AUTORITÉ DE SÛRETÉ NUCLÉAIRE

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ASN REPORT

on the state of nuclear safety and radiation protection in France in 2017

AUTORITÉ
DE SÛRETÉ
NUCLÉAIRE

The Nuclear Safety Authority
presents its report on the state of nuclear safety
and radiation protection in France in 2017.

This report is required by 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 and transmitted
to the Parliamentary Office for the Evaluation
of Scientific and Technological Choices, pursuant
to the above-mentioned Article.

Summary

ASN actions

Activities regulated by ASN

A year that was on the whole satisfactory: a less worrying context, but several subjects requiring vigilance

FROM LEFT TO RIGHT
Sylvie CADET-MERCIER - Commissioner
Pierre-Franck CHEVET - Chairman
Lydie ÉVRARD - Commissioner
Margot TIRMARCHE - Commissioner
Philippe CHAUMET-RIFFAUD - Commissioner

Montrouge, 1st March 2018

In 2017, the safety of the operation of the large nuclear facilities and radiation protection in the industrial and medical fields remained on the whole satisfactory. However, with regard to the EDF NPP fleet, vigilance is required in the light of the difficulties encountered in the management of equipment conformity. In the medical sector, the persistence of level 2 incidents, more specifically in radiotherapy and during fluoroscopy-guided interventions, also warrants reinforced oversight.

The general context would appear to be less worrying:

- With regard to the carbon segregation anomaly in the steels of certain large components of nuclear power reactors, a number of important steps were taken: for the plants in operation, checks were requested on the steam generators more specifically concerned, which had been manufactured in Japan, leading to the early shutdown of 12 reactors one year ago. As for the EPR reactor pressure vessel, reinforced in-service checks will be required and the closure head should be replaced before the end of 2024.
- The review of all manufacturing files at the Creusot Forge plant is taking place satisfactorily: this review, requested by ASN, aims to detect any irregularities, notably the potential falsification of manufacturing documents. ASN will be vigilant in ensuring that this review, scheduled for the end of 2018, is seen through to completion and that all relevant lessons are learned.
- EDF and Areva have completed their reorganisation and their recapitalisation: their full deployment should enable these companies to regain the financial and technical capability they need to address the challenges facing them today. ASN will pay particularly close attention to this.

Unprecedented challenges face all the nuclear stakeholders. To a large extent, they were foreseeable:

- The nuclear industrial fleet was built about forty years ago, or even slightly before as concerns the CEA research facilities: the question today arises of extending the lifetime of these ageing facilities. It implies the examination of three subjects: compliance with their original design and construction baselines, management of ageing phenomena and improvements bringing them closer to today's safety baselines. These three subjects are technically complex and essential for safety; they require a strong industrial commitment.
- New nuclear facilities are currently under construction: whether the Flamanville EPR reactor, the Jules Horowitz reactor or the ITER project in Cadarache are concerned, there have been numerous difficulties and significant delays, mainly owing to the lack of design and construction experience.

There is another major issue: the lessons learned from the Fukushima Daiichi accident. This led to a large number of safety reinforcements on all French nuclear facilities; nonetheless major works will still be needed in the coming years.

Against this backdrop, ASN considers that vigilance is required to ensure that the operating safety of the large installations and radiation protection in the industrial and medical fields are maintained at a satisfactory level, with particular attention being paid to the detection of incidents, their notification and their processing, all of which are key factors in the continuous improvement of safety.

For the medium and long term, ASN has two messages:

- The electrical system must have sufficient margin to be able to deal with a generic anomaly affecting the NPP fleet. ASN already issued an opinion on this point in 2013: the French fleet is standardised and this feature was an advantage not only in terms of safety, but also in economic terms. Maintaining this advantage presupposes, on the one hand, continuing to detect anomalies as early as possible and, on the other, preparing to deal with the combined shutdown of several nuclear reactors concerned by a major anomaly.
- A lasting solution must be found for high and intermediate level, long-lived waste: existing or future surface and even sub-surface interim storage facilities are able to manage this waste in the short to medium term, but not on the time-scale of several hundred thousand years, the period for which they are harmful. Over time-scales such as these, nobody can guarantee the existence of the human and societal control necessary to maintain the safety of a sub-surface facility. The internationally adopted reference solution for long-term management is deep geological disposal. This is the solution chosen by France, which has also determined that a repository such as this must be reversible for a period of about a century. The *Cigéo* project, for which the safety options constitute significant progress, is designed to address this need. Its creation authorisation application should be submitted in 2019.

In this context made complex by safety and budget constraints, ASN has overhauled its regulation and oversight strategy: its aim is to focus on areas producing the greatest benefit for the protection of humans and the environment, taking account of both the risks inherent in the activities and the behaviour of those responsible for them. Conversely, for situations considered to be positive, ASN must be able to explicitly scale back its regulation and oversight.

Over the past three years, ASN and IRSN were granted additional resources. ASN is fully conscious of the efforts made in this respect by the Government and by Parliament. However, it reaffirms the need for reforms in the financing of the regulation and oversight of nuclear safety and radiation protection, which would enable it in the future to have access to resources that could be easily adapted to its needs.

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Falsification, changes required in monitoring and oversight practices

The review of the quality of production by the Creusot Forge plant highlighted a number of irregularities: concealment of technical anomalies from the customer and the regulatory authority and potential falsification of measurement or examination results. These irregularities were detected neither by the Creusot Forge plant's internal checks, nor by the monitoring carried out by Areva and EDF. Nor were the inspections carried out by ASN able to identify them. ASN has examined ways of improving the oversight and monitoring arrangements in order to improve the prevention and detection of this type of irregularity. The resulting action plan will be finalised in the first half of 2018.

Increased safety requirements for continued operation of the facilities

In 2020, ASN plans to issue a generic opinion on the continued operation of the 900 MWe reactors beyond their fourth periodic safety review. The public will participate in the drafting of this generic opinion. The safety reviews of the thirty-four 900 MWe reactors will run from 2020 to 2030; the first safety review report will be that of Tricastin 1 in 2020.

The safety review will be carried out on the basis of the safety requirements applicable to the most recent reactors, more specifically with regards to internal and external hazards and severe accidents. Equipment compliance with the initial baseline safety requirements will also need to be verified, with particular attention paid to ageing phenomena.

Installations other than power reactors cover a wide variety of activities (research, fuel cycle, waste management, production of radiopharmaceuticals and industrial irradiators, etc.) These installations are also often ageing. Several tens of these installations underwent a periodic safety review in 2017, many of them for the first time.

Given the complexity of the subjects to be dealt with, this periodic safety review approach will take several years, both for the licensees and for ASN.

EPR, advances in safety but a difficult construction phase

The Flamanville EPR reactor is a "Generation III" pressurised water reactor, offering a significantly higher level of safety than the reactors currently in service. The EPR in particular offers greater protection against external hazards and more effective means of mitigating the consequences of accidents with core melt.

ASN underlines the fact that EDF still needs to carry out significant work before loading fuel into the reactor, to demonstrate on the one hand the serviceability of the nuclear pressure equipment, the primary and secondary systems in particular and, on the other, the performance of the safety systems.

In 2018, ASN will be particularly vigilant with respect to the performance of the pre-startup tests, a key factor in guaranteeing the facility's compliance with its baseline safety requirements.

Radioactive waste management, a major safety challenge

The public debate which should be held at the end of 2018 on the National Radioactive Material and Waste Management Plan (PNGMDR) will be an opportunity to obtain the opinion of the public on the most important issues: the reusable nature of materials, storage capacity, in particular for spent fuels and the highest level wastes, the management of very low level waste with a view to forthcoming decommissioning work, as well as the disposal of low level, long-lived waste and the disposal of high and intermediate level, long-lived waste.

The periodic studies conducted to assess the consistency of the fuel cycle, taking account of possible changes in energy policy, are input into the PNGMDR. In 2018, ASN will issue an opinion on the consistency of the fuel cycle in the light of the consequences for nuclear safety and radiation protection, as well as on the storage facilities, which offer little capacity margin.

ASN aims to ensure that the national system for radioactive materials and waste management remains pertinent on a long-term basis. In this respect, France welcomed an Artemis mission in early 2018. This is an international review by experts coordinated by the International Atomic Energy Agency. The auditors pointed out that the French system, which deals with all the issues, has a number of strong points, more particularly in terms of skills and the continuous progress approach. Improvement suggestions were made and will be taken into account in the next PNGMDR.

Progress necessary in radiotherapy and interventional radiology

ASN observes that there are still inadequacies in certain radiotherapy units, more particularly in the management of technological or organisational changes. Vigilance is thus still required, all the more so as four incidents rated level 2 on the ASN-SFRO scale were notified in 2017.

There is a significant rise in interventions using X-ray imaging, thus constituting a growing concern for ASN. Inspections in this field show the persistence of radiation protection difficulties, both for the patients and for the health care personnel, as borne out by the notification of three significant events rated level 2 on the INES scale. These difficulties are primarily the result of a lack of radiation protection culture and often inadequate levels of medical physics staffing, owing to the budget difficulties experienced by the facilities.

Radioactive sources, our first steps in the field of security

ASN is at present contributing to finalising the regulations on source security. It will therefore be updating its resolution on the content of authorisation applications for the possession and utilisation of these sources. After an inventory conducted by the ASN regional divisions and the implementation of specialised training for staff, the first inspections in this field will take place in the second half of 2018.

Improved protection of the population in the event of an accident

The latest iodine tablets information and distribution campaign, which began in 2016, was completed in 2017 within the 10 km radius of the NPPs.

Following the recent extension of the off-site emergency plans around the NPPs, in which this radius is increased from 10 km to 20 km, an information campaign will be carried out among the local residents prior to the distribution of iodine tablets outside the 10 km radius. ASN will support this approach alongside other local and national stakeholders. For the NPPs at the borders, particular attention will be given to coordinating steps taken by the various States concerned.

Radon, new public protection measures

Prolonged exposure to radon, a radioactive gas of natural origin, can lead to the risk of lung cancer. Whether in the professional sector, in public buildings or private homes, steps must be taken to reduce this exposure, particularly in priority geographical areas in which the geological characteristics amplify the exhalation of radon.

The deployment of the 3rd National Plan (2016-2019) for Radon Risk Management, published by ASN in January 2017, and the new map of the municipalities considered to be high-risk, are two steps forward in ensuring better protection of the public. The home is where the dose received during the course of a lifetime is often the highest (time spent there, significant concentration in some rooms in the home). For existing homes, the plan therefore comprises new provisions concerning mandatory information of buyers and tenants, as well as the installation of measurement systems.

Towards a European approach to nuclear safety and radiation protection

Internationally, more specifically at the European level, ASN is heavily involved in the work done by ENSREG[1], WENRA[2] and HERCA[3].

Within ENSREG, ASN produced a report in 2017 on the management of the ageing of the French reactors. The reports produced by the member States concerned will be reviewed in 2018 by experts from the European safety regulators. Pending its decision on continued operation, ASN will pay particular attention to the conclusions of this review.

At an ENSREG conference, ASN presented its own opinions on the improvement of the oversight and regulation system, in order to improve the prevention and detection of irregularities such as those detected in the Creusot Forge plant.

ASN also informed its counterparts of its technical analysis of the carbon segregation anomaly in the steel used to produce large components, which could eventually lead to changes in the manufacturing codes.

Within HERCA, ASN is more specifically involved in European coordination of population protection measures in the event of a nuclear accident.

1. *European Nuclear Safety Regulators Group.*
2. *Western European Nuclear Regulators Association.*
3. *Heads of the European Radiological protection Competent Authorities.*

Olivier GUPTA
Director General

Towards a new regulation policy

Montrouge, 1st March 2018

The question has been heard a number of times: is ASN under pressure? It cannot be denied that the current context is a potential source of tensions and the workload is considerable, but the very nature of ASN's duties requires that it issue its resolutions rigorously yet calmly. This is what we did throughout 2017 and this is to a large extent the result of a working method profoundly rooted in the very culture of ASN itself.

However, the context required that we redefine a strategic plan in order to take account of the challenges of the current period and that we take a fresh look at our regulation and oversight policy: this fundamental work has been carried out and 2018 will see the implementation of the resulting changes.

ASN's working method, a real advantage in the current context

ASN devotes efforts to identifying subjects on which it wishes to see progress being made in the nuclear safety and radiation protection situation. These subjects are often complex, of long duration and require a degree of perseverance.

The case of social, organisational and human factors is a prime example of this. After the Fukushima Daiichi accident, ASN considered that this subject needed to be looked at again, with the involvement of all stakeholders concerned and, as early as 2012, it created a steering committee for social, organisational and human factors. The work done by several thematic groups set up within this committee, more particularly on maintenance and emergency situations, was completed in 2017 and their reports were made public.

On a completely different point, ASN has for a long time been pointing out that the monitoring of the security of radioactive sources – in other words their protection against malicious acts – was covered by no State structure and proposed taking charge of this point. This has now been done and the first inspections on the subject will take place in 2018. The ASN working method, its ability to adapt and the flexibility of its organisation are no doubt crucial in its ability to take on new subjects and ensure progress in dealing with them, year after year.

ASN has built a decision-making process that is rigorous, collective and open.

Rigorous: each decision on a complex subject is the result of an investigation conducted by ASN in accordance with procedures. This demands real know-how, that of being able to identify the issues, ask oneself questions, listen to the licensee, collect the opinions of experts and check that all aspects of importance for the decision have been examined.

Collective: the decisions are prepared within ASN by several persons who together assess various options and their consequences.

Open: ASN consults the public on its draft resolutions, both directly and indirectly, via the Local Information Committees.

Finally, ASN is particularly active in networks involving foreign counterparts, with which it has built up a relationship of trust enabling difficult subjects to be discussed. With regard to the carbon segregation anomaly in the steels used to manufacture certain large components, the discussions between ASN and its counterparts in 2017 will thus lead to this subject being better incorporated into the industrial standards in the future. On a different topic, at its plenary session of October 2017, the Western European Nuclear Regulators Association (WENRA) decided to start work on the safety improvements to reactors that could be reasonably envisaged beyond forty years in service. This work will be of great value to ASN when preparing its own resolutions on the subject.

With regard to resources, ASN has so far obtained the resources it needs to carry out its duties. Fifty positions were created at ASN between 2015 and 2017, together with an increased workload which, in the current public budget context, represents a significant effort on behalf of the regulation and oversight of nuclear safety and radiation protection. For the coming three years, ASN evaluates its needs at 15 additional posts, both to absorb the workload involved in the ongoing subjects and to allow the implementation of regulation to address the problem of fraud.

At the same time, ASN is working on making its regulation and oversight more efficient: After creating a categorisation of nuclear facilities according to the potential consequences, in 2016, ASN extended the remote-notification system in 2017 and reviewed the regulation and oversight arrangements for small-scale nuclear facilities. Actions in this area will continue in 2018, together with the new ASN Strategic Plan.

A new strategic plan and a new regulation and oversight policy

Throughout the course of 2017, ASN worked on an in-depth overhaul of its strategy and on an adaptation of its regulation and oversight methods to present and future issues. Apart from an analysis of the current context, ASN listened to the various stakeholders, including interviews with the licensees and activity managers, the representative learned societies in the medical nuclear field, representatives of civil society, trade union organisations in the nuclear industries, the main administrations and organisations with which ASN is in contact, as well as foreign counterparts.

All the ASN staff contributed to drafting a new three-year strategic plan and a new regulation and oversight policy, which they will be implementing on a daily basis, as of this year.

The regulation and oversight policy thus defined emphasises the reinforcement of a graded approach. Two parameters must be taken into consideration when evaluating regulation and oversight priorities: on the one hand, the risks inherent in the activities for individuals and the environment and, on the other, the behaviour of those responsible for the activities and the means they deploy to manage these risks.

ASN thus intends to reinforce its regulation and oversight of fields or facilities considered to have priority; one example of this being the “reinforced monitoring” of a facility. Conversely, when the potential consequences are low, or for situations considered to be positive in terms of protection of individuals and the environment, it aims to scale back its regulation and oversight.

This graded approach must apply not only to regulation and oversight, but also to the procedures and methods for information of and participation by the public and the stakeholders: these methods and procedures must be adapted so that they better inform the debates and decisions for those subjects with the most significant implications and consequences.

This graded approach will be implemented both for basic nuclear installations and for small-scale nuclear facilities, including for medical activities. In this field, concrete measures were already taken in 2017. Regulation and oversight priorities were redefined per activity sector. Inspections are now more modular, to take better account of the actual situation in the field.

Over and above the graded approach, three other aspects resulting from ASN's strategy are worth underlining.

First of all, the fact that ASN continues to place emphasis on technical dialogue with the licensees, because its resolutions are based on a technical assessment – in the broadest sense of this term, in other words including social, organisational and human aspects. This goes hand in hand with regulations which set goals rather than means. As this technical dialogue lies at the heart of the examination processes, ASN intends to further reinforce its technical involvement in the analysis of the files submitted to it. It also intends to ensure improved management and monitoring of external analysis and assessment.

Then, as of 2018, ASN intends to implement changes to its regulation and oversight methods. I am more specifically thinking of those which are made necessary in order to deal with fraud, including by carrying out inspections at the suppliers. More broadly speaking, ASN intends to reinforce the effectiveness of its actions in the field, by more closely linking examination of the files submitted by the licensees to the field inspections and reinforcing the ability of the inspectors to qualify and rank the anomalies they detect.

Finally, ASN intends to continue its involvement at an international and more specifically European level, with two goals: to promote top-down harmonisation and benefit from the opinion of its peers. ASN has succeeded in creating a European safety doctrine with its counterparts, extensively inspired by the French approach. The aim is now to go further in harmonising rules and practices. ASN more particularly hopes that the launch of a review of the WENRA association's strategy will be an opportunity to promote a voluntary interaction between all the European safety regulators in the construction of national decision-making and to increase the use made of the European technical support organisations within ETSON (European Technical Safety Organisations Network).

Much has been accomplished during the course of 2017, be it in terms of preparing major resolutions (such as that on the EPR reactor pressure vessel or the safety options file for *Cigéo*), regulatory work (such as the transposition of Directives concerning basic radiation protection standards), or the preparation of the new strategy. This report also bears witness to the diversity and scale of the actions taken.

