complete the examination of the LAMA delicensing application;
- continue examining the decommissioning files for the AMI (Chinon), Comurhex and Eurodif (Tricastin), UP2-400 and STE2 (La Hague), ATUE and Rapsodie (Cadarache), and the Procédé BNI and Support BNIs (Fontenay-aux-Roses);
- start examining the decommissioning files for the solid radioactive waste management area (Saclay);
- examine the periodic safety review files Superphénix and APEC.

APPENDIX 1

LIST of Basic Nuclear Installations delicensed and undergoing decommissioning as at 31st December 2015

INSTALLATION LOCATION	BNI	TYPE OF INSTALLATION	COMMISSIONED	FINAL SHUTDOWN	LAST REGULATORY ACTS	CURRENT STATUS
IDE Fontenay-aux-Roses (FAR)	(former BNI 10)	Reactor (500 kWth)	1960	1981	1987: removed from BNI list	Decommissioned
Triton FAR	(former BNI 10)	Reactor (6,5 MWth)	1959	1982	1987: removed from BNI list and classified as ICPE	Decommissioned
ZOÉ FAR	(former BNI 11)	Reactor (250 kWth)	1948	1975	1978: removed from BNI list and classified as ICPE	Confined (museum)
Minerve FAR	(former BNI 12)	Reactor (0,1 kWth)	1959	1976	1977: removed from BNI list	Dismantled at FAR and reassembled at Cadarache
EL2 Saclay	(former BNI 13)	Reactor (2,8 MWth)	1952	1965	Removed from BNI list	Partially decommissioned, remaining parts confined
EL3 Saclay	(former BNI 14)	Reactor (18 MWth)	1957	1979	1988: removed from BNI list and classified as ICPE	Partially decommissioned, remaining parts confined
Peggy Cadarache	(former BNI 23)	Reactor (1 kWth)	1961	1975	1976: removed from BNI list	Decommissioned
César Cadarache	(former BNI 26)	Reactor (10 kWth)	1964	1974	1978: removed from BNI list	Decommissioned
Marius Cadarache	(former BNI 27)	Reactor (0,4 kWth)	1960 at Marcoule, 1964 at Cadarache	1983	1987: removed from BNI list	Decommissioned
Le Bouchet	(former BNI 30)	Ore processing	1953	1970	Removed from BNI list	Decommissioned
Gueugnon	(former BNI 31)	Ore processing	1965	1980	Removed from BNI list	Decommissioned
STED FAR	BNI 34	Processing of liquids and solid waste	Before 1964	2006	2006: removed from BNI list	Integrated into BNI 166
Harmonie Cadarache	(former BNI 41)	Reactor (1 kWth)	1965	1996	2009: removed from BNI list	Destruction of the ancillaries building
ALS	(former BNI 43)	Accelerator	1958	1996	2006: removed from BNI list	Cleaned out institutional controls (**)
Saturne	(former BNI 48)	Accelerator	1966	1997	2005: removed from BNI list	Cleaned out institutional controls (**)
Attila* FAR	(former BNI 57)	Reprocessing pilot	1968	1975	2006: removed from BNI list	Integrated into BNIs 165 and 166
LCPu FAR	(former BNI 57)	Plutonium chemistry laboratory	1966	1995	2006: removed from BNI list	Integrated into BNIs 165 and 166
BAT 19 FAR	(former BNI 58)	Plutonium metallurgy	1968	1984	1984: removed from BNI list	Decommissioned
RM2 FAR	(former BNI 59)	Radio-metallurgy	1968	1982	2006: removed from BNI list	Integrated into BNIs 165 and 166
LCAC Grenoble	(former BNI 60)	Fuel analysis	1975	1984	1997: removed from BNI list	Decommissioned
STEDs FAR	(former BNI 73)	Radioactive waste decay storage	1989		2006: removed from BNI list	Integrated into BNI 166
ARAC Saclay	(former BNI 81)	Fabrication of fuel assemblies	1981	1995	1999: removed from BNI list	Cleaned-out
IRCA	(former BNI 121)	Irradiator	1983	1996	2006: removed from BNI list	Cleaned out institutional controls (**)
FBFC Pierrelatte	(former BNI 131)	Fuel fabrication	1990	1998	2003 : removed from BNI list	Cleaned out institutional controls (**)
SNCS Osmanville	(former BNI 152)	Ioniser	1983	1995	2002: removed from BNI list	Cleaned out institutional controls (**)

APPENDIX 1

LIST of Basic Nuclear Installations delicensed and undergoing decommissioning as at 31st December 2015

INSTALLATION LOCATION	BNI	TYPE OF INSTALLATION	COMMISSIONED	FINAL SHUTDOWN	LAST REGULATORY ACTS	CURRENT STATUS
Miramas uranium warehouse	(former BNI 134)	Uranium bearing materials warehouse	1964	2004	2007: removed from BNI list	Cleaned out institutional controls (**)
Siloette Grenoble	(former BNI 21)	Reactor (100 kWth)	1964	2002	2007: removed from BNI list	Cleaned out institutional controls (**)
Mélusine Grenoble	(former BNI 19)	Reactor (8 MWth)	1958	1988	2011: removed from BNI list	Cleaned-out
Strasbourg university reactor	(former BNI 44)	Reactor (100 kWth)	1967	1997	2012: removed from BNI list	Cleaned out institutional controls (**)
Siloé Grenoble	(former BNI 20)	Reactor (35 MWth)	1963	2005	2015: removed from BNI list	Cleaned out institutional controls (**)
Chooz AD (formerly-Chooz A)	163 (former BNIs 1, 2, 3)	Reactor (1,040 MWth)	1967	1991	2007: amendment of the MAD-DEM decree	Decommissioning in process
Chinon A1D (formerly-Chinon A1)	133 (former BNI 5)	Reactor (300 MWth)	1963	1973	1982: Chinon A1 confinement decree and creation of the Chinon A1 D storage BNIi	Partially decommissioned, remaining parts confined integrated in BNI. Decommissioning file to submit
Chinon A2 D (formerly-Chinon A2)	153 (former BNI 6)	Reactor (865 MWth)	1965	1985	1991: partial decommissioning decree for Chinon A2 and creation of the Chinon A2 D storage BNI	Partially decommissioned, remaining parts confined integrated in BNI. Decommissioning file to submit
Chinon A3 D (formerly-Chinon A3)	161 (former BNI 7)	Reactor (1,360 MWth)	1966	1990	2010: final shutdown and decommissioning (MAD-DEM) decree	Decommissioning in process
Rapsodie Cadarache	25	Reactor (40 MWth)	1967	1983		Preparation for decommissioning
EL4-D (formerly-EL4 Brennilis)	162 (former BNI 28)	Reactor (250 MWth)	1966	1985	1996: decree ordering decommissioning and creation of the EL-4D storage BNI 2006: amendment of the MAD-DEM decree 2007: decision of the *Conseil d'État* (state council) cancelling the 2006 decree 2011: partial decommissioning decree	Partially decommissioned, remaining parts confined integrated in BNI. Decommissioning in process decommissioning file to submit
Spent fuel reprocessing plant (UP2) La Hague	33	Transformation of radioactive substances	1964	2004	2013: partial MAD-DEM decree	Decommissioning in process
STE2 (La Hague)	38	Effluent treatment facility	1964	2004	2013: partial MAD-DEM decree	Decommissioning in process
Sted and high level waste storage unit (Grenoble)	36 et 79	Waste treatment and storage facility	1964/1972	2008	2008: partial MAD-DEM decree	Decommissioning in process
Bugey 1	45	Reactor (1,920 MWth)	1972	1994	2008: partial MAD-DEM decree	Decommissioning in process
Saint-Laurent A1	46	Reactor (1,662 MWth)	1969	1990	2010: decommissioning decree	Decommissioning in process
Saint-Laurent A2	46	Reactor (1,801 MWth)	1971	1992	2010: decommissioning decree	Decommissioning in process

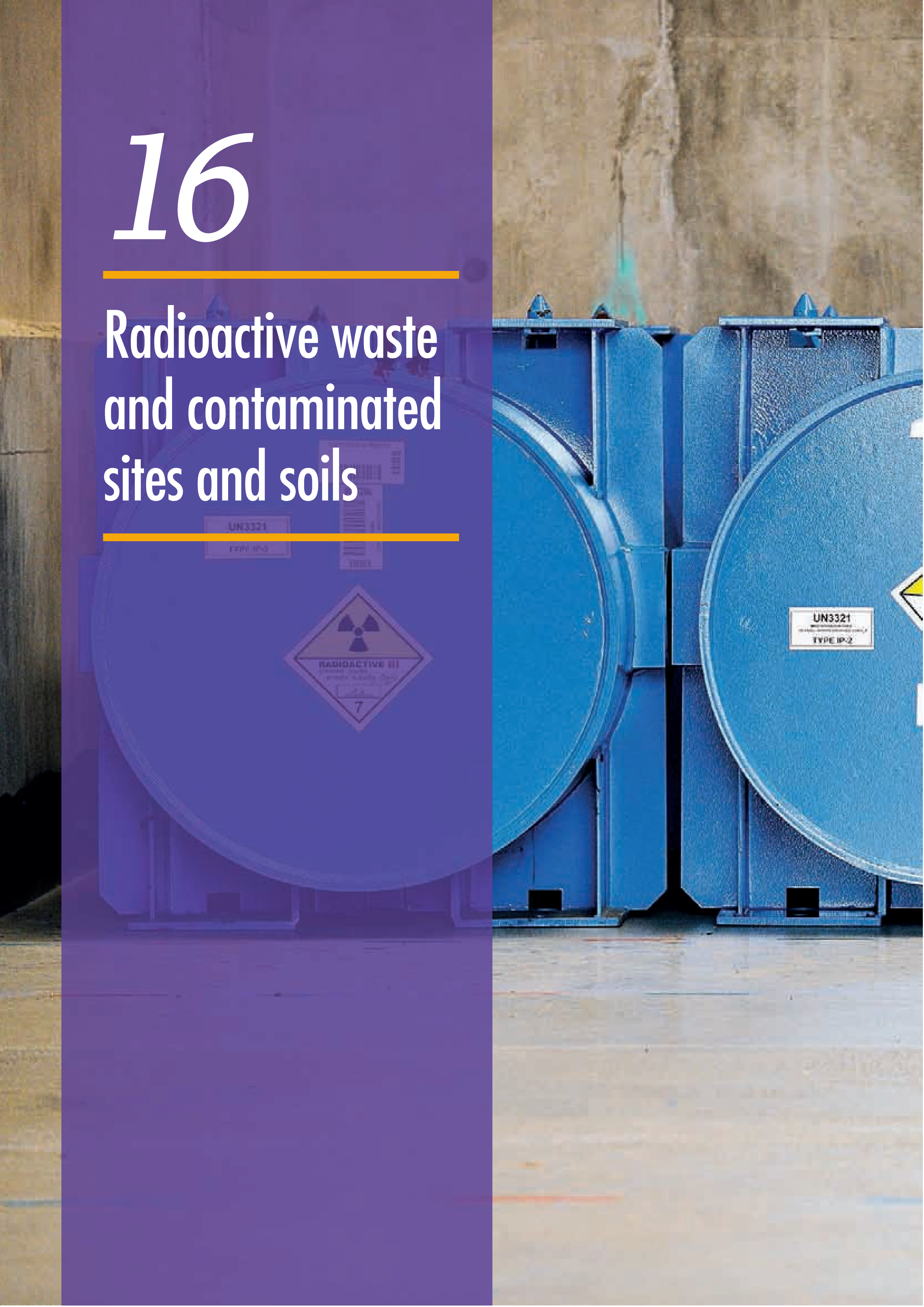
LIST of Basic Nuclear Installations delicensed and undergoing decommissioning as at 31st December 2015

INSTALLATION LOCATION	BNI	TYPE OF INSTALLATION	COMMISSIONED	FINAL SHUTDOWN	LAST REGULATORY ACTS	CURRENT STATUS
ÉLAN IIB La Hague	47	Caesium-137 source fabrication	1970	1973	2013: decommissioning decree	Decommissioning in process
High Activity Laboratory (LHA) Saclay	49	Laboratory	1960	1996	2008: final shutdown and decommissioning (MAD-DEM) decree	Decommissioning in process
ATUE Cadarache	52	Uranium processing	1963	1997	2006: final shutdown and decommissioning (MAD-DEM) decree	Decommissioning in process
LAMA Grenoble	61	Laboratory	1968	2002	2008: final shutdown and decommissioning (MAD-DEM) decree	Delicensing in process
SICN Veurey-Voroize	65 et 90	Fuel fabrication plant	1963	2000	2006: final shutdown and decommissioning (MAD-DEM) decree	Delicensing in process
HAO (High Level Oxide) Facility (La Hague)	80	Transformation of radioactive substances	1974	2004	2009: final shutdown and decommissioning (MAD-DEM) decree	Decommissioning in process
ATPu Cadarache	32	Fuel fabrication plant	1962	2003	2009: final shutdown and decommissioning (MAD-DEM) decree	Decommissioning in process
LPC Cadarache	54	Laboratory	1966	2003	2009: final shutdown and decommissioning (MAD-DEM) decree	Decommissioning in process
Superphénix Creys-Malville	91	Reactor (3,000 MWth)	1985	1997	2009: final shutdown and decommissioning (MAD-DEM) decree	Decommissioning in process
Comurhex Tricastin	105	Uranium chemical transformation plant	1979	2009		Preparation for final shutdown
LURE	(former BNI 106)	Particle accelerators	From 1956 to 1987	2008	2015: removed from BNI list	Cleaned out AIC(***)
Procédé FAR	165	Grouping of former process installations	2006		2006: final shutdown and decommissioning (MAD-DEM) decree	Decommissioning in process
Support FAR	166	Waste packaging and processing	2006		2006: final shutdown and decommissioning (MAD-DEM) decree	Decommissioning in process
Ulysse Saclay	18	Reactor (100 kW)	1967	2007	2014: final shutdown and decommissioning (MAD-DEM) decree	Decommissioning in process
Phénix Marcoule	71	Reactor (536 MWth)	1973	2009		Preparation for decommissioning

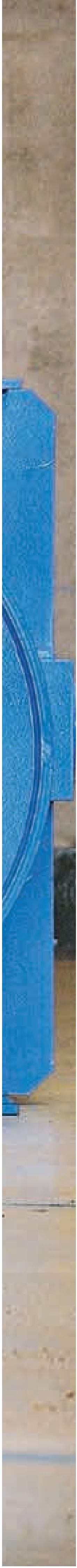
** Attila: reprocessing pilot located in a unit of BNI 57.*
*** Institutional controls.*
**** Active institutional controls.*

16

Radioactive waste and contaminated sites and soils




RADIOACTIVE III
7



This chapter presents the role and actions of ASN in the management of waste generated by activities involving radioactive substances and the management of sites contaminated by radioactive substances. It describes in particular the steps taken to define and determine the main radioactive waste management orientations and the controls carried out by ASN with respect to nuclear safety and radiation protection in facilities involved in the management of radioactive waste.

The term radioactive waste implies radioactive substances for which no subsequent use is planned or envisaged. These substances can come from both nuclear activities and non-nuclear activities in which the radioactivity naturally contained in substances, which are not used for their radioactive properties, may have been concentrated by the processes employed.

A site contaminated by radioactive substances is any site, either abandoned or in operation, on which natural or artificial radioactive substances have been or are employed or stored in conditions such that the site can constitute a hazard for health and the environment. Contamination by radioactive substances can be the result of industrial, medical or research activities.

A highlight of 2015 was the development of the 2016-2018 French National Radioactive Material and Waste Management Plan (PNGMDR). This three-year plan reviews the situation of the radioactive substance management policy in France, lists the new needs and determines the objectives, particularly in terms of studies and research for creating new management routes.

2015 also saw regulatory changes in the framework applicable to the operational management of radioactive waste in the facilities. The ASN resolution relative to the waste management study and the assessment of the waste produced in the Basic Nuclear Installations (BNI), indicating the provisions of the Order of 7th February 2012 setting the general rules relative to BNIs, was signed by the ASN Commission on 21st April 2015 and approved by the Minister responsible for Nuclear Safety. The public consultation for its application guide and that for the ASN resolution relative to the packaging of radioactive waste and acceptance of radioactive waste packages in repository BNIs also took place in 2015.

1. RADIOACTIVE WASTE

Nuclear activities produce waste which must be managed in accordance with specific and stringent conditions. Pursuant to the provisions of the Environment Code, the producers of spent fuel and radioactive waste are responsible for these substances, without prejudice to the liability of those who hold these substances in their role as persons or entities responsible for nuclear activities. Moreover, waste producers must pursue the objective of minimising the volume and harmfulness of their waste, both before production by appropriate design and operation of the facilities and after production, by appropriate sorting, treatment and packaging.

The different forms of radioactive waste differ widely in their radioactivity (specific activity, nature of the radiation, half-life) and their physical and chemical form (scrap metal, rubble, oils, etc.).

Two principal parameters can be used to assess the radiological risk that radioactive waste represents: firstly the activity, which contributes to the toxicity of the waste, and secondly the half-life of the radionuclides present in the waste which determines the required waste containment time. A distinction is therefore made between very low, low, intermediate and high level waste, on the one hand, and on the other very short-lived waste (whose activity level is halved in less than 100 days) resulting mainly from medical activities, short-lived waste (chiefly containing radionuclides whose activity level is halved in less than 31 years) and long-lived waste (which contains a large quantity of radionuclides whose activity level is halved in more than 31 years).

Each type of waste requires the implementation of an appropriate and safe management solution in order to control the risks it represents, particularly the radiological risk.

1.1 Radioactive waste management regulatory framework

Radioactive waste management falls within the general waste management framework defined in Book V, Part IV, Chapter I of the Environment Code and its implementing Decrees. Particular provisions concerning radioactive waste were introduced first by Act 91-1381 of 30th December 1991 on research into high level, long-lived waste, and then by Planning Act 2006-739 of 28th June 2006 on sustainable management of radioactive waste, called the "Waste Act", which gives a legislative framework to management of all radioactive materials and waste (these Acts are extensively codified in Book V, Part IV, Chapter II of the Environment Code).

This Waste Act has set a new calendar for research into High and Intermediate-Level, Long-Lived (HL and IL-LL) waste and a clear legal framework for ring-fencing the funds needed for decommissioning and for the management of radioactive waste. It also provides for the drafting of the PNGMDR, which prescribes a periodic assessment and the defining of the prospects for the radioactive substance management policy. It also consolidates the missions of Andra, the French national radioactive waste management Agency. Finally, it prohibits the disposal in France of foreign waste, by providing for the adoption of rules specifying the conditions for the return of waste resulting from the reprocessing in France of spent fuel and waste from abroad.

This framework was amended in 2016 with the publication of Ordinance 2016-128 of 10th February 2016 which made it possible to:
- transpose Council Directive 2011/70/Euratom of 19th July 2011 establishing a European community framework for the responsible and safe management of spent fuel and radioactive waste;
- adapt the existing legislation to the provisions transposing this Directive without calling into question the prohibition of disposal in France of radioactive waste from abroad and of radioactive waste resulting from reprocessing spent fuels and radioactive waste from abroad provided for in Article L. 542-2 of the Environment Code, and clarify the conditions of application of this prohibition;
- define a procedure for the administrative authority to re-qualify materials as radioactive waste;
- reinforce the existing administrative and criminal penalties and provide for new penalties in the event of disregard of the provisions applicable to radioactive waste and spent fuel or in the event of a breach of the said provisions.

Among these provisions, ASN notes the importance of defining a procedure for the administrative authority to re-qualify materials as radioactive waste.

1.1.1 Production of radioactive waste in installations regulated by ASN

ASN does not regulate all the activities associated with radioactive waste management. Thus, nuclear activities associated with national defence are regulated by the ASND (Defence Nuclear Safety Authority). Furthermore, some radioactive waste management facilities that do not fulfil the conditions defined in Decree 2007-830 of 11th May 2007 relative to the BNI nomenclature can have the status of ICPE (Installations Classified on Environmental Protection grounds) in which case they are placed under the control of the Prefects, or can be licensed by ASN under the Public Health Code.

Decree 2014-996 of 2nd September 2014, which modified the nomenclature of classified installations, defines the attribution of competences with regard to the oversight of installations which manage radioactive substances. Thus the licensing of radioactive substances in sealed form (called sealed sources) is now governed solely by the Public Health Code and is therefore regulated by ASN. The licensing of radioactive substances in non-sealed form and of radioactive waste, however, is governed by the Environment Code if the volume present in the facility exceeds $10m^3$, and by the Public Health Code if it is less than $10m^3$.

Production of radioactive waste in the BNIs

In France, the management of radioactive waste in BNIs is governed in particular by the Order of 7th February 2012 setting the general rules relative to BNIs, of which Part VI concerns waste management.

A noteworthy characteristic of the French regulations is that there are no clearance levels[1]. In concrete terms, application of this doctrine leads, in BNIs, to the establishment of a waste zoning plan which identifies the zones in which the waste produced is or could be contaminated or activated. As a protective measure, the waste produced in these zones is managed as if it were radioactive and must be directed to specific routes. Waste from other parts of the installation, once confirmed as being free of radioactivity, is sent to authorised routes dedicated to the management of hazardous, non-hazardous or inert waste, depending on its properties.

1. Activity thresholds below which it would be possible to consider that very low-level waste produced in a nuclear facility could be managed in a conventional disposal route without a requirement for traceability.

The regulations also require licensees to conduct waste studies, indicating the targets with regard to prevention, reduction at source, harmfulness of the waste and the means implemented to reduce waste volumes and harmfulness through sorting and appropriate treatment and packaging.

ASN resolution 2015-DC-0508 of 21st April 2015 relative to the waste management study and the assessment of the waste produced in the BNIs details the provisions of the Order of 7th February 2012, particularly concerning:
- the content of the waste management study, which must be submitted when a BNI is commissioned and kept up to date throughout its operation;
- the procedures for drawing up and managing the waste zoning plan;
- the content of the annual waste management assessment which each installation must transmit to ASN.

A guide to the application of this resolution (Guide No. 23) will be published by ASN in 2016.

Production of radioactive waste by a nuclear activity authorised under the Public Health Code

Article R. 1333-12 of Public Health Code states that the management of effluents and waste contaminated by radioactive substances originating from all nuclear activities related to medicine, human biology, or biomedical research that involve a risk of exposure to ionising radiation must be examined and approved by the public authorities. ASN resolution 2008-DC-0095 of 29th January 2008 lays out the technical rules that the disposal of effluents and waste contaminated or potentially contaminated by radionuclides owing to a nuclear activity must satisfy. ASN published a guide (Guide No. 18) to the application of this resolution in January 2012.