2018 will be no less dense. Over and above the day to day regulation and oversight actions, apart from the workload which will continue to grow in order to prepare the major resolutions, ASN intends to carry out the various projects which will constitute the tangible implementation of the strategic orientations decided on in 2017. Thanks to the constant engagement by all ASN staff and the strength of our common culture, I am confident of our ability to successfully carry out all of these actions, further enhancing the protection of individuals and the environment.

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.

On behalf of the State, ASN ensures the oversight of nuclear safety and radiation protection in order to protect people and the environment. It informs the public and contributes to enlightened societal choices.

ASN decides and acts with rigour and discernment: its aim is to exercise an oversight that is recognised by citizens and regarded internationally as a benchmark for good practice.

Competence
Independence
Rigour
Transparency

ASN

Roles

Regulating

ASN contributes to drafting regulations, by giving the Government its opinion on draft decrees and Ministerial Orders, or by issuing technical regulations. It ensures that the regulations are clear, accessible and proportionate to the safety issues.

Authorising

ASN examines all individual authorisation applications for nuclear facilities. It can grant all licenses and authorisations, with the exception of major authorisations for Basic Nuclear Installations, such as creation and decommissioning. ASN issues the licenses provided for in the Public Health Code concerning small-scale nuclear activities and issues licenses 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. Since the Energy Transition for Green Growth Act of 17th August 2015, ASN's roles now include monitoring the security of radioactive sources against malicious acts. Inspection is ASN's primary monitoring activity. Nearly 2,000 inspections are thus carried out every year in the fields of nuclear safety and radiation protection. ASN has a range of notification and enforcement powers (formal notice, administrative fines, daily fines, ability to carry out seizure, take samples or require payment of a guarantee, etc.). ASN's sanctions will be enforced by a Sanctions Committees, created within ASN, in order to maintain the principle of separation between the investigative and sentencing functions.

Informing

ASN informs the public and other stakeholders (environmental protection associations, Local Information Committees, media, etc.) about its activities and the state of nuclear safety and radiation protection in France. ASN's main information channel is its website *www.asn.fr.*
In line with the principle of transparency, ASN supports the actions of the Local Information Committees of the nuclear facilities.

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 facilities.

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 ("small-scale nuclear facilities"); several hundred thousand shipments of radioactive substances nationwide, every year.

The support of experts

When drawing up its resolutions, ASN calls on outside technical expertise, in particular that of the French Institute for Radiation Protection and Nuclear Safety (IRSN). The ASN Chairman is a member of the IRSN Board. ASN also calls on the opinions and recommendations of seven Advisory Committees of Experts, from a variety of scientific and technical backgrounds.

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	Sylvie CADET-MERCIER Commissioner	Lydie ÉVRARD Commissioner	Margot TIRMARCHE Commissioner
12th November 2012 for 6 years	10th December 2014 for 6 years	21st December 2016 for 6 years	10th mars 2017 for 6 years	12th November 2012 for 6 years

APPOINTED BY the President of the Republic (Pierre-Franck CHEVET, Philippe CHAUMET-RIFFAUD, Sylvie CADET-MERCIER)

APPOINTED BY the President of the Senate (Lydie ÉVRARD)

APPOINTED BY the President of the National Assembly (Margot TIRMARCHE)

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.

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 oversight 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 regional divisions assist the Prefect of the *département*[1], who is in charge of protecting the general public, and supervise the operations carried out to safeguard the facility on the site.

1. *Administrative region headed by a Prefect.*

Commission figures in 2017

86 sessions

17 opinions

42 resolutions

Key figures in 2017

508 staff members

83% management

311 inspectors

1,751 inspections

19,894 inspection follow-up letters
available on *www.asn.fr*
as at 31st December 2017

386 technical opinions
sent to ASN by IRSN

22 Advisory Committee meetings

2,888 individual licenses
for facilities or activities

€84.4 million
total budget for ASN

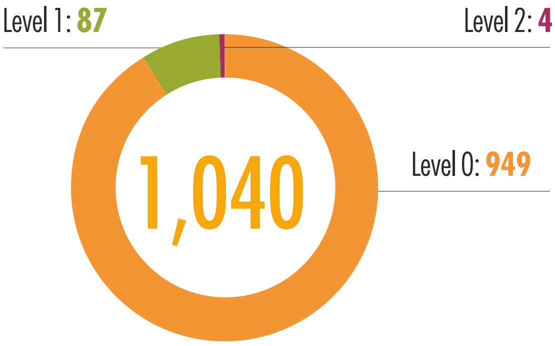
€84.3 million
IRSN budget devoted to analysis and assessment work on behalf of ASN

16 press conferences

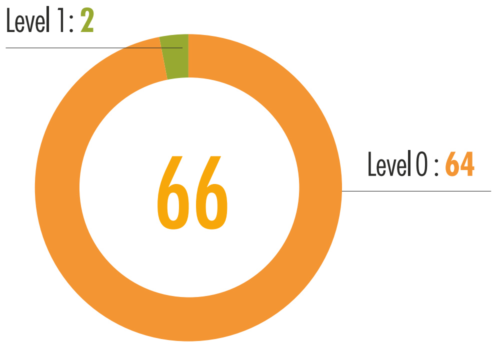
87 press releases and information notices

10 emergency exercises

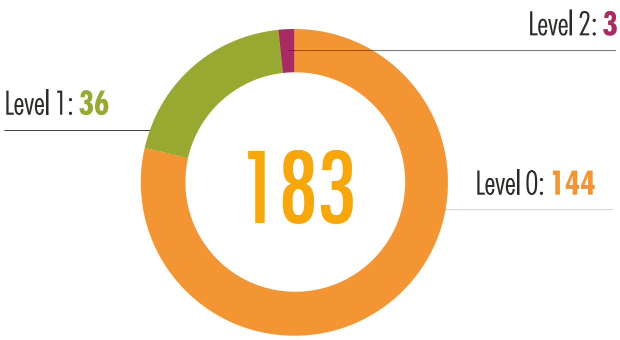
Number of significant events rated on the INES scale



Basic Nuclear Installations (BNIs)

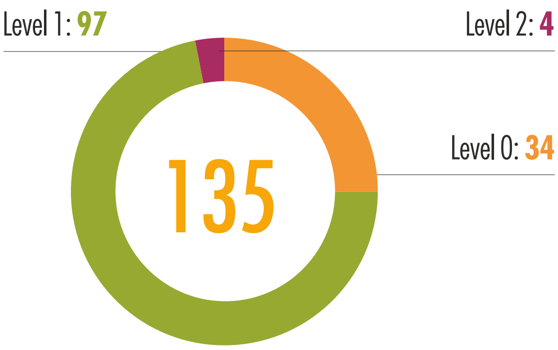


Transport of radioactive substances



Small-scale nuclear activities (medical and industry)

Number of significant events rated on the ASN-SFRO scale



INES
International Nuclear and Radiological Event Scale.

ASN-SFRO
Scale for radiation protection events affecting patients undergoing a medical radiotherapy procedure.

ASN organisation chart as at 1st March 2018

COMMISSION

Commissioners
Sylvie Cadet-Mercier
Philippe Chaumet-Riffaud
Lydie Évrard
Margot Tirmarche

Chairman
Pierre-Franck Chevet

Head of Private Office
Laurent Felber

GENERAL DIRECTORATE

Deputy Directors General
Julien Collet
Daniel Delalande
Anne-Cécile Rigail

Director General
Olivier Gupta

Chief Inspector
Christophe Quintin

Head of Staff
Ambroise Pascal

DEPARTMENTS

Nuclear power plant department
Rémy Catteau

Nuclear pressure equipment department
Simon Liu

Waste, research facilities and fuel cycle facilities department
Christophe Kassiotis

Transport and sources department
Fabien Féron

Ionising radiation and health department
Jean-Luc Godet

Environment and emergency department
Christophe Quintin (acting)

International relations department
Frédéric Joureau

Communication and public information department
Céline Acharian

General Secretariat
Brigitte Rouède

Management and Appraisal Mission
Alain Rivière

REGIONAL DIVISIONS

Bordeaux division
Regional representative: N...
Regional Head: Hermine Durand

Caen division
Regional representative: Patrick Berg
Regional Head: Hélène Héron

Châlons-en-Champagne division
Regional representative: Emmanuelle Gay
Regional Head: Jean-Michel Férat

Dijon division
Regional representative: Thierry Vatin
Regional Head: Marc Champion

Lille division
Regional representative: Vincent Motyka
Regional Head: Rémy Zmyslony

Lyon division
Regional representative: Françoise Noars
Regional Head: Marie Thomines

Marseille division
Regional representative: Corinne Tourasse
Regional Head: Aubert Le Brozec

Nantes division
Regional representative: Annick Bonneville
Regional Head: Pierre Siefridt

Orléans division
Regional representative: Christophe Chassande
Regional Head: Pierre Boquel

Paris division
Regional representative: Jérôme Goellner
Regional Head: Bastien Poubeau

Strasbourg division
Regional representative: Emmanuelle Gay
Regional Head: Pierre Bois

ASN in the regions

DROM-COM

Division Caen and Orléans respectively involved in the Bretagne region and Ile-de-France region for control of the only BNIs.

Significant events and outlook

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, radon emanations from the ground and exposure to cosmic radiation.

Nuclear activities include those conducted in Basic Nuclear Installations (BNIs) and the transport of radioactive substances, as well as activities conducted in all medical, veterinary, industrial and research facilities where ionising radiation is used.

Ionising radiation 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" (clinical effects such as erythema, radiodermatitis, radionecrosis or cataract); these effects occur systematically once the radiation dose exceeds a certain threshold. Ionising radiation is also the cause of probabilistic effects, primarily the occurrence of cancers, the probability of which increases with the dose received by the subject. The protective measures against ionising radiation aim to avoid deterministic effects, but also to minimise the probability of occurrence of radiation-induced cancers, which constitute the main risk.

Understanding the risks linked to ionising radiation is based on follow-up studies of cohorts of exposed subjects (Hiroshima, Nagasaki, nuclear accidents, etc.) epidemiological surveys, the study of cancer registers and pre-clinical experimentation data. Risk management is based on the hypothesis of the linear relationship without threshold and evaluation of the low-dose risks by an extrapolation from those observed at high doses.

Numerous unknown factors and uncertainties nonetheless persist, more particularly with regard to the actual effects at low doses, the deterministic risks for the vascular system, the radio-sensitivity of certain subjects and the existence or otherwise of a radiological signature for radiation induced cancers.

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 2015, varying by a factor of from 1 to 3 depending on the location, the eating habits, the medical exposures, etc. The sources of this exposure are as follows:

- accounting for about 2.9 mSv/year, radioactivity of natural origin, including 0.6 mSv/year for telluric radiation (except radon), 0.3 mSv/year for cosmic radiation, 0.6 mSv/year for internal exposure due to food or tobacco, as well as about 1.4 mSv/year for radon, although with considerable variations linked to the geological characteristics of the land and the buildings themselves. A new national radon exhalation potential map was drawn up in 2011. In the zones defined as high priority, periodic measurements must be taken in places open to the public and in workplaces; a third national action plan has been defined for the period 2016-2019;
- accounting for about 1.6 mSv/year (2012 estimation), radiological diagnostic examinations, trending upward (+ 23% between 2007 and 2012); particular attention must be given to managing the doses delivered to patients;
- accounting for 0.02 mSv/year, the other sources of artificial exposure: past airborne nuclear tests, accidents in facilities, discharges from nuclear facilities.

Nuclear workers receive specific monitoring (more than 370,000 people in 2016); in 2015, the annual dose remained below 1 mSv (annual effective dose limit for the public) for 96% of the workforce monitored and the regulation limit of 20 mSv applicable to nuclear workers was only exceeded once; the collective dose has fallen by about 50% since 1996 even though the population monitored has grown by about 60%.

Finally, aircrews are subject to particularly close monitoring owing to their exposure to cosmic radiation at high altitude. Of the recorded doses, 82% are between 1 mSv per year and 5 mSv per year, while 18% are below 1 mSv per year.

Outlook

For occupational radiation protection, monitoring of exposure of the lens of the eye, with gradual compliance with the new limit for this tissue (set at 20 mSv/year as of 2022) constitutes the main objective in the next few years, more specifically in the field of fluoroscopy-guided interventional medical practices.

Managing the doses of ionising radiation delivered to persons during a medical examination remains a priority for ASN. A second action plan, which continues on from the previous one (2011-2017), was drawn up jointly with the stakeholders (institutional and professional) and will be published in the first quarter of 2018.

Deployment of the 3rd National Plan for Radon Risk Management, which accompanies the publication of the new map of the municipalities considered as high-priority with respect to this risk, should allow improved communication aimed at the public in order to encourage the implementation of measurements in existing homes and gradually organise the collection and analysis of the results.

02 The principles of nuclear safety and radiation protection and the regulation and oversight stakeholders

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 stipulates that the costs resulting from the measures to prevent, reduce and combat pollution must be borne by the polluter;
- 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;
- 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 safety approach, governed more particularly by the ten fundamental principles of the International Atomic Energy Agency (IAEA), is characterised by the requirement for continuous improvement.

The nuclear activity regulators

The French nuclear safety and radiation protection regulation and oversight organisation is defined more specifically in the Environment Code. It was recently reinforced by the Energy Transition for Green Growth Act (TECV) 2015-992 of 17th August 2015 and Ordinance 2016-128 of 10th February 2016 containing various nuclear-related provisions.

Parliament defines the applicable legislative framework and monitors its implementation, more particularly via its specialist committees or the Parliamentary Office for the Evaluation of Scientific and Technological Choices (OPECST) to which ASN presents its report each year on the state of 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 takes major individual decisions concerning BNIs (creation authorisation, etc.). It is responsible for civil protection in an emergency.

In the current Government organisation, the Minister for Ecological and Solidarity-based Transition is responsible for nuclear safety and, together with the Minister for Solidarity and Health, for radiation protection.

In each *département* , the Prefect – as the State's representative – is responsible for population protection measures in the event of an accident. 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. 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 body of statutory texts by issuing regulations. 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. If non-compliance is detected, ASN may adopt enforcement measures and apply sanctions. ASN contributes to France's European and international actions within its areas of competence. Finally, it provides its assistance for management of radiological emergencies.

On technical matters, ASN relies on the expertise provided by IRSN and by the Advisory Committees of Experts. 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, to meet the medium to long term expert assistance requirements. It has set up a Scientific Committee.

ASN is run by a Commission of five full-time, irrevocable Commissioners, nominated for a non-renewable 6-year mandate. The President of the Republic nominates the Chairman and two Commissioners. The President of the Senate and the President of the National Assembly each nominate one Commissioner.

A Sanction Committee within ASN, established under the TECV Act, will be responsible for the application of administrative fines in the event of any breach of the regulations.

ASN has head office departments and eleven regional divisions around the country. Its total workforce stands at 508 employees. In 2017, the ASN budget stood at €84.41 million. Moreover, about 400 IRSN staff work on providing ASN with technical support. In 2017, IRSN thus devoted €84.3 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 €179.27 million in 2017.

Consultative bodies

The organisation of nuclear security and transparency is also based on 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 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 the High Council for the Prevention of Technological Risks tasked with giving an opinion on some draft regulatory texts. For each BNI, consultation takes place within a Local Information Committee (CLI).

Outlook

ASN will be implementing its new 2018-2020 multi-year strategic plan, notably with reinforced implementation of a graded and efficient approach to its regulation and oversight, improved oversight of technical investigations and consolidation of its operations to enhance regulation and oversight. In a context of unprecedented safety challenges, the ASN opinion of 1st June 2017 recalled that for the next three-year plan for 2018-2020, it has requested 15 additional full-time equivalent staff.

03 | Regulations

The specific legal framework for radiation protection and nuclear activities is based on the international norms, standards or recommendations drawn up by various organisations, in particular the International Commission for Radiological Protection, 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 of 5th December 2013 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 safety of nuclear installations, modified by Directive 2014/87/Euratom of 8th July 2014. Council Directive 2011/70/Euratom of 19th July 2011 also establishes a European Community framework for the responsible and safe management of spent fuel and radioactive waste.

At the national level, the Public Health Code defines general population protection rules (dose limits for the public, etc.) and creates a system of oversight for nuclear activities. The Environment Code sets rules applicable to the large nuclear installations and to the management of radioactive wastes. 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. This legal framework has been the subject of profound overhauls in recent years, notably owing to the transposition into national law of the European directives adopted under the EURATOM Treaty.

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 (imaging, radiotherapy, nuclear medicine), human biology, research, industry and certain veterinarian, forensic or foodstuff conservation applications.

The Public Health Code, modified at the beginning of 2018 to ensure the transposition of Directive 2013/59/Euratom, creates a new system of procedures for the manufacture, possession, distribution - including import and export - and utilisation of radionuclides. The existing simple notification system will thus be extended to activities which in the past required licensing and, for other activities the licensing system will be simplified with the implementation of a new system of registration. This new system will be gradually implemented as of 1st July 2018.

The Public Health Code changes made at the beginning of 2018 were accompanied by new provisions concerning protection against malicious acts for the most dangerous radioactive sources, the implementation of the justification principle, the implementation of the optimisation principle with the introduction of reference levels for exposure to naturally occurring radiation, for the management of nuclear or radiological emergency situations and for the management of sites and soils contaminated by radioactive substances.

The general rules applicable to small-scale nuclear facilities are the subject of ASN regulations. In 2017, the minimum technical design rules applicable to premises in which electrical devices generating X-rays are used were updated (ASN resolution 2017-DC-0591 of 13th June 2017) and new radiation protection continuous training arrangements for health professionals were defined (ASN resolution 2017-DC-0585 of 14th March 2017).

The Labour Code was also profoundly overhauled at the beginning of 2018, with reinforcement of the occupational risk assessment approach, possible out-sourcing of the function of adviser to certified organisations and a gradual reduction in the dose limit for the lens of the eye (the exposure limit for the lens of the eye is reduced from 150 mSv/year to 20 mSv/year, with a transitional period running from 1st January 2018 to 31st December 2022 during which the exposure limit value is set at 100 mSv over five years, without exceeding 50 mSv/year).

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. The reference level in premises open to the public and in the workplace was reduced from 400 Bq/m^3 to 300 Bq/m^3. In the workplace, after optimisation, an annual dose value higher than 6 mSv/year will lead to the workers being classified as "exposed workers".

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 130 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.

In the event of final shutdown of a facility, its licensee proceeds with decommissioning in the conditions defined by a decree issued on the advice of ASN in accordance with the principle of immediate dismantling.

In 2017, ASN took part in the continued drafting of the regulatory part of the Environment Code for BNIs, the transport of radioactive substances and Pressure Equipment (PE).

ASN is working on an overhaul of the BNI general technical regulations: after publication of the Ministerial Order of 7th February 2012 setting the general rules for BNIs, ASN began to publish a series of fifteen statutory resolutions; in 2017, it adopted four resolutions and published four new guides. These guides, which are not legally binding, present ASN doctrine in the form of recommendations. 30 guides have so far been published in all the fields in which ASN is competent.

The PE specifically designed for BNIs is subject to particular rules, overhauled in 2015 and 2016, which will be supplemented by an order. This will itself be followed by a number of regulations.

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 to be 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-operational clean-out of the contaminated premises and remediation of soil must be managed, from the site up to storage or disposal.

The revision of the provisions of the Public Health Code will make it possible to implement institutional controls for contaminated sites and soils.

Outlook

2018 will in particular be devoted to continued implementation of the reforms adopted in 2015 and 2016 on the legislative texts and to contributing to preparing the implementing orders for the decrees modifying the Environment, Public Health and Labour Codes.

ASN is also expected to adopt resolutions tailoring its oversight more closely to the issues, in particular through a change in the rules applicable in the event of the modification of a BNI and the implementation of the new system for notification and registration of certain small-scale nuclear activities. It will continue to create general technical regulations for BNIs, contribute to the revision of the Order of 7th February 2012 and the definition of the framework applicable to the protection of radioactive sources against malicious acts.

04 Regulation of nuclear activities and exposure to ionising radiation

In France, the party responsible for a nuclear activity must ensure that this activity is safe.

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 nuclear safety and radiation protection, in order to protect people and the environment from risks associated with radioactivity.

Inspection is the key means of monitoring available to ASN: one or more ASN inspectors (nuclear safety inspectors, radioactive substance transport safety inspectors, labour inspectors and radiation protection inspectors) go to a site or department, or to carriers of radioactive substances. 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*.

The inspection concerns material, organisational and human aspects.

ASN's regulatory actions are also carried out by other means such as examination of authorisation applications and analysis of significant events. It is proportionate to the level of risk presented by the facility or activity. Following safety and radiation protection assessments in each activity sector, its regulatory and oversight activities lead to issue of resolutions, prescriptions, inspection follow-up documents, plus administrative or criminal penalties as applicable.

Assessment

In 2017, ASN was notified of:

- 1,165 significant events concerning nuclear safety, radiation protection and the environment in BNIs; 1,040 of these events were rated on the INES scale[1] (949 events rated level 0, 87 events rated level 1 and 4 events rated level 2). Of these events, 18 significant events were rated as "generic events" including three at level 1 and three at level 2 on the INES scale;
- 66 significant events concerning the transport of radioactive substances, including two events rated level 1 on the INES scale;
- 655 significant events concerning radiation protection in small-scale nuclear activities, including 183 rated on the INES scale (of which 36 were level 1 events and 3 were level 2 events).

2017 was marked by several events rated level 2 on the INES scale in the field of NPPs and in the medical field.

In 2017, following the inspections carried out, the ASN inspectors transmitted twelve reports to the Public Prosecutors.

In 2017, ASN took three administrative actions (formal notice, deposit of sums, etc.) against managers of nuclear activities.

With regard to protection of the environment, 2017 was marked by the adoption of ASN resolution 2017-DC-0588 of 6th April 2017 setting rules for the intake and consumption of water, the discharge of effluents and environmental monitoring specifically applicable to PWR nuclear reactors, and by the launch of the 2016-2021 micro-pollutants plan, through which ASN will closely monitor the gradual reduction in copper and zinc discharges from the NPPs.

1. INES: International Nuclear and Radiological Event Scale.

Finally, the October 2017 meeting of the action plan follow-up committee created following the publication of the tritium White Paper was able to measure the latest progress made in understanding the origins, levels and behaviour of tritium in the environment.

Outlook

In 2018, ASN intends to perform about 1,800 inspections of BNIs, of radioactive substances transport activities, activities involving the use of ionising radiation, organisations and laboratories that it has approved and activities related to pressure equipment.

Further to the irregularities found in the manufacture of certain NPP equipment items, ASN in 2017 initiated a review of BNI licensee monitoring of their contractors and subcontractors.

ASN will also implement the conclusions of its review of the reinforced effectiveness of the oversight of small-scale nuclear activities. Furthermore, the revision of the Labour Code and the Public Health Code will enable ASN to finalise the revision of the criteria and procedures for the notification of significant radiation protection events.

In the field of environmental protection, ASN will continue with its regulatory work to implement the provisions of the TECV Act and the transposition to BNIs of the 24th November 2010 Directive on Industrial Emissions, known as the "IED Directive" and the 4th July 2012 Directive concerning major accidents involving hazardous substances, known as the "Seveso 3 Directive".

05 | Radiological emergency and post-accident situations

Despite all the precautions taken, an accident can never be completely ruled out and the necessary provisions for managing a radiological emergency situation must be planned for, regularly tested and revised.

These emergency situations are covered by specific material and organisational arrangements, which involve both the licensee and the party responsible for the activity and the public authorities.

ASN takes part in management of these situations, for questions concerning the regulation and oversight of nuclear safety and radiation protection. It has the following four roles:

- 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 to deal with a nuclear accident in a BNI more specifically comprises:

- the participation of ASN staff in the various units of the French Interministerial Crisis Committee;
- at the national level, an emergency centre in Montrouge, consisting of three Command Posts (PC): a Strategic Command Post consisting of the ASN Commission, a Technical Command Post in constant contact with its technical support organisation, IRSN, and a Communication Command Post.
- at the local level, ASN representatives visit the *département* and zone Prefects to help them with their decisions and their communication actions; ASN inspectors may also go to the site affected by the accident.

Significant events

In 2017, the national emergency centre was activated on 14 occasions, for four real situations and ten national exercises. Of the national exercises, two concerned defence BNIs or sites under the responsibility of the Defence Nuclear Safety Authority (ASND) and two included a malicious initiator.

The programme of exercises comprised two atypical exercises: an NRBC exercise (Nuclear, Radiological, Bacteriological or Chemical malicious act) and a training exercise for the ***départements*** in the Auvergne-Rhône-Alpes region in the deployment of post-accident measures (restrictions on the consumption and sale of local produce).

The real situations in 2017 concerned two Greenpeace intrusions on the Cattenom and Cruas-Meysse NPPs, and two activations of the On-site Emergency Plan (PUI) on the Bugey NPP. The first activation, as a result of a fire on a roof in a controlled area during a worksite, had no environmental consequences, as the fire was rapidly extinguished, and was rated level 0 on the INES scale. The second event concerned the blockage of a valve which led to the shutdown of reactor 2. The licensee implemented its incident management procedures, enabling a controlled state to be restored in a few hours. This event, rated level 1 on the INES scale, had no environmental impact. Following each of these events, ASN carried out inspections and learned the necessary lessons.

In 2017, ASN also took part in several international exercises organised by the IAEA, Switzerland and Spain, as well as one tabletop exercise with Germany.

Finally, during the national exercise on the Cattenom NPP, ASN tested coordination with representatives of the German nuclear safety regulator and the Government of Luxembourg.

ASN resolution 2017-DC-0592 of 13th June 2017 supplements the provisions of the BNI Order of 7th February by specifying the licensees' obligations for preparedness for and management of emergency situations, as well as ASN's requirements regarding the content of the PUI. Most of the provisions of this resolution give official status to existing practices which were not incorporated into the regulations. This resolution also transposes certain WENRA[1] reference levels and takes account of the lessons learned from the Fukushima Daiichi accident. It more particularly requires that the emergency crew members take part in at least one simulation or exercise per year and specifies the information that the licensee must transmit to the authorities.

Outlook

The nuclear safety Authorities confirmed the need to continue with international work to improve the coordination of the respective approaches by each country in an emergency situation. In 2018, ASN will continue with the European initiatives taken with a view to harmonising actions on either side of the borders to protect populations in an emergency situation and to develop a coordinated response in the event of an accident, more specifically as part of the follow-up to the HERCA[2]/WENRA approach.

Following the Government's September 2016 adoption of the principle of extending the radius of the PPI perimeter around NPPs from 10 to 20 km and the pre-distribution of stable iodine tablets up to 20 km, ASN will in 2018 contribute to the PPI update work done by the offices of the Prefects and to the new population information and iodine tablets distribution campaign for inhabitants in the zone between 10 and 20 km from the NPPs.

In 2018, ASN will continue to play an active role in the work carried out on the national plan for response to a major nuclear or radiological accident, in particular that concerning the perimeters of the Off-site Emergency Plans (PPI) for BNIs other than NPPs. ASN will also take part in the revision, coordinated by the General Secretariat for Defence and National Security of the Interministerial Directive of 7th April 2005 on the action of the public authorities in the case of an event leading to a radiological emergency situation. It will also initiate the revision of the post-accident doctrine through the work of the Steering Committee for Management of the Post-accident Phase (Codirpa).

In order to control urban development around nuclear sites, ASN will in 2018 be restarting a working group on the examination of active institutional controls, together with the services of the Ministry responsible for the Prevention of Risks and Urban Development, as well as the Ministry of the Interior.

The adoption of an on-call duty system at ASN is a priority action for 2018 in order to reinforce ASN's ability to deal with a nuclear or radiological emergency situation.

Finally, in 2018, ASN will be publishing a guide for a standard On-site Emergency Plan (PUI) template and its justification part, following on from the publication of its June 2017 resolution on emergency situations.

1. Western European Nuclear Regulators Association.

2. Heads of European Radiological Protection Competent Authorities.

06 | Informing the public and the other audiences

For ASN, information of the public lies at the very heart of its activities. The 2006 Acts on Transparency and Security in Nuclear matters[1] and the 2015 Act on Energy Transition for Green Growth[2], explicitly gave ASN the role of ruling on the state of nuclear safety and radiation protection in France. All year round, ASN therefore informs the citizens, media, institutional audience and professionals of the situation of the BNIs and small-scale nuclear activities with regard to the requirements of nuclear safety and radiation protection. It reports on all of

1. Act 206-686 of 13th June 2006 on Transparency and Security in the Nuclear field (TSN Act).

2. Energy Transition for Green Growth Act 2015-992 of 17th August 2015 (TECV Act).

its regulation and oversight activities and the corresponding actions it takes, and disseminates its resolutions and position statements, with explanations whenever necessary.

ASN encourages the involvement of civil society in the drafting of its resolutions: for example, it consults the stakeholders and the public regarding draft resolutions and ensures that the principles of nuclear safety and radiation protection are understood by as many people as possible: it produces explanatory documents and aims to make the most technical issues accessible to the general public.

It also publishes notices, guides and reports aimed at professionals and an informed audience.

Significant events

In 2017, ASN continued the information and iodine distribution campaign in the vicinity of the BNIs, systematically issuing reminders to the facilities open to the public which were behind schedule.

To improve information of the public, a new version of the ASN website was created, simplifying access to information and to published documents (more than 87 information notices and press releases in 2017), and meeting new browsing requirements (maps, enriched content). After this overhaul, the number of visitors to the site increased by 40%.

The ASN news feeds on the social networks put across the main position statements and were followed by more than 8,000 subscribers on Twitter, more than 4,500 on LinkedIn and nearly 3,000 on Facebook. The bi-monthly ASN newsletter, which summarises topical events, was distributed to more than 4,000 subscribers.

The exhibition produced by ASN and IRSN visited about sixty different locations during the course of 2017 (the travelling exhibition is the responsibility of both IRSN and ASN).

ASN gave about twenty local and national press conferences and its spokespersons were on hand to reply to more than 600 press queries in 2017.

In 2017, ASN was given about ten hearings by Parliament concerning its activities and in November presented its report to the OPECST on the *State of nuclear safety and radiation protection in France in 2016* (previous edition of this present document). ASN regularly consulted the public on its draft resolutions. Three consultations concerned draft regulations and three other draft guides.

ASN contributed to the smooth running of the 35 CLIs, that also play an important role in transparency and information on nuclear safety. It ensured that they were correctly informed about matters relating to nuclear facilities and brought the CLI representatives together for a national conference in November. Throughout the year, representatives of the ASN regional divisions were available for CLI meetings.

ASN created or updated and then published and distributed six guides for the attention of a professional audience (can be consulted on *www.asn.fr*). Two new numbers of the *"La Sécurité du patient"* (patient safety) bulletin, co-signed by several learned societies, were sent out to the 180 radiotherapy centres in France. ASN organised several professional seminars for physicians or for those in possession of radioactive sources.

ASN prepared itself for crisis communications about ten times in 2017, by means of "simulated media pressure" during emergency exercises.

Outlook

In 2018, ASN will be reinforcing its general public information measures, aiming to make the technical subjects presented more accessible. It will continue its actions to promote the transparency of information on nuclear matters. It will notably improve the conditions in which the public can be consulted on draft opinions and regulatory texts.

It will assist with implementing steps to inform the populations located within the PPI zones around nuclear facilities, which have been extended out from 10 to 20 kilometres. It will ensure that the local populations in these PPI zones are actually kept regularly informed.

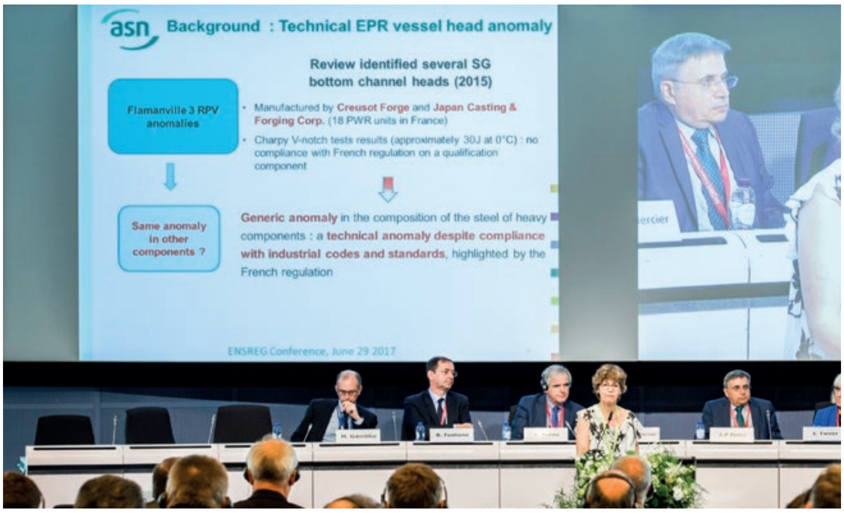
In 2018, ASN will develop public information about its roles, its fields of work and its regulation and oversight activities. It will hold discussions with elected officials and stakeholders and will remain at their disposal to shed light on any question concerning nuclear safety and radiation protection.

ASN will continue to support the activities of the CLIs – more particularly in their public information role – and will maintain a high-quality dialogue with them.

07 | International relations

ASN is active in international cooperation in order to advance nuclear safety and radiation protection in France and around the world. Being active means publicising our regulations and their foundations, informing our counterparts of some of our technical analyses, in order to promote the establishment of the most demanding doctrines and regulations, primarily at the European level and then within multilateral frameworks. For our facilities, this implies taking advantage of international operating experience feedback.

ASN's international actions are carried out within bilateral, European and multilateral frameworks.



Significant events

ASN informed the international community of the problem relating to the carbon macrosegregations detected on certain forged components of nuclear pressure equipment. Our main counterparts have taken this subject on board, firstly on a bilateral basis and then within WENRA, which led to the definition of a draft recommendation concerning the manufacturing checks to be carried out by the licensees and the changes to the manufacturing codes.

ASN was also a driving force in the drafting of major documents concerning the transposition of the European "BSS" (Basic Safety Standards) Directive, more specifically application of the justification principle in the medical and radon fields.

ASN was also heavily involved in the work to implement the 2009/71/Euratom "safety" Directive, modified in 2014. The revised national action plan concerning post-Fukushima measures was submitted to the European Nuclear Safety Regulators Group (ENSREG) which is currently chaired by ASN. ASN is also vice-chair of the steering committee for the first thematic peer review of management of the ageing of power reactors and research reactors: ASN experts are also contributing to this review. This review process is considered to be a central instrument which will make it possible to promote best practices in the field. Pending its decision on continued operation, ASN will pay particular attention to the conclusions of this review. ASN is also vice-chair of the steering committee for the stress tests review to be conducted by the European Union in Belarus in 2018.

Finally, ASN was in charge of organising the ENSREG 2017 conference held on 28th and 29th June 2017 in Brussels, which attracted more than 400 stakeholder representatives on the subject of nuclear safety. Four round tables tackled the issues involved in the implementation of European Directives on Waste and Safety, but also looked at possible longer-term efforts to converge the authorisation processes for power reactors, the implications of continued reactor operations beyond 40 years, notably the introduction of safety improvements resulting from the most recent standards and, finally, a new challenge following the discovery of irregularities in the production of certain major reactor components. ASN's first thoughts on adapting oversight in the light of the risk of fraud were thus shared and enhanced: promoting the safety culture, processing of the information collected, in particular from whistle-blowers, protecting data integrity, adapting surveillance and monitoring methods, were extensively debated.

From a multilateral viewpoint, ASN in 2017 became the first regulator to have hosted two international audit missions (IRRS – Integrated Regulatory Review Service) run by the IAEA and covering all of its activities. With 40 recommendations and suggestions applied (or applied *"subject to completion of the currently ongoing measures"*), the audit team, chaired by William Dean (NRC – American Nuclear Regulatory Commission), concluded that France had significantly reinforced the framework of its regulation and oversight of nuclear safety and radiation protection. The IAEA did however point out that ASN needed to demonstrate vigilance with regard to the question of human resources, in the light of the safety issues facing nuclear facilities in France. The mission also suggested to ASN that its action should disseminate the safety culture in-house as broadly as possible and specify the conditions for the classification of emergency situations by the licensees.