1.1.2 The national inventory of radioactive materials and waste

Article L. 542-12 of the Environment Code assigns Andra the duty of *"establishing, updating every three years and publishing the inventory of radioactive materials and waste present France, along with their location on the national territory"*.

The last issue of the national inventory of radioactive materials and waste was published in June 2015. It presents in particular information relative to the quantities, the nature and the location of the radioactive materials and waste at the end of 2013 and projections for the end of 2020 and the end of 2030. A prospective exercise was also conducted considering two contrasting scenarios for France's long-term energy policy. This inventory is a source of information for the PNGMDR.

ASN was on the steering committee that supervised the exercise.

1.1.3 The French National Plan for the Management of Radioactive Materials and Waste

Article L.542-1-2 of the Environment Code requires the production of the French National Plan for the Management of Radioactive Materials and Waste (PNGMDR), which is revised every three years and serves to *"review the existing management procedures for radioactive materials and waste, to identify the foreseeable needs for storage and disposal facilities, specify the necessary capacity of these facilities and the storage durations and, for radioactive waste for which there is as yet no final management solution, to determine the objectives to be met"*. The main provisions of the plan are then set by Decree.

TO BE NOTED

ASN's opinion on the reusability of radioactive materials

As part of the PNGMDR, at the end of 2014 the owners of radioactive materials submitted a report presenting their update of the envisaged reuse processes, with their analysis of the match between the prospects for reuse and the quantities held or to be held. ASN issued an opinion on the reusability of radioactive materials on 9th February 2016, in line with its opinion of 6th February 2014.

ASN considers that the recyclable nature of a radioactive material depends on the control of the reuse process, the industrial strategies of the owners, the foreseeable technical-economic and socio-political conditions, the balance between the quantities held, their production flow and the projected consumption flows. ASN also considers that the conditions for reusing a substance cannot always be identical, and will depend on its content, speciation, isotopy or association with other substances, and that the assessment of reuse possibilities must take into account interdependencies with other radioactive substances. To assess this last criterion, ASN considers it necessary that the prospective scenarios for future issues of the national inventory of radioactive materials and waste be further developed to take into account the objectives of the Energy Transition for Green Growth Act.

On the basis of the abovementioned criteria, ASN asks that additional justifications be provided for certain substances, including depleted uranium, recycled uranium from spent fuel reprocessing, plutonium, spent fuels from research reactors and thorium. ASN also considers that the quantities of depleted uranium held or resulting from the held stock which cannot be used in the current fleet of thermal-neutron reactors should be re-qualified as radioactive waste as a protective measure in order to ring-fence the financing of their long-term management.

TO BE NOTED

The PNGMDR

The French National Plan for the Management of Radioactive Materials and Waste (PNGMDR) constitutes an ideal tool for ensuring rigorous and sustainable management of radioactive waste within the framework set by the Environment Code and the Act of 28th June 2006 relative to the sustainable management of materials and radioactive waste. The PNGMDR, which must be updated every three years, assesses the situation of the management policy for radioactive substances on French territory, lists the new requirements and determines the objectives, particularly with regard to studies and research to develop new management routes. The strength of the PNGMDR lies in its comprehensiveness: it concerns at once the ultimate waste and the reusable radioactive materials, the existing management routes and those that are planned, under development or to be defined; it also concerns all categories of radioactive waste, whatever their origin.

Its validity was confirmed at European level by the adoption on 19th July 2011 of Council Directive 2011/70/Euratom establishing a community framework for the responsible and safe management of spent fuel and radioactive waste.

Each edition of the PNGMDR is produced on the basis of discussions held within the pluralistic working group, co-chaired by ASN and representatives of the Ministry responsible for Energy, chiefly comprising environmental protection associations, experts, representatives of local information committees and oversight authorities, industrial players and producers and managers of radioactive waste. This working group has held 52 meetings since 2003.

The main recommendations of the PNGMDR and the milestones and time frames with regard to the management of radioactive materials and waste are taken up as prescriptions in a Ministerial Decree on which ASN issues a formal opinion. With a view to fully informing the public, all the documents drawn up on account of the PNGMDR (Plan, ASN opinions, studies submitted, minutes of the working group's discussions, etc.) are made public on the websites of ASN and of the Ministry responsible for Energy.

In application of Article L. 122-4 of the Environment Code, the analysis of the environmental impacts of the PNGMDR is now the subject of an environmental report drawn up concomitantly with this plan. The report will be submitted to the environmental authority[2] for its opinion, along with the draft PNGMDR, in the first half of 2016.

The last plan published covers the 2013-2015 period. Decree No.2013-1304 of 27th December 2013 sets out the corresponding prescriptions. It is to be succeeded by the 2016-2018 Plan, the formal adoption of which is planned in 2016 after consulting the environmental authority and the public.

With a view to establishing the PNGMDR 2016-2018, ASN issued seven opinions to the Government on various subjects relating to the management of radioactive materials and waste:
- evaluation of the reusable nature of radioactive materials;
- management of temporary or legacy situations;
- management of Very Low-Level (VLL) and Low- and Intermediate-Level, Short-Lived Waste (LL/ILW-SL);
- management of radioactive waste that requires specific work;
- evaluation of the impact of uranium mine tailings and management of former uranium mining sites ;
- management of Low-Level, Long-Lived Waste (LLW-LL);
- management of High and Intermediate-Level, Long-Lived Waste (HL/ILW-LL).

2. It is the CGEDD (French Departmental Council for the Environment and Sustainable Development).

1.2 ASN's role in the radioactive waste management system

The public authorities, and ASN in particular, are attentive to the fact that there must be an operational management route for all radioactive waste and that each step of waste management is carried out under safe conditions. ASN thus considers that the development of management routes appropriate to each waste category is of vital importance and that any delay in the search for long-term waste disposal solutions will increase the volume and size of the storage areas in the facilities and the inherent risks. ASN takes care, particularly within the framework of the PNGMDR but also by regularly assessing the licensees' waste management strategy, to ensure that the system made up by all these routes is optimised through an overall and coherent approach to management. This approach must take into account all the safety, radiation protection, traceability and waste volume minimisation issues.

Finally, ASN considers that this management approach must be conducted in a manner that is transparent for the public and involves all the stakeholders. The PNGMDR is thus developed within a pluralistic working group co-chaired by ASN and the General Directorate for Energy and Climate (DGEC) as described in chapter 2. ASN also publishes the PNGMDR, its synthesis, the minutes of the abovementioned working group's meetings, the studies required by the PNGMDR and the associated ASN opinions on its website.

1.2.1 Oversight of the BNIs

With regard to radioactive waste management, ASN's oversight and inspection activities aim at verifying on the one hand correct application of the waste management regulations on the production sites and on the other hand the safety of the facilities dedicated to radioactive waste management (waste reprocessing, packaging, storage and disposal facilities).

These activities are described in this chapter as well as in chapters 8 and 13.

1.2.2 Oversight of the packaging of waste packages

Regulations

The Order of 7th February 2012 defines the requirements associated with waste packaging. Producers of radioactive waste are instructed to package their waste taking into account the requirements associated with their subsequent management, and more particularly their acceptance at the disposal facilities.

ASN has written a draft resolution specifying the requirements regarding waste packaging for disposal and the conditions of acceptance of waste packages in the disposal BNIs. This text was made available for consultation by the stakeholders and the public in 2015. It will be signed by the ASN Commission in 2016.

Production of waste packages intended for existing disposal facilities

The waste package producers prepare an approval application file based on the acceptance specifications of the disposal facility that is to receive the packages. Andra delivers an approval formalising its agreement on the package manufacturing process and the quality of the packages. Andra verifies the conformity of the packages with the delivered approvals by means of audits and monitoring actions on the package producers' premises and on the packages received at its facilities.

Waste packages intended for projected disposal facilities

With regard to disposal facilities currently being studied, the waste acceptance specifications have of course not yet been defined. Andra therefore cannot issue approvals to govern the production of packages for LLW-LL (Low-Level, Long-Lived Waste), HLW (High-Level Waste) or ILW-LL (Intermediate-Level, Long-Lived Waste) waste.

Consequently, the production of waste packages for a disposal facility currently being studied is subject to ASN authorisation on the basis of a file called "packaging baseline requirement". This file must demonstrate that the packages display no unacceptable behaviour under the disposal conditions on the basis of existing knowledge and the currently known requirements of the disposal facilities being studied.

This provision also avoids delaying waste retrieval and packaging operations.

Checks and inspections

Alongside Andra's surveillance of approved packages, ASN checks that the licensee correctly applies the requirements of the approval and has a satisfactory command of the packaging processes. For waste packages intended for disposal facilities still being studied, ASN applies particular vigilance to ensuring that the packages comply with the conditions of the issued authorisations.

ASN also ensures through inspections that Andra takes adequate steps to verify the quality of the packages accepted in its disposal facilities. This is because ASN considers that Andra's role in the approvals issuing process and in monitoring the waste package producers is vital in guaranteeing the package quality necessary to comply with the safety case of the waste repositories.

1.2.3 Drafting recommendations for sustainable waste management

ASN issues opinions on the studies submitted in application of the Decree setting the requirements of the PNGMDR. ASN can also give the Government its recommendations concerning the disposal projects for long-lived radioactive waste.

1.2.4 Developing the regulatory framework and issuing prescriptions to the licensees

ASN can issue statutory resolutions. Thus, the provisions of the Order of 7th February 2012 defining the general regulations applicable to BNIs concerning the management of radioactive waste have been applied in ASN resolutions on the subjects of waste management in BNIs and the packing of waste. Other ASN resolutions may detail, among other things, the prescriptions applicable to the storage of radioactive waste and to the facilities intended for its disposal.

Lastly, ASN is consulted for its opinion on draft regulatory texts relative to radioactive waste management.

More generally, ASN issues requirements relative to the management of waste from the BNIs. These requirements are set out in ASN resolutions which are subject to public consultation and published on its web site.

1.2.5 Evaluation of the nuclear financial costs

The regulatory framework designed to ring-fence the financing of nuclear facility decommissioning costs or, for radioactive waste disposal facilities, the final shutdown, maintenance and surveillance costs, in addition to the cost of managing spent fuel and radioactive waste, is described in chapter 15 (see point 1.4).

1.2.6 ASN's international action in the area of waste

ASN participates in the work of WENRA (Western European Nuclear Regulators' Association) aiming at harmonising nuclear safety practices in Europe by defining "reference safety levels" which must be transposed into the national regulations of its member countries. As such, the WGWD (Working Group on Waste and Decommissioning) is more specifically tasked with defining reference levels concerning the safety of radioactive waste and spent fuel storage and of radioactive waste repositories. Following the work already carried out on storage and decommissioning, ASN has drawn up and presented its evaluation of the disposal reference levels. A plan of action has been drawn up for transposition of the levels not reached to date. It is based more specifically on the ASN resolutions that will detail the provisions of the Order of 7th February 2012 defining the general regulations applicable to BNIs.

Finally, ASN is a participant in the International Atomic Energy Agency's (IAEA) Waste Safety Standards Committee (WASSC), whose role is to draft and then approve the international standards, particularly concerning the management of radioactive waste. It also takes part in the work of ENSREG (European Nuclear Safety Regulators Group) group 2 which is assigned to subjects relative to radioactive waste management.

ASN also participates in projects of a technical nature with the European Union (SITEX) and IAEA (GEOSAF, HIDRA).

Lastly, ASN coordinated the authoring of the French national report on the implementation of the obligations of the Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management which France sent to the IAEA in October 2014. This report presents the implementation of the obligations of the Joint Convention by all the French actors concerned. It also details the developments in the European and French regulatory frameworks, in the spent fuel and radioactive waste management policies, and the issues raised by the decommissioning of nuclear facilities. The report also specifies the new steps taken by France to integrate the lessons learned from the Fukushima Daiichi accident. It was examined from 11th to 22nd May 2015 in Vienna.

ASN's international actions are presented more generally in chapter 7 covering international relations.

1.3 Long-term management solutions for radioactive waste

1.3.1 Disposal of Very-Low-Level (VLL) waste

CIRES (Industrial Centre for nuclear Waste Collection, Storage and Disposal), located in the towns of Morvilliers and La Chaise in the Aube department and operated by Andra, includes a disposal facility for Very-Low-Level (VLL) waste. This facility, which has ICPE status, has been operational since 2003.

At the end of 2015, the volume of waste in the CIRES repository was about 303,000 m^3, or 47% of the authorised capacity (650,000 m^3). The latest production estimates for VLL waste indicate that the needs will exceed the capacity planned for when the centre was designed. However, the annual VLL waste production streams have been lower than projected in the last few years.

In 2015, under the 2013-2015 PNGMDR, Andra submitted a comprehensive industrial scheme meeting the needs for new VLL waste disposal capacity. ASN examined this scheme and gave the Government an opinion on VLL waste management on 18th February 2016.

ASN considers that Andra and the waste producers must continue their efforts to reduce the quantity of VLL waste, particularly by optimising its production and densification. ASN also considers that consolidation of the VLL waste production projections is a vital step to guide future choices in the overall optimisation of the management route. ASN also points out that the absence of release thresholds for the management of contaminated, activated or potentially activated waste must remain the cornerstone of VLL waste management in France and that reuse of VLL waste is a practice which must not become commonplace and could only be permitted as a waiver under certain conditions, first and foremost in the nuclear sector[3]. ASN considers moreover that the possibilities for reusing VLL waste within the nuclear sector must be fully exploited before turning to other outlets if necessary.

3. A pluralistic working group (ASN, licensees, government departments, associations, etc.), mandated by ASN and the DGEC under the PNGMDR, has identi�d potential conditions of reuse of VLL waste. The report submitted in 2015 is available on the ASN website.

Due to the projected saturation of the authorised disposal capacities by 2025-2030, ASN considers that Andra must examine the possibility and conditions of increasing the volume capacity of CIRES without changing its ground coverage area and, subject to these conditions being favourable, filing as soon as possible a request to increase this volume.

ASN considers that a second VLL waste disposal facility will ultimately be necessary to maintain the availability of disposal capacities for this waste. ASN also considers that the VLL waste producers must engage themselves in an approach that allows an in-depth examination of the feasibility of creating disposal facilities appropriate for certain types of VLL waste on their sites.

1.3.2 Disposal of Low and Intermediate-Level, Short-Lived waste (LL/IL-SL)

The majority of Low and Intermediate-Level Short-Lived (LL/IL-SL) waste is disposed of in surface disposal facilities operated by Andra. Once these facilities are closed, they are subject to surveillance during an "oversight phase" set by convention at 300 years. The facility safety case – which is updated periodically, including during the oversight phase – must show that at the end of this phase the residual activity contained in the waste is such that human and environmental exposure levels are acceptable, even in the event of a significant loss of the containment properties of the facility.

There are two such repositories in France.

The Manche repository (BNI 66)

The Manche waste Disposal Facility (CSM), which was commissioned in 1969, was the first radioactive waste repository operated in France. 527,225 m^3 of waste packages are emplaced in it. Disposal of waste in the CSM repository stopped in July 1994 and it entered the oversight phase in January 2003.

ASN considers that the state and the operation of the facilities are satisfactory. Andra must continue its efforts to reinforce the stability of the cover and to eliminate the residual infiltrations of water into the repository at the edge of the membrane. An interim review of the work on the repository cover was presented in 2015 and is currently being examined by ASN.

The Aube repository (BNI 149)

Authorised by the Decree of 4th September 1989, the Aube repository (CSA) took over from the Manche repository (CMS), benefiting from the experience gained with it. This facility, situated in Soulaines-Dhuys, has a disposal capacity of one million cubic metres of LL/IL-SL waste. The operations authorised on the facility include waste packaging by injection of mortar into metal crates of 5 m^3 or 10 m^3 volume, or by compacting 200-litre drums.

At the end of 2015, the volume of waste in the repository was about 305,000 m^3, or 30% of the authorised capacity. In the context of the 2013-2015 PNGMDR, Andra had been asked to produce for mid-2015 a forward-looking filling schedule for the CSA, presenting in particular the anticipated development of the occupation of the repository's radiological capacity.

The Aube repository.

ASN notes that in 2015 Andra completed the package inspection facility modification work designed to provide high-performance inspection means for checking the quality of the packages received in its facilities. Commissioning of this inspection facility, planned for 2016, will require ASN approval. In addition to this, construction of the disposal structures of tranche 9, for which ASN gave its agreement, continued in 2015.

ASN considers that the CSA is operated satisfactorily, in line with previous years.

The CSA will provide a periodic safety review file in 2016.

1.3.3 Management of High and Intermediate-Level, Long-Lived Waste (HL/ILW-LL)

The “Waste” Act of 28th June 2006 states that research into the management of High and Intermediate-Level, Long-Lived Waste (HL/ILW-LL) should be pursued in three complementary directions: separation and transmutation of long-lived radioactive elements, storage, and reversible disposal in a deep geological repository, in continuity with the Act of 30th December 1991. ASN considers that studies in these three directions are on the whole proceeding satisfactorily.

Separation/Transmutation

Separation/transmutation processes aim to isolate and then transform long-lived radionuclides in radioactive waste into shorter-lived radionuclides or even stable elements. The transmutation of the minor actinides contained in the waste could have an impact on the size of the disposal facility, by reducing both the heating power of the packages placed in it and the repository inventory. However, the impact of the disposal facility on the biosphere, which originates essentially from the mobility of the fission and activation products, would not be significantly reduced.

Under the PNGMDR, during 2015 CEA submitted an interim assessment report on the industrial prospects of the separation/transmutation processes. On 25th February 2016, ASN issued another opinion on this file, in line with its opinion of 4th July 2013.

ASN considers that the expected gains from the transmutation of minor actinides in terms of safety, radiation protection and waste management do not appear to be decisive, particularly given the resulting constraints on the fuel cycle facilities, the reactors and the transport operations, which would involve highly radioactive materials at all stages of the fuel cycle. ASN also considers that these gains do not eliminate the need for a deep disposal facility and would only be tangible assuming more than one hundred years’ operation of a nuclear fleet with a level of production sufficient to maintain overall consistency with the characteristics of the fuel cycle facilities. ASN has therefore asked CEA to justify the long-term benefits for waste safety and management of continuing all or part of the studies on separation and transmutation.

Storage

The Waste Act states that storage studies must be carried out by Andra so that *“no later than 2015, new storage facilities can be created or existing facilities modified to meet the needs, particularly in terms of capacity and duration”*. The needs to extend or create storage facilities must be anticipated and listed. ASN notes that uncertainties subsist with regard to the schedule for commissioning a deep geological disposal facility, the delivery time frames that Andra will adopt, and the acceptability of certain waste packages. ASN is thus attentive to ensuring that the holders of HL/IL-LL waste have storage facilities with sufficient margins on storage capacities and possible storage times.

To verify the robustness of these margins, the opinion issued by ASN asked that the waste producers study the consequences of postponing the date of Cigéo commissioning by several years beyond the planned date of 2030. This will allow the identification of any threshold effects in terms of future storage requirements or extensions to the operating duration of ageing storage facilities. ASN moreover considers that the PNGMDR should keep track of the filling status of storage facilities.

Andra is tasked with gathering and building on experience feedback from the construction and operation of existing facilities or those being developed, and for conducting research on the behaviour of the materials used to construct the storage structures and package materials as well as oversight techniques, with a view to optimising the durability, the monitoring, the heat removal and, if necessary, the versatility of these storage facilities.

The 2013-2015 PNGMDR required Andra to produce, after consultation with Areva, CEA and EDF and before 31st December 2014, recommendations for the design of storage facilities to complement the disposal process.

Analysis of the documents communicated by Andra shows no significant progress can be expected from further detailing the engineering design of future storage facilities in a generic context. Nevertheless, these studies have allowed the identification of several guidelines which must be put into application in the design of new storage facilities or when the licensees conduct their periodic safety reviews.

Lastly, Andra indicates that it has stopped its research into near-surface disposal facilities due notably to the management of groundwater, which is extremely complex – particularly with regard to ventilation management when exothermic waste is involved – and less flexibile. The insufficient degree of technical detail of the document submitted by Andra does not however allow a ruling on the appropriateness of the definitive abandonment of the near-surface storage facility design option. ASN thus considers that Andra must detail the technical and economic elements allowing a comparison of the advantages and drawbacks of near-surface storage facilities compared with above-ground or partially buried facilities, particularly in terms of robustness and safety with respect to external hazards.

Reversible deep geological disposal

The studies of deep geological disposal fit into the guidelines of Article L. 542-1-2 of the Environment Code, namely that *"after storage, ultimate radioactive waste which, for nuclear safety or radiation protection reasons, cannot be disposed of on the surface or at shallow depth, shall be disposed of in a deep geological repository"*.

The Waste Act assigns Andra the task of designing a deep geological disposal facility, which is considered to be a BNI and therefore subject to ASN oversight.

The principle of this type of disposal

Deep geological disposal of radioactive waste consists in placing packages of radioactive waste – without the intention of retrieving them – in an underground facility situated in a deep geological formation whose characteristics ensure the containment of the radioactive substances present in the waste. Such a disposal facility – unlike storage facilities – must be designed such that long-term safety is ensured passively, that is to say without depending on human actions (such as monitoring or maintenance activities) which require institutional control, the durability of which cannot be guaranteed beyond a limited period of time. Lastly, the depth of the disposal structures must be such that they cannot be significantly affected by the expected external natural phenomena (erosion, climate change, earthquakes, etc.) or by "normal" human activities.

Under these conditions, in its opinion of 1st February 2006, ASN considers deep geological disposal to be an *"unavoidable definitive management solution"*.

In 1991 ASN published basic safety rule RFS III-2-f defining the objectives to be set in the design and works phases for final disposal of radioactive waste in deep geological formations, in order to ensure safety after the operational life of the repository. In 2008 it published an update of this document which became Safety guide No.1.

Underground laboratory of Meuse/Haute-Marne

Studies on deep geological disposal necessitate research and experiments in an underground laboratory. Andra has been operating such an underground laboratory within the Bure municipality since 1999.

ASN issues recommendations concerning the research and experiments, and ascertains through follow-up inspections that they are carried out using processes that guarantee the quality of the results.

Technical instructions

Under the Act of 30th December 1991 through until 2006, and then under the Waste Act of 28th June 2006 and the PNGMDR, Andra has carried out studies and submitted reports and files on deep geological repository. These studies and reports have been examined by ASN - referring in particular to the Safety guide of 2008 - and it has issued an opinion on them.

ASN has thus examined the files submitted by Andra in 2005 and at the end of 2009. ASN gave the Government its opinion on these files on 1st February 2006 and 26th July 2011.

Andra is continuing its work and ASN examines the files submitted to it to measure the progress of the studies and work carried out.