France also presented its national report at the 7th review meeting of the contracting parties to the Convention on Nuclear Safety, held at the IAEA headquarters. This presentation enabled ASN to communicate about nuclear safety and radiation protection issues, in particular those which will require closer attention in the coming years: finalisation of implementation of the post-Fukushima measures; technical cooperation on the subject of carbon macrosegregations for certain nuclear pressure equipment; the irregularities detected in the production of some of this equipment; the periodic safety review and continued operation beyond 40 years of the power reactors, but also of fuel cycle facilities.

Finally, at the beginning of 2018, France hosted an ARTEMIS mission (Integrated Review Service for Radioactive Waste and Spent Fuel Management, Decommissioning and Remediation), an international review by experts organised by the IAEA. This review offered foreign experts an opportunity to assess the French system for management of radioactive wastes and spent fuel, decommissioning and post-operational clean-out. The auditors more specifically underlined the many strong points of the French system, in particular the coverage of all the issues linked to the management of radioactive waste, as well as the skills available and the continuous progress approach adopted. The auditors also made suggestions and spotlighted best practices.

Outlook

ASN will continue its actions within a European framework, with regard to nuclear safety and radiation protection, more particularly through bilateral cooperation agreements, but also and above all through involvement in the work of ENSREG, notably the thematic review concerning management of the ageing of power reactors and research reactors with a power level of more than 1 MWth, a review which led to the drafting of a national report published in December 2017.

ASN will also aim to ensure that its policies and positions carry weight within multilateral frameworks, in particular with respect to the IAEA.

To this end, ASN:
- will continue bilateral exchanges with foreign safety regulators on regulatory practices and on priority subjects such as monitoring of the manufacture of nuclear pressure equipment;
- will actively take part in the work of HERCA, WENRA, IAEA, the Nuclear Energy Agency (NEA) and INRA (International Nuclear Regulators Association);
- will present the national report to the first thematic peer review of ageing management (ENSREG) to be held from 14th to 18th May 2018 in Luxembourg;
- will contribute to the performance of stress tests on the Ostrovets NPP in Belarus;
- will contribute to examining the definition of technical objectives to improve safety, as related to Article 8 of the 2014 Directive;
- will be a driving force behind the WENRA task force which is to define a strategy document;
- will examine the possibility of holding a transboundary "Large Region" conference on nuclear safety and radiation protection, in order to achieve more balanced cooperation;
- will present the national report within the framework of the Joint Convention (2018);
- will continue its involvement in the European cooperation instruments assisting third party countries in the field of nuclear safety.

08 Regional overview of nuclear safety and radiation protection

ASN has 11 regional divisions through which it carries out its regulatory responsibilities throughout metropolitan France and in the French overseas *départements* and regional authorities. Consequently, several ASN regional divisions can be required to coordinate their work in a given administrative region. As at 31st December 2017, the ASN regional divisions comprised 225 staff members, including 159 inspectors.

Under the authority of the regional representative (see chapter 2, point 2.3.2), the ASN regional divisions carry out field inspections on the BNIs, on radioactive substance transport and on small-scale nuclear activities; they examine the majority of the licensing applications submitted to ASN by the persons/entities in charge of nuclear activity within their regions. They check application within these installations of the regulations relative to nuclear safety and radiation protection, to pressure equipment and to Installations Classified for Protection of the Environment. They ensure labour inspectorate duties in the nuclear power plants.

In radiological emergency situations, the ASN regional divisions check the on-site measures taken by the licensee to make the installation safe and assist the Prefect of the *département*, who is responsible for protection of the population. To ensure preparedness for these situations, they help prepare the emergency plans drafted by the Prefects and take part in the 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 of the BNIs, and maintain regular relations with the local media, elected officials, associations, licensees and local administrations.

This chapter presents ASN's overall assessment by broad sector of activity as well as its assessment of nuclear safety and radiation protection in each region. It also reports on the local issues and procedures that are particularly representative of the regional action of ASN, especially with regard to informing the public and cross-border relations.

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 population's exposure 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. Protection of the patients benefiting from medical imaging examinations or therapeutic care using ionising radiation is regulated by the Public Health Code, while that of personnel working in the corresponding facilities is regulated by the Labour Code.

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, 232 nuclear medicine units using unsealed sources for *in vivo* or *in vitro* diagnostics and for internal radiotherapy.

In addition, as at the end of 2017, 172 external radiotherapy centres equipped with 476 treatment devices, handling some 200,000 patients every year, were identified by ASN. 750 radiation oncologists were listed.

Nuclear medicine comprises about 700 specialist practitioners, along with another 1,000 physicians from other

specialities working together in nuclear medicine units (residents, cardiologists, endocrinologists, etc.)

In 2017, ASN issued 634 licenses, of which 56% were in computed tomography, 24% in nuclear medicine, 16% in external-beam radiotherapy and 4% in brachytherapy.

Significant Radiation Protection Events (ESR) in 2017

Remote-notification of significant events via a single vigilance portal created by the Ministry for Solidarity and Health was extended to the entire medical field in April 2017.

Since 2012, the number of events notified to ASN stands at about 500 per year. In 2017, the number of ESRs notified to ASN in the medical field increased (568 in 2017 as opposed to 493 in 2016). This rise is mainly due to a large number of notified events in radiology (conventional and computed tomography) and, to a lesser extent, in nuclear medicine. On the other hand, the number of events notified in radiotherapy has been gradually falling for the past two years (about 150 in 2016 and 2017 as against about 240 from 2008 until 2015).

About 80% of the events notified come from computed tomography (29%), radiotherapy (25%) and nuclear medicine (26%) units.

The events notified in the medical field mainly concern exposure of patients (53%) and foetuses in women unaware that they were pregnant (30%), this latter category seeing a significant rise (with no consequences for the unborn child).

The events of which ASN was notified in 2017 reveal that the most significant activities from the radiation protection viewpoint concern:

- for workers: fluoroscopy-guided interventional practices with overdoses (external exposure of operators and in particular their hands) and nuclear medicine (contamination of workers, external exposure);
- for patients: interventional practices with deterministic effects observed in patients having undergone long and complex procedures, radiotherapy with overdoses linked more particularly to overlapping procedures and prescription errors and, lastly, nuclear medicine, with radiopharmaceutical delivery errors;
- for the public and the environment: nuclear medicine, with source losses, leaks from pipes and radioactive effluent containment systems.

Four level 2 events (ASN-SFRO[1] scale) were notified in 2017 in radiotherapy. These were overdoses following overlapping of two treatments, a prescription error (target volume) and an overdose in contact radiotherapy. In addition, three events involving the regulation dose limits of the extremities (hands) of interventional practitioners being exceeded were notified at the end of 2017 and rated level 2 on the INES scale.

State of radiation protection in external-beam radiotherapy and brachytherapy

The safety of health care using external-beam radiotherapy and brachytherapy has been a priority area of regulation and oversight since 2007. ASN used to systematically inspect radiotherapy centres every two years, but since 2016 it inspects every three years. An annual frequency is however applied in certain particular cases, more specifically for centres which are at risk in terms of human resources or organisation.

In external-beam radiotherapy, although the fundamentals of safety are in place (equipment checks, training of professionals, quality and risk management policy), ASN continues to observe considerable disparities between the centres. Difficulty is being experienced with maintaining quality and in some cases it is even regressing, more particularly owing to a lack of evaluation or to the departure of the operational quality manager. In addition, risk assessments remain relatively theoretical and insufficiently deployed ahead of an organisational or technical change. ASN stresses that the long-term involvement of all professionals in the management of quality and risks, in particular radiation oncologists, is necessary to enhance health care security.

With regard to brachytherapy, although the departments benefit from the organisation set up for external-beam radiotherapy, concerning the deployment of a quality management system, the same disparities are observed. ASN also considers that efforts must be continued to reinforce the radiation protection training of workers if a high-level source is present.

The radiation protection situation in nuclear medicine

ASN considers that the radiation protection of workers and patients and protection of the environment continued on the whole to make progress, in particular in the performance of internal inspections and continuous training. However, shortcomings persist with regard to coordinating the general worker protection measures during an intervention by an outside contractor, and also with regard to improving the safe delivery of the radiopharmaceutical drug to the patients and optimisation of the protocols for the use of scanners coupled with gamma cameras.

The radiation protection situation in computed tomography

In 2017, ASN continued its monitoring of radiation protection in the field of computed tomography, given the increase in the contribution of this imaging technique to the exposure of the population.

Even if radiation protection of the workers is satisfactorily addressed, that of the patients must be improved. The justification for the examination request, the search for a non-irradiating alternative technique and the training of professionals in radiation protection of patients, in particular external physicians on temporary assignment, must be reinforced. The same applies to optimisation of the examination protocols and the revision of practices after analysis of the diagnostic reference levels.

The radiation protection situation in interventional practices

Owing to the implications for both professionals and patients and owing to a lack of radiation protection culture among intervention personnel, in particular in the operating theatres, ASN maintained its monitoring of the facilities performing fluoroscopy-guided interventions as a national inspection priority.

The inspection findings confirm the observations made over the last few years. Thus, radiation protection of professionals is still applied to a greater extent in the fixed interventional radiology facilities (cardiology, neuro-radiology, vascular imaging, etc.) than in the operating theatres in which mobile devices are used.

Regulatory deviations are frequently observed during inspections, concerning radiation protection of both patients and professionals and ASN is regularly notified of overdoses on the hands of interventional surgeons. These inadequacies concern the training of all the professionals associated with health care, especially those who have not received initial university level patient radiation protection training, the intervention by the medical physicist and the means allocated to the Radiation Protection Experts-Officers[2].

As in the previous year, ASN considers that the measures it has been recommending for several years to improve the radiation protection of patients and professionals during interventional procedures in operating theatres are still not sufficiently implemented.

1. ASN-SFRO scale for classifying radiation protection events affecting patients undergoing medical radiotherapy procedures.

2. In France, the Radiation Protection Expert-Officer (RPE-O) [formerly referred to in ASN documents as the PCR (Person Competent in Radiation protection), reflecting the French term and acronym "Personne compétente en radioprotection *(PCR)"], is appointed by the employer of persons exposed to ionising radiation in the course of their work. Under the responsibility of the employer, the RPE-O participates in preparing the notification or licensing file and assessing the nature and extent of the risks to which the workers are exposed and in organising radiation protection. The RPE-O carries out internal radiation protection controls and keeps track of third-party radiation protection controls carried out by approved organisations. The RPE-O monitors worker radiation protection. Lastly, the RPE-O is involved in defining and implementing worker safety training for aspects concerning radiation protection and participates in the management of cases where worker exposure limit values are exceeded. These duties correspond to those of both Radiation Protection Expert (RPE) and Radiation Protection Officer (RPO), hence the adoption of the umbrella term Radiation Protection Expert-Officer (RPE-O).*

Outlook

In the field of radiotherapy, ASN will continue to support the work done by the learned societies looking to implement clinical peer reviews (audits) of practices, considering that these audits constitute a necessary complement to the quality management system it has been monitoring for several years. ASN will remain particularly attentive to the question of the means needed to deploy these audits. ASN will also set up a committee to coordinate intelligence regarding new techniques and new practices using ionising radiation in the medical field, bringing together the institutions, learned societies and professional associations involved in radiotherapy. Finally, work to better anticipate and manage organisational and technical changes will be continued in 2018, with volunteer radiotherapy centres and the assistance of professionals, hospital federations and health care institutions.

Verification of the control of doses in medical imaging remains a priority for ASN, particularly when associated with interventional practices. The recent and rapid development of new imaging techniques, including the arrival of CT scanners in the operating theatre 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 reinforcement of the actions conducted by ASN. ASN called on the Advisory Committee for Radiation Protection in medical and forensic applications of ionising radiation to issue recommendations to improve the radiation protection of both professionals and patients in operating theatres.

At the beginning of 2018, ASN will publish a new action plan for improved control of doses in imaging, in order to continue to promote a radiation protection culture among professionals, following on from the plan drawn up in 2011.

10 Sources of ionising radiation and industrial, veterinary and research uses of these sources

Industrial and research sectors have been using sources of ionising radiation in a wide range of applications and locations for many years now. The radiation sources used are either radionuclides – essentially artificial – in sealed or unsealed sources, or electrical devices generating ionising radiation. The main applications are industrial irradiation, gamma radiography inspection of materials, verification of physical parameters such as dust or density, and various detection techniques. Electrical devices emitting ionising radiation are used mainly in non-destructive testing and for veterinary diagnostic radiology.

Assessment

In 2017, ASN examined and notified 280 new licenses, handled 942 license renewals or updates and revoked 235 licenses for users and holders of ionising radiation sources. It granted 146 licences and renewed 319 licenses to use electrical devices generating X-rays and issued 346 notification acknowledgements. With regard to the suppliers, 62 licence or license renewal applications were examined. ASN also carried out 340 inspections of users and suppliers.

Industrial radiography activities remain an inspection priority for ASN, with 106 inspections in this field in 2017. ASN finds that the way the companies address the risk varies widely. ASN considers that the preparation for interventions is on the whole inadequate and that the flaws observed in radiological zoning is worrying, because this is the main means of radiation protection, more particularly in a worksite configuration.

As in 2016, contrary to previous years, no incident was rated level 2 on the INES scale in 2017. Analysis of the 18 notified events confirms that zoning is a key step in preparing for gamma radiography inspection sites. Experience feedback also shows that a correct check on the safety position of the source is essential in controlling the dosimetric consequences of this activity. The most significant incident in 2017 concerns the abnormal exposure of two operators who were working in the operation area while the source had not been returned to its safety position. The operators' passive dosimeters recorded effective doses of 3 and 9 mSv, which, for one of the operators, corresponded to an overdose in a single operation of more than one quarter the regulation annual individual dose limit (20 mSv).

In the veterinary sector, after the efforts made by the profession in recent years, the ASN inspectors observe that good practices are observed in the field in most structures.

ASN also continued its monitoring of facilities equipped with a cyclotron and producing radionuclides. The radiation protection organisation of these facilities is satisfactory and they are familiar with the regulations. National action plans have been put in place by the licensees and their implementation is monitored by ASN in order to ensure continuous improvement of radiation protection and safety in these facilities.

ASN's monitoring of establishments and laboratories using radioactive sources for research purposes shows a distinct improvement in radiation protection. However, in this field, ASN observes that notification of events is anything but systematic and that their analysis is insufficient. Nearly half of the structures which were inspected have no procedures for managing significant events.

The significant events notified are still mainly the theft or loss of radioactive sources or the discovery of legacy sources. These events can be explained essentially by poor general source traceability: failure to dispose of them when the laboratories ceased operations in the past, irregular and incomplete inventories.

Finally, in 2017, after the publication of Ordinance 2016-128 of 10th February 2016, ASN – together with the Defence and Security High Official of the Ministry responsible for the Environment – continued to prepare texts necessary for effective implementation of the monitoring and protection of sources against malicious acts. As ASN was designated the oversight authority for these measures regarding most radioactive sources, it also continued the steps begun to plan ahead for training of its staff and develop appropriate tools so that this new role could be taken on board rapidly and efficiently. In the civil sector, this concerns about 4,000 sources distributed around some 250 facilities in France.

Outlook

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.

It will prepare the entry into force of the new administrative systems applicable to nuclear activities, by issuing the necessary resolutions as early as possible, so that the nuclear activities concerned can be classified in the notification or registration systems and it will define the legally binding requirements to be satisfied when exercising the activities. It will also modify the resolutions concerning the content of the license application files, more specifically including the elements necessary for monitoring the protection of sources against malicious acts.

ASN will extend its electronic notification portal to all activities subject to notification, simplifying the process for the professionals (this arrangement is already in use for notification of transport activities and in the medical field).

11 | Transport of radioactive substances

About 770,000 consignments of radioactive substances are transported each year in France. This represents about 980,000 packages of radioactive substances, accounting for about 3% of all dangerous materials shipments. 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.

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.

The main participants in transport arrangements are the consignor and the carrier. 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 in particular from fire, mechanical impact, water ingress into the packaging (which would facilitate criticality reactions) and chemical reactions between package components. 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. If a package is unable to meet all the regulatory requirements, the regulations nonetheless allow for its transport by means of a shipment under special arrangement which requires ASN approval of the proposed compensatory measures.

Assessment

In 2017, ASN issued 47 approval certificates for packages or for special arrangement shipments. In 2017, the Advisory Committee for Transports (GPT) made a number of proposals to improve the approval application submitted by Areva TN for the new TN G3 package model, designed for shipment of spent fuel from the EDF NPPs to the La Hague plant. In 2018, ASN will rule on the latest undertakings by the applicant to take account of the GPT's recommendations.

Since the implementation of the Order of 7th February 2012, on-site transports of radioactive substances within the facilities must be covered by the licensee's baseline safety requirements. In 2017, ASN authorised on-site transport operations for dangerous goods taking place in the EDF NPPs and within the perimeter of the Areva plant at La Hague. In 2018, it will inspect the implementation of the baseline requirements and will continue its efforts with licensees who have not yet integrated these on-site transport operations into their general operating rules.

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. Inspections also concern preparedness for emergency situations. In 2017, ASN carried out 105 inspections on radioactive substance transports.

ASN considers that the radiation protection situation of the carriers could be improved, in particular for the carriers of radiopharmaceuticals, who are significantly more exposed than the average worker.

In 2017, concerning the transport of radioactive substances, ASN was notified of 62 events rated level 0 and 2 events rated level 1 on the INES scale. More than half of these events concern the nuclear industry. The medical and non-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 the event of an accident involving transport, emergency management should be able to minimise the consequences for the public and the environment. In 2017, ASN therefore drew up a document providing guidelines for the emergency services. It contains general information about radioactivity, general recommendations for the emergency services so that their response can take account of the specific nature of radioactive substance transports, plus sheets organised per type of substance, providing more detailed information and advice for the emergency response coordinator.

ASN also expressed the desire to see the stress tests approach extended to the transport field, in the same way as was done in the BNIs. The GPT therefore met in 2017 to decide on the ASN methodology applying the stress tests approach to transports.

From a regulatory viewpoint, ASN actively participates in the international work being carried out under the aegis of the IAEA since 2015 on the revision of the recommendations regarding the transport of radioactive substances. This work will continue in 2018.

Outlook

In 2018, ASN will continue its work on emergency management preparedness. It will thus contribute to training the emergency services in managing radioactive substance transport accidents and will implement the GPT stress test recommendations, more particularly by updating the guide on the risk assessment of transport infrastructures.