On 16th May 2103, ASN issued an opinion on four documents submitted by Andra between 2009 and 2012 concerning:
- the Waste Management Industrial Programme (PIGD);
- the results of the 3D seismic campaign carried out in 2010 over the 30 km² Zone of Interest for In-depth Studies (ZIRA), to determine the location of the underground facilities of the future disposal centre;
- a progress report on the development of an operational model of release of radionuclides by spent fuel from EDF reactors under disposal conditions, requested as part of the PNGMDR;
- Andra's responses further to an independent study carried out at the request of the Bure CLIS (Local Information and Monitoring Committee) by an American institute, the Institute for Energy and Environmental Research (IEER).

ASN also published its positions taken further to the examination of the files entitled *"Projet Cigéo - Esquisse Jesq03 (2012)"* (Cigéo Project – Outline milestone 03(2012)) in November 2013, and *"Ouvrages de fermeture"* (Closing structures) in October 2014.

In 2015, ASN examined a file submitted by Andra entitled *"Maîtrise des risques en exploitation au niveau esquisse du projet Cigéo"* (Control of in-service risks at the outline level of the Cigéo project). ASN observed that this file contains some significant progress regarding in-service risk control, which confirms the developments already noted during examination of the *"Esquisse - Jesq03"* outline milestone file. ASN nevertheless underlines that information still has to be provided concerning the procedure, the safety requirements and the risks presented in the file, and on the operational control of the facility and restoring the various disposal functions following an accident situation. ASN informed Andra of its observations in a letter dated 9th October 2015, so that they could be taken into account in the safety options file Andra has said it will submit in 2016, and in the future creation authorisation application file.

The authorisation process

The process for examining a creation authorisation application for a deep geological repository has not started and will not start until Andra submits an authorisation application. According to the schedule provided for in the Waste Act, this file was to be submitted in 2015. Following submission of the conclusions of the public debate, Andra proposed a change to this schedule through a deliberation of its board of directors on 5th May 2014.

On the basis of this new schedule, Andra would submit a proposed master plan for the operation of Cigéo along with a safety options file and a retrievability technical options file, before submitting the creation authorisation application for this facility, now announced for 2018.

ASN approves of Andra's decision to submit a safety options file to it. ASN considers that this type of file contributes to the continuation of a development process through organised and controlled steps. In December 2014, ASN informed Andra of its expectations regarding the content of this file and the elements it must contain for its examination to take place. ASN more specifically asked Andra to ensure the completeness of the file with regard to the notion of disposal system[4] defined in the abovementioned ASN Safety guide.

In July 2014, ASN asked the IAEA to organise an international peer review of this safety options file. This review should take place at the end of 2016.

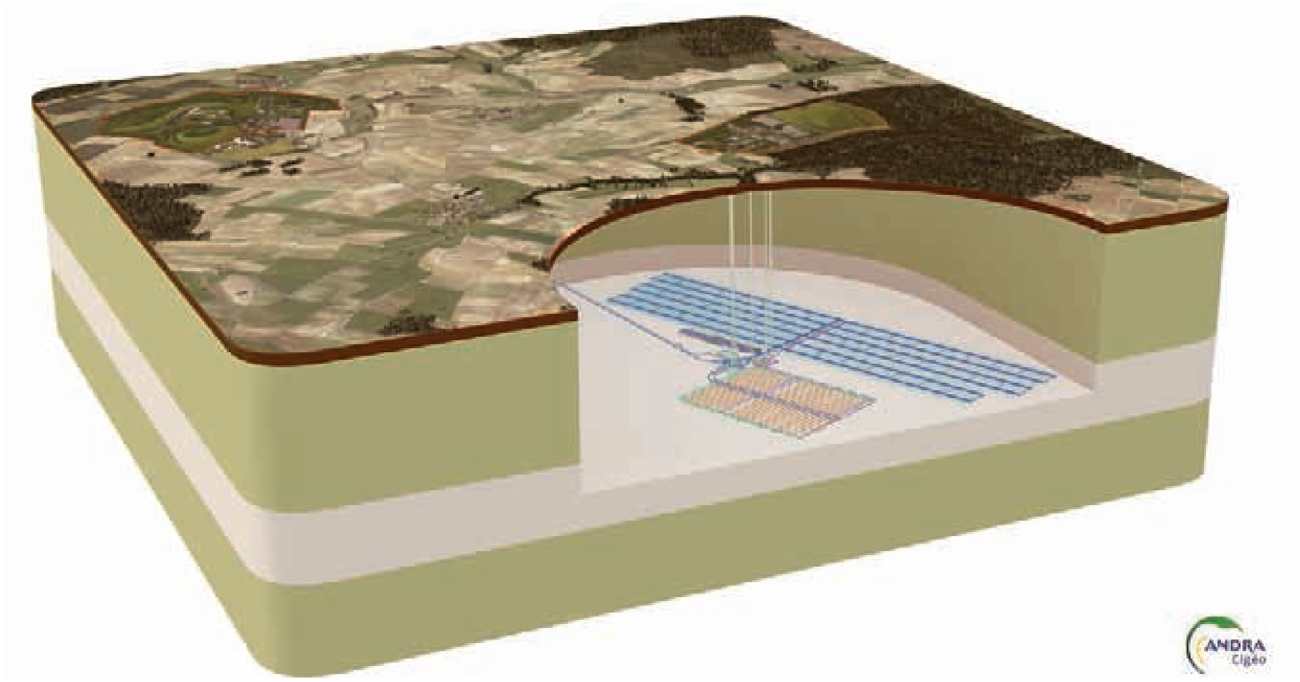
Project cost evaluation

On 10th February 2015, ASN issued its opinion on a costing file drawn up by Andra in October 2014 which was referred to ASN by the Minister responsible for Energy at the end of 2014.

The previous evaluation of between 13.5 and 16.5 billion euros (€Bn), dated from 2005; ASN estimated in its opinion that an update of the reference cost was necessary. This update could be carried out on the basis of the Andra file, which is documented and substantiated and represents significant progress, more specifically through greater focus on safety.

4. The system of disposal in deep geological formation comprises the waste packages, the disposal facility and the geological environment. The disposal facility comprises the waste package disposal structures and the access structure.

SCHEMATIC of the Cigéo facilities



TO BE NOTED

ASN's position on reversibility

The reversibility of deep geological disposal is a requirement contained in the Environment Code. This requirement is to be detailed in a future Act. In 2016, Andra will submit a file to ASN presenting the main technical options to ensure the retrievability of the emplaced waste packages. ASN informed Andra of its expectations on this subject.

ASN considers that the notion of reversibility must not only guarantee retrievability, in other words the possibility of retrieving the waste packages already emplaced for a given period of time, but also that the facility is adaptable in order to guarantee the possibility of modifying the previously adopted provisions during construction and operation of the disposal facility. As such, ASN considers that Andra must demonstrate that a change in the waste inventory intended for deep geological disposal further to – for example – a political decision in terms of energy policy leading to the direct disposal of spent fuel, does not call into question the safety of disposal.

To ensure that these safety issues are integrated as of the design phase, ASN considers it essential that the technical requirements associated with reversibility be defined by Parliament prior to submission of the creation authorisation application for such a disposal facility. ASN will publish its position on reversibility in 2016.

ASN nevertheless considered that some of the technical and economic hypotheses adopted by Andra were too optimistic and consequently did not satisfy the requirement for caution imposed by such an evaluation. Moreover, at this stage of project development, uncertainties are inevitable. ASN therefore considered that it was essential to provide a mechanism for regularly updating the reference cost, particularly during key stages of project development.

ASN pointed out that this evaluation is one of the bases for calculating the funds required by the licensees to cover the expenses associated with management of their radioactive waste. The purpose of these funds is to ensure that these costs will not be borne by future generations.

In accordance with the procedure stipulated in Article L. 542-12 of the Environment Code, after consideration of ASN's opinion and the comments of the radioactive waste producers, the Minister responsible for Energy issued an Order on the reference cost of the Cigéo disposal project on 15th January 2016: a *"cost is set at €25 Bn under the economic conditions prevailing on 31st December 2011, the year in which the cost evaluation work began"*. This Order also specifies that the cost must be updated regularly and *"at least at the key stages of project development (creation authorisation, commissioning, end of the "industrial pilot phase", periodic safety reviews), in accordance with the opinion of ASN."*

ASN visit to the Bure underground laboratory, July 2015.

1.3.4 Management of Low-Level, Long-Lived Waste (LLW-LL)

Low-Level Long-Lived Waste (LLW-LL) comprises two main categories: graphite waste resulting from the operation of the Graphite-moderated Gas-Cooled Reactor (UNGG) nuclear power plants, and radium-bearing waste, from the radium industry and its offshoots. Other types of waste fall into this category, such as certain bituminised effluents, substances containing radium, uranium and thorium with low specific activity, as well as certain disused sealed radioactive sources.

The 2013-2015 PNGMDR required the various actors involved to carry out studies (characterisation and waste treatment possibilities, geological investigations on a site identified by Andra, design studies and preliminary safety analyses) so that in 2016 the State can specify guidelines for the management of LLW-LL waste.

The holders of LLW-LL waste have thus made progress in the characterisation of their waste and in the processing possibilities, particularly with regard to graphite waste and some types of bitumen-solidified waste. More specifically, the radiological inventory for chlorine-36 and iodine-129 has been considerably reduced.

As part of the PNGMDR, Andra submitted a report in July 2015 containing:
- proposals of choices of management scenarios for graphite and bituminous waste, notably with the possibility of reinitiating the search for a site for an "intact cover disposal" type repository or not;
- a feasibility file for the project for a "reworked cover disposal[5]" type disposal facility, the types of waste to be placed in it and the schedule for its deployment.

This report is currently being examined by ASN which will issue an opinion on the management of LLW-LL waste at the beginning of 2016. ASN will be particularly attentive not only to waste characterisation but also to the characteristics of the prospective site with regard to the safety requirements (thickness and depth of the clay layer, position of aquifers, examined intrusion scenarios) and the inventory of envisaged waste.

5. Reworked cover disposal is disposal at shallow depth achieved by open-cast excavation of a layer with a clayey or marly component to reach the storage level. Once filled, the vaults are covered by a layer of compacted clay followed by a protection layer of planted vegetation reconstituting the site's natural level.

1.4 Socodei melting/incineration facility

The Centraco low-level waste processing facility (BNI 160), located in Codolet near the Marcoule site (Gard *département*), is operated by Socodei, a subsidiary of EDF.

The purpose of the Centraco plant is to sort, decontaminate, reuse, treat and package - particularly by reducing their volume - waste and effluents with low levels of radioactivity. The waste is then routed to the Andra CSA repository.

The facility comprises:
- a melting unit melting a maximum of 3,500 tonnes of metallic waste per year;
- an incineration unit incinerating a maximum of 3,000 tonnes of solid waste and 2,000 tonnes of liquid waste per year;
- storage areas for ash and clinkers, liquid wastes, leaching effluents and metallic waste;
- a maintenance unit.

At the start of 2015 the incineration unit underwent a long and complete technical shutdown during which the refractory material, various internal equipment items and the quenching tower were replaced.

2015 saw the restarting of the melting unit, shut down since 2011 following an accident that occurred in the facility's melting furnace in September 2011. An ASN resolution of 27th September 2011 made restarting of the furnace subject to ASN authorisation on the basis of a file submitted by the licensee presenting the analysis and lessons learned from the accident of 12th September 2011, the conclusions of a design and operation review of the melting unit with regard to the explosion risk, an assessment of the repair and equipment modification work necessary for operation of the melting unit and an assessment of the tests concerning safety.

After examining the restarting application file and in particular the risks analysis carried out by the CTIF[6] (French Metal Casting Research and Development Centre) with respect to the explosion risk, ASN authorised Socodei to carry out furnace calibration tests on 26th September 2014. After taking into account the results of these tests in the licensee's baseline safety requirements (general operating rules, procedures, etc.), ASN authorised Socodei to restart the melting furnace on 9th April 2015.

6. Centre Technique des Industries de la Fonderie *(French metal casting research and development centre) is a reference organisation for the appraisal of metallic material casting and transformation processes.*

In July 2015 an incident occurred during an operation preceding the melting process. ASN noted that the licensee rapidly implemented the safety procedures. ASN asked the licensee to conduct an in-depth safety analysis of this event and to increase its vigilance during melting operations.

In 2015 the licensee made a new application for gradual extension of the treatment capacities of the "Centraco 3" BNI 160 (increase in the annual tonnage of very low-level liquid waste and occasional treatment of tritiated waste, and in particular Isotopchim orphan waste). This application is currently being reviewed by ASN.

1.5 The radioactive waste management strategies of the nuclear licensees

ASN requires that licensees define a management strategy for all the radioactive waste produced in their facilities and periodically evaluates this strategy.

These management strategies can be based on facilities specific to each licensee but also on facilities operated by other licensees (Andra and Socodei), described earlier.

The waste management procedures adopted by the three main waste producers are presented below.

1.5.1 CEA waste management

Types of waste produced by CEA

CEA operates diverse installations covering all the activities associated with the nuclear cycle, ranging from laboratories and plants involved in research on the fuel cycle to experimental reactors.

CEA also carries out numerous decommissioning operations.

Consequently, the types of waste produced by CEA are varied and include more specifically:
- standard waste resulting from operation of the research facilities (protective garments, filters, metal parts and components, liquid waste, etc.);
- waste resulting from legacy waste retrieval and packaging projects (sodium, magnesium and mercury-bearing waste);
- decommissioning waste following the final shutdown and decommissioning of facilities (graphite waste, rubble, contaminated soils, etc.).

The contamination spectrum of this waste is also varied: presence of alpha emitters in activities relating to fuel cycle research, beta-gamma emitters for operational waste from the experimental reactors.

CEA has specific facilities for managing this waste (processing, packaging and storage). It is to be noted that some of these facilities are shared between all the CEA centres, such as the liquid effluent treatment station in Marcoule or the solid waste treatment station in Cadarache.

ASN's opinion on CEA's waste management strategy

ASN's last examination of CEA's strategy, which was concluded in 2012, showed that waste management on the whole had improved since the previous examination in 1999. CEA's organisation and the implementation of management tools must enable it to evaluate the movements of waste produced in the coming years and to forecast storage and transport packaging needs. Nevertheless, given the diversity of the projects and the corresponding waste produced, disparities have been observed in the quality of the results, particularly with regard to the management of long-lived intermediate-level solid waste and low or intermediate-level liquid waste. Since then, CEA has provided responses to the majority of the 34 commitments made further to the examination of its file. These elements are currently being examined by ASN.

The issues and implications

The two main issues for CEA with regard to radioactive waste management are:
- bringing new waste processing and storage facilities on-line or renovating existing ones within a time frame compatible with its commitments to shut down old installations whose level of safety no longer complies with current requirements;
- the management of certain legacy waste retrieval and packaging projects.

As in the preceding years, ASN notes the difficulty CEA has in fully managing these two issues and conducting all the associated projects at the same time. CEA has still not defined its strategy for managing the solid radioactive waste produced on the Saclay site following the shutdown of the ZGDS (see BNI 72, page 498).

More particularly, the very significant increases in the projected duration of decommissioning operations and the quantity, non-standard nature and difficulty in characterising certain substances or waste that will be removed from storage or produced during the decommissioning operations have led ASN and ASND to jointly ask CEA to conduct an overall review in 2016 of its decommissioning and radioactive materials and waste management strategies for the next fifteen years.

Facilities operated by CEA to support this strategy

Facilities under construction

• **Diadem (BNI 177)**

After having provided a safety options file in November 2007, CEA submitted an authorisation application file in April 2012 for the creation of a facility to store irradiating IL-LL waste that cannot be stored in Cedra. The waste in question comes chiefly from decommissioning of the Phénix installation (see chapter 15) and the sites of Saclay and Fontenay-aux-Roses.

The main nuclear risks are exposure to ionising radiation, dissemination of radioactive substances, explosion of gases produced by radiolysis, release of heat from waste and criticality. The main safety issues for Diadem are thus the maintaining of container containment quality during the storage period, monitoring the containers during that period, archiving and conserving the information concerning the stored waste and the possibility of retrieving the waste at any time.

In its opinion of 12th November 2015 concerning the draft creation authorisation Decree, ASN emphasised the following factors resulting from its examination:
• Diadem occupies an important position in CEA's management strategy for ILW-LL and LL/ILW-SL radioactive waste. Its creation will more specifically allow the retrieval and packaging of legacy waste (particularly at the Fontenay-aux-Roses centre) and the decommissioning of some of its installations, particularly the Phénix NPP (BNI 71), to be carried out successfully.
• Diadem is not designed for the repackaging of radioactive waste packages which could turn out to be necessary during their storage should the surveillance programme detect cases of deterioration in package properties. This implies that the safety of this storage facility also depends on the availability of a facility that is licensed to perform these operations.
• The surveillance programme put in place by CEA must allow the evolution of the content of certain packages containing potentially degradable radioactive waste, especially organo-halogenated compounds, to be monitored.
• CEA has not yet defined the definitive packaging procedures that will be adopted to adapt the waste packaging to the acceptance specifications of the receiving storage facilities. These procedures should be taken into account to optimise the initial packaging of the waste that will be stored in Diadem. CEA must study these procedures following a schedule to be defined before the facility is commissioned.
• At this stage of the examination, the design of Diadem with regard to internal and external hazards is considered to comply with ASN's requirements for new facilities. Compliance will be examined again before the facility is commissioned on the basis of in-depth studies by the licensee and taking into account the as-built facility.

Diadem construction site.

At present, CEA plans for this facility to be commissioned in 2018.

Installations in operation

On the Cadarache site

• **Agate facility (BNI 171)**

The function of the Agate facility, which was authorized by Decree on 25th March 2009, is to concentrate, through evaporation, radioactive aqueous liquid effluents chiefly containing beta- and gamma-emitting radionuclides. The resulting concentrates must then be conditioned in the liquid effluents treatment station of Marcoule.

ASN authorised commissioning of this facility on 29th April 2014. An end-of-startup file incorporating experience feedback from the facility's first year of operation was communicated by CEA on 30th October 2015 and is currently being examined.

Although the measures for monitoring outside contractors need to be improved, ASN considers that the organisational set-up, which takes good account of the Social, Organizational and Human Factors (SOHF), can ensure a satisfactory level of safety. The inspections and periodic tests, particularly those concerning system sealing, must be improved.

• **Cedra facility (BNI 164)**

The purpose of the Cedra facility, which was authorized by the Decree of 4th October 2004, is to process Intermediate-Level, Long-Lived Waste (ILW-LL) and store ILW-LL packages with a low and intermediate dose rate. Storage would be for a period of 50 years, pending the commissioning of an appropriate disposal route.

ASN authorised commissioning of the first section of the storage facility for low-level waste (two storage buildings) and intermediate-level waste (one storage building) in April 2006. ASN specified the conditions for commissioning the sections not built to date in a resolution of 22nd July 2014. At the end of May 2015, the filling rate was 35% for the LLW halls and 29% for the ILW hall. According to CEA's projections, the LLW halls should be filled to capacity after 2029 and the ILW hall in 2028, but this latter time frame is highly dependent on the rate of removal of waste from BNI 56. The construction schedule for the new tranches therefore depends on the retrieval and packaging of waste from BNI 56. ASN considers that the experience feedback from the first years of operation is satisfactory. The CEA will submit the guidelines file for the first periodic safety review of the facility in May 2016.

- **Cascad facility (BNI 22)**

The Cascad facility, which was authorised by the Decree of 4th September 1989, is used for the dry storage of spent fuel. In June 2015, 84% of the storage wells were occupied.

Through a resolution of 8th July 2014, ASN authorised a further ten years of storage for the spent fuels that have already been present in the facility for more than fifteen years.

This resolution is without prejudice to the conclusions of the next periodic safety review of the installation, planned for 2017.

Regarding the development of the source term over the next ten years, CEA estimates that the Cascad well will be filled to 91% capacity in 2026 (on condition that the Phénix spent fuel is removed from storage before 2023) and therefore considers that it is not necessary to build the second tranche provided for in Article 2 of the Decree of 4th September 1989. CEA has started a strategic reflection on the need to modify the Decree of 4th September 1989 accordingly.

ASN opinion on the safety of operation of the Cascad facility is generally positive.

- **Chicade facility (BNI 156)**

Chicade (BNI 156) (Chemistry, Waste Characterisation) is a facility for research and development on low and intermediate level waste. This work mainly concerns:
- the destructive and non-destructive characterisation of radioactive objects, waste sample packages and irradiating objects;
- the development and qualification of nuclear measurement systems;
- the development and implementation of chemical and radiochemical analysis methods;
- assessment and monitoring of waste packaged by the waste producers.

Creation of the facility was authorised by the Decree of 29th March 1993 and its definitive commissioning was authorised in 2003.

The periodic safety review file for the facility must be submitted to ASN in 2016. CEA submitted a guidelines file for this review in 2015, and ASN has examined it. The licensee is also considering upgrading its facility in the medium term to incorporate metal waste cutting and packaging activities.

<u>On the Saclay site</u>

- **Stella facility (BNI 35)**

BNI 35, declared by CEA by letter on 27th May 1964, is dedicated to the treatment of radioactive liquid effluents. By Decree of 8th January 2004, CEA was authorised to create an extension in the BNI, called Stella, for the purpose of treating and packaging low-level short-lived aqueous effluents from the Saclay centre. These effluents are concentrated by evaporation then immobilised in a cementitious matrix in order to produce packages acceptable by Andra's surface waste disposal centres.

The concentration process was put into service in 2010, but the appearance of cracks in the first packages led ASN to limit the packaging operations. CEA has thus only packaged certain effluents coming from one of the installation's tanks that contains 40 m^3 of concentrates.

ASN considers that CEA must continue the studies and discussions with Andra to obtain, before mid-2017, the approvals allowing packaging of the concentrates and transfer of the packages produced to the Aube disposal centre.

Renovation or shutdown of old facilities

<u>On the Cadarache site</u>

- **Radioactive Effluent and Solid Waste Treatment Station (BNI 37)**

The function of BNI 37, which was declared by CEA by a letter dated 27th May 1964, is the treatment and packaging of liquid and solid radioactive waste. The two independent facilities that it comprises – the Solid waste Treatment Station (STD) and the Effluent Treatment Station (STE) – were registered respectively as BNI 37-A and 37-B by resolution of the ASN Chairman in July 2015. The registrations were made after defining the perimeters of these two BNIs by Orders of the Minister responsible for Nuclear Safety on 9th June 2015. The registration resolutions for these two BNIs act as a Creation Authorisation Decree.

ASN considers that safety management on these facilities must be improved.

Serious shortcomings in the management of verifications and periodic tests had been observed during inspections.

Although significant improvements have been made, ASN still notes a lack of follow-up of deviations detected during the verifications, periodic tests and regulatory checks and remains extremely vigilant regarding the interfaces with the general services of the centre and the monitoring of outside contractors in particular.

The current monitoring of outside contractors must be rapidly consolidated.

- **Solid waste Treatment Station (STD) – BNI 37-A**

At present, the STD is CEA's only civil BNI licensed for packaging LL/ILW-LL radioactive waste before it is stored in the Cedra facility (BNI 164) pending transfer to a deep geological repository (Cigéo project).

In this respect the STD holds a strategic position in the management of CEA's ILW-LL waste, and in particular for the outcome of some of its projects (decommissioning of facilities on the Fontenay-aux-Roses site, removal of waste from BNI 72 on the Saclay site).

The main nuclear risks associated with the operations carried out on radioactive waste in the STD are exposure to ionising radiation, dissemination of radioactive substances, criticality and explosion resulting from the materials present in the treated drums or containers (production of hydrogen by radioloysis, compacting of drums containing explosive gases or a reaction of a metal [aluminium, zinc] with the injected mortar).

The first periodic safety review of the STD was held in 1998 (at the same time as that of the STE). It revealed significant shortcomings, notably in static containment, control of the fire risk and earthquake resistance. Since then CEA has been examining reinforcement scenarios for the STD with the aim of continuing the activity in BNI 37-A over the long term. It is noteworthy that the Decree for BNI 164 provides for a treatment building which will therefore not be used. In the context of the second periodic safety review of the STD (file submitted in March 2012) conducted by CEA with a view to continuing operation of the solid IL-LL waste treatment functions for a period of at least ten years, CEA presented the safety options for the renovated facility. The file indicates that CEA plans completing the STD renovation work in 2020.

An ASN resolution will govern the implementation of protective measures in the short term and the facility renovation work. Furthermore, in compliance with the BNI Order, CEA transmitted a production authorisation request for each family of packages (CEA-050 and CEA-060) produced in BNI 37-A since 2012 to ASN.

ASN will be particularly attentive to the meeting of the commitments made further to the periodic safety review of the facility concerning containment, fire and the seismic risk.

- **Effluent Treatment Station (STE) – BNI 37-B**

The STE facility stopped receiving radioactive effluents on 1st January 2012 in accordance with an ASN resolution of 27th January 2011. The use of the STE's treatment units also stopped on 31st December 2013. The facility is therefore definitively shut down and has been functionally replaced by the Agate facility, commissioned in 2014. The civil engineering and processes (capacities) investigation programme is continuing. CEA plans transmitting the periodic safety review guidelines file to ASN in January 2016. CEA plans submitting the STE decommissioning file in 2017, at the same time as the periodic safety review file.

Effluent Treatment Station (STE) – BNI 37-B, CEA Cadarache.

Spent fuel and legacy waste and effluents recovery operations

On the Saclay site

- **Solid radioactive waste management zone (BNI 72)**

BNI 72, which was authorised by Decree on 14th June 1971, serves for waste storage and packaging as well as waste retrieval from small-scale nuclear activities[7] (sources, scintillating liquids, ion exchange resins) and storage of radioactive sources.

For several years now the licensee has been having difficulty in significantly improving the tracking of and compliance with the prescriptions set by ASN (characterisation of sources, updating of the safety analysis report, etc.) and the commitments made during the periodic safety review or after inspections. ASN does nevertheless note some improvements, notably the implementation of a procedure that has enabled CEA to prioritise the accomplishing of its commitments according to the stakes they represent.

CEA has also undertaken to shut down the installation's waste processing units and to remove the spent fuel stored in the pool and the concrete storage structures in 2017. Consequently, CEA transmitted the final shutdown and decommissioning authorisation application for the installation in December 2015. Lastly, ASN considers that CEA must rapidly take appropriate measures for managing the Saclay site waste after installation shutdown.

ASN considers that, although the safety of the installation remains satisfactory on the whole, it is vital for CEA to maintain constant vigilance to ensure there are no delays in performing the actions with serious safety implications required in the coming years (removal of spent fuel, waste and sealed sources from the installation, preparation for final shutdown and decommissioning), and that substantial technical, financial and human resources must be deployed for this installation. Progress is moreover still required in the monitoring of outside contractors.

- **Liquid effluent management zone (BNI 35)**

The Decree of 8th January 2004 authorising the creation of Stella (see above) required CEA to remove old effluents stored in the MA500 and HA4 tanks of BNI 35 within ten years. CEA was unable to meet this deadline due to technical difficulties in the retrieval and packaging of this waste. Indeed, only half of the initial source term had been removed (19,256 GBq in 2004) as at 8th January 2014. ASN does nevertheless note that all the radioactive organic effluents contained in tank HA4, which presented greater safety risks, had been removed by the end of 2013.

Through a resolution of 15th July 2014, ASN prescribed new retrieval deadlines for these effluents and obliged CEA to have them removed by the end of 2018, with intermediate milestones at the end of 2014, 2015 and 2016.

CEA continued these removal operations in 2015.

On the Cadarache site

- **Radioactive waste storage area (BNI 56)**

BNI 56, which was declared in January 1968, is used for storing solid radioactive waste.

The installation comprises six pits, five trenches, three pools and hangars containing primarily Intermediate-Level, Long-Lived Waste (ILW-LLL) from the operation or decommissioning of the CEA's installations which cannot be disposed of at the CSA repository. The installation also includes storage areas for Very-Low-Level (VLL) legacy waste, which is characterised and packaged at the STARC ICPE, then transferred to the CIRES repository. CEA will transmit the report presenting the conclusions of the installation's periodic safety review to ASN in 2016.

The waste present on the installation must be retrieved as soon as possible, packaged and stored in appropriate facilities (Cedra in particular). Retrieval of the waste from the pits and trenches requires the deployment of new procedures.

ASN notes the delays in the waste retrieval and packaging projects due to the technical complexity of the retrieval solutions to be devised as well as contractual difficulties in managing outside contractors. The waste retrieval and packaging operations will be long and complex and will require specific studies and infrastructures. These operations shall be governed by a decommissioning decree and particular ASN prescriptions.

ASN notes that significant improvements have been made in safety management at this installation over the last few years.

- **Pégase (BNI 22)**

The Pégase reactor entered service on the Cadarache site in 1964 and was operated for about ten years. By Decree on 17th September 1980, CEA was authorised to reuse the Pégase facilities to store spent fuel elements.

The Pégase installation is now a facility for storing irradiated fuel elements in the pool and for radioactive substances and materials.

7. Small-scale nuclear activities represent all activities using ionising radiation but not covered by the BNI regime. Small-scale nuclear activities concern many fields such as medicine (radiology, radiotherapy, nuclear medicine), human biology, research and industry.

This installation does not meet current storage standards and must stop functioning. Consequently, removal of the spent fuel and stored waste began in January 2006.

ASN considers that CEA must continue retrieval of the fuel elements stored in the Pégase pool as rapidly as possible.

Of the 900 spent-fuel cans initially stored in the pool in 2004, at the end of May 2015 there remained 52 cans of spent fuel not coated in araldite to be removed before the end of 2016 and 114 araldite-coated cans of spent fuel. Removal of the remaining fuel from storage requires the finalising of a reprocessing process that is currently being developed on the STAR facility.

The last periodic safety review of Pégase was in 2003. Submission of the next Pégase periodic safety review file is planned for November 2017.

ASN will be particularly attentive to CEA's operations to remove material from the Pégase pool.

ASN's assessment of the operating safety of Pégase is positive on the whole, but it remains vigilant with regard to the licensee's commitments concerning the short- and medium-term future of this facility.

1.5.2 Areva waste management

ASN's opinion on Areva's waste management strategy

The spent fuel reprocessing plant at La Hague produces most of Areva's radioactive waste. The waste present on the La Hague site comprises on the one hand the waste resulting from reprocessing of the spent fuel, which generally comes from nuclear power plants but also from research reactors, and on the other, the waste resulting from operation of the various facilities on the site. Most of this waste remains the property of the licensees who have their spent fuel reprocessed (whether French or foreign).

Areva's Tricastin site also produces waste associated with the upstream activities of the cycle, essentially contaminated by alpha emitters.

The last waste management strategy review for Areva NC La Hague took place in 2005. ASN asked Areva to submit a file presenting the waste management strategy for the group as a whole and its practical application on the La Hague and Tricastin sites by mid-2016.

The issues and implications

The main issues relating to the management of waste from the licensee Areva concern:
- the safety of the storage facilities for the legacy waste present on the La Hague site. ASN has effectively observed recurrent delays in the retrieval of legacy waste at La Hague (see chapter 13);
- the defining of solutions for waste packaging, in particular for legacy waste.

As concerns this second point, Article L. 542-1-3 of the Environment Code requires that IL-LL waste produced before 2015 be packaged no later than the end of 2030. ASN therefore reminded Areva of the need to define and finalise solutions for packaging this waste within a time frame enabling the 2030 deadline to be met. These solutions will require the prior approval of ASN in accordance with the provisions of Article 6.7 of the Order of 7th February 2012 (see point 1.2.2).

Within the framework of the waste retrieval and packaging operations, Areva NC is examining packaging solutions that necessitate the development of new processes, particularly for the following IL-LL waste:
- the sludge from the STE2 facility;
- the alpha technological waste coming primarily from the La Hague and MELOX plants, which is not suitable for surface disposal.

For other types of IL-LL waste resulting from the waste retrieval and packaging operations, Areva NC is examining the possibility of adapting existing processes (compaction, cementation, vitrification). Part of the packaging baseline requirements are currently being examined by ASN.

Facilities operated by Areva

The waste management strategy of Areva is based essentially on the La Hague site. Like all the fuel cycle installations, this site is presented in chapter 13.

- **Ecrin (BNI 175)**

The Areva NC plant on the Malvési site transforms the concentrates from the uranium mines into uranium tetrafluoride. The transformation process produces liquid effluents containing nitrated sludge loaded with natural uranium. These effluents are settled and evaporated in ponds. The sludge is stored in ponds and the supernatant is evaporated in evaporation ponds.

The entire plant is subject to the Seveso threshold II ICPE system.

Only two sludge storage ponds (B1 and B2) are subject to the BNI system due to the presence of traces of artificial radioisotopes from the processing of reprocessed uranium from the Marcoule site. Ponds B1 and B2 have not been used for the settling of liquid effluents since the B2 pond embankment failed in 2004 (utilisation prohibited by Prefectural Order). Once commissioned, BNI 175 situated on the site of ponds B1 and B2 will also contain the solid residues from the Malvési site's ponds B5 and B6, which will be emptied when the facility enters service. Ponds B1 and B2 and their content will be covered with a bituminous cover.

ASN issued a favourable opinion (ASN opinion 2015-AV-0228 of 26th March 2015) on the draft creation Decree for the Ecrin BNI. The Ecrin facility was authorised by Decree of 20th July 2015 for the storage of radioactive waste for a period of thirty years with a volume of waste not exceeding 400,000 m^3 and total radiological activity of less than 120 terabecquerels (TBq).

The Ecrin facility commissioning authorisation application was submitted by Areva NC on 15th October 2015 and will be examined in 2016.

1.5.3 EDF waste management

EDF waste management strategy

The waste produced by EDF nuclear power plants is activated waste (from reactor cores) and waste resulting from their operation and maintenance. To this can be added some legacy waste and waste resulting from ongoing decommissioning operations. EDF is also the owner, for the share attributed to it, of HL and IL-LL waste resulting from spent fuel reprocessing in the Areva NC La Hague plant.

Activated waste

This waste notably comprises control rod assemblies and poison rod assemblies used for reactor operation. This is IL-LL waste that is produced in small quantities. This waste is currently stored in the NPP pools pending transfer to the ICEDA facility.

Operating and maintenance waste

Some of the waste is processed by the Centraco facility in Marcoule in order to reduce the volume of ultimate waste. The other types of operational and maintenance waste are packaged on the production site then shipped to the CSA or CIRES repositories for disposal (see points 1.3.1 and 1.3.2). This waste contains beta and gamma emitters, and few or no alpha emitters.

At the end of 2013, EDF submitted a file presenting its waste management strategy. This file was examined by the competent Advisory Committees of Experts (GPE) in 2015. ASN will issue a position statement on this file in 2016.

The issues and implications

The main issues related to the EDF waste management strategy concern:
- the management of legacy waste. This primarily concerns structural waste (graphite sleeves) from the graphite-moderated gas-cooled reactor fuels. This waste could be disposed of in a repository for LLW-LL (see point 1.3.4). It is stored primarily in semi-buried silos at Saint-Laurent-des-Eaux. Graphite waste is also present in the form of stacks in the gas-cooled reactors currently being decommissioned.
- changes linked to the fuel cycle. EDF's fuel use policy (see chapter 12) has consequences for the fuel cycle installations (see chapter 13) and for the quantity and nature of the waste produced. This subject was examined by the Advisory Committee of Experts for Nuclear Reactors (GPR) and the Advisory Committee of Experts for Laboratories and Plants (GPU) on 30th June 2010. Following this examination, in its letter of 5th May 2011, ASN asked EDF to implement a more rigorous policy for managing its storage capacity for substances before their disposal, treatment or reprocessing (see chapter 13). More specifically with regard to waste, EDF must for example ensure that the available packaging containers can meet the disposal needs.

Facilities operated by EDF to support this strategy

- **ICEDA (BNI 173)**

The purpose of the ICEDA facility, authorised by Decree on 23rd April 2010, is to process and store activated waste from operation of the EDF installations and from the decommissioning of the first-generation reactors and of the Creys-Malville NPP.

The construction licence for the facility, cancelled by the Administrative Court of Lyon on 6th January 2012 was re-granted to EDF on 4th December 2014 following an appeal.

Work on the construction site started again in April 2105 after a four-month phase of contractor remobilisation. The ongoing works concern the finalising of civil engineering work, assembly of the electro-mechanical equipment, installation of the linings in the cells, and painting the premises.

The suspension of the construction work means that the projected commissioning of facility is at least three years behind schedule. The ICEDA commissioning authorisation application file should be submitted to ASN in the first quarter of 2016 with commissioning planned for 2017 after conducting the prior tests.

ASN carried out two inspections in 2015 to verify the conditions of resuming work on the construction site and its management. The results of these inspections were generally satisfactory. Work on the site resumed with rigour and the worksite is well managed. The level of surveillance put in place by EDF is appropriate for the risks. ASN will remain attentive to the quality of work performance in 2016 to allow the facility to be commissioned.

- **Saint-Laurent-des-Eaux silos (BNI 74)**

The installation, which was authorised by the Decree of 14th June 1971, comprises two silos which are used to store irradiated graphite sleeves (LLW-LL) from the operation of the graphite-moderated gas-cooled

ICEDA construction site, August 2015.

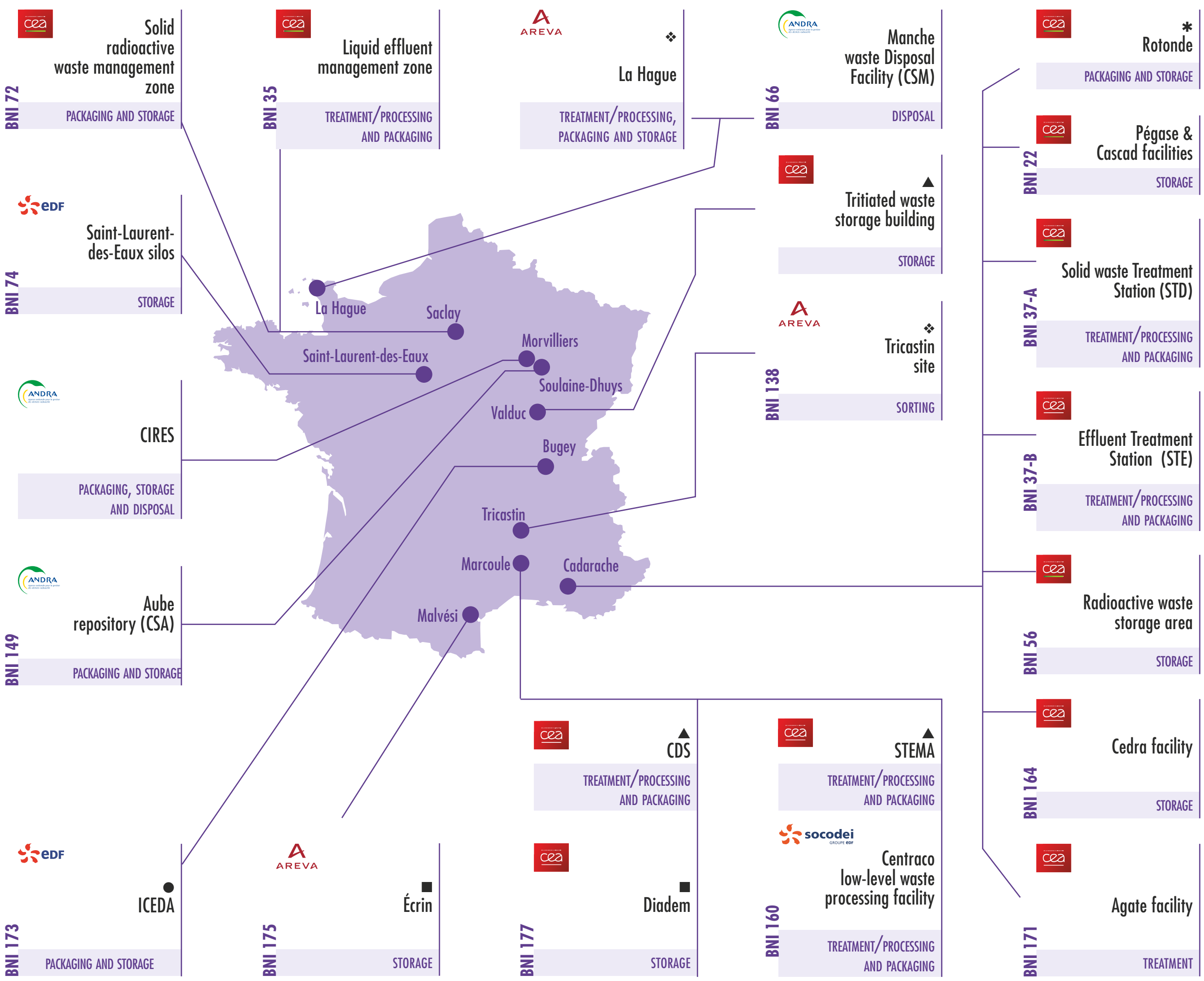
reactors of Saint-Laurent A. The static containment of this waste is ensured by the concrete structures of the silo bunkers which are sealed by a steel liner. In 2010, EDF installed a geotechnical containment around the silos, reinforcing control of the risk of dissemination of radioactive substances, which is the main risk presented by the installation.

Operation is limited to surveillance and maintenance measures (inspections and radiological monitoring of the silos, checking there is no water ingress, checking the relative humidity, the dose rates in the vicinity of the silos, the activity of the water table, monitoring the condition of civil engineering structures).

In 2015, ASN completed its examination of the commitments made by EDF following the periodic safety review of the installation which ended in 2014. ASN considers that nothing calls operation of the BNI into question provided that the dates of waste removal from these silos are respected, but it is waiting for additional studies from EDF which must be transmitted as part of the periodic safety review conclusions file. The additional studies primarily concern the seismic risk and surveillance of the condition of the civil engineering structures.

Examination of the resolutions governing the Saint-Laurent-des-Eaux site discharges also ended in early 2015. ASN more specifically asked EDF to conduct a study to evaluate the possible presence of diffuse discharges from the silos.

THE MAIN FACILITIES involved in radioactive waste management



● Waiting for commissioning ✱ Comes under the status of ICPE ❖ See chapter 13 on the nuclear fuel cycle
■ Creation Authorisation Decree (DAC) pending ▲ Comes under the status of SBNI

1.6 Management of waste from small-scale nuclear activities

1.6.1 Management of waste from non-BNI nuclear activities

The issues and implications

The use of unsealed sources in nuclear medicine, biomedical or industrial research creates solid and liquid waste: small laboratory equipment used to prepare sources, medical equipment used for administration, residues of food eaten by patients who have received diagnostic or therapeutic doses, etc. Radioactive liquid effluents also come from source preparation as well as from the patients who eliminate the radioactivity administered to them by natural routes.

The diversity of waste from small-scale nuclear activities, the large number of establishments producing it and the radiation protection issues involved have led the public authorities to regulate the management of the waste generated by these activities.

Management of disused sealed sources considered as waste

Sealed sources are used for medical, industrial, research and veterinary applications (see chapters 9 and 10). When they reach end of life, and if their suppliers do not envisage their reuse in any way, they are considered radioactive waste and must be managed as such.

The management of sealed sources considered as waste, and their disposal in particular, must take into consideration the dual constraint of concentrated activity and a potentially attractive nature in the event of human intrusion after loss of the memory of a disposal facility. This therefore limits the types of sources that can be accepted in disposal facilities, especially surface facilities.

As required by the 2013-2015 PNGMDR, CEA (which ensured secretary ship of a working group led jointly by the DGPR - General Directorate for Risk Prevention, and the DGEC - General Directorate for Energy and Climate) submitted a work synthesis report to the Government at the end of 2014, covering:
- continuation of Andra's study of the conditions of acceptance of these sealed sources in disposal facilities;
- consolidated batching of used sealed sources in order to determine a reference solution for each batch;
- with regard to the existing disposal centres, Andra's assessment of the conditions for acceptance of disused sealed sources, if necessary modifying the acceptance specifications but without compromising the safety of the disposal centres;
- a study of the requirements in terms of treatment and packaging facilities to enable them to be accepted in existing or planned disposal centres;
- a study of the requirements in terms of interim storage facilities;
- optimised technical and economic planning of the conditions for acceptance and elimination of disused sealed sources, in the light of the availability of processing, storage and disposal facilities and transport constraints.

Furthermore, Decree 2015-231 of 27th February 2015 enables holders of disused sealed sources to call upon not only the initial source supplier but also any licensed supplier or - as a last resort - Andra, to manage these sources. These provisions should bring a reduction in the costs of collecting disused sources and provide a recovery route in all situations.

Management by Andra of waste from non-BNI nuclear activities

Article L. 542-12 of the Environment Code entrusts Andra with a public service mission for waste produced by small-scale nuclear activities. Yet until 2012 Andra was not equipped with its own facilities for the management of waste from small-scale nuclear activities. Consequently, Andra made agreements with other nuclear licensees, and CEA in particular, which stores waste on the Saclay site.

Andra started reconfiguring the route in 2012 by creating at CIRES, situated in the towns of Morvilliers and La Chaise, a collection centre and a storage facility for waste from small producers other than nuclear power plants. Nevertheless, the tritiated solid waste will be managed in a storage facility operated by CEA and pooled with the waste from ITER (INTERMED project).

ASN considers that the approach adopted by Andra will be sufficient to meet the duties entrusted to it under Article L. 542- 12 of the Environment Code and that this must be continued.