ASN will be publishing a guide in 2018 to help carriers achieve a clearer understanding of the regulatory requirements and best practices with regard to radiation protection.

In 2018, ASN will maintain its oversight of the manufacture and maintenance of packages requiring approval, in particular for the older packaging and of how irregularities in the manufacture of certain package components are addressed. Lastly, it will finalise the examination of the approval applications for the two new package models, TN G3 and DN 30.

12 | EDF Nuclear Power Plants

Nuclear Power Plants (NPPs) operated by EDF are at the heart of the nuclear industry in France. The 58 French reactors are technically very similar and thus form a standardised fleet. ASN imposes stringent requirements on these facilities, the regulation and oversight of which mobilises nearly 200 inspectors and as many IRSN experts, on a daily basis.

ASN has developed a proportionate and integrated approach to regulation that covers not only the design of new installations, their construction, the operation of existing reactors, modifications, integration of feedback, but also social, human and organisational factors, radiation protection, environmental protection, occupational safety and the application of labour legislation.

Nuclear reactors operated by EDF

2017 was marked by four significant events rated level 2 on the INES scale, each of which affected several reactors. Of particular note is the event concerning the resistance deficiency found in the Donzère-Mondragon canal embankment protecting the Tricastin NPP. In September 2017, this event led ASN to require that EDF temporarily shut down the four reactors of the NPP as rapidly as possible. In December 2017, further to the investigations and repairs carried out by EDF, ASN considered that the condition of the Donzère-Mondragon canal embankment allowed restart of the reactors of the Tricastin nuclear power plant.

The three other events rated level 2 on the INES scale involved the availability of certain systems important for the safety of the installations, such as electrical systems or the heat sink. Some of the defects identified are linked to equipment design, others to its assembly or maintenance.

These events highlight the difficulties experienced by EDF in ensuring the conformity of its facilities and maintaining this over time. These difficulties also underline the need to continue with the design reviews in

progress: these are bearing fruit and revealing anomalies, some of which have been present since the reactors were built. Detection of these deviations also indicates inadequacies in the maintenance programmes of certain equipment items.

ASN also considers that EDF must reinforce its actions and decision-making processes in dealing with deviations.

Non-compliance with general operating rules is still the cause of a considerable number of significant events. These events also reveal flaws in the oversight of the drafting processes for the general operating rules and the preventive maintenance programmes.

ASN considers that the quality of maintenance work could still be improved, as the number of maintenance work quality defects found remains high.

The inspections carried out by ASN on deployment of the modifications resulting from the third periodic safety review of the 1,300 MWe reactors show that EDF experiences difficulties in ensuring consistency between the physical state of the installations at the time of reactor restart and the state considered in the general operating rules. ASN asked EDF to regularise the situation and learn the necessary lessons from this deployment in preparation for the fourth periodic safety review of the 900 MWe reactors.

The organisation in place on the sites for managing skills, qualifications and training is on the whole satisfactory. EDF has allocated major investments to hiring and training, in order to anticipate the renewal of skills as a result of staff retirements.

In a context of a rising volume of maintenance work, the collective dosimetry on all the reactors fell in 2017. On no occasion was the annual regulation limit for whole body external dosimetry (20 mSv) exceeded.

ASN considers that EDF's organisation for management of NPP detrimental effects and impacts on the environment is satisfactory on most sites. Operational management of radioactive and conventional waste on the worksites could on the whole be improved across the NPPs.

The ASN assessments of each NPP are detailed in chapter 8 of the report. Certain sites stand out positively:
- in the field of nuclear safety: Fessenheim;
- in the field of environmental protection: Fessenheim;
- in the field of radiation protection: Chinon and, to a lesser extent, Civaux.

Other sites are on the contrary under-performing with respect to at least one of these three topics:
- in the field of nuclear safety: Belleville-sur-Loire and, to a lesser extent, Gravelines and Chooz;

- in the field of radiation protection: Nogent-sur-Seine;
- in the field of environmental protection: Dampierre-en-Burly and Nogent-sur-Seine.

Irregularities detected at the Areva NP Creusot Forge plant

The anomalies brought to light in the production by Areva NP's Creusot Forge plant, more specifically carbon segregation problems, led ASN in 2016 to ask the manufacturer to carry out a review of the manufacturing files on the components forged in this plant. These reviews revealed production irregularities concerning inconsistencies, modifications or omissions in the production files and concerning manufacturing parameters or test results.

In its resolution 2017-DC-0604 of 15th September 2017 ASN ordered EDF to send it the results of the review of the production files for the components forged by Creusot Forge, for each reactor in service and no later than two months before its scheduled restart following its next refuelling outage. EDF is required to complete its review no later than 31st December 2018.

The ASN review of the deviations on the first reactors led to additional justification requests but did not reveal any deviations requiring repair or replacement before restart.

In conjunction with this review, ASN is continuing to investigate the irregularity detected on the shell of a steam generator on Fessenheim reactor 2. Following the discovery of this anomaly, ASN suspended the steam generator test certificate on 18th July 2016, the effect of which was to keep this reactor shut down. In July 2017, Areva NP transmitted a file demonstrating the mechanical strength of the component concerned. ASN intends to issue a position statement on this subject in the first half of 2018.

These irregularities revealed unacceptable practices at the Creusot Forge plant that are incompatible with the principles underpinning the safety culture. They reveal shortcomings in EDF's surveillance of its suppliers. Other irregular situations, more specifically concerning repair or modification work on equipment installed in the NPPs, were detected in 2017. EDF presented ASN with an action plan which it has begun to implement.

Experience feedback from the Fukushima Daiichi accident

EDF deployed temporary or mobile measures to reinforce the management of situations involving a total loss of heat sink or electrical power supplies. The Nuclear Rapid Intervention Force (FARN) has been fully operational since the end of 2015. EDF has also begun to implement a large part of the final measures, more particularly the construction of buildings intended to house the ultimate back-up diesel generator sets.

2017 was marked by continued work to install the equipment of the "hardened safety core". More specifically, the first performance tests on the ultimate back-up diesel generator sets intended for the 900 MWe reactors were successfully run on the Saint-Laurent-des-Eaux site in May 2017. In 2017, ASN also continued examinations to verify that the hardware changes proposed by EDF will be able to meet the safety targets set.

Examination of NPP operating life extensions

After its position statement in April 2016 on the orientation of the generic study programme to be carried out in preparation for the fourth periodic safety review of the 900 MWe NPP reactors, ASN continued in 2017 to examine the generic studies related to this review. These more specifically aim to demonstrate the serviceability of the reactor pressure vessels, the attainment of the safety reinforcement goals for the spent fuel pools, the mitigation of the potential consequences of accidents - including accidents with core melt - and improved resistance of the facilities to internal and external hazards.

The deployment of most of the modifications to the facilities as a result of this periodic safety review and performed during the fourth ten-yearly outage inspection of the 900 MWe reactors, will run until 2030.

The Flamanville 3 EPR reactor

ASN is continuing to examine the commissioning authorisation application for the Flamanville EPR transmitted by EDF in March 2015. In 2017, it issued a position statement on the safety case studies, more particularly the safety of fuel storage and handling.

In December 2015, ASN issued a position statement on the approach adopted by Areva NP to demonstrate the serviceability of the Flamanville EPR reactor pressure vessel closure head and bottom head following the anomaly in the chemical composition of their steel. In 2017, ASN examined the technical file from Areva NP presenting the implementation of the approach. ASN considers that this anomaly is not such as to compromise the commissioning of the reactor pressure vessel, provided that specific checks are carried out during operation, to ensure that no flaws appear. As the feasibility of these checks cannot at present be confirmed for the closure head, ASN considers that the current closure head cannot be used beyond 2024.

Evaluation of the manufacture of nuclear pressure equipment

During the course of 2017, ASN continued to assess the conformity of the manufacture of the replacement nuclear pressure equipment for the NPPs in service and the Flamanville EPR reactor. ASN and the organisations it approves are reviewing the technical documentation and the monitoring of the on-site assembly operations. In 2017, ASN confirmed the conformity of several equipment items.

ASN ensured that all the industrial firms have taken on-board the lessons learned from the carbon segregation anomalies detected in 2016 and the irregularities in the Areva NP Creusot Forge plant.

Outlook

Operating experience feedback from the NPP reactors reveals that there are still inadequacies in the processes employed by EDF to obtain conformity of the facilities with their design and operating baseline requirements and then maintain this compliance over the long term. In 2018, ASN will reinforce its oversight of the processes used by EDF to ensure that they are actually able to detect and then process all deviations from the design and operating baseline requirements, in good time.

Management of the conformity of the facilities in service will be a major focal point of ASN inspections in 2018.

In 2018, ASN will continue to check the performance of the file reviews for all the components manufactured in the past by the Creusot Forge plant. It will ensure that this review process is seen through to completion, in order to assess all the irregularities which could have affected past production and draw all the possible conclusions for the safety of the facilities.

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 2018, ASN will continue to review the design, construction and operating provisions adopted by EDF to address the requirements concerning the "hardened safety core". ASN will also continue to oversee the work to deploy this "hardened safety core" on the sites, more particularly the ultimate backup diesels, ultimate water source and local emergency centre.

In 2018, examination of the generic studies will continue for the fourth periodic safety review of the 900 MWe reactors. ASN envisages issuing a position statement on the generic phase of the review at the end of 2020. As part of the actions initiated by the HCTISN in 2017, ASN will also take part in public consultation measures planned for 2018 concerning the steps proposed by EDF to meet the objectives set for this review.

In 2018, ASN will examine the initial review conclusions reports for the third ten-yearly outage inspections of the 1,300 MWe reactors, so that it can issue a position statement on the continued operation of these reactors.

ASN will continue to oversee the installation of equipment, the performance of start-up tests and the preparation of the various support documents for the operation of the Flamanville 3 EPR reactor. In 2018, ASN will issue a position statement on the partial commissioning authorisation application to allow the arrival of nuclear fuel on the site.

Finally, in 2018, ASN will continue the important in-depth work started in 2015 with the manufacturers, licensees and approved organisations, with regard to the application of the regulations concerning nuclear pressure equipment.

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 are on the Orano (ex-Areva NC) Tricastin (Comurhex, TU5, W, Georges Besse II), Marcoule (Mélox), La Hague, Malvési sites and on the Framatome (ex-Areva NP) site of Romans-sur-Isère.

Significant events

Restructuring of the Areva group

2017 was marked by the restructuring of the Areva group, which was split up into several entities, notably Framatome and Orano. With regard to nuclear safety, this entailed a break-up of the group headquarters (engineering in particular) and various organisational changes on the Tricastin, La Hague, Romans-sur-Isère and Marcoule sites. The new entities resulting from this break-up will retain strong operational ties with each other in the exercise of their responsibilities as nuclear licensees. ASN will be particularly attentive to ensuring that the Framatome and Orano BNI licensees are in full possession of the capabilities needed to meet their responsibilities.

A new spent fuel storage capacity

Given the timeline identified for saturation of spent fuel storage capacity in France and the time needed to design and build a new facility, EDF submitted a safety options file in

2017 for a centralised spent fuel pool project taking account of current safety requirements. This project, for which the location has not yet been decided, should allow storage of spent fuels for which reprocessing or disposal cannot yet be envisaged in the near future. The envisaged operating life for this storage facility is about a century. ASN will issue an opinion on the safety options in early 2019.

Monitoring the status of the evaporators at La Hague

For the periodic safety review of BNI 116, ASN asked Areva in 2011 to examine the conformity and ageing of the fission products concentration evaporators in the La Hague plants. In 2014, Areva NC informed ASN that the corrosion of these items was on a scale greater than that considered in the design. As the maintained integrity of these items has major safety implications, the ASN Commission stipulated the conditions to be met by Areva NC for continued operation of these evaporators. ASN is monitoring the development of corrosion on this equipment, prior to its post-maintenance restart.

In November 2016, ASN issued a position statement on the safety options proposed by Areva NC for the construction of new evaporators, for which commissioning is expected in 2021. In 2017, ASN authorised the construction of the civil engineering works intended for this replacement equipment.

Outlook

Fuel cycle consistency

In 2016, ASN started an examination of the "Cycle impact" file update covering the period 2016-2030 and aimed at anticipating the various emerging needs in order to ensure the management and consistency of the nuclear fuel cycle operations in France, in terms of safety. ASN will in particular focus on monitoring the level of occupancy of the spent fuel underwater storage facilities (Orano and EDF). It asked EDF, as client, 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 circuit, as well as the solutions designed to guarantee that sufficient storage capacity is maintained on a long-term basis.

In 2018, ASN will issue its conclusions on the "Cycle Impact" file submitted in 2016, which will notably be the subject of a joint review by the Advisory Committees for Laboratories and Plants (GPU), for Waste (GPD), for Reactors (GPR) and for Transports (GPT).

Tricastin site

The BNI licensees on the Tricastin platform asked for authorisation to modify their organisation, with the creation of joint management systems. This reorganisation entails transfer of nuclear licensee responsibility to a single party: Orano. ASN will issue a position statement on these subjects in 2018.

Romans-sur-Isère site

Following their periodic safety review and after a year 2017 marked by the continued shutdown of the research reactors fuel fabrication plant for several months, ASN will in 2018 define the conditions for the continued operation of the plants on this site.

La Hague site

In 2018, ASN will remain particularly vigilant with regard to the development of corrosion in the fission products concentration evaporators. Orano shall continue with reinforced inspection of this equipment. Orano will also be required to maintain its efforts so that it can effect the replacement it envisages between 2020 and 2021. ASN will examine the applications for the construction of new evaporators.

With regard to changes to the site BNIs, ASN will examine the licensee's application to expand compacted waste package storage capacity, which will entail the holding of a public inquiry.

14 | Nuclear research and miscellaneous industrial facilities

Nuclear research or miscellaneous industrial facilities are operated by CEA or other research organisations (for example the Laue-Langevin Institute (ILL), the ITER international organisation and the national large heavy ions accelerator - Ganil) or by industrial firms (for instance CIS bio international, Synergy Health and Ionisos, which operate facilities producing radiopharmaceuticals, or industrial irradiators).

The safety principles applicable to these facilities are similar to those applied to power reactors and nuclear fuel cycle facilities, while taking account of their specificities with regard to risks and detrimental effects.

Significant events and assessment

CEA

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.

Construction work on the Jules Horowitz Reactor (RJH) is continuing. 2017 was marked by the end of the civil engineering work. CEA asked for a four-year extension to the commissioning date for its facility owing to a series of delays in the construction work. ASN will examine this application for postponement of commissioning to 2023.

ASN inspected the start-up tests, the aim of which is to check correct operation of the equipment and of the Cabri reactor, more particularly tests on the equipment of the new pressurised water loop. At the beginning of 2018, it granted the authorisation necessary for performance of the first experimental test.

The Éole-Minerve reactors and the Fissile Materials Central Warehouse (MCMF) were finally shut down at the end of 2017. The decommissioning files should be submitted in July 2018 and November 2018 respectively.

Other licensees

ASN supervised the new strategy for gradual commissioning of ITER up until 2035.

ILL continued to install the cooling backup systems and carried out reinforcement work on the High-Flux Reactor (RHF). This work is primarily in response to the undertakings made as a result of the lessons learned from the Fukushima Daiichi accident.

ASN considers that the level of safety of the RHF is satisfactory. It did however observe several deviations from the regulations in terms of safety management. ASN therefore expects ILL to reinforce its organisation, more specifically to improve the management of equipment modifications, as well as the management of periodic checks and tests.

Delays were observed in the implementation of a number of technical requirements for the operation of Ganil. ASN is closely attentive to the resources devoted by Ganil to nuclear safety, so that the requirements are met rigorously and the projects are run efficiently.

With regard to CIS bio international, ASN notes that efforts have been made, in particular the reinforcement and modification of its organisation and its operating processes, making safety management of the UPRA facility more efficient. However, the nature of the significant events which have occurred, the causes of which are almost always organisational and human failures, reflects an unsatisfactory operational safety situation.

ASN also observes that, in the light of the delays that have built up in recent years and despite the efforts made since the end of 2016, the licensee has difficulty in complying with the requirements resulting from the previous periodic safety review, with ASN therefore initiating a formal notice to comply procedure at the beginning of 2018. To conclude, ASN expects to see a lasting turnaround in operating rigour and projects management at CIS bio international.

Outlook

Examination of the 26 periodic safety review conclusion reports submitted in 2017, including 16 for CEA, and ASN's future position statements on the continued operation of the facilities concerned (research reactors, laboratories, plants, waste and decommissioning) are particular challenges for the coming years.

CEA

ASN will remain vigilant to ensuring compliance with the commitments made by CEA, both for its facilities in service and those being decommissioned.

In 2018, it will issue a position statement on the CEA's new decommissioning and waste management strategy, covering all the facilities.

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, Orphée, MCMF, LECA, Eole-Minerve). The drafting of all these decommissioning files and then performance of the decommissioning operations represent a major challenge for CEA, for which it must actively prepare.

In 2018, ASN also intends to:
- continue monitoring the construction of the RJH;
- start the examination of the authorisation application for the substantial modification of Masurca (in-depth refurbishment, notably with the construction of a new storage and handling building).

Other licensees

ASN will continue to pay particular attention to monitoring the facilities being built, that is ITER and the Ganil extension.

ASN will remain vigilant with regard to the safety organisation put into place at Ganil and to compliance with ASN's requirements, more specifically those resulting from the last periodic safety review.

ASN will also remain vigilant with regard to the expected improvements at ILL, in particular for management of material modifications and the management of periodic checks and tests, as well as the satisfactory implementation in 2018 of the new ILL integrated management system, for which deployment began in 2017.

Finally, ASN will maintain its reinforced monitoring of CIS bio international in 2018.

15 | Decommissioning of basic nuclear installations

Decommissioning covers all the activities carried out after shutdown of a nuclear facility, following which the facility can be delicensed. In 2017, 35 nuclear facilities of all types (power and research reactors, laboratories, fuel reprocessing plants, waste treatment facilities, etc.) had been shutdown or were undergoing decommissioning in France, representing more than one quarter of all BNIs.

Significant events and assessment

2017 was notably marked by the examination of the decommissioning and waste management strategies for the CEA and Areva facilities. EDF also gave ASN confirmation of its intention to carry out final shutdown of the Fessenheim NPP once the Flamanville EPR is commissioned: the final shutdown declaration has not yet been sent.

In 2017, ASN called EDF to a hearing about its change in decommissioning strategy for its Gas-Cooled Reactors (GCR) and initiated an examination of the acceptability of this new strategy in the light of the regulatory requirements which demand decommissioning of nuclear facilities as rapidly as possible. ASN also inspected EDF on this subject at the end of 2017.

A comparison of these strategy files with the three-year files updating the long-term costs to be borne by the licensees, examined by ASN on behalf of the Government, shows that the time-lines linked to the technical scenarios and budgets associated with decommissioning are managed by the licensees with difficulty. At this stage, ASN considers that the decommissioning context is a subject of concern for the medium-term. Thus, the financial aspects and the lack of technical expertise in complex projects can lead the licensees to postpone decommissioning, notwithstanding the requirements of the law.

2017 was marked by the final shutdown of BNIs 92 (Phébus reactor), 42 (ÉOLE reactor), 95 (Minerve reactor) and 53 (MCMF) operated by CEA.

2017 saw the continued examination of four decommissioning files, which were the subject of an opinion by the Environmental Authority of the General Council for the Environment and Sustainable Development and were opened up for a public inquiry: BNI 93 Eurodif and BNI 105 Comurhex on the Tricastin site (Areva), BNI 94 AMI Chinon (EDF) and BNI 52 ATUe in Cadarache (CEA).

ASN also began to examine step two of the decommissioning decree for the Superphénix fast neutron reactor (BNI 91) so that the license could be issued for decommissioning of the reactor vessel internals.

Examinations of the periodic safety reviews (BNIs 33, 38 and 47) and of the complete decommissioning files (BNIs 33 and 38) for the Areva La Hague plant were continued in 2017 and presented to the ASN Advisory Committee in April 2017. This latter concluded that the risk management measures taken for the decommissioning operations were on the whole appropriate.

2017 was also marked by the submission of the periodic safety review conclusion reports for most of these facilities.

Finally, BNI 61 LAMA in Grenoble (CEA) was delicensed.

Outlook

ASN's key actions in 2018 will concern the monitoring of progress in decommissioning and waste management projects, especially the retrieval and packaging of CEA and Areva legacy waste, where delays are particularly detrimental to the safety of the sites concerned. ASN will issue a position statement on these files once examination is completed.

In 2018, ASN will examine the justification data concerning the change in EDF strategy regarding the decommissioning of its first-generation GCR reactors, as well as data concerning the safety of these reactors during the period pending decommissioning. ASN will issue a position statement on EDF's request for a strategy change on completion of all the technical and regulatory examinations.

The scheduling of final shutdown and operations in preparation for decommissioning of the reactors of the Fessenheim NPP, the first 900 MWe PWR reactors connected to the grid, will also be a major safety challenge.

The periodic safety reviews of the installations undergoing decommissioning, for which the majority of the conclusions files were submitted by the licensees in 2017, will also be the subject of technical examinations tailored to the risks and detrimental effects these installations represent. In 2018 and 2019, a further ten or so facilities will submit their decommissioning files.

Lastly, in order to clarify the decommissioning and waste management regulations updated by the Ordinance of 10th February 2016, ASN will continue to develop new guides in these areas as well as in the area of contaminated sites and soils in the BNIs.

16 | Radioactive waste and contaminated sites and soils

Radioactive wastes are radioactive substances for which no subsequent use is planned or envisaged or which have been reclassified as such by the administrative authority pursuant to Article L. 542-13-2 of the Environment Code. They come from nuclear activities processing artificial or natural radioactive substances, provided that this radioactivity warrants the implementation of radiation protection checks.

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, craftwork, medical or research activities.

Significant events

2017 saw the adoption of the National Plan for Radioactive Materials and Waste Management (PNGMDR) 2016-2018, which was transmitted to Parliament in February. This three-year plan presents the results 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. It is supplemented by Decree 2017-231 of 23rd February 2017 implementing Article L. 542-1-2 of the Environment Code and establishing the requirements of the PNGMDR and the Order of 23rd February 2017 implementing the Decree of 23rd February 2017.

On 8th June 2017, ASN issued its opinion on the fourth three-yearly reports transmitted by the licensees in 2016. These reports describe the evaluation of the costs relating to decommissioning and waste management, the methods applied for calculation of the corresponding provisions and the choices made with regard to the composition and management of the assets allocated to coverage of these provisions. ASN more particularly considers that the contents of the reports issued by the licensees do not all contain the same level of detail and that the EDF file does not contain enough information for ASN to be able to adopt a position on the exhaustiveness of the evaluation of its financial costs.

2017 was marked by the examination of the safety options file for the *Cigéo* deep geological disposal project, submitted by the National Radioactive Waste Management Agency (Andra) in 2016. In January 2018, ASN issued its opinion on this file. It considers that these safety options represent a significant step forward, stipulates which additional justifications will be necessary for a possible creation authorisation application and underlines its reservations with regard to bituminised wastes.

Examination has begun on the Areva and CEA files concerning waste management and facilities decommissioning strategies. ASN and the Defence Nuclear Safety Authority (ASND) will issue a position statement on these strategies in 2018.

Finally, ASN published resolution 2017-DC-587 on 23rd March 2017 relative to the packaging of radioactive waste and the conditions of acceptance of the radioactive waste packages in the disposal BNIs.

Assessment and outlook

ASN considers that the French radioactive waste management system, built around a specific legislative and regulatory framework, a national plan and an agency (Andra) dedicated to the management of radioactive waste, independently of 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.

The PNGMDR

ASN will continue to monitor the work done on the PNGMDR 2016-2018, more particularly via the pluralistic working group it chairs with the General Directorate for Energy and Climate. Depending on the decision by the National Public Debates Commission, which will be involved in the drafting of the PNGMDR 2019-2021 with regard to the procedures for organising participation of the public, ASN will work alongside the Ministry for Ecological and Solidarity-based Transition, to allow this involvement of the public in the drafting of the plan. ASN will also prepare for drafting of the next PNGMDR through its opinions, as of 2018, on the studies provided for in the PNGMDR 2016-2018.

Finally, ASN will take part in the HCTISN working group on the management of very low level waste.

The regulations concerning the management of radioactive waste

In 2018, ASN will continue with the drafting of resolutions relative to radioactive waste disposal and storage facilities. These draft texts will be made available for consultation by the stakeholders and the public.

ASN will also closely monitor the work to transpose Directive 2013/59/Euratom of 5th December 2013 setting the basic standards for radiation protection.

The licensees' radioactive materials and waste management strategies

In 2018, ASN will continue to monitor the satisfactory performance of the legacy waste and spent fuel retrieval and packaging operations, focusing on those presenting the most significant implications for safety.

ASN, together with the ASND, will complete its examination of Areva's waste management strategy, submitted in mid-2016, and that of CEA, submitted at the end of 2016. ASN and the ASND will present their conclusions in 2018.

In 2018, ASN will continue its monitoring to ensure that CEA meets its commitments concerning its old installations which no longer comply with current safety requirements. ASN will also monitor the progress of CEA's strategic waste management projects (Diadem, BNI 37-A, solid and liquid waste management on the Saclay site) and the preparation of the decommissioning files for the old storage facilities (BNI 56, Pégase, BNI 37-B).

Low Level, Long-Lived Waste (LLW-LL)

With regard to low level, long-lived radioactive waste (LLW-LL), ASN considers that progress in the creation of management solutions is essential. Analysis of the file submitted by Andra in 2015, pursuant to the PNGMDR, showed that it will be difficult to demonstrate the feasibility – in the zone investigated – of a repository for all LLW-LL type waste. In its opinion of 29th March 2016, ASN asked that in accordance with the PNGMDR, Andra submit a report by mid-2019, presenting the technical and safety options for this disposal facility and an industrial management system for LLW-LL waste established jointly with the producers of these wastes. Andra has undertaken to send ASN an interim report on this subject in 2018.

Depending on the conclusions of this report, the waste producers shall if necessary, 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 2018, ASN will work on revising the safety guide relative to the disposal of LLW-LL type radioactive waste.

High-Level and Intermediate-Level Long-Lived Waste (HLW and ILW-LL)

With regard to the *Cigéo* project for disposal of HLW and ILW-LL waste, ASN will in 2018 monitor the preparation of the creation authorisation decree application by Andra, notably the steps taken following its requests concerning the safety options file.

ASN asks that Andra be vigilant with regard to the industrial development times associated with the results of the R&D programme carried out by Andra and the regulatory milestones in the *Cigéo* installation authorisation process.

ASN underlines the importance it attaches to the progress that the waste producers must make in packaging their waste, particularly the waste resulting from retrieval and repackaging operations.

Periodic safety reviews of radioactive waste management BNIs

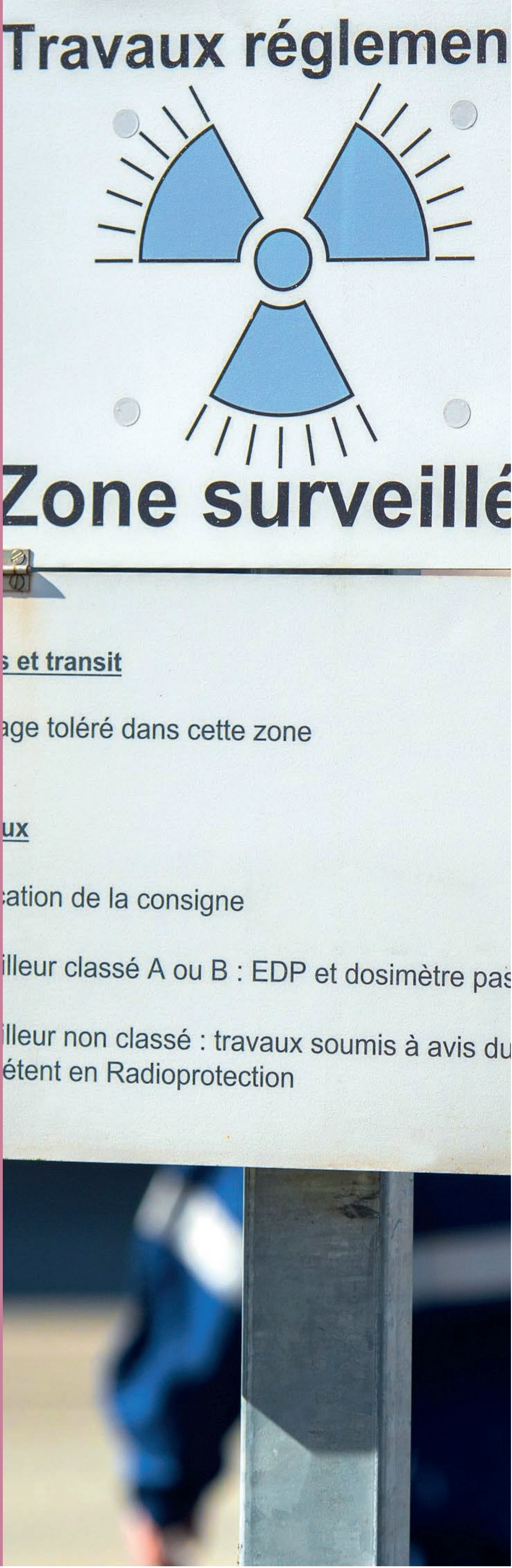
In 2018, ASN will continue to examine the conclusion reports of the periodic safety reviews of waste management facilities received in 2016 and 2017. It will continue to monitor the progress of the action plans defined by the licensees for those BNIs for which the files have already been examined.

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

With regard to the former uranium mining sites, ASN will continue to support the public authorities with regard to 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.

With regard to the management of contaminated sites and soils, ASN will continue its analysis of contaminated site remediation projects, on the basis of the principles of its doctrine published in October 2012.

Together with the administrations concerned and the other stakeholders, ASN will also continue to monitor remediation programmes in progress.



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Nuclear activities: ionising radiation and health and environmental risks

01

Ionising radiation may be of natural origin or be produced by nuclear activities of human origin. The exposure of the population to naturally occurring ionising radiation results from 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 are 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

FUNDAMENTALS

UNSCEAR

The UNSCEAR 2016 Report *Sources, effects and risks of ionising radiation* takes stock more particularly of current knowledge concerning exposure of the public to ionising radiation resulting from the electricity production industries. The first part of the report presents the developments of the methodology used to estimate public exposure due to radioactive discharges from the electricity generation industry. It compares the exposure to ionising radiation resulting from the different electricity generation sources: nuclear, coal, gas, oil, geothermal, solar and wind. Particular attention was focused on the contribution of the industries generating electricity from nuclear energy and coal. The results show that the coal cycle industry, contributes more than half of the collective dose received by the public for one year of electricity production. For a given quantity of electricity produced, the coal cycle makes the largest contribution to the collective dose of the public, followed by nuclear energy and, to a lesser extent, the other sources with the exception of geothermal energy.

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

150th anniversary of the birth of Marie Curie.

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 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 young people exposed during their childhood. The consequences of the Fukushima Daiichi accident on the health of the neighbouring populations are not yet sufficiently known and analysed to draw epidemiological lessons from them.

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 radiation-induced cancers represent the predominant health risk associated with exposure to ionising radiation.

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

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 is complementary to 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 (cumulative doses over several years).

These results support the justification of radiological protection of populations exposed to low doses of ionising radiation (nuclear industry workers, medical personnel, medical exposure for diagnostic purposes, 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 the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR), the International Commission on Radiological Protection (ICRP) has published the risk coefficients for death by cancer due to ionising radiation, i.e. 4.1% excess risk per Sievert (Sv) for workers and 5.5% per Sievert for the general public (see ICPR publication 103, chapter 3, point 1.1.1).

The evaluation of the risk of lung cancer due to radon[2] is based on a large number of epidemiological studies conducted directly in the home in France and on an international scale. These studies have revealed a linear relationship, even at low exposure levels (200 Bq/m^3) over a period of 20 to 30 years. The World Health Organisation (WHO) has made a synthesis of the studies and recommends maximum annual exposure levels of between 100 and 300 Bq/m^3 for the general public. ICRP publication 115 compared the risks of lung cancer observed through studies on uranium miners with those observed in the overall 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 consolidate 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 high radon concentrations. According to InVS (French Health Monitoring Institute) figures from 2007, 1,200 to 2,900 deaths from lung cancer can be attributed each year in France to radon exposure in the home, that is to say 4 to 10% of deaths due to lung cancer (30,555 deaths, INCa [National Cancer Institute] – 2015). A national 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. Many uncertainties persist; they induce ASN to remain attentive to the results of scientific work in progress in radiobiology and radiopathology for example, with possible consequences for radiation protection, particularly with regard to management of risks associated with low doses.

One can mention, for example, several areas of uncertainty concerning radiosensitivity, the effects of low doses, the existence of signatures (specific mutations of DNA) that could be observed in radiation-induced 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 or 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 persons suffering from genetic diseases affecting the repair of DNA and cellular signalling; in these individuals they can 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 still be confirmed in the clinical environment before being integrated into medical practices.

The monitoring of individual radiosenstivity in a medical treatment context through validated tests is not yet fully operational despite the progress of ongoing research.

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 (ICRP in particular) to prepare for the ASN regulations that might or will have to be issued.

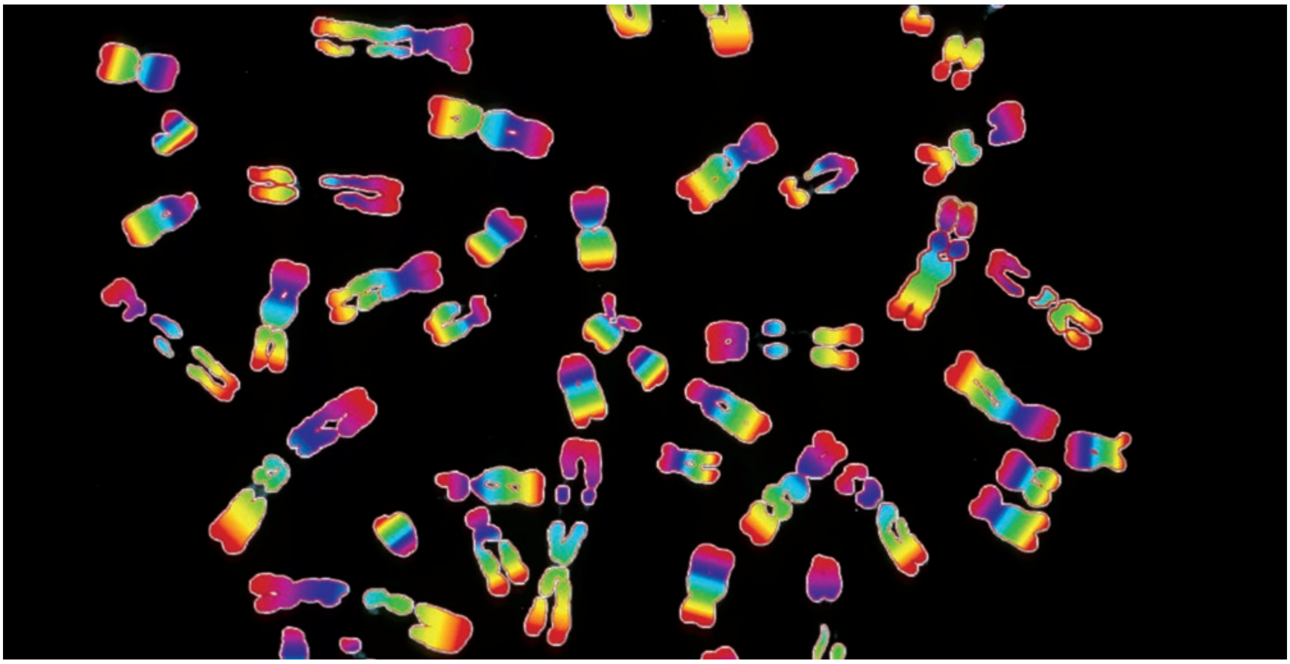
At this stage, there should be no unnecessary, that is to say without good reason, exposure of individuals to ionising radiation. Children should receive particular attention when exposed to ionising radiation for medical purposes.

1.3.2 Effects of low doses

The Linear No-Threshold (LNT) relationship. The 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. Some 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 others 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 duration of exposure. 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 associated with chronic exposures at low doses established over many years, whether as a result of external exposure or internal contamination.