1.6.2 Management of waste containing enhanced natural radioactivity

Some professional activities using raw materials which naturally contain radionuclides but which are not used for their radioactive properties, may lead to an increase in specific activity in the resulting products, residues or waste. This is known as technologically enhanced natural radioactivity. The majority of these activities are (or were) regulated by the ICPE regime and are listed by the order of 25th May 2005 concerning professional activities involving raw materials that naturally contain radionuclides and which are not used for their radioactive properties.

Waste containing enhanced natural radioactivity can be accepted in various types of facilities, depending on its specific activity:
- in a waste disposal facility authorised by prefectural order if the conditions of acceptance provided for in the circular of 25th July 2006 relative to classified installations "Acceptance of waste containing enhanced or concentrated natural radioactivity in the waste disposal facilities" are fulfilled;
- in the very low level waste disposal facility, CIRES;
- in a storage facility. Some of this waste is waiting for a disposal route, in particular the commissioning of a disposal centre for long-lived, low level waste.

Four hazardous waste disposal facilities are authorised to receive waste containing enhanced natural radioactivity, namely:
- Villeparisis in Ile-de-France, authorised until 31st December 2020, for an annual capacity of 250,000 t/year;
- Bellegarde in Languedoc-Roussillon, authorised until 4th February 2029, for an annual capacity of 250,000 t/year until 2018 and 105,000 t/year beyond this;
- Champteussé-sur-Baconne in Pays de la Loire, authorised until 2049, for an annual capacity of 55,000 t/year;
- Argences in Basse-Normandie, authorised until 2023, for an annual capacity of 30,000 t/year.

The 2013-2015 PNGMDR required the implementation of regulatory changes in order to improve knowledge of the deposits of enhanced naturally radioactive waste and improve its traceability.

The transposition of Directive 2013/59/Euratom of 5th December 2013 setting the basic standards for radiation protection provides for a reinforcement of the provisions applicable to radiation of natural origin, and notably to human activities involving the presence of natural sources of radiation that lead to a notable increase in the exposure of workers or the public, and therefore including the activities of industries involving enhanced natural radioactivity. Their scope of application will extend to substances, products and materials that naturally contain radionuclides (potassium-40 and chains of uranium-238 and 235 and of thorium-232) at a level necessitating a radiation protection verification. The currently applicable regulations concerning activities involving enhanced natural radioactivity could therefore be modified or supplemented within the framework of this transposition.

1.6.3 Management of mining residues and mining waste rock from the old uranium mines

Uranium mines were worked in France between 1948 and 2001, producing 76,000 tons of uranium. Exploration, mining and processing work was carried out on about 250 sites in France spread over 27 *départements*. Ore processing was carried out in 8 plants. The former uranium mines are now almost all under the responsibility of Areva Mines.

The working of uranium mines produced two categories of products:
• mining waste rock, that is to say the rocks excavated to gain access to the ore; the quantity of mining waste rock extracted is estimated at about 167 million tonnes;
• static or dynamic processing tailings, which are the products remaining after extraction of the uranium from the ore. In France, these tailings represent 50 million tonnes spread over 17 disposal sites. The radioactivity measurements carried out on the disposal sites give values of the same order as the measurements taken in the environment of the site.

The regulatory context

The uranium mines and their annexes, and their conditions of closure, are covered by the mining code.

The disposal facilities for radioactive mining tailings are governed by section 1735 of the ICPE nomenclature.

Furthermore, the Minister of the Environment and the ASN Chairman issued a circular on 22nd July 2009 defining a plan of action relative to the management of the former uranium mines comprising the following lines of work:
• monitor the former mining sites;
• improve understanding of the environmental and health impact of the former uranium mines and their surveillance;
• manage the mining waste rock (better identify the uses and reduce impacts if necessary);
• reinforce information and consultation.

Most of the mining waste rock remains on the site where it was produced (mine in-fill, redevelopment work or spoil heaps). Nonetheless, 1 to 2% of the mining waste rock may have been used as backfill, in earthworks or for road beds in public places situated near the mining sites. Although the transfer of waste rock to the public domain has been traced since 1984, knowledge of transfers prior to 1984 remains incomplete. ASN and the Ministry of the Environment, in the framework of the action plan of the Circular of 22nd July 2009, asked Areva Mines to inventory the mining waste rock reused in the public domain in order to verify the compatibility of uses and to reduce the impacts if necessary.

Areva Mines has thus deployed a plan of action comprising three broad phases:
• aerial overflight around the former French mining sites to identify radiological singularities;
• inspection on the ground of areas identified in the overflight to confirm the presence of waste rock;
• treatment of areas of interest incompatible with the land usage.

The second phase of this action plan was completed in 2014. The DGPR defined the procedures for managing cases of confirmed presence of mining waste rock in its Instruction to Prefects of 8th August 2013. The resulting inventory maps are provisional maps submitted for public consultation. Members of the public are asked to communicate their observations to correct or supplement the maps on the basis of their memory of the utilisations of waste rock, where applicable. The definitive maps are associated with remediation action proposals if necessary. Some work has already been carried out on priority sites in 2015, that is to say sites where the calculation of the added annual effective dose excluding radon due to the presence of waste rock on generic scenarios exceeds the value of 0.6 mSv/year on the basis of a radiological impact study. All these operations are under the administrative surveillance of the Prefect, on the basis of proposals from the Regional directorate for the environment, planning and housing (Dreal). ASN provides assistance for the radiation protection of workers and the public and the management routes. In this context it encourages the complete clean-out of the sites when this is technically possible and asks that any other procedure implemented be justified with regard to this strategy. Furthermore, it is particularly vigilant to cases that could result in the exposure of persons, particularly to radon, in order to identify and deal with any cases similar to that of the house of Bessines-sur-Gartempe. Lastly, it ensures that the actions are carried out in complete transparency with maximum involvement of the local actors.

The long-term behaviour of the mining residue disposal sites

Redevelopment of the uranium processing tailings disposal sites consisted in placing a solid cover over the tailings to provide a protective barrier to limit the risks of intrusion, erosion, dispersion of the stored products and the risks of external and internal (radon) exposure of the surrounding populations.

The studies submitted for the 2013-2015 PNGMDR, based on ASN opinion 2012-AV-0168 of 11th October 2012, have provided greater insight into:
- the strategy chosen for the changes in the treatment of water collected from former mining sites;
- a doctrine for assessing the long-term integrity of the embankments surrounding the tailings disposal sites;
- the comparison of the surveillance data and the results of modelling to improve the relevance of the systems of surveillance and evaluation of the long-term dosimetric impact of the tailings disposal sites;
- the evaluation of the long-term dosimetric impact of the mining waste rock piles and the mining waste rock in the public domain in relation to the results obtained in the context of the Circular of 22nd July 2009;
- transport of uranium from the waste rock piles to the environment;
- the mechanisms governing the mobility of uranium and radium within uranium-bearing mining tailings.

These various studies have to be continued under the next two waste management plans, PNGMDR 2016-2018 and 2019-2021, as requested in ASN opinion of 9th February 2016 in order to:
- supplement the studies of the long-term evolution of processing residues and mining waste rock;
- supplement the method of evaluating the long-term resistance of embankments;
- study the possibilities of upgrading or shutting down the water treatment stations and ultimately proposing concrete risk- and impact-reduction actions on the various sites.

With regard to mining waste rock, the treatment of sites with uncovered waste rock must be continued. The consultation process must also be continued with the stakeholders on all these subjects, within the framework of the PNMGDR as well as at the local level.

Long-term management of the former mining sites

ASN is contributing to a technical guide on the management of former uranium mining sites that is currently being prepared under the coordination of the Ministry responsible for the Environment. It shall more particularly respond to several recommendations resulting from the report of the Limousin Pluralistic Expert Group (GEP) of September 2010: it will address the administrative status of the sites, the procedures for stopping mining work and the requirements in terms of redevelopment in the long-term perspective.

The Pluralistic Expert Group (GEP), the involvement and informing of the stakeholders

Set up in 2005, the Limousin Pluralistic Expert Group (GEP) submitted a first report containing its recommendations for the short-, medium- and long-term management of former uranium mining sites in France to the Minister responsible for the Environment and to the Chairman of ASN in September 2010. ASN and the Ministry responsible for the Environment are thus engaged in a plan of action dedicated to the implementation of these recommendations.

A second report was submitted to the Minister in 2013; it presents the results drawn from the presentation of the GEP's conclusions and recommendations to the local and national consultative bodies and an evaluation of the implementation of its recommendations. The GEP considers its involvement to have brought positive results and notes that its recommendations remain fully relevant. ASN and the Ministry responsible for the Environment have proposed the creation of a network of experts from the site monitoring commissions who would be assigned expert appraisal missions on questions of both local and national scope where justified by the societal aspect.

In 2014 ASN continued its involvement in the steering committee for the national inventory of uranium mining sites MIMAUSA (Memory and impact of uranium mines: summary and archives, available on *www.irsn.fr)*. This mining site inventory was updated in summer 2013; it provides access to all the environmental assessments submitted by Areva on account of the Circular of 22nd July 2009. It will ultimately be supplemented by a mining waste rock inventory.

2. MANAGEMENT OF SITES AND SOILS CONTAMINATED BY RADIOACTIVITY

A site contaminated by radioactive substances is defined as any site, whether abandoned or in operation, on which natural or artificial radioactive substances have been or are employed or stored in conditions such that the site may constitute a hazard for health and the environment.

Contamination by radioactive substances can be the result of industrial, medical or research activities involving radioactive substances. It can concern the places where these activities are carried out, but also their immediate or more remote vicinity. The activities concerned are generally either "nuclear activities" as defined by the Public Health Code, or activities concerned by enhanced natural radioactivity, as covered by the Order of 25th May 2005.

However, most of the sites contaminated by radioactive substances and today requiring management in fact concern past industrial activities, dating back to a time when radioactive hazards were not perceived in the same way as at present. The main industrial sectors from which the radioactive contamination identified today originated are: radium extraction for medical and para-pharmaceutical needs, from the early 20th century up to the end of the 1930s; the manufacture and application of luminescent radioactive paint for night vision and the industries working ores such as monazite or zircons. Sites contaminated by radioactive substances are managed on a case-by-case basis, requiring a precise diagnosis of the site and the contamination.

Several inventories of contaminated sites are available to the public and are complementary: Andra's national inventory, which is updated every 3 years and comprises the sites identified as contaminated by radioactive substances (the June 2015 edition is available on *www.andra.fr)* as well as the databases accessible from the web portal of the Ministry responsible for the Environment *(www.sites-pollues.ecologie.gouv.fr)* and dedicated to contaminated sites and soils.

In October 2012, ASN finalised its doctrine specifying the fundamental principles it has adopted for the management of sites polluted by radioactive substances. It thus considers that the reference procedure to adopt, when technically possible, is to completely clean out sites contaminated with radioactivity, even if the human exposure induced by the radioactive contamination seems limited.

ASN also believes that the solution involving the contamination being maintained in-situ can only be an interim solution or reserved for cases in which complete clean-out cannot be envisaged owing, in particular, to the volume of waste to be excavated.

ASN also considers that the management of contaminated sites requires public involvement when choosing the solution adopted, in order to create a climate of trust and minimise conflicts.

ASN also points out that in application of the "polluter-pays" principle written into the Environment Code, those responsible for the contamination are responsible for financing the operations to rehabilitate the contaminated site and to remove the waste resulting from these operations. If the responsible entities default, Andra, on account of its public service remit and by public requisition, ensures the rehabilitation of radioactive contaminated sites.

Lastly, ASN reiterates in its doctrine for the management of radioactive contaminated sites that any stance adopted by ASN is duly justified and presented in complete transparency to the stakeholders and the audiences concerned.

2.1 Regulatory framework

Article 542-12 of the Environment Code specifies that Andra is tasked in particular with collecting, transporting and dealing with radioactive waste and rehabilitating sites with radioactive contamination at the request of and expense of those responsible, or when requisitioned by the Government if those responsible for this waste or these sites have defaulted. Andra thus has a state subsidy which contributes to financing the missions of public interest entrusted to it. The French National Funding Commission for Radioactive Matters (CNAR) was set up within Andra in 2007. It is chaired by the Director-General of Andra and includes representatives of the Ministries responsible for the Environment, Energy and Health, of ASN, of IRSN, of the Association of Mayors of France, of environmental defence associations and qualified personalities.

Site of the Feursmetal plant (Loire *département)*, undergoing decontamination.

The commission met in 2015, more specifically to decide on the allocation of public funds for the management of contaminated sites considered to be priorities, such as Orflam-Plast in Pargny-sur Saulx, a clock-making site in Charquemont, the Isotopchim site in Ganagobie and the radium diagnosis operation.

Circular DGS/SDEA1/DGEC/DGPR/ASN No. 2008-349 of 17th November 2008 of the Minister responsible for the Environment relative to the management of certain radioactive waste and sites with radioactive contamination describes the applicable procedure for the management of contaminated radioactive sites governed by the ICPE regime and the Public Health Code, whether the party responsible is solvent or not. Whatever the case, the Prefect relies on the opinion of the classified installations inspectorate, ASN and the ARS (Regional Health Agency), to validate the site rehabilitation project, and issues a prefectural order to govern implementation of the rehabilitation measures. ASN may thus be called upon by the services of the Prefectures and the classified installations inspectors to give its opinion on the clean-out objectives of a site. The Ministry responsible for the Environment started updating this circular in 2015. ASN is involved in this work. Chapter 8 details the various demands concerning contaminated sites and soils to which the ASN divisions responded.

ENERGY TRANSITION FOR GREEN GROWTH ACT

A system of active institutional controls governing the management of land, constructions or structures that could cause human exposure to the harmful effects of ionising radiation and justifying radiation protection control and coming under the Public Health Code is currently being defined.

By Ordinance 2016-128 of 10th February 2016, the Government created a system of active institutional controls relating to radioactive substances, as already exists for the ICPEs and BNIs, when radioactive substances subsist on a plot of land or in a building (due to contamination by radioactive substances, after decontamination or in the presence of naturally radioactive materials) in order to maintain a record that will serve with regard to future uses and to define, if necessary, restrictions on use or prescriptions governing future development or demolition work.

2.2 The Radium Diagnosis operation

In October 2010, the State decided to carry out diagnoses in order to detect and if necessary treat any radium contamination resulting from past activities. Discovered by Pierre and Marie Curie in 1898, radium has been used in certain medical (the first cancer treatments) and craftwork activities (clock-making until the 1950s, due to its property of radioluminescence, and the manufacture of lightning arresters and cosmetic products).

These medical or craft activities have left traces of radium on certain sites. The diagnosis of the sites having accommodated an activity that used radium is a continuation of the many actions engaged by the State in recent years, such as the rehabilitation of sites on which research and radium extraction activities were carried out at the beginning of the 20th century, or the retrieval of radioactive objects from private households, etc.

This operation is free of charge for the occupants of the places concerned: the diagnosis consists in taking systematic measurements to detect the presence of any traces of radium or to confirm the absence of radium. These measurements are performed by a team of IRSN specialists, accompanied by an ASN coordinator, who contacts the occupant beforehand to explain the operation. On completion of the diagnosis, the occupants are informed verbally of the results, with subsequent written confirmation by letter. If traces of contamination are detected, rehabilitation operations are performed by Andra free of charge, with the agreement of the property owners. Ultimately, each person concerned is given a certificate guaranteeing the results of the operation.

New addresses were added to the initial list as the diagnosis operation progressed, with more than 160 sites in France being concerned at the end of 2014.

In 2015, 36 sites in Ile-de France and one site in Annemasse had been examined. The Annemasse site was diagnosed before the operation was launched in the Rhône-Alpes region, at the owner's request because a real estate transaction was envisaged in the near future.

Eight of the 36 sites in Ile-de-France were excluded outright because the buildings are too recent with respect to the period of potential manipulation of radium to be able to display any radioactive contamination.

IRSN has carried out more than 430 diagnoses since the operation began; in effect, the majority of the sites involve either one building with many apartments or several individual plots. The fact that the occupants were informed and that the operation was free of charge were vital factors in obtaining the occupants' agreement. There were only nine refusals out of more than 430 diagnoses performed.

These diagnoses led to twenty-five rehabilitation and renovation operations (twenty-one in Ile-de-France and four in Annemasse).

More than five years after the operation started, experience feedback shows that it is relatively well accepted by the occupants and environmental protection associations. The vast majority of the premises diagnosed are clear of radiological contamination. The contamination levels recorded are low and confirm that there is no health risk; the maximum dosimetry received is less than 2.4 mSv/ year (added value), which is approximately the same order of magnitude as the dose received per year by the French population from naturally occurring sources of radioactivity.

The engagement of further diagnosis operations has been suspended in Ile-de-France since March 2014 at the request of the Ministry responsible for the Environment, in order more specifically to modify the conditions of performance of the operation. ASN would like the diagnoses to be resumed rapidly in order to finalise the operation in Ile-de-France and start diagnoses in other regions. ASN considers moreover that ambitious treatment targets must be maintained for the contaminated sites.

2.3 ASN's international action in the management of contaminated sites and soils

ASN has participated since 2012 in the meetings of the International Working Forum on Regulatory Supervision of Legacy Sites (RSLS)[8] organised by the International Atomic Energy Agency (IAEA). The aim of this forum is to promote interchanges between the various organisations responsible for regulating and monitoring "legacy sites" in order to identify the sites' needs in terms of management and means for preventing the creation of future "legacy sites".

Moreover, ASN contributes to the work carried out under the CIDER project (Constraints to Implementing Decommissioning and Environmental Remediation programmes) initiated in 2012 by the IAEA. This project aims to identify the main difficulties that contracting parties can encounter, particularly in site rehabilitation, and propose aids to overcome them.

In 2015, ASN continued its collaboration with the United States Environmental Protection Agency (US-EPA), tasked with managing the "Superfund" programme to protect American citizens against the risks associated with sites polluted by abandoned or unmonitored hazardous waste and particularly sites contaminated by radioactive substances.

8. International forum on the regulations for sites contaminated by radionuclides, presenting a risk for health and/or the environment and which are a subject of concern for the Authorities.

3. OUTLOOK

ASN broadly considers that the French radioactive waste management system, based on a specific body of legislative and regulatory texts, a National Plan for the Management of Radioactive Materials and Waste (PNGMDR) and an Agency dedicated to the management of radioactive waste (Andra) that is independent from the waste producers, is capable of regulating and implementing a structured and coherent national waste management policy. ASN considers that there must eventually be safe management for all waste, more specifically by means of a disposal solution. Updating of the PNGMDR which is planned for 2016 will provide the opportunity to set new short- and medium-term objectives to achieve this goal.

The regulations concerning the management of radioactive waste

ASN will finalise the resolution relative to the packing of radioactive waste in 2016. It will draw up draft resolutions concerning radioactive waste disposal and storage facilities and a draft guide to application of the resolution concerning waste studies. These draft texts will be made available for consultation by the stakeholders and the public in 2016. ASN will also finalise the guide to application of the resolution concerning the waste management study and the assessment of the waste produced in the BNIs.

ASN will also be vigilant in ensuring that the work to transpose Directive 2013/59/Euratom of 5th December 2013 setting basic radiation protection standards does not call into question the French policy in which there are no clearance levels for waste from basic nuclear installations while at the same time reinforcing oversight of waste containing enhanced natural radioactivity.

Concerning licensee waste management strategies

ASN periodically assesses the strategies implemented by the licensees to ensure that each type of waste has an appropriate management route and that the different routes are mutually coherent. ASN in particular remains attentive to ensuring that the licensees have the necessary treatment or storage capacity for managing their radioactive waste and anticipate sufficiently far in advance the construction of new facilities or renovation work on older facilities. In 2016, ASN will continue to closely monitor the legacy waste or spent fuel retrieval and packaging operations, focusing on those presenting the most significant safety implications.

In this respect, ASN will give the conclusions of its assessment of EDF's waste management strategy and receive the waste management strategies of CEA and Areva in 2016.

ASN will be attentive to ensuring that CEA meets its final shutdown commitments concerning its old facilities which no longer comply with safety requirements, and particularly its decommissioning file submission schedule (BNI 56 in 2017, BNI 37-B in 2017, BNI 22 in 2020). ASN will also be attentive to the progress of the strategic projects for the decommissioning and legacy waste retrieval operations (Diadem, BNI 37-A, the solid waste part, management of waste on the Saclay site).

Concerning Low-Level, Long-Lived Waste (LLW-LL)

ASN considers that it is vital to move forward in setting up management routes for low-level long-lived radioactive waste. Andra's mid-2015 submission of the report required by the PNGMDR is an essential and strategic step in setting up such routes. ASN considers it necessary that, following the examination of this report in early 2016, the Government set new objectives for commissioning management solutions for this waste. Furthermore, depending on the results of this report, the waste producers may have to firstly deploy new storage capacities to avoid delaying the decommissioning operations, and secondly speed up the deployment of alternative strategies if their waste is not compatible with Andra's project.

In 2016, ASN will start revising the safety guide relative to the disposal of low-level long-lived radioactive waste.

Concerning the High and Intermediate-Level, Long-Lived Waste (HL/ILW-LL)

With regard to the Cigéo project for the disposal of high and intermediate level, long-lived waste, 2016 will see the submission of Andra's safety options file for Cigéo, containing more specifically the project's safety options, the technical retrievability options, a preliminary version of the waste acceptance specifications and a project development plan. This file will constitute the first overall dossier on the safety of the facility since 2009. It will be subject to an international peer review under the auspices of the IAEA before ASN issues its opinion.

In November 2015, several members of the National Assembly submitted a bill indicating the conditions for creation of a reversible deep geological repository for high and intermediate-level long-lived radioactive waste which should be debated in Parliament during 2016. It must in particular define the notion of reversibility. ASN will publish its doctrine concerning reversibility in 2016.

ASN again underlines that it is important for the waste producers to make progress in the packaging of their waste, particularly waste resulting from waste retrieval and packaging operations, and notes that this preliminary version of the waste acceptance specifications drafted by Andra will enable requirements concerning the future waste packages to be detailed.

The Cigéo project is thus entering an industrial phase in which the responsibility of the various actors and stakeholders must comply with the requirements of the Environment Code and the BNI System.

ASN recommends that the cost of disposal of the substances that could potentially be placed in deep geological disposal but which are not included in the current project inventory - spent fuels in particular - be updated.

Concerning the management of the former uranium mining sites and polluted sites and soils

With regard to the former uranium mining sites, in 2016 ASN will endeavour to address the requests of the Dreals (Regional directorates for the environment, planning and housing) regarding the Areva Mines action plan for the management of mining waste rock. It will focus in particular on the management of potentially sensitive situations, especially with regard to the radon risk. It will aim to ensure that the measures are taken in complete transparency and with the involvement of local stakeholders and it will continue its work on the management of former mining sites in collaboration with the Ministry responsible for the Environment.

As far as the contaminated sites and soils are concerned, ASN will continue in 2016 to state its position on the projects for the rehabilitation of contaminated sites on the basis of the principles of the doctrine it published in October 2012 and will work with the Ministry responsible for the Environment on the revision of Circular No. 2008-349 of 17th November 2008 relative to the management of certain types of radioactive waste and radioactive contamination sites on the basis of its experience feedback. It will also maintain its investment in the operational management of the Radium Diagnosis operation. It will pursue its action in collaboration with the government departments concerned and the other stakeholders.

ASN will also continue its involvement in international work on these subjects, in particular with the IAEA, ENSREG, WENRA, and bilaterally with its counterparts.

Appendix A
List of Basic Nuclear Installations as at 31st December 2015

To regulate all civil nuclear activities and installations in France, ASN has set up a regional organization comprising 11 regional divisions based in Bordeaux, Caen, Châlons-en-Champagne, Dijon, Lille, Lyon, Marseille, Nantes, Orléans, Paris and Strasbourg.

The Paris division also covers the French overseas *départements* and collectivities. The Caen and Orléans divisions are responsible for BNI regulation in the Brittany and Ile-de-France regions respectively.

A Basic Nuclear Installation (BNI) is one which, by its very nature or owing to the quantity or activity of the radioactive substances it contains, is subject to specific regulatory arrangements as defined by the TSN Act of 13th June 2006 (codified in Books I and V of the Environment Code by Order 2012-6 of 5th January 2012). These installations must be authorised by decree issued following a public inquiry and an ASN opinion. Their design, construction, operation and decommissioning are all regulated.

The following are BNIs:
1. Nuclear reactors;
2. Large installations for the preparation, enrichment, fabrication, treatment or storage of nuclear fuels or the treatment, storage or disposal of radioactive waste;
3. Large installations containing radioactive or fissile substances;
4. Large particle accelerators;
5. The deep geological repositories for radioactive waste.

With the exception of nuclear reactors and the possible future deep geological repositories for radioactive waste, which are all BNIs, Decree 2007-830 of 11th May 2007 relative to the nomenclature of basic nuclear installations sets the threshold for entry into the BNI system for each category.

For technical or legal reasons, the concept of a basic nuclear installation can cover a number of different physical situations: for example in a nuclear power plant, each reactor may be considered as a separate BNI, or a given BNI might in fact consist of two reactors. Similarly, a fuel cycle plant or a CEA centre can comprise several BNIs.

These different configurations do not alter the regulatory conditions in any way.

The following are subject to the BNI system:
- facilities under construction, provided that they are the subject of a creation authorisation decree;
- facilities in operation;
- facilities shut down or undergoing decommissioning, until they are delicensed by ASN.

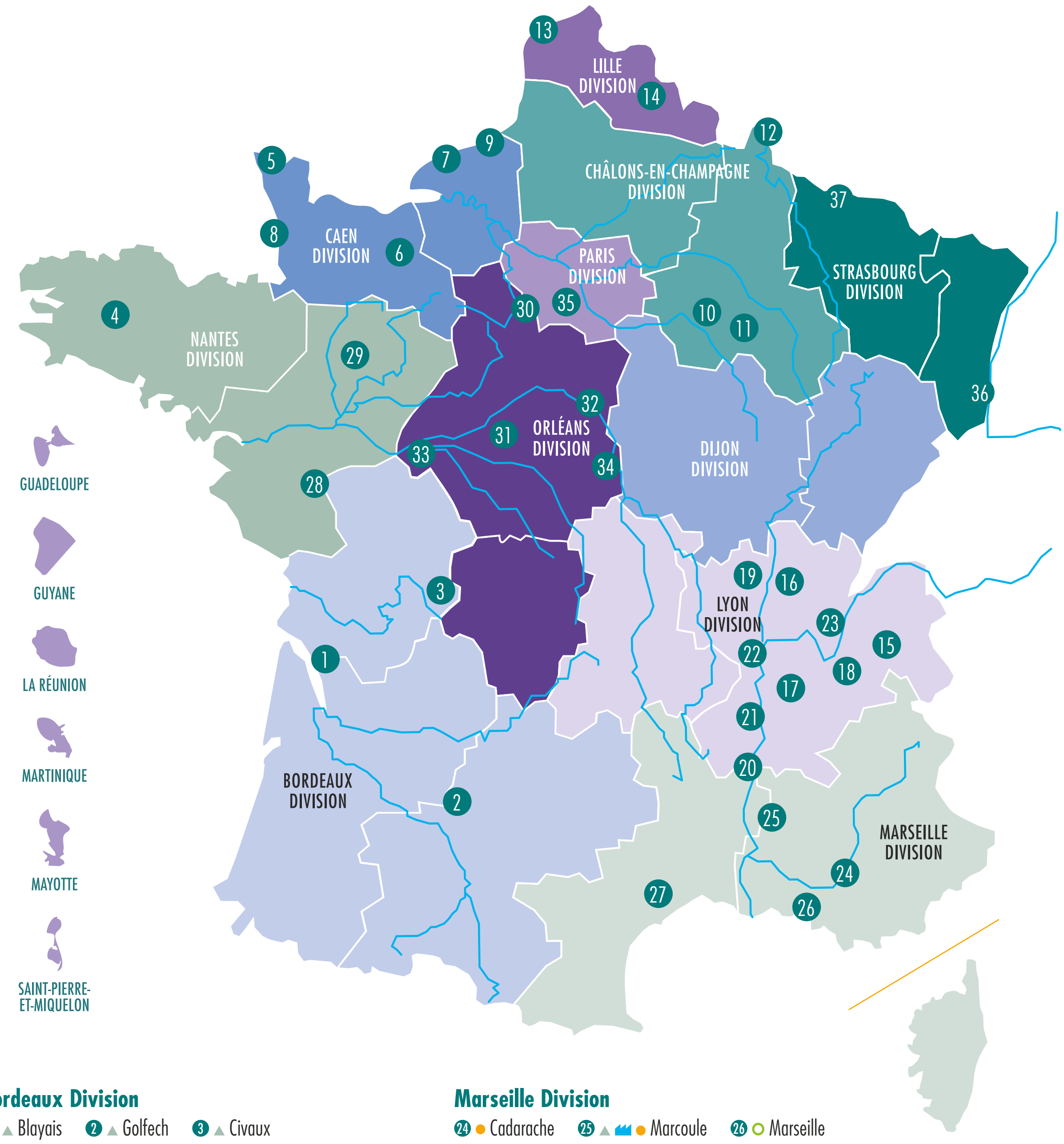
As at 31st December 2015, there were 125 BNIs (legal entities).

The declared BNIs are those which existed prior to publication of Decree n° 63-1228 of 11th December 1963 concerning nuclear installations and for which said decree did not require authorisation but simply notification to the Minister in charge of Atomic Energy.

The notified BNIs are those which existed prior to the publication of Decree 63-1228 of 11th December 1963 concerning nuclear facilities and for which neither said decree nor the TSN Act of 13th June required authorisation but simply notification on the basis of the acquired rights (see Articles 33 and 62 of the TSN Act, codified in Articles L. 593-35 and L. 593-36 of the Environment Code).

The missing BNI numbers correspond to facilities that figured in previous issues of the list, but which no longer constitute BNIs further to their delicensing (see chapter 15) or their licensing as new basic nuclear installations.

SITES REGULATED by the ASN regional divisions



Bordeaux Division
1 ▲ Blayais 2 ▲ Golfech 3 ▲ Civaux

Caen Division
4 ▲ Brennilis 5 Factory ■ La Hague 6 ○ Caen 7 ▲ Paluel
8 ▲ Flamanville 9 ▲ Penly

Châlons-en-Champagne Division
10 ▲ Nogent-sur-Seine 11 ■ Soulaines-Dhuys 12 ▲ Chooz

Lille Division
13 ▲ Gravelines 14 ○ Maubeuge

Lyon Division
15 ● Grenoble 16 ▲ ○ Bugey 17 Factory Romans-sur-Isère
18 Factory Veurey-Voroize 19 ○ Dagneux 20 ▲ Factory ○ Tricastin
21 ▲ Cruas-Meysse 22 ▲ Saint-Alban 23 ▲ Creys-Malville

Marseille Division
24 ● Cadarache 25 ▲ Factory ● Marcoule 26 ○ Marseille
27 ○ Narbonne

Nantes Division
28 ○ Pouzauges 29 ○ Sablé-sur-Sarthe

Orléans Division
30 ● Saclay 31 ▲ Saint-Laurent-des-Eaux
32 ▲ Dampierre-en-Burly 33 ▲ ○ Chinon
34 ▲ Belleville-sur-Loire 35 ● Fontenay-aux-Roses

Strasbourg Division
36 ▲ Fessenheim 37 ▲ Cattenom

Type of installation
▲ Nuclear power plant
Factory
● R&D laboratory
■ Disposal of waste
○ Other

SITE NAME	NAME AND LOCATION OF THE INSTALLATION	LICENSEE	TYPE OF INSTALLATION	BNI
LOCATION OF INSTALLATIONS REGULATED BY THE BORDEAUX DIVISION				
1 BLAYAIS	BLAYAIS NUCLEAR POWER PLANT (reactors 1 and 2) 33820 Saint-Ciers-sur-Gironde	EDF	Reactors	86
1 BLAYAIS	BLAYAIS NUCLEAR POWER PLANT (reactors 3 and 4) 33820 Saint-Ciers-sur-Gironde	EDF	Reactors	110
2 GOLFECH	GOLFECH NUCLEAR POWER PLANT (reactor 1) 82400 Golfech	EDF	Reactor	135
2 GOLFECH	GOLFECH NUCLEAR POWER PLANT (reactor 2) 82400 Golfech	EDF	Reactor	142
3 CIVAUX	CIVAUX NUCLEAR POWER PLANT (reactor 1) BP 1 86320 Civaux	EDF	Reactor	158
3 CIVAUX	CIVAUX NUCLEAR POWER PLANT (reactor 2) BP 1 86320 Civaux	EDF	Reactor	159
LOCATION OF INSTALLATIONS REGULATED BY THE CAEN DIVISION				
4 BRENNILIS	MONTS D'ARRÉE EL4D 29218 Huelgoat	EDF	Reactor undergoing decommissioning	162
5 LA HAGUE	SPENT FUEL REPROCESSING PLANT (UP2) 50107 Cherbourg	AREVA NC	Transformation of radioactive substances (decommissioning in progress)	33
5 LA HAGUE	EFFLUENT AND SOLID WASTE TREATMENT STATION (STE2) AND SPENT NUCLEAR FUELS REPROCESSING FACILITY (AT1) 50107 Cherbourg	AREVA NC	Transformation of radioactive substances (decommissioning in progress)	38
5 LA HAGUE	ELAN IIB FACILITY 50107 Cherbourg	AREVA NC	Transformation of radioactive substances (decommissioning in progress)	47
5 LA HAGUE	MANCHE WASTE REPOSITORY (CSM) 50448 Beaumont-Hague	ANDRA	Disposal of radioactive substances (under surveillance)	66
5 LA HAGUE	HAO (HIGH LEVEL OXIDE) FACILITY 50107 Cherbourg	AREVA NC	Transformation of radioactive substances (decommissioning in progress)	80
5 LA HAGUE	REPROCESSING PLANT FOR SPENT FUEL ELEMENTS FROM LIGHT WATER REACTORS "UP3 A" 50107 Cherbourg	AREVA NC	Transformation of radioactive substances	116
5 LA HAGUE	REPROCESSING PLANT FOR SPENT FUEL ELEMENTS FROM LIGHT WATER REACTORS "UP2 800" 50107 Cherbourg	AREVA NC	Transformation of radioactive substances	117
5 LA HAGUE	LIQUID EFFLUENT AND SOLID WASTE TREATMENT STATION "STE3" 50107 Cherbourg	AREVA NC	Transformation of radioactive substances	118
6 CAEN	NATIONAL LARGE HEAVY ION ACCELERATOR (GANIL) 14021 Caen Cedex	GIE GANIL	Particle accelerator	113
7 PALUEL	PALUEL NUCLEAR POWER PLANT (reactor 1) 76450 Cany-Barville	EDF	Reactor	103
7 PALUEL	PALUEL NUCLEAR POWER PLANT (reactor 2) 76450 Cany-Barville	EDF	Reactor	104
7 PALUEL	PALUEL NUCLEAR POWER PLANT (reactor 3) 76450 Cany-Barville	EDF	Reactor	114
7 PALUEL	PALUEL NUCLEAR POWER PLANT (reactor 4) 76450 Cany-Barville	EDF	Reactor	115
8 FLAMANVILLE	FLAMANVILLE NUCLEAR POWER PLANT (reactor 1) 50830 Flamanville	EDF	Reactor	108
8 FLAMANVILLE	FLAMANVILLE NUCLEAR POWER PLANT (reactor 2) 50830 Flamanville	EDF	Reactor	109
8 FLAMANVILLE	FLAMANVILLE NUCLEAR POWER PLANT (reactor 3 - EPR) 50830 Flamanville	EDF	Reactor	167
9 PENLY	PENLY NUCLEAR POWER PLANT (Reactor 1) 76370 Neuville-lès-Dieppe	EDF	Reactor	136
9 PENLY	PENLY NUCLEAR POWER PLANT (Reactor 2) 76370 Neuville-lès-Dieppe	EDF	Reactor	140

SITE NAME	NAME AND LOCATION OF THE INSTALLATION	LICENSEE	TYPE OF INSTALLATION	BNI
LOCATION OF INSTALLATIONS REGULATED BY THE CHÂLONS-EN-CHAMPAGNE DIVISION				
10 NOGENT-SUR-SEINE	NOGENT NUCLEAR POWER PLANT (reactor 1) 10400 Nogent-sur-Seine	EDF	Reactor	129
10 NOGENT-SUR-SEINE	NOGENT NUCLEAR POWER PLANT (reactor 2) 10400 Nogent-sur-Seine	EDF	Reactor	130
11 SOULAINES-DHUYS	AUBE WASTE REPOSITORY (CSA) 10200 Bar-sur-Aube	ANDRA	Radioactive waste surface repository	149
12 CHOOZ	CHOOZ B NUCLEAR POWER PLANT (reactor 1) 08600 Givet	EDF	Reactor	139
12 CHOOZ	CHOOZ B NUCLEAR POWER PLANT (reactor 2) 08600 Givet	EDF	Reactor	144
12 CHOOZ	ARDENNES NUCLEAR POWER PLANT CNA-D 08600 Givet	EDF	Reactor undergoing decommissioning	163
LOCATION OF INSTALLATIONS REGULATED BY THE LILLE DIVISION				
13 GRAVELINES	GRAVELINES NUCLEAR POWER PLANT (reactors 1 and 2) 59820 Gravelines	EDF	Reactors	96
13 GRAVELINES	GRAVELINES NUCLEAR POWER PLANT (reactors 3 and 4) 59820 Gravelines	EDF	Reactors	97
13 GRAVELINES	GRAVELINES NUCLEAR POWER PLANT (reactors 5 and 6) 59820 Gravelines	EDF	Reactors	122
14 MAUBEUGE	NUCLEAR MAINTENANCE FACILITY 59600 Maubeuge	SOMANU	Nuclear maintenance	143
LOCATION OF INSTALLATIONS REGULATED BY THE LYON DIVISION				
15 GRENOBLE	EFFLUENT AND SOLID WASTE TREATMENT STATION 38041 Grenoble Cedex	CEA	Transformation of radioactive substances (decommissioning in progress)	36
15 GRENOBLE	ACTIVE MATERIALS ANALYSIS LABORATORY (LAMA) 38041 GRENOBLE CEDEX	CEA	Utilisation of radioactive substances (decommissioning in progress)	61
15 GRENOBLE	HIGH FLUX REACTOR (RHF) 38041 Grenoble Cedex	Institut Max von Laue Paul Langevin	Reactor	67
15 GRENOBLE	DECAY INTERIM STORAGE FACILITY 38041 Grenoble Cedex	CEA	Storage of radioactive substances (decommissioning in progress)	79
16 BUGEY	BUGEY NUCLEAR POWER PLANT (reactor 1) BP 60120 - 01155 Lagnieu Cedex	EDF	Reactor undergoing decommissioning	45
16 BUGEY	BUGEY NUCLEAR POWER PLANT (reactors 2 and 3) BP 60120 - 01155 Lagnieu Cedex	EDF	Reactors	78
16 BUGEY	BUGEY NUCLEAR POWER PLANT (reactors 4 and 5) BP 60120 - 01155 Lagnieu Cedex	EDF	Reactors	89
16 BUGEY	BUGEY INTER-REGIONAL WAREHOUSE BP 60120 - 01155 Lagnieu Cedex	EDF	Storage of new fuel	102
16 BUGEY	ACTIVATED WASTE PACKAGING AND STORAGE INSTALLATION (ICEDA) 01120 SAINT VULBAS	EDF	Packaging and interim storage of radioactive substances	173
17 ROMANS-SUR-ISÈRE	NUCLEAR FUELS FABRICATION UNIT 26104 Romans-sur-Isère	AREVA NP	Fabrication of radioactive substances	63
17 ROMANS-SUR-ISÈRE	NUCLEAR FUELS FABRICATION UNIT 26104 Romans-sur-Isère	AREVA NP	Fabrication of radioactive substances	98
18 VEUREY-VOROIZE	NUCLEAR FUELS FABRICATION PLANT 38113 Veurey-Voroize	SICN	Fabrication of radioactive substances (decommissioning in progress)	65
18 VEUREY-VOROIZE	PELLET FABRICATION FACILITY 38113 Veurey-Voroize	SICN	Fabrication of radioactive substances (decommissioning in progress)	90
19 DAGNEUX	DAGNEUX IONISATION PLANT Z.I. Les Chartinières 01120 Dagneux	IONISOS	Utilisation of radioactive substances	68
20 TRICASTIN	TRICASTIN NUCLEAR POWER PLANT (reactors 1 and 2) 26130 Saint-Paul-Trois-Châteaux	EDF	Reactors	87
20 TRICASTIN	TRICASTIN NUCLEAR POWER PLANT (reactors 3 and 4) 26130 Saint-Paul-Trois-Châteaux	EDF	Reactors	88

SITE NAME	NAME AND LOCATION OF THE INSTALLATION	LICENSEE	TYPE OF INSTALLATION	BNI
20 TRICASTIN	GEORGES BESSE PLANT FOR URANIUM ISOTOPE SEPARATION BY GASEOUS DIFFUSION (EURODIF) 26702 Pierrelatte Cedex	EURODIF PRODUCTION	Transformation of radioactive substances	93
20 TRICASTIN	URANIUM HEXAFLUORIDE PREPARATION PLANT (COMURHEX) 26130 Saint-Paul-Trois-Châteaux	AREVA NC	Transformation of radioactive substances	105
20 TRICASTIN	URANIUM CLEAN-UP AND RECOVERY FACILITY 26130 Saint-Paul-Trois-Châteaux	SOCATRI	Factory	138
20 TRICASTIN	INSTALLATION TU 5 BP 16 - 26701 Pierrelatte	AREVA NC	Transformation of radioactive substances	155
20 TRICASTIN	TRICASTIN OPERATIONAL HOT UNIT (BCOT) BP 127 - 84504 Bollène Cedex	EDF	Nuclear maintenance	157
20 TRICASTIN	GEORGES BESSE 2 PLANT FOR CENTRIFUGAL SEPARATION OF URANIUM ISOTOPES 26702 Pierrelatte Cedex	SET	Transformation of radioactive substances	168
20 TRICASTIN	AREVA TRICASTIN ANALYSIS LABORATORY (ATLAS) 26700 Pierrelatte	AREVA NC	Laboratory for the utilisation of radioactive substances	176
21 CRUAS-MEYSSE	CRUAS NUCLEAR POWER PLANT (reactors 1 and 2) 07350 Cruas	EDF	Reactors	111
21 CRUAS-MEYSSE	CRUAS NUCLEAR POWER PLANT (reactors 3 and 4) 07350 Cruas	EDF	Reactors	112
22 SAINT-ALBAN	SAINT-ALBAN/SAINT-MAURICE NUCLEAR POWER PLANT (reactor 1) 38550 Le Péage-de-Roussillon	EDF	Reactor	119
22 SAINT-ALBAN	SAINT-ALBAN/SAINT-MAURICE NUCLEAR POWER PLANT (reactor 2) 38550 Le Péage-de-Roussillon	EDF	Reactor	120
23 CREYS-MALVILLE	SUPERPHENIX REACTOR 38510 Morestel	EDF	Reactor undergoing decommissioning	91
23 CREYS-MALVILLE	FUEL STORAGE FACILITY 38510 Morestel	EDF	Storage of radioactive substances	141
LOCATION OF INSTALLATIONS REGULATED BY THE MARSEILLE DIVISION				
24 CADARACHE	TEMPORARY DISPOSAL FACILITY (PEGASE) AND SPENT NUCLEAR FUEL DRY STORAGE INSTALLATION (CASCAD) 13115 Saint-Paul-lez-Durance Cedex	CEA	Storage of radioactive substances	22
24 CADARACHE	CABRI 13115 Saint-Paul-lez-Durance Cedex	CEA	Reactor	24
24 CADARACHE	RAPSODIE 13115 Saint-Paul-lez-Durance Cedex	CEA	Reactor	25
24 CADARACHE	PLUTONIUM TECHNOLOGY FACILITY (ATPu) 13115 Saint-Paul-lez-Durance Cedex	CEA	Fabrication or transformation of radioactive substances (decommissioning in progress)	32
24 CADARACHE	SOLID WASTE TREATMENT STATION (STD) 13115 Saint-Paul-lez-Durance Cedex	CEA	Transformation of radioactive substances	37-A
24 CADARACHE	EFFLUENT TREATMENT STATION (STE) 13115 Saint-Paul-lez-Durance Cedex	CEA	Transformation of radioactive substances	37-B
24 CADARACHE	MASURCA 13115 Saint-Paul-lez-Durance Cedex	CEA	Reactor	39
24 CADARACHE	EOLE 13115 Saint-Paul-lez-Durance Cedex	CEA	Reactor	42
24 CADARACHE	ENRICHED URANIUM PROCESSING FACILITY (ATUE) 13115 Saint-Paul-lez-Durance Cedex	CEA	Fabrication of radioactive substances (decommissioning in progress)	52
24 CADARACHE	ENRICHED URANIUM AND PLUTONIUM WAREHOUSE 13115 Saint-Paul-lez-Durance Cedex	CEA	Storage of radioactive substances	53
24 CADARACHE	CHEMICAL PURIFICATION LABORATORY 13115 Saint-Paul-lez-Durance Cedex	CEA	Transformation of radioactive substances (decommissioning in progress)	54
24 CADARACHE	ACTIVE FUEL EXAMINATION LABORATORY (LECA) AND SPENT FUEL REPROCESSING, CLEAN-OUT AND REPACKAGING STATION (STAR) 13115 Saint-Paul-lez-Durance Cedex	CEA	Storage of radioactive substances	55
24 CADARACHE	RADIOACTIVE WASTE INTERIM STORAGE AREA 13115 Saint-Paul-lez-Durance Cedex	CEA	Storage of radioactive substances	56