2. Radon is a natural radioactive gas, a daughter product of uranium and thorium, an emitter of alpha particles and is classified as a known human pulmonary carcinogen by the International Agency for Research on Cancer - IARC.



Pairs of chromosomes have characteristic bands of colouring (Inserm).

Hereditary effects. 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).

1.3.3 Molecular signature in radiation-induced 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. Recent work however (Behjati et *al.* 2016) seems to indicate that two types of mutations are apparently more frequent; the small sample size nevertheless necessitates the validation of these data through more extensive studies.

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 control 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 external exposure dose rate values 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 IRSN (the Institute of Radiation Protection and Nuclear Safety) (2015), the average dose per individual would be about 0.32 mSv per year. The average concentration of potassium-40 in the organism is about 55 Bq 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.

RADON EXHALATION POTENTIAL in metropolitan France (source: IRSN)

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) has been estimated by IRSN through measurement campaigns which were then followed by statistical analyses (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). A finer classification per municipality will be based on this and will be available in 2018.

Ultimately, the new obligation placed on dosimetry laboratories to communicate the dosimeter results to IRSN should enhance knowledge of radon exposure in France (see the 3rd National Plan for Radon Risk Management, published in January 2017 and accessible on *www.asn.fr*).

2.1.3 Cosmic radiation

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.

| Thomas Pesquet, astronaut.

Considering the average time spent inside the home (which itself attenuates the ionic component of 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. The average annual effective dose per individual in France is 0.32 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 BNIs;
- 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 2017 figures in an appendix to this report.

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. They must more particularly ensure compliance 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 withstand the foreseeable transport conditions.
- The reliability of the transport operations constitutes the second line of defence.
- Finally, the third line of defence consists of the means of response implemented in the event of an incident or accident.

2.2.3 Small-scale nuclear activities

Ionising radiation, whether emitted by radionuclides or generated by electrical equipment, is used in many areas, including medicine (radiology, radiotherapy, nuclear medicine), biology, research, industry, but also in veterinary applications and 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.

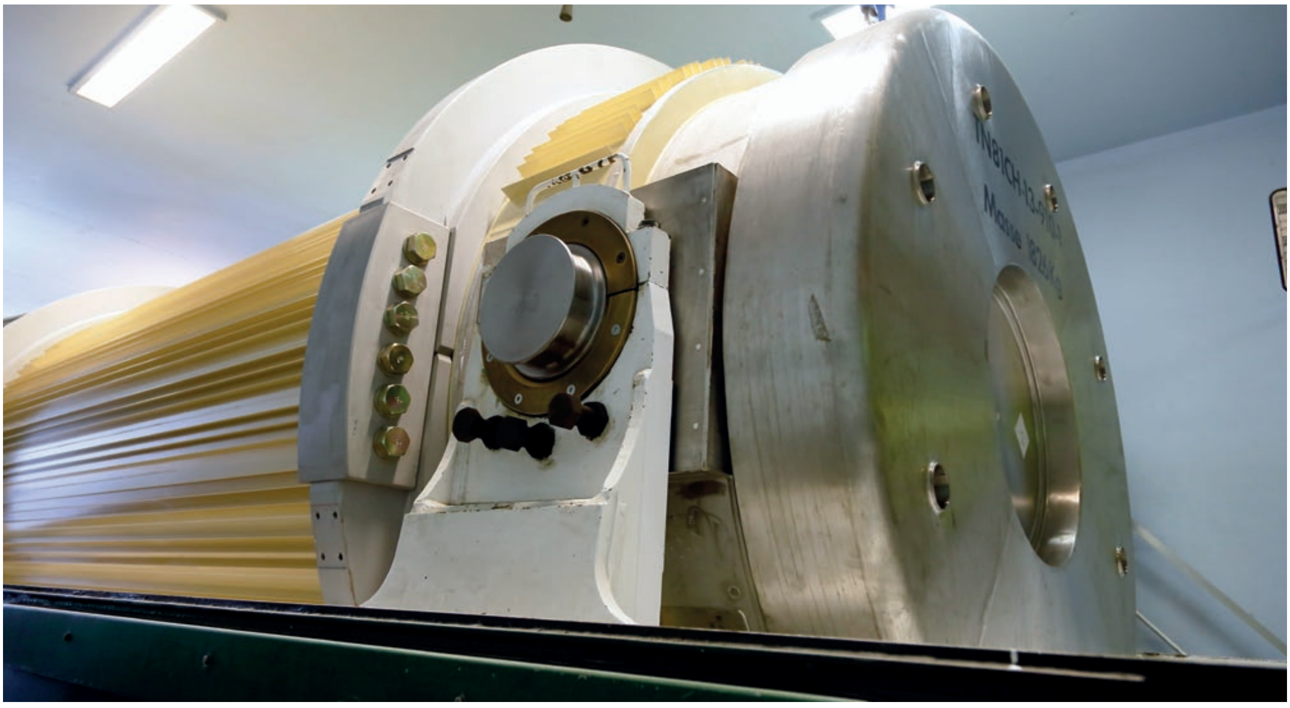
The technical management provisions to be implemented must be tailored to the hazard presented by the radioactive waste. This hazard can be assessed primarily through two parameters: the activity level, which contributes to the toxicity of the waste, and the half-life, the time after which the activity 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 and future uses of the site, decontamination objectives must be set. 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 through to storage or disposal. The management of contaminated objects also follows these same principles.



Transport packaging.

2.2.6 Activities using radioactive substances of natural origin

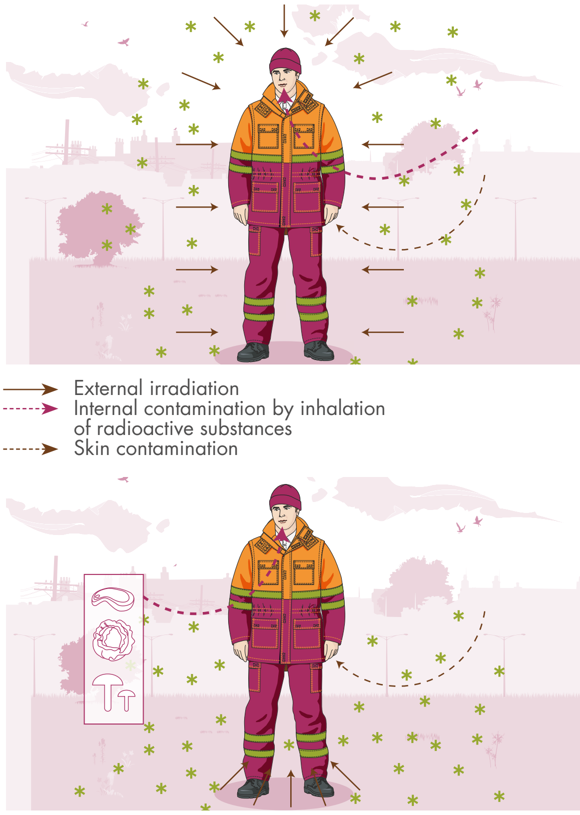
Exposure to ionising radiation of natural origin, when increased due to human activities, justifies monitoring measures if it is likely to create a hazard for the exposed workers and, where applicable, the neighbouring population.

Thus, certain activities included in the definition of "nuclear activities" can use materials containing Naturally Occurring Radioactive Materials (NORM, see definition in chapter 3, point 1.2.2) at concentration levels that could significantly increase the exposure of workers to ionising radiation and, to a lesser extent, the exposure of populations living near the places in which these activities are carried out.

The natural families of uranium and thorium are the main radionuclides found. Among the industries concerned, we can mention:
- the production of oil and gas, geothermal energy, titanium dioxide, phosphate fertilizers and cement;
- the extraction of rare earths and granites;
- the casting of tin, lead and copper.

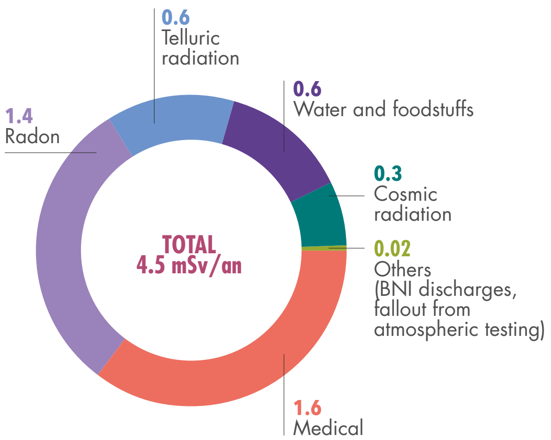
The radiation protection measures to take in this area target not only the workers (risk of external irradiation and internal contamination, radon) but also the general public, for example in the case of effluent discharges into the environment or the production of residues that could be reused, in construction materials for example.

SOURCES AND ROUTES OF EXPOSURE to ionising radiation



3. Monitoring of exposure to ionising radiation

DIAGRAM 1: Average exposure of the French population to ionising radiation (mSv/year)*



Source: IRSN 2015

** This diagram does not integrate the data published in ICRP 167 of January 2018.*

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.

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 with the exception of the radon risk.

3.1 Doses received by workers

3.1.1 Exposure of persons working in nuclear facilities

The system for monitoring the external exposure of persons liable to be exposed to ionising radiation, particularly those 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, 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 person working in nuclear facilities, including workers from subcontractor companies. They are grouped together in Siseri (Ionizing radiation exposure monitoring information system) 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 25% of the collective dose, the nuclear industry however, which represents about 20% of the headcount, accounts for more than 45% of the collective dose. The industrial sector, which represents just 10% of the headcount, accounts for 28% of the collective dose.

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 decrease in 2013, for the first time since 2001, the years 2014, 2015 and 2016 again show a slight increase in the number of persons monitored.

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 60%). The collective dose did however display an upward trend between 2006 and 2009, followed by a levelling off over the 2009-2012 period. After a singular increase in 2013, the collective dose for (63.2 man.Sv in 2016) has since 2015 returned to values similar to those observed over the 2009-2012 period.

The number of monitored workers whose annual dose exceeded 20 mSv has fallen since 2015; only one case exceeding the effective annual dose was observed in 2106 (effective dose of 65.2 mSv for a worker in the non-destructive testing sector) (see Diagram 3).

With regard to the dosimetry of the extremities (fingers and wrist), 28,672 workers were monitored in 2016 (i.e. 7.7% of the total number of persons monitored). Out of all the persons monitored, there were two cases where the 500 mSv regulatory equivalent dose limit at the extremities was exceeded (568 mSv and 800 mSv for two workers in the medical imaging sector).

For the second year running, data relative to monitoring of the lens of the eye are available. Four thousand four hundred

TABLE 1: Monitoring of external exposure of nuclear workers (year 2016)

Source: IRSN

	NUMBER OF PERSONS MONITORED	COLLECTIVE DOSE (man-Sv*)	INDIVIDUAL DOSE > 20 mSv
Reactors and energy production (EDF)	25,483	7.83	0
Fuel cycle; decommissioning	7,690	2.25	0
Transport	853	0.12	0
Logistics and maintenance (contractors)	15,574	11.15	0
Effluent, waste	84	0	0
Others	20,725	6.75	0

** Man.Sv: Unit of quantity of collective dose. For information, the collective dose is the sum of the individual doses received by a given group of persons.*

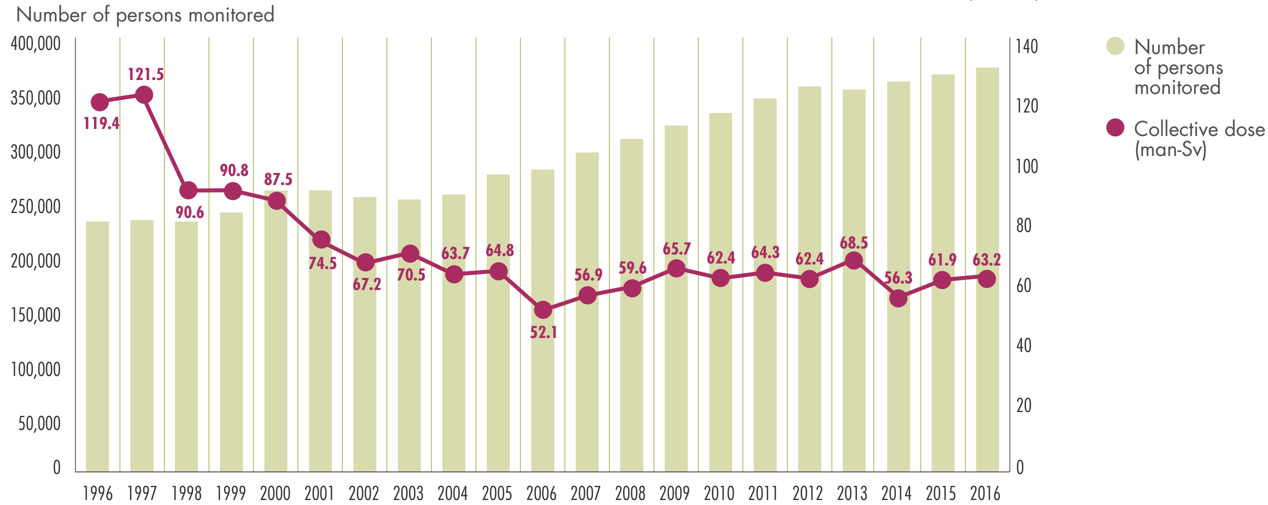
TABLE 2: Monitoring of external exposure of workers in small-scale nuclear activities (year 2016)

Source: IRSN

	NUMBER OF PERSONS MONITORED	COLLECTIVE DOSE (man-Sv*)	INDIVIDUAL DOSE > 20 mSv
Medecine	129,541	11.43	0
Dental	51,238	2.13	0
Veterinary	21,490	0.6	0
Industry	38,127	17.8	1
Research	11,635	0.41	0
Miscellaneous	25,711	1.36	0

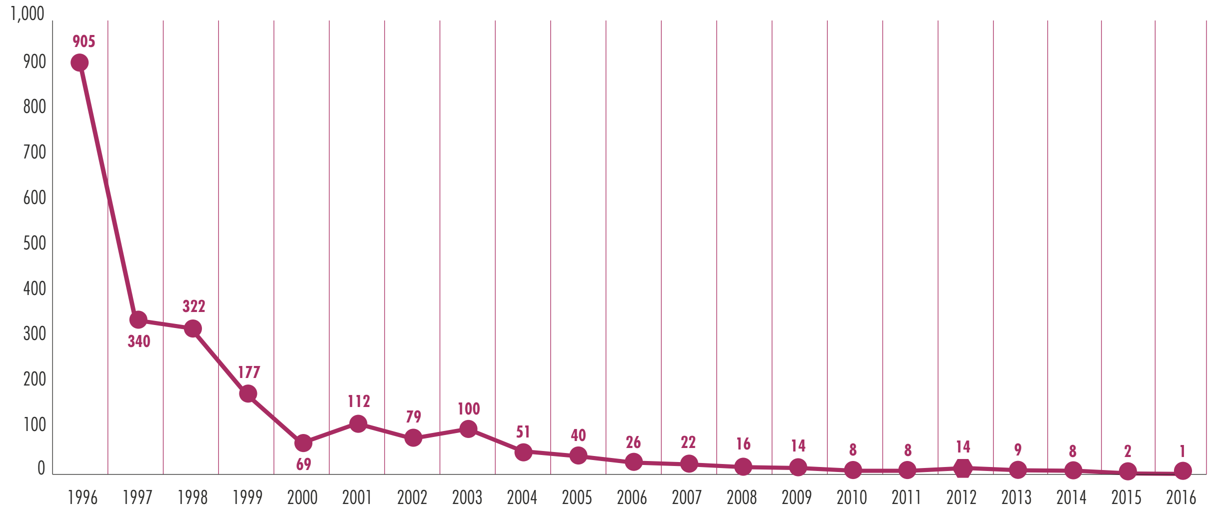
** Man.Sv: Unit of quantity of collective dose. For information, the collective dose is the sum of the individual doses received by a given group of persons.*

DIAGRAM 2: Monitored population and collective dose trends, from 1996 to 2016



Source: IRSN

DIAGRAM 3: Evolution of number of workers monitored, with an annual effective dose in excess of 20 mSv from 1996 to 2016



Source: IRSN

and thirty one people were subject to monitoring of lens of the eye exposure. The maximum dose recorded is 21.8 mSv and concerns the area of medical applications. This value should be compared with the new regulatory dose limit for the lens of the eye: cumulative value of 100 mSv over five years, without exceeding 50 mSv in a given year (20 mSv/year as from 2023).

The results of dosimetric monitoring of worker external exposure in 2016 published by IRSN in June 2017 show on the whole that the prevention system introduced in facilities where sources of ionising radiation are used is effective, because for 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). Exceeding the regulatory limit values remains exceptional.

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

Occupational exposure to TENORM 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. The trends observed and published in 2010 are still valid in view of the files received up to 2015. No new study was transmitted in 2016.

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Results of dosimetry monitoring of worker external exposure to ionising radiation in 2016

(Source: *Occupational exposure to ionising radiation in France* - IRSN results, June 2017)

- Total population monitored: 372,262 workers.
- Monitored population for whom the dose remained below the detection threshold: 283,195 workers, or nearly 76%.
- Monitored population for whom the dose remained between the detection threshold and 1 mSv: 74,849 workers, or about 20%.
- Monitored population for whom the dose remained between 1 mSv and 20 mSv: 14,217 workers, or nearly 4%.
- Monitored population for whom the annual effective dose exceeded 20 mSv: 1 worker above 50 mSv.
- Collective dose (sum of individual doses): 63.2 man-Sv.
- Annual average individual dose in the population which recorded a dose higher than the detection threshold: 0.71 mSv.

Results of internal exposure monitoring in 2016

- Number of routine examinations carried out: 275,659 (of which fewer than 0.5% were considered positive).
- Population for which a dose estimation was made: 497 workers.
- Number of special monitoring examinations or verifications performed: 10,660 (of which 15% were above the detection threshold).
- Population having recorded a committed effective dose exceeding 1mSv: 5 workers.

Results of cosmic radiation exposure monitoring in 2015 (civil aviation)

- Collective dose for 19,875 flight crew members: 40.7 man-Sv.
- Annual average individual dose: 2 mSv.

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.