SITE NAME	NAME AND LOCATION OF THE INSTALLATION	LICENSEE	TYPE OF INSTALLATION	BNI
24 CADARACHE	PHEBUS 13115 Saint-Paul-lez-Durance Cedex	CEA	Reactor	92
24 CADARACHE	MINERVE 13115 Saint-Paul-lez-Durance Cedex	CEA	Reactor	95
24 CADARACHE	LABORATORY FOR RESEARCH AND EXPERIMENTAL FABRICATION OF ADVANCED NUCLEAR FUELS (LEFCA) 13115 Saint-Paul-lez-Durance Cedex	CEA	Fabrication of radioactive substances	123
24 CADARACHE	CHICADE BP 1 - 13108 Saint-Paul-lez-Durance Cedex	CEA	R&D laboratory	156
24 CADARACHE	CEDRA 13115 Saint-Paul-lez-Durance Cedex	CEA	Packaging and interim storage of radioactive substances	164
24 CADARACHE	MAGENTA 13115 Saint-Paul-lez Durance Cedex	CEA	Reception and shipment of nuclear materials	169
24 CADARACHE	EFFLUENT ADVANCED MANAGEMENT AND PROCESSING FACILITY "AGATE" 13115 Saint-Paul-lez Durance Cedex	CEA	Packaging and interim storage of radioactive substances	171
24 CADARACHE	JULES HOROWITZ REACTOR (JHR) 13115 Saint-Paul-lez Durance Cedex	CEA	Reactor	172
24 CADARACHE	ITER 13115 Saint-Paul-lez-Durance Cedex	International organisation ITER	Nuclear fusion reaction experiments with tritium and deuterium and deuterium plasmas	174
25 MARCOULE	PHENIX 30205 Bagnols-sur-Cèze	CEA	Reactor	71
25 MARCOULE	ATALANTE Chusclan 30205 Bagnols-sur-Cèze	CEA	R&D laboratory and study of actinides production	148
25 MARCOULE	NUCLEAR FUELS FABRICATION PLANT (MELOX) BP 2 - 30200 Chusclan	AREVA NC	Fabrication of radioactive substances	151
25 MARCOULE	CENTRACO 30200 Codolet	SOCODEI	Radioactive waste and effluent processing	160
25 MARCOULE	GAMMATEC 30200 Chuslan	Synergy Health Marseille	Ionisation treatment of materials, products and equipment, for industrial purposes and for research and development	170
26 MARSEILLE	GAMMASTER IONISATION PLANT – M.I.N. 712 13323 Marseille Cedex 14	Synergy Health Marseille	Ionisation installation	147
27 NARBONNE	CONTAINED STORAGE OF CONVERSION RESIDUES (ÉCRIN) (Malvési) 11100 Narbonne	AREVA NC	Storage of radioactive substances	175
LOCATION OF INSTALLATIONS REGULATED BY THE NANTES DIVISION				
28 POUZAUGES	POUZAUGES IONISATION PLANT Z.I. de Monlifant 85700 Pouzauges	IONISOS	Ionisation installation	146
29 SABLÉ-SUR-SARTHE	SABLÉ-SUR-SARTHE IONISATION PLANT Z.I. de l'Aubrée 72300 Sablé-sur-Sarthe	IONISOS	Ionisation installation	154
LOCATION OF INSTALLATIONS REGULATED BY THE ORLÉANS DIVISION				
30 SACLAY	ULYSSE (Saclay) 91191 Gif-sur-Yvette Cedex	CEA	Reactor undergoing decommissioning	18
30 SACLAY	ARTIFICIAL RADIONUCLIDES PRODUCTION FACILITY 91191 Gif-sur-Yvette Cedex	CIS Bio International	Fabrication or transformation of radioactive substances	29
30 SACLAY	LIQUID EFFLUENT MANAGEMENT ZONE 91191 Gif-sur-Yvette Cedex	CEA	Transformation of radioactive substances	35
30 SACLAY	OSIRIS-ISIS 91191 Gif-sur-Yvette Cedex	CEA	Reactors	40
30 SACLAY	HIGH ACTIVITY LABORATORY 91191 Gif-sur-Yvette Cedex	CEA	Utilisation of radioactive substances (decommissioning in progress)	49
30 SACLAY	SPENT FUEL TEST LABORATORY (LECI) 91191 Gif-sur-Yvette Cedex	CEA	Utilisation of radioactive substances	50
30 SACLAY	SOLID RADIOACTIVE WASTE MANAGEMENT ZONE 91191 Gif-sur-Yvette Cedex	CEA	Storage and packaging of radioactive substances	72
30 SACLAY	POSEIDON IRRADIATION FACILITIES 91191 Gif-sur-Yvette Cedex	CEA	Utilisation of radioactive substances	77

SITE NAME	NAME AND LOCATION OF THE INSTALLATION	LICENSEE	TYPE OF INSTALLATION	BNI
30 SACLAY	ORPHEE 91191 Gif-sur-Yvette Cedex	CEA	Reactor	101
31 SAINT-LAURENT-DES-EAUX	SAINT-LAURENT-DES-EAUX NUCLEAR POWER PLANT (reactors A1 and A2) 41220 La Ferté-Saint-Cyr	EDF	Reactors undergoing decommissioning	46
31 SAINT-LAURENT-DES-EAUX	INTERIM STORAGE OF IRRADIATED GRAPHITE SLEEVES 41220 La Ferté-Saint-Cyr	EDF	Storage of radioactive substances	74
31 SAINT-LAURENT-DES-EAUX	SAINT-LAURENT-DES-EAUX NUCLEAR POWER PLANT (reactors B1 and B2) 41220 La Ferté-Saint-Cyr	EDF	Reactors	100
32 DAMPIERRE-EN-BURLY	DAMPIERRE NUCLEAR POWER PLANT (Reactors 1 and 2) 45570 Ouzouer-sur-Loire	EDF	Reactors	84
32 DAMPIERRE-EN-BURLY	DAMPIERRE NUCLEAR POWER PLANT (Reactors 3 and 4) 45570 Ouzouer-sur-Loire	EDF	Reactors	85
33 CHINON	IRRADIATED MATERIALS FACILITY 37420 Avoine	EDF	Utilisation of radioactive substances	94
33 CHINON	CHINON INTER-REGIONAL WAREHOUSE 37420 Avoine	EDF	Storage of new fuel	99
33 CHINON	CHINON NUCLEAR POWER PLANT (reactors B1 and B2) 37420 Avoine	EDF	Reactors	107
33 CHINON	CHINON NUCLEAR POWER PLANT (reactors B3 and B4) 37420 Avoine	EDF	Reactors	132
33 CHINON	CHINON A1D 37420 Avoine	EDF	Reactor undergoing decommissioning	133
33 CHINON	CHINON A2 D 37420 Avoine	EDF	Reactor undergoing decommissioning	153
33 CHINON	CHINON A3 D 37420 Avoine	EDF	Reactor undergoing decommissioning	161
34 BELLEVILLE-SUR-LOIRE	BELLEVILLE NUCLEAR POWER PLANT (reactor 1) 18240 Léré	EDF	Reactor	127
34 BELLEVILLE-SUR-LOIRE	BELLEVILLE NUCLEAR POWER PLANT (reactor 2) 18240 Léré	EDF	Reactor	128
35 FONTENAY-AUX-ROSES	PROCEDE 92265 Fontenay-aux-Roses Cedex	CEA	Decommissioning research installation	165
35 FONTENAY-AUX-ROSES	SUPPORT 92265 Fontenay-aux-Roses Cedex	CEA	Installation for treatment of effluents and storage of decommissioning waste	166
LOCATION OF INSTALLATIONS REGULATED BY THE STRASBOURG DIVISION				
36 FESSENHEIM	FESSENHEIM NUCLEAR POWER PLANT (reactors 1 and 2) 68740 Fessenheim	EDF	Reactors	75
37 CATTENOM	CATTENOM NUCLEAR POWER PLANT (reactor 1) 57570 Cattenom	EDF	Reactor	124
37 CATTENOM	CATTENOM NUCLEAR POWER PLANT (reactor 2) 57570 Cattenom	EDF	Reactor	125
37 CATTENOM	CATTENOM NUCLEAR POWER PLANT (reactor 3) 57570 Cattenom	EDF	Reactor	126
37 CATTENOM	CATTENOM NUCLEAR POWER PLANT (reactor 4) 57570 Cattenom	EDF	Reactor	137

Appendix B
Acronyms and abbreviations

ACCIRAD	Guidelines on a risk analysis of ACCIdental and unintended exposures in RADiotherapy
ACN	Aarhus Convention and Nuclear (Anccli initiative)
ACO	Orsay Collider Ring (LURE - CNRS - Orsay)
ACRO	Association for the Control of Radioactivity in the West
ADNR	Agreement on the transport of dangerous substances on the river Rhine
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
ADS	Accelerator Driven System (nuclear reactor driven by a particle accelerator)
AEN	French acronym for the Nuclear Energy Agency (NEA-OECD)
AERB	Atomic Energy Regulatory Board (Indian regulatory body)
AFCEN	French Association for NSSS Equipment Construction Rules
AFCN	Federal Agency for Nuclear Control (Belgium)
AFPPE	French Association of Radiographers
AFSSAPS	French Health Product Safety Agency (replaced by the ANSM as of December 2011)
AGATE	Effluent Advanced Management and Processing Facility (CEA - Cadarache)
AIEA	French acronym for the International Atomic Energy Agency (IAEA)
ALARA	As Low As Reasonably Achievable (radiation protection principle also called "optimization principle")
ALS	Saclay Linear Accelerator (CEA)
AMI	Irradiated Material Facility (EDF - Chinon)
ANCCLI	National Association of Local Information Commissions and Committees (since 2009)
ANDRA	French National Radioactive Waste Management Agency
ANR	French National Research Agency
ANSES	French National Agency responsible for Health and Safety of Food, the Environment and Work (since July 2010)
ANSM	French National Agency for Drug and Health Product Safety (formerly AFSSAPS)
AP-913	Maintenance doctrine (EDF)
APEC	Fuel Evacuation Facility (EDF - Creys-Malville - Isère département)
AP-HP	Public Health Service – Paris Hospitals
AREVA	Industrial group active in the nuclear fuel cycle and construction of nuclear installations
AREVA NC	Fuel cycle licensee (Areva group)
AREVA NP	Designer and builder of nuclear power plants (Areva group)

ARS	Regional Health Agency (since 2010)
ASG	Steam Generator Auxiliary Feedwater system (PWR)
ASIT	Swiss Technical Inspection Association
ASN	*Autorité de Sûreté Nucléaire,* the French nuclear regulatory body, also referred to as the French Nuclear Safety Authority
ASND	Defence Nuclear Safety Authority (structure responsible for regulating nuclear safety and radiation protection with regard to defence-related nuclear activities and installations. It is placed under the authority of DSND)
ASN-SFRO	This scale is designed to allow communication with the public in comprehensible, explicit terms with regard to radiation protection events leading to unexpected or unforeseeable effects on patients undergoing external-beam radiotherapy medical procedures.
ASR	Simple Refuelling Outage (PWR)
ASTRID	Advanced Sodium Technological Reactor for Industrial Demonstration (prototype Sodium-cooled Fast Reactor (SFR) project (CEA))
AT1	Former pilot reprocessing plant for spent fuel from fast neutron reactors (CEA - La Hague)
ATALANTE	Alpha Facility and Laboratory for Transuranian elements Analysis and Reprocessing Studies (CEA - Marcoule)
ATEX	EXplosive ATmospheres (ATEX regulation)
ATMEA	Joint venture between Areva and MHI responsible for the development, commercialisation, certification and sale of ATMEA 1, a new 1,100 MWe reactor
ATPu	Plutonium Technology Facility (Areva NC - Cadarache)
ATUE	Enriched uranium processing facility (CEA - Cadarache)
AZF	Former name of the company operating the fertiliser plant destroyed in the 21st September 2001 accident in Toulouse
BCOT	Tricastin Operational Hot Unit (nuclear maintenance installation - EDF - Bollène)
Bel V	Technical Safety Organisation and subsidiary of FANC (since 2008)
BK	BK Fuel Building
BMU	German Federal Ministry of the Environment, Nature Conservation and Nuclear Safety
BRGM	Geological and Mining Research Office
BSM	Fissile Materials Storage and Handling Building (MASURCA reactor)
BSS	Basic Safety Standards
CABRI	Research reactor (CEA - Cadarache)
CADA	Administrative Documents Access Commission
CANR	CNRA Committee on Nuclear Regulatory Activities
CARSAT	French retirement and occupational health insurance fund
CASCAD	Cadarache bunker research reactor spent fuel storage facility (CEA)
CCAP	French Central Committee for Pressure Vessels
CCP	Joint consultative commission
CCSN	Canadian Nuclear Safety Commission (CNSC)
CE	European Community - "CE mark" - mandatory and regulatory conformity mark for some products in the European Union to ensure that the product conforms with the "essential requirements" defined by a European Directive

CEA	French Atomic Energy Commission (now the Atomic Energy and Alternative Energy Commission)
CEDAI	Internal Authorisations Assessment Committee
CEDRA	Radioactive waste packaging and interim storage unit (CEA - Cadarache)
CEE	European Economic Community
CEIDRE	Construction and Operation Expert Appraisal and Inspection Centre (EDF)
CELIMENE	Former cell for examining the fuel from the EL3 reactor (CEA – Saclay)
CENTRACO	Low-level waste processing and packaging centre (SOCODEI - Marcoule)
CEPN	Nuclear Protection Evaluation Centre
CERCA	Company for the Design and Fabrication of Atomic Fuel
CERN	European Organization for Nuclear Research
CGA	French Armed Forces General Inspectorate
CGEDD	General Council for the Environment and Sustainable Development (Ministry of the Environment, Energy and the Sea)
CH	Hospital Centre
CHICADE	Chemistry, waste characterization (CEA Cadarache)
CHRU	Regional University Hospital
CHSCT	Committee for Health, Safety and Working Conditions
CHU	University Hospital
CIC	French Inter-ministerial Crisis Committee
CICNR	Inter-ministerial Committee for Nuclear or Radiological Emergencies
CIESCT	Inter-Company Working Conditions and Safety Committee
CIGEO	Industrial Geological Disposal Facility
CIPR	International Commission on Radiological Protection (ICRP)
CIRC	International Agency for Research on Cancer (part of the WHO - Lyon)
CIREA	Interministerial Commission for Artificial Radioelements
CIRES	Industrial centre for collection, storage and disposal (Andra)
CIS bio International	Company specialising in international biomedical technologies, especially radiopharmaceuticals
CISSCT	Inter-firm Health, Safety and Working Conditions Committee (for EDF power plants)
CITMD	French Interministerial Commission for the Carriage of Hazardous Goods
ClF_3	Chlorine trifluoride
CLCC	Anti-cancer Centre
CLI	Local Information Committee
CLIGEET	Tricastin Major Energy Facility Local Information Committee (name of the CLI on the Tricastin site since 2008)
CLIO	Accelerator (see PHIL)
CLIS	Local Committee for Information and Follow-up - name of the CLI for underground laboratories
	Local Committee for Information and Monitoring (name of the CLI at the Fessenheim plant since 2009)
CMIR	Mobile Radiological Intervention Unit

CNA-D	Equipment storage facility during decommissioning of the Chooz A reactor (EDF - Chooz)
CNAM	French National Health Insurance Fund
CNAR	French National Funding Commission for Radioactive Matters
CNPE	Nuclear Power Generation Site (NPP) - EDF
CNRA	Committee on Nuclear Regulatory Activities (NEA)
CNRS	French National Centre for Scientific Research
COCT	Working Conditions Guidance Council
COD	Departmental Operations Centre
CODERST	Council for the Environment and for Health and Technological Risks
Codex alimentarius	Collection of food health safety and consumer protection standards produced by a commission set up by the FAO and the WHO
CODIRPA	Steering committee for managing the post-accident phase of a nuclear accident or radiological emergency situation
CODIS-CTA	Departmental Fire and Emergency Operational Centre - Alert Processing Centre
COFRAC	French Accreditation Committee
COFREND	French Non-Destructive Testing Confederation
COFSOH	Social, Organisational and Human Factors Steering Committee
COMURHEX	*Société pour la COnversion de l'Uranium en métal et en HEXafluorure* (Company for converting uranium into metal and hexafluoride) (Areva group)
CP0	First series of 900 MWe nuclear reactors (EDF)
CPP	Main Primary (cooling) System (PWR)
CPY	Second series of 900 MWe nuclear reactors (EDF)
CRPPH	Committee on Radiation Protection and Public Health (NEA)
CSA	Aube Waste Repository (Andra) (former name of the CSFMA)
CSD-C	Standard Compacted Waste Package
CSD-V	Standard Vitrified Waste Package
CSIN	French acronym for the CSNI (Committee on the Safety of Nuclear Installations - NEA)
CSM	Manche Waste Repository (Andra)
CSN	*Consejo de Seguridad Nuclear* (Spanish regulatory body)
CSP	Main Secondary Cooling System (PWR)
CSPRT	High Council for the Prevention of Technological Risks (since 2010)
CSS	Commission on Safety Standards (IAEA)
CSTB	Building Industry Scientific and Technical Centre
CSWG	Codes and Standards Working Group (part of the MDEP programme)
CTC	Technical Emergency Centre
CTIF	French metal casting research and development centre
CTP	ASN Social Dialogue Committee
DAC	Authorisation Creation Decree (BNI Procedure)
DCI	Communication and Public Information Department (ASN)
DCN	Nuclear Power Plants Department (ASN)

DEP	Nuclear Pressure Equipment Department (ASN)
DEU	Environment and Emergency Department (ASN)
DFCI	French equivalent of Ionisation Chamber Smoke Detector (ICSD)
DFK	*Deutsch-Französische Kommission für Fragen der Sicherheitkerntechnischer Einrichtungen* (Franco-German commission on questions of nuclear installation safety)
DGAC	General Directorate for Civil Aviation (Ministry of the Environment, Energy and the Sea)
DGEC	General Directorate for Energy and Climate (Ministry of the Environment, Energy and the Sea and Ministry of the Economy and Finance)
DGITM	General Directorate for Infrastructure, Transport and the Sea (Ministry of the Environment, Energy and the Sea)
DGOS	General Directorate for Health Care (Ministry of Social Affairs and Health)
DGPR	General Directorate for Risk Prevention (Ministry of the Environment, Energy and the Sea)
DGS	General Directorate for Health (Ministry of Social Affairs and Health)
DGSCGC	General Directorate for Civil Protection and Crisis management (Ministry of the Interior)
DGSNR	General Directorate for Nuclear Safety and Radiation Protection (ASN central structure until the November 2006 reform)
DGT	General Directorate for Labour (Ministry of Labour, Employment, Professional Training and Social Dialogue)
DHOS	Directorate for Hospitalisation and Health Care Organisation (Ministry of Social Affairs and Health)
DIADEM	Irradiating or Alpha Waste from Decommissioning
DICWG	Digital Instrumentation and Control Working Group (part of the MDEP programme)
DIS	Ionising Radiation and Health Department (ASN)
DIRECCTE	Regional Directorate for Businesses Competition Policy Consumer Affairs Labour and Employment
DOrS	Safety Guidance Document
DOS	Safety Options File (for BNIs)
DOT	Department of Transportation (United States)
DPSN	Nuclear Safety and Protection Division (CEA)
DRC	Nuclear Waste, Research Facilities, and Cycle Department (ASN)
DREAL	Regional Directorate for the Environment, Planning and Housing
DRI	International Relations Department (ASN)
DRIEE	Inter-Department Regional Directorate for Environment and Energy (Ile-de-France region)
DSND	Delegate for Nuclear Safety and Radiation Protection for National Defence Installations and Activities (see ASND)
DSWG	Design Specific Working Group
DTS	Transport and Sources Department (ASN)
DTI	Total Indicative Dose
EAN	European ALARA Network (the aim of which is to promote implementation of the ALARA principle)
EACA	European Association of Competent Authorities on the transport of radioactive material

EAS	Reactor Building Containment Spray System (PWR)
ECRIN	Contained storage of conversion residues
ECS	Stress tests
EDE	Containment annulus ventilation system (PWR)
EDF	*Électricité De France*
EEVSE	Glass Storage Building
EFRS	European Federation of Radiographer Societies
EEVLH	Glass Storage Building Extension on the La Hague site (Areva NC - La Hague)
EFOMP	European Federation of Organisations in Medical Physics
EGRA	Expert Group on Regulatory Authorisation (sub-group of the NEA's CRPPH)
EGRPM	Expert Group on the Radiological Aspects of the Fukushima Accident
EHESP	French School of Public Health
EIL	Inter-Laboratory Tests
EIP	Elements Important for Protection
EIS	Elements Important for Safety
ÉLAN II B	Former sealed source fabrication installation (CEA - La Hague)
EL3	Heavy water reactor No. 3 (former experimental reactor - CEA - Saclay)
EL4	Heavy water reactor No. 4 (former Monts d'Arrée nuclear power plant - EDF - Brennilis)
EL4-D	Equipment interim storage installation for decommissioning of the Monts d'Arrée nuclear power plant
ENEF	European Nuclear Energy Forum
ENSREG	European Nuclear Safety REgulators Group (high-level group set up by the European Commission to deal with nuclear safety and waste management - former HLG)
EOLE	Research reactor (CEA - Cadarache)
EPA	Environmental Protection Agency (United States)
EPI	French acronym for Personal Protective Equipment (PPE)
EPR	Evolutionary Pressurized water Reactor (new type of nuclear reactor developed by Areva NP)
EPRUS	Health Emergency Preparedness and Response Organisation
EPS	Probabilistic Safety Study
EPSF	French Railway Safety Authority
ERPAN	European Radiation Protection Authorities Network
ERR	European Radiation Research society
ESE	Significant Environmental Event
ESP	Pressure Vessel
ESPIC	Private health establishment of collective interest
ESPN	Nuclear Pressure Vessel
ESR	Significant Radiation Protection Event
European Society of Radiology	European Synchrotron Radiation Facility (synchrotron implanté à Grenoble)
ESS	Significant Safety Event
ETP	French acronym for Full-Time Equivalent (FTE)