Since 1st July 2014, the date of entry into effect of the Order of 17th July 2013 relative to the medical and dosimetric monitoring card for workers exposed to ionising radiation, the Sievert system (system put in place by the DGAC - General Directorate for Civil Aviation, IRSN, the Paris Observatory and the French Institute for Polar Research Paul-Emile Victor (*www.sievert-system.com*), has been changed. It is IRSN that calculates the individual doses via the SievertPN application on the basis of the flight and personnel presence data provided by the airlines. These data are subsequently transmitted to Siseri, the French national worker dosimetry registry.

2016, the first year of full operation of SievertPN, represents a consolidation period for this system. On 31st December 2016, SievertPN had sent Siseri all the flight crew doses for ten airlines having subscribed to the system, giving a total of 19,875 flight crew members monitored by this new system.

In 2016, 18% of the individual doses were below 1 mSv and 82% of the individual doses were between 1 mSv and 5 mSv per year.

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 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).

Legacy situations, such as atmospheric nuclear tests and the Chernobyl accident (Ukraine), 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 0.01 mSv and 0.03 mSv/year (IRSN 2001). That due to the fall-out from atmospheric testing was estimated in 1980 at about 0.02 mSv. Given a decay factor of about 2 in 10 years, current doses are estimated at well below 0.01 mSv per year (IRSN, 2015). 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 Naturally Occurring Radioactive Materials (NORM)

Exposure due to natural radioactivity in drinking water. The results of the monitoring of the radiological quality of the tap water distributed to consumers carried out by the regional health agencies 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 basically satisfactory assessment also applies to the radiological quality of the bottled water 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 the public, especially in educational institutions and healthcare 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 the priority geographical areas.

On the basis of the results communicated by the ASN-accredited organisations for the 2016/2017 campaign, more than 95% of the screenings were carried out in educational institutions and healthcare and medical-social institutions (45% and 51% of screenings respectively). The radon activity concentration is lower than the action threshold of 400 Bq/m^3 in 78% of educational institutions and 84% of the healthcare and medical-social institutions screened.

For the institutions in which the radon activity concentration exceeds 400 Bq/m^3, simple remediation measures or works must be carried out to lower the radon activity concentration to below this threshold. Nearly 50% of the post-work inspections carried out by the ASN-accredited organizations confirmed that the radon activity concentration had been brought below the 400 Bq/m^3 threshold.

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.

Informing and heightening the awareness of the public and the main actors concerned by the radon risk (regional authorities, employers, etc.) are therefore essential and are now entered as

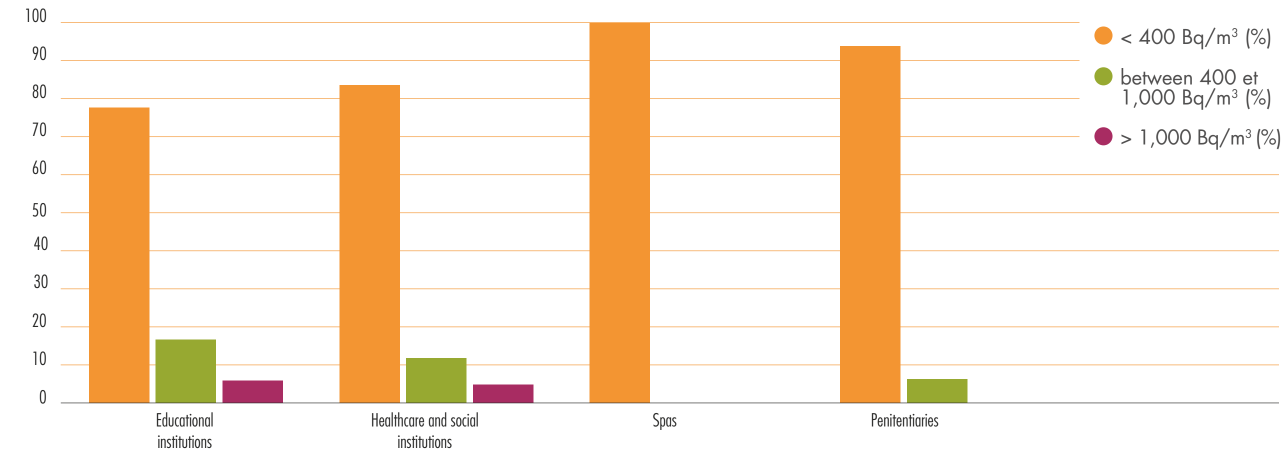
FOCUS

The 3rd National Plan for Radon Risk Management

In January 2017, ASN published the 2016-2019 National Plan for Radon Risk Management.

In this new edition, informing and heightening the awareness of the public and the main stakeholders concerned by the radon risk (regional authorities, employers, etc.) are now top priority strategic directions. This strategy of informing and raising awareness is based on the new legislative measures adopted in 2016. These include two flagship measures: 1) making it obligatory to inform real-estate property buyers and renters of the health risks linked to radon in the home and 2) taking radon into account in the indoor air quality management system.

DIAGRAM 4: Distribution of radon activity concentrations by type of institution screened (in %), 2016/2017 campaign



a top strategic priority in the 3rd National Plan for Radon Risk Management. This national plan for the 2016-2019 period is coordinated by ASN.

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 either not exposed or received doses of less than 1 mSv. The average individual effective dose increased by 23% between 2007 and 2012 (it was 1.3 mSv in 2007).

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%).

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.

ASN inspection in interventional radiology at the Strasbourg University Hospital, May 2017.

Lastly, it is noteworthy that:

- in a sample of about 600,000 persons covered by health insurance, 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.
- 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).

The substantial uncertainties in these studies with regard to the average effective dose values per type of procedure must nevertheless be taken into account, which justifies the need for progress in estimating doses in the next exposure study of the general population.

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	71.2
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 2014

FOCUS

The second plan of action for controlling the doses of ionising radiation delivered to persons in medical imaging

Controlling the doses delivered to patients for diagnostic or therapeutic purposes leads to measures to ensure that the principles of justification and optimisation are embraced in the exercise of medical practices that use ionising radiation.

A second ASN plan of action to control the doses of ionising radiation delivered to persons in medical imaging will be published in early 2018. It aims at continuing the promotion of a culture of radiation protection in medical professionals with the reinforcement of skills and harmonisation of practices in an updated regulatory framework taking into account the transposition of Directive 2013/59/Euratom of 5th December 2013 laying down basic safety standards relative to protection against the dangers arising from exposure to ionising radiation [see chapter 3].

This new plan of action follows on from the previous one (2011-2017) to expand effect to different areas, including human resources and training, quality and safety of professional practices, and equipment.

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.

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 guarantee the protection of other species.

Protection of the environment against 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. On the basis of the IRSN appraisal report, the Advisory Committee for Radiation Protection in Industrial and Research Applications of Ionising Radiation and for the Environment adopted an opinion in September 2015. In 2016, ASN started work with a view to adopting a position on this subject which should be published as an opinion in mid-2017.

4. Outlook

As in the preceding years, the results for the doses received by the workers in 2016 remained stable, with the annual dose received remaining below 1 mSv for about 96% of the workers liable to be exposed, and only one case exceeding the annual limit dose of 20 mSv. Monitoring of exposure of the lens of the eye with, for this tissue, compliance with the new limit, constitutes the main objective of radiation protection in the immediate years and more specifically in the area of fluoroscopy-guided interventional medical practices.

Controlling the doses of ionising radiation delivered to persons during medical examinations remains a priority for ASN. A second plan of action, which extends the previous one (2011-2017), drawn up in collaboration with the stakeholders (institutional and professional) shall be published in the first quarter of 2018.

Deployment of the 3rd National Plan for Radon Risk Management, which accompanies the updating of the regulations in this area and the publication of the new map of municipalities considered as priorities with respect to this risk, is intended to intensify the communication efforts directed towards the public. The installation of measuring devices in existing housing shall be encouraged, particularly in the context of implementation of the new provisions concerning the obligation to inform house buyers and tenants. Collection and analysis of the results can then be gradually organised.

AUTORITÉ

The principles of nuclear safety and radiation protection and the regulation and oversight stakeholders

02

Nuclear security is defined in the Environment Code as comprising *"nuclear safety, radiation protection, prevention and combating of malicious acts and civil protection actions in the event of an accident"* 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"*. 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, which covers related areas such as chronic pollution of all types emitted by certain nuclear activities, is based on technical analysis and expert assessment, particularly that provided by the Institute for Radiation Protection and Nuclear Safety (IRSN).

At the State level, the prevention of and fight against malicious acts which could affect nuclear materials, their installations and their transportation are the responsibility of the Minister for Ecological and Solidarity-based Transition, who can draw on the services on the High Official for Defence and Security (HFDS). Although clearly separate, the two fields of nuclear safety and the prevention of malicious acts are inextricably linked and the authorities responsible cooperate closely.

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 the IAEA (see box below 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

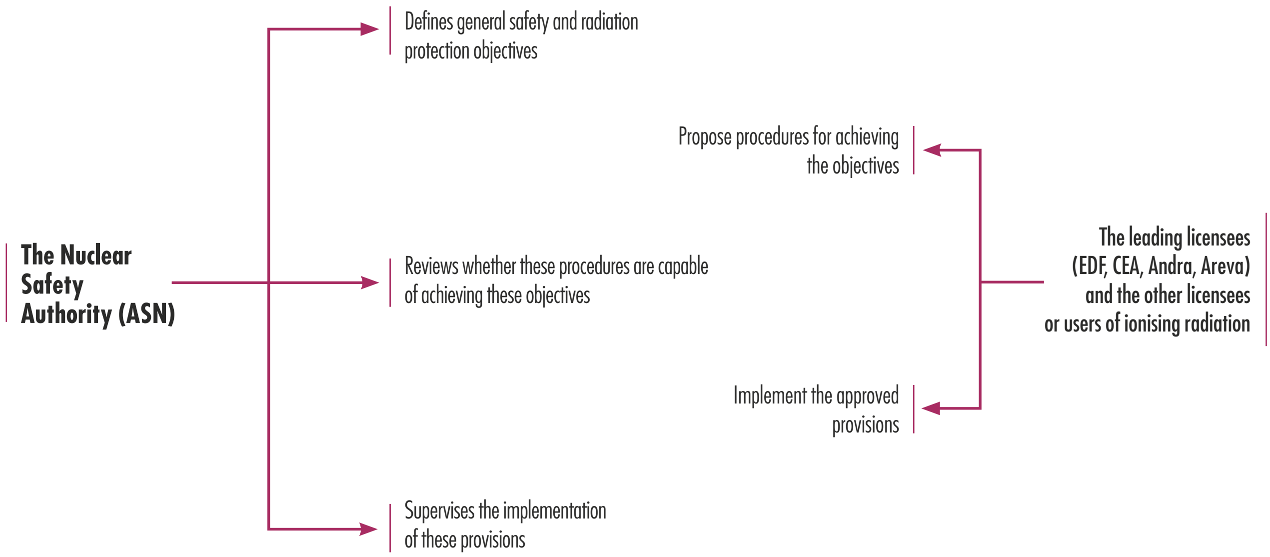
The "polluter pays" principle, contained in Article 110-1 of the Environment Code, stipulates that the costs resulting from the measures to prevent, mitigate and fight against pollution must be borne by the polluter.

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.

RESPONSIBILITY of licensees and responsibility of ASN



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 participate in the taking of public decisions affecting the environment"*.

In the nuclear field, this principle notably leads to the organisation of national public debates, which are mandatory prior to the construction of a nuclear power plant for example, or now before certain plans and programmes subject to strategic environmental assessments, such as the National Radioactive Materials and Waste Management Plan (PNGMDR). One should also mention the public inquiries, notably during examination of the files concerning the creation or decommissioning of nuclear installations, consultation of the public on draft resolutions with an impact on the environment, or the submission by a Basic Nuclear Installation (BNI) licensee of its file concerning a modification to its installation liable to lead to 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 to reduce the appearance of probabilistic effects in the long term to the lowest level possible.

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. 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.

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 the 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 initiatives. 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 "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.

FUNDAMENTALS

The fundamental safety principles

The 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.

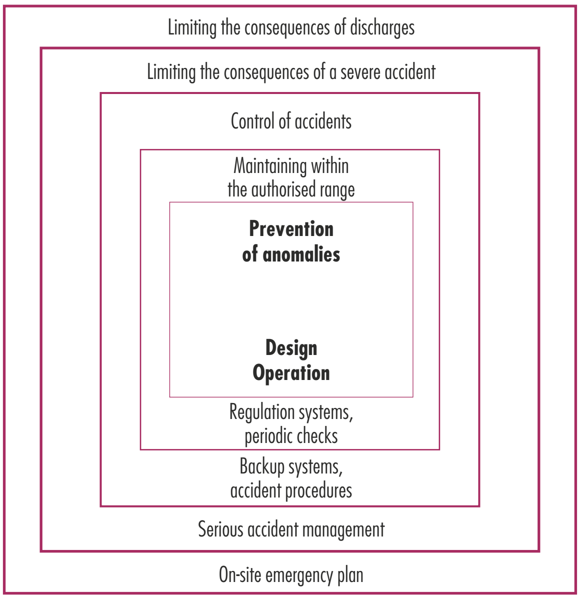
7. People and the environment, both present and future, must be protected against radiation risks.

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.

THE 5 LEVELS of "Defence in Depth"



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. Condition monitoring and correct operation of systems form 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. In addition, the single failure criterion is applied, in other words we postulate that in the accident situation and in addition to the accident, there will be the most prejudicial failure of one of the components used to manage this situation. 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.

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 is however unable to identify the most probable scenarios because it focuses attention on accidents studied with pessimistic hypotheses.

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 uncertainties concerning the reliability data and 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 for example include:
- 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 acquired experience to be shared (for implementation of preventive measures in a structure that learns from past experience). A first goal of 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 (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 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 (SOHF)

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, construction, 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 persons involved. 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 goal must be achieved at an acceptable cost to the persons concerned (in terms of fatigue or stress) and provide a benefit to them (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 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 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 European Council Directive 2009/71/Euratom of 25th June 2009 concerning nuclear safety, the provisions of which were in turn 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: Act 2006-686 of 13th June 2006, on Transparency and Security in the Nuclear field (TSN Act) and Programme Act 2006-739 of 28th June 2006, on the sustainable management of radioactive materials and waste.

In 2015, Parliament adopted Act 2015-992 of 17th August 2015 concerning Energy Transition for Green Growth (TECV Act), an entire section of which is devoted to nuclear matters (Title VI – "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.

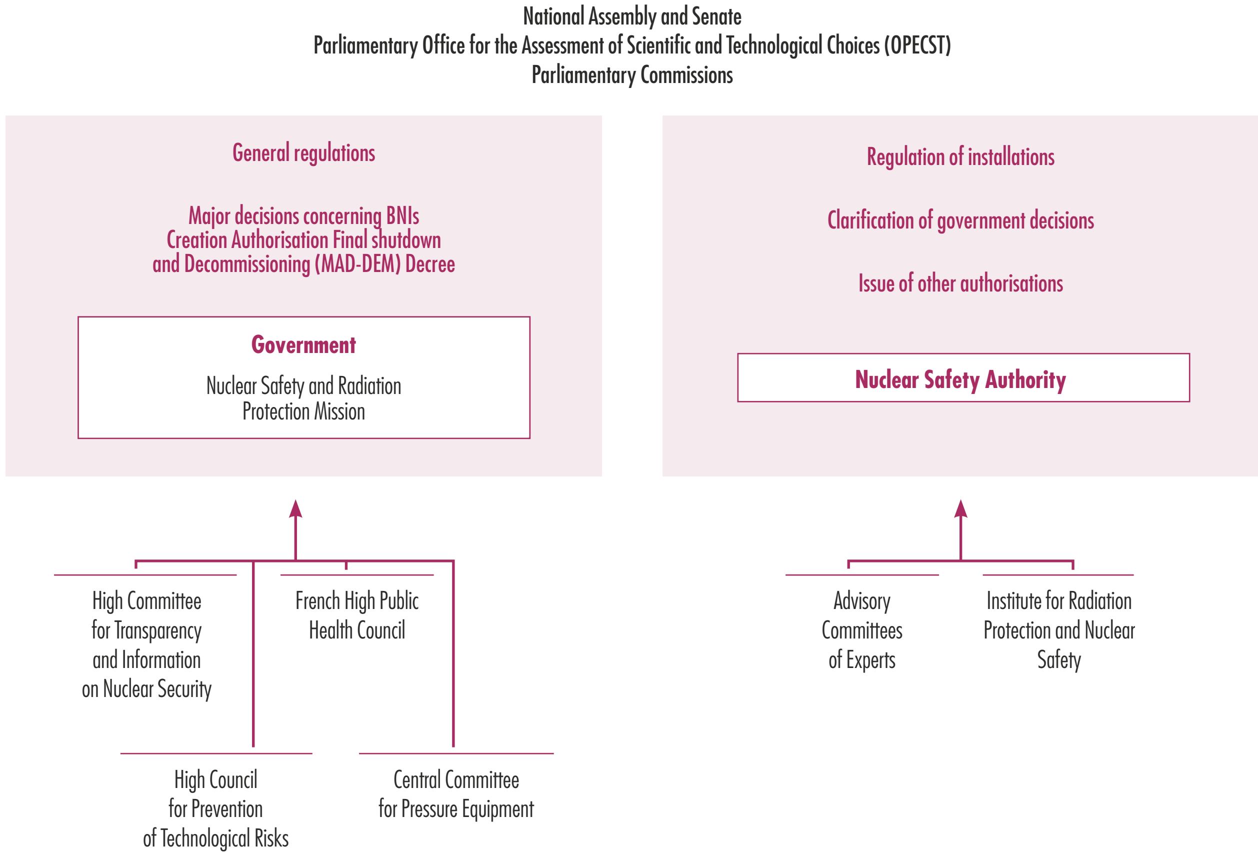
The exchanges between ASN and elected officials are presented in more detail in chapter 6.

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 Security (HCTISN).

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

REGULATION of nuclear safety and radiation protection in France



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 (PE) specifically designed for these installations.

Also on the advice of and, as applicable, further to proposals from ASN, this same Minister takes major licensing 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 - and on the basis of ASN proposals if necessary - the Minister responsible for Radiation Protection defines the general regulations applicable to radiation protection.

The regulation of worker radiation protection is the responsibility of the Minister for Labour. That concerning