EURATOM	EURopean ATOMic energy community Treaty
EURODIF	EUROpean gaseous DIFfusion enrichment plant
EVEREST	French acronym for “evolving towards entry without standard suit” (entry into a controlled area in working overalls - initiative implemented by EDF)
FA-MA	Low Level - Intermediate Level wastes
FANR	Federal Authority for Nuclear Regulation (UAE)
FAO	Food and Agriculture Organization of the United Nations
FARN	Nuclear rapid intervention force
FA-VL	Low Level - Long Lived Waste (LLW-LL)
FBFC	Franco-Belgian Fuel Fabrication Company (Pierrelatte and Romans-sur-Isère)
FMA	Low or Intermediate Level Waste (LLW/ILW)
FMA-VC	Low or Intermediate Level, Short-Lived Waste (LLW/ILW-SL)
FRAMATOME	French NSSS builder (now known as Areva NP)
FRAMATOME	Framatome - Advanced Nuclear Power (company set up by Areva and Siemens to develop the new EPR reactor type – now known as Areva NP)
FRAREG	FRAmatome REGulators (Association of regulatory bodies in countries operating power plants of French design)
FSOH	French acronym for Social, Organisational and Human Factors (SOHF)
GALICE	Nuclear fuel management method (EDF)
GAMMATEC	Ionisation installation (company ISOTRON France in Marcoule)
GANIL	National Large Heavy Ion Accelerator (Caen)
GB II	Georges Besse II plant
Génération IV	International “Forum” of ten countries and the European Union to develop future nuclear reactors, known as 4th Generation (GEN IV)
GEOSAF	International Project on Demonstrating the Safety of Geological Disposal (IAEA project)
GEP	Pluralistic Expert Group
GFR	Gas-cooled Fast Reactor (see RNR-G)
GIAG	Severe Accident Action Guide
GIE	Economic Interest Grouping
GIF	Generation IV International Forum (see GEN IV)
GPE	Advisory Committee of Experts (reporting to ASN)
GPD	Advisory Committee of Experts for Waste (reporting to ASN)
GPESPN	Advisory Committee of Experts for Nuclear Pressure Equipment (reporting to ASN)
GPMED	Advisory Committee of Experts for Radiation Protection in Medical and Forensic Applications of Ionising Radiation (reporting to ASN)
GPMDR	Advisor Committee of Experts on Radioactive Materials and Waste (Anccli)
GPPA	Advisory Committee of Experts on “Post-Accident and regions” (Anccli)
GPR	Advisory Committee of Experts for Nuclear Reactors (reporting to ASN)
GPRADE	Advisory Committee of Experts in Radiation protection for industrial and research applications of ionising radiation and in the Environment (reporting to ASN)

GPT	Advisory Committee of Experts for Transport (reporting to ASN)
GPU	Advisory Committee of Experts for Laboratories and Plants (reporting to ASN)
GRS	*Gesellschaft für Anlagen und Reaktorsicherheit* (technical support organisation for the German regulatory body)
GT	French acronym for Working Group (WG)
GV	French acronym for Steam Generator (SG)
G8	Group of the 8 leading industrial nations (Germany, Canada, United States, France, Italy, Japan, United Kingdom and Russia)
HAO	Oxide High Activity facility (Areva NC - La Hague)
HARMONIE	Former fast neutron source reactor (CEA - Cadarache)
HAS	French National Authority for Health – since 2005
HATVP	High Authority for Transparency in Public Life
HA	High Level (HL waste)
HCFDC	French High Committee for Civil Defence
HCSP	French High Public Health Council
HCTISN	French High Committee for Transparency and Information on Nuclear Security (created by the 13th June 2006 Act)
HDR	High Dose-Rate
HERCA	Heads of the European Radiological protection Competent Authorities
HFD	Defence High Official
HFDS	Defence and Security High Official
HIDRA	Human Intrusion in the context of Disposal of Radioactive Waste (IAEA project on the unintentional impact of human activities on deep geological disposal repositories)
man-Sv	Man-sievert: the SI unit for collective dose. For information, the collective dose is the sum of the individual doses received by a given group of persons. To give an example, the collective dose of 10 people having each received 1 mSv equals 10 man-mSv.
HTR	High Temperature Reactor (thermal neutron high temperature reactor)
Hydro-téléray	Network for continuous measurement of radioactivity in major rivers (IRSN)
ICEDA	Activated waste packaging and interim storage installation (EDF interim storage project)
ICPE	Installation Classified on Environmental Protection grounds (owing to its potential impact on the public and the environment, installation subject to the regulations defined in part I of Book V of the French Environment Code)
ICSN	Nuclear Safety Cooperation Instrument (NSCI) (European Union)
IDN	International Decommissioning Network
IEER	Institute for Energy and Environmental Research
IFFO-RME	French Institute of Trainers in Major Risks and Environmental Protection
IFSN	Swiss Federal Nuclear Safety Inspectorate
ILL	Laue-Langevin Institute - Grenoble
IMDG	International Maritime Dangerous Goods code
IMRT	Intensity Modulated Radiation Therapy
INAPARAD	NAtional Inventory of RADioactive Lightning Arresters
INB	Basic Nuclear Installation (BNI)

INBS	Secret Basic Nuclear Installation (SBNI)
INCa	French National Cancer Institute
INERIS	French National Institute for the Study of Industrial Environments and Risks
INES	International Nuclear and Radiological Event Scale
INRA	International Nuclear Regulators' Association (grouping the German, Canadian, Spanish, US, French, Japanese, UK and Swedish nuclear regulators)
	French National Institute for Agricultural Research
INSAG	International Nuclear Safety Advisory Group (IAEA)
INSTN	French National Institute for Nuclear Science and Technology - CEA
InVS	French Health Monitoring Institute
IONISOS	Company operating ionisation installations
IOTA	Installations, Structures, Works and Activities
IRE	National Radioelements Institute, Fleurus - Belgium
IRCA	CAdarache IRradiator (CEA)
IRM	Magnetic Resonance Imaging (MRI)
IRPA	International Radiation Protection Association
IRRS	Integrated Regulatory Review Service (audit on the organisation of a regulatory body performed by the IAEA)
IRSN	French Institute for Radiation Protection and Nuclear Safety
ISIS	Research reactor (CEA - Saclay)
ISO	International Organisation for Standardisation
ISWG	Issue Specific Working Group (part of the MDEP programme)
ITER	International Thermonuclear Experimental Reactor (nuclear fusion reactor to be installed at Cadarache)
JFR	French Radiology Days (annual conference organised by SFR)
JOUE	French acronym for the *Official Journal of the European Union* (OJEU)
KINS	Korea Institute of Nuclear Safety (technical support organisation for the South Korean regulatory body)
LAMA	Active Materials Analysis Laboratory (CEA - Grenoble)
LCPu	Plutonium Chemistry Laboratory (CEA - Fontenay-aux-Roses)
LDAC	Fuel Assembly Shearing Laboratory (CEA - Cadarache)
LDR	Low Dose-Rate
LECA	Active Fuel Examination Laboratory (CEA - Cadarache)
LECI	Spent Fuel Testing Laboratory (CEA - Saclay)
LEFCA	Laboratory for Research and Experimental Fabrication of Advanced nuclear Fuels (CEA - Cadarache)
LFR	Lead cooled Fast Reactor
LHA	High Activity Laboratory (CEA - Saclay)
LHC	Large Hadron Collider (CERN - Geneva)
LIDEC	Ceidre Integrated Assessments Laboratory (EDF)
LPC	Chemical Purification Laboratory (Areva NC - Cadarache)

LUDD	Laboratories, Plants, Waste and Decommissioning
LURE	Electromagnetic Radiation Laboratory (CNRS - Orsay)
MAGENTA	Cellular nuclear materials storage facility project (CEA - Cadarache)
MASURCA	Cadarache fast-breeder mockup (research reactor - CEA - Cadarache)
MA-VL	Intermediate Level, Long-Lived Waste (ILW-LL)
MCMF	Central Fissile Material Warehouse (CEA - Cadarache)
MDEP	Multinational Design Evaluation Programme (multinational initiative in which secretaryship is ensured by the NEA, and which aims at pooling the knowledge of the safety authorities who will be responsible for the regulatory evaluation of new reactors)
MEA	Management and Appraisal Mission (ASN)
MEDDE	Ministry of Ecology, Sustainable Development and Energy (from November 2012 to February 2016)
MEEM	Ministry of the Environment, Energy and the Sea (since February 2016)
MELOX	MOX fuel fabrication plant (Marcoule)
MÉLUSINE	Research reactor (CEA - Grenoble)
MIMAUSA	History and impact of uranium mines: summary and archives - Programme for an inventory of uranium mining sites
MINERVE	Research reactor (CEA - Cadarache)
MIR	Inter-regional Fuel Stores (EDF - Bugey and Chinon)
MOX	Mixed OXide fuel (mix of uranium and plutonium oxides)
MSNR	Nuclear Safety and Radiation Protection Mission (MEEM/DGPR)
MSR	Molten Salt Reactor
MTMD	Hazardous Materials Transport Mission
NECSA	Nuclear Energy Corporation of South Africa (South-African public entity carrying out R&D in the nuclear power field)
NF	French Standard
NMA	Maximum Permissible Level (MPL) (for radioactive contamination of foodstuffs of livestock feed)
NNR	National Nuclear Regulator (South African regulatory body)
NNSA	National Nuclear Safety Administration (Chinese regulatory body)
	National Nuclear security Administration (an agency of the US DOE, United States Department of Energy)
NRA	Nuclear Regulation Authority (Japanese regulatory body)
NRBC	Nuclear Radiological Biological Chemical
NRC	Nuclear Regulatory Commission (American regulatory body)
NRD	French acronym for Diagnostic Reference Level (DRL)
NRPA	Norwegian Radiation Protection Authority
NSGC	Nuclear Security Guidance Committee
NSSC	Nuclear Safety and Security Commission (South Korean nuclear regulator)
NUSSC	NUclear Safety Standards Committee (IAEA)
OA-LA	Approved Body - Approved Laboratory (for inspection/testing)
OACI	French acronym for the International Civil Aviation Organization (ICAO)
OARP	Bodies Approved for Radiation Protection inspections

OCDE	French acronym for the Organisation for Economic Cooperation and Development (OECD)
OEEI	EDF project to "Obtain Installations in Exemplary Condition"
OFSP	Federal Public Health Office (Swiss radiation protection inspection agency)
OIT	French acronym for the International Labour Organisation (ILO)
OMS	French acronym for the World Health Organisation (WHO - United Nations)
ONR	Office for Nuclear Regulation (United Kingdom nuclear regulator)
ONU	French acronym for the United Nations Organization (UNO)
OPAL	Tool for raising local stakeholder awareness of post-accident issues
OPECST	Parliamentary Office for the Evaluation of Scientific and Technological Choices
ORAMED	Optimization of Radiation protection for MEDical staff
ORPHEE	Research reactor (CEA - Saclay)
ORSEC	General plan organising the emergency services at departmental, defence zone, or maritime prefecture level, should a disaster be declared by the State
ORSEC-TMR	The ORSEC plan specific to the Transport of Radioactive Materials
OSART	Operational Safety Review Team (IAEA -organised mission to assess the operational safety of nuclear power plants)
OSIRIS	Research reactor (CEA - Saclay)
OSPAR	Convention for the Protection of the Marine Environment of the North-East Atlantic (signed in 1992 and combining and updating the Oslo 1972 and Paris 1974 conventions)
P4	First series of 1,300 MWe PWRs (EDF)
P'4	Second series of 1,300 MWe PWRs (EDF)
PAA	*Panstwowa Agencja Atomistyki* (Polish National Atomic Energy Agency)
PACA	Provence-Alpes-Côte d'Azur (region)
PC	Command Post
PCC	Command and Control Post (EDF)
PC Com	Communication Command Post (ASN)
PCD	Command and Decision Post
PCL	Local Command Post (installation operation)
PCM	Resources Command Post (logistics)
PCR	Person Competent in Radiation protection
PCRD	Research and Development Framework Programme
PCS	Local Safeguard Plan
PDR	Pulsed Dose-Rate
PEGASE	Spent fuel and radioactive substances interim storage installation (CEA - Cadarache)
PHÉBUS	Research reactor (CEA - Cadarache)
PHÉNIX	Fast neutron reactor (CEA - Marcoule)
PHIL	Linear electron accelerator (CNRS - Orsay)
PIGD	Industrial Waste Management Programme
PIRATE	Response plans that are integrated in an overall heightened security, prevention, protection and counter-terrorism approach
PLECI	Extension of the LECI (BNI 50)

PNGMDR	French National Plan for the Management of Radioactive Materials and Waste (instituted by the 28th June 2006 Programme Act on the sustainable management of radioactive materials and waste)
POPM	Organisational Plan in Medical radiation Physics
POSÉIDON	Irradiation facility (CEA - Saclay)
PPI	Off-site Emergency Plan (specific emergency plan drawn up by the State addressing risks associated with the existence and operation of specific installations or structures)
PRISME	Eurodif project for intensive rinsing followed by venting
PROCEDE	Decommissioning research facility (CEA - Fontenay-aux-Roses)
PRSE2	Regional Health Environment Plan
PSP	Multi-year Strategic Plan
PSRPM	Medical Radiation Physicist
PTR	Reactor cavity and spent fuel pit cooling and treatment system (PWR)
PUI	On-site Emergency Plan (crisis management plan drawn up by a BNI licensee)
PV	Report Minutes of a meeting Violation report
RANET	Response Assistance NETwork (network for response to requests for assistance in the case of a radiological emergency - IAEA)
RAPSODIE	Former fast neutron experimental reactor (CEA - Cadarache)
RASSC	Radiation Safety Standards Committee (IAEA)
RCC	Design and Construction Rules
RCC-E	Design and Construction Rules for Electrical equipment
RCC-G	Design and Construction Rules for Civil Engineering
RCC-M	Design and Construction Rules for Mechanical equipment
RCD	Waste Recovery and Packaging
RCF	Regulatory Cooperation Forum
RCMI	French acronym for Intensity Modulated Radiation Therapy (IMRT)
RCN	RCN Act: Act on Civil Liability in the field of nuclear energy
RCV	Chemical and Volume Control System (PWR)
REA	*Rosenergoatom* (Russian nuclear power plant operator)
REC II	Reception, shipment and monitoring unit for uranium hexafluoride containers (Georges Besse II plant)
REP	Pressurised Water Reactor
RFS	Basic Safety Rule
RGE	General Operating Rules
RHF	High Flux Reactor (Institut Laue-Langevin - Grenoble)
RIA	Radio Immunology Assay
RIC	Regulatory Information Conference (annual public conference held by the United States regulatory body)
RID	Regulations governing the international carriage of dangerous goods by rail
RIS	Safety Injection System (PWR)
RIV	Targeted internal radiotherapy
RJH	Jules Horowitz Reactor (irradiation reactor: CEA - Cadarache)
RM2	Former RadioMetallurgy laboratory No. 2 (CEA - Fontenay-aux-Roses)

RNM	French national network of environmental radioactivity measurements
RNR	Fast Neutron Reactor
RNR-G	Gas-cooled Fast Neutron Reactor
RNR-Na	Sodium-cooled Fast Neutron Reactor
ROTONDE	Solid waste management installation project (CEA - Cadarache)
RPE	Radiation Protection Expert
RPO	Radiation Protection Officer
RPS	Preliminary Safety Analysis Report (BNI Procedure)
RRA	Residual Heat Removal System (PWR)
RRI	Component Cooling System (PWR)
RSE-M	Rules for In-service Monitoring of Mechanical equipment
RSN	Regulation concerning the Safety of Ships
RTN	*Rostekhnadzor* (Russian Nuclear Safety Authority, attached to the Federal Service of Industrial, Environmental and Nuclear Regulation)
RTGV	Steam Generator Tube Rupture
RTR	Research and Test Reactors (fuel assemblies known as "aluminides" used in research reactors)
RWMC	Radioactive Waste Management Committee (NEA)
R & D	Research and Development
SAMU	French Emergency Medical Service
SAPPRE	Reflex Phase Population Alert System
SATURNE	Former particle accelerator (CEA - Saclay)
SCWR	SuperCritical Water Reactor
SDIS	Departmental Fire and Emergency Service
SEC	Essential Service Water System (ESWS) (PWR)
SEIVA	Valduc Information Exchange Structure (Association created around the CEA centre at Valduc)
SET	*Société d'Enrichissement du Tricastin*
SEVESO	"Seveso" Directive: name given to Council Directive 96/82/EC of 9th December 1996 on the control of major-accident hazards involving dangerous substances (with reference to the site of a 1976 accident in a chemical plant)
SFMN	French Nuclear Medicine and Molecular Imaging Society
SFPM	French Society of Medical Physics
SFR	French Society of Radiology
SFRO	French Society for Radiation Oncology
SFRP	French Radiation Protection Society
SG	Office of Administration (ASN)
SGDN	French General Secretariat for National Defence (until 2009)
SGDSN	General Secretariat for Defence and National Security (since 2010)
SICN	*Société Industrielle de Combustible Nucléaire* (Industrial Nuclear Fuel Company)
SILOE	Research reactor (CEA - Grenoble)
SILOETTE	Research reactor (CEA - Grenoble)
SISERI	Ionising Radiation Exposure Monitoring Information System
SMI	French acronym for Integrated Management System (IMS)

SMQ	French acronym for Quality Management System (QMS)
SNM	Military Nuclear System (either a weapon system designed or adapted to deploy a nuclear weapon, or a military vessel propelled by nuclear power)
SNRIU	State Nuclear Regulatory Inspectorate of Ukraine (Ukrainian nuclear regulatory body)
SOC	Organised disposal of hulls (Areva NC - La Hague)
SOCATRI	*SOCiété Auxiliaire du TRIcastin* (company operating an Areva owned clean-up and uranium recovery installation at Bollène - Vaucluse département)
SOCODEI	*SOciété pour le COnditionnement des Déchets et Effluents Industriels* (Company for industrial effluent and waste treatment - EDF group)
SOLEIL	LURE Optimised Source of Intermediary Energy Light (synchrotron located in Saint- Aubin, Essonne *département*)
SOMANU	*SOciété de MAintenance Nucléaire* (Nuclear Maintenance Company - Areva group - Maubeuge)
SPIRAL	Radioactive Accelerated Ion Beam Production Source (GANIL - Caen)
SSM	*Sträl Säkerhets Myndigheten* (Swedish nuclear safety and radiation protection Authority)
STAR	Treatment, Clean-out and Reconditioning Station (CEA - Cadarache)
STD	Waste Treatment Station
STE	Technical Operating Specifications
	Effluent Treatment Station
STED	Effluent and Waste Treatment Station
STEDS	Radioactive Effluent and Solid Waste Treatment Station
STE2	Effluent collection and treatment and precipitation sludge storage facility (Areva NC - La Hague)
STE3	Effluent collection and treatment and bituminous package storage facility (Areva NC - La Hague)
STELLA	Active liquid effluent treatment station project (CEA - Saclay)
STUK	*Säteilyturvakeskus* (Radiation and Nuclear Safety Authority - Finnish regulatory body)
SUP	French acronym meaning "active institutional controls"
SUPERPHÉNIX	Fast Breeder Reactor undergoing decommissioning (Creys-Malville - Isère *département*)
SUPPORT	Effluent treatment and waste storage facility undergoing decommissioning (CEA - Fontenay-aux-Roses)
T7	Vitrification facility (Areva NC - La Hague)
TAEK	*Türkiye Atome Enerjisi Kurumu* (Turkish Nuclear Safety Authority)
TAR	Cooling Tower
TCSP	Exclusive Lane Public Transport
TDM	TomoDensitoMeter (Computed Tomography scanner)
TECV	TECV Act: Act of 17th August 2015 relative to Energy Transition for Green Growth
Téléhydro	Network for continuous monitoring of waste water radioactivity in major cities (IRSN)
Téléray	Ambient radioactivity measurement network
TEMP	French acronym for Single Photon Emission Computed Tomography (SPECT)
TEMP-TDM	French acronym for Single Photon Emission Computed Tomography coupled with a CT scanner (SPECT-CT)

TEP	French acronym for Positron Emission Tomography (PET)
TEP-TDM	Positron Emission Tomography associated with a Computed Tomography scanner (PET-CT)
TEPCO	Tokyo Electric Power Company (Japanese electric utility)
TFA	French acronym for Very Low Level (VLL waste)
TGAP	General Tax on Polluting Activities
THA	French acronym for Very High Level (VHL waste)
TMD	Transport of Dangerous Goods
TMR	Transport of Radioactive Materials
TN International	International subsidiary of AREVA NC specializing in the packaging, transport and interim storage of nuclear materials
TNA	Sodium (Na) treatment installation (EDF - Creys-Malville - Isère *département)*
TRANSSC	TRANsport Safety Standards Committee (IAEA committee on radioactive materials transport safety standards)
TSN	TSN Act: Act of 13th June 2006 on Transparency and Security in the Nuclear field
TU5	Fuel cycle installation (Areva NC - Pierrelatte)
UCD	Alpha Waste Conditioning Central Unit (Areva NC - La Hague)
UE	French acronym for European Union (EU)
ULYSSE	"Teaching" reactor (CEA - Saclay)
UNE	Enriched Natural Uranium
UNGG	Graphite-moderated gas-cooled reactor (old-generation nuclear reactor process)
UNSCEAR	United Nations Scientific Committee on the Effects of Atomic Radiation
UP2-400	Spent fuel reprocessing plant (Areva NC - La Hague)
UP2-800	Spent fuel reprocessing plant (Areva NC - La Hague)
UP3-A	Spent fuel reprocessing plant (Areva NC - La Hague)
UPRA	Artificial radionuclide production plant
URE	Enriched Reprocessing Uranium (fuel assemblies)
USIE	Unified System for Information Exchange in Incidents and Emergencies - (IAEA tool proposed to member countries for the notification of nuclear events occurring on their territory)
UTE	*Union Technique de l'Électricité* (French electrical engineering standardising body)
VD	Ten-yearly outage
VD1	1st ten-yearly outage
VD2	2nd ten-yearly outage
VD3	3rd ten-yearly outage
VD4	4th ten-yearly outage
VHTR	Very High Temperature Reactor
VICWG	Vendor Inspection Cooperation Working Group (part of the MDEP programme)
VP	Partial Inspection Outage
VVP	Main Steam System
W	Fuel cycle plant (Areva NC - Pierrelatte)
WANO	World Association of Nuclear Operators
WASSC	Waste Safety Standards Committee (IAEA)

WENRA	Western European Nuclear Regulators' Association (extended in 2003 to all "nuclear" Member States of the European Union or negotiating membership at that time)
WGIP	Working Group on Inspection Practices (NEA)
WGWD	Working Group on Waste and Decommissioning (WENRA)
WNA	World Nuclear Association
WPNEM	Working Party on Nuclear Emergency Matters (within the NEA)
ZGDS	Solid Radioactive Waste Management Zone (CEA - Saclay)
ZGEL	Liquid Radioactive Waste Management Zone (CEA - Saclay)
ZPP	Population Protection Zone
ZST	Tightened Surveillance Zone

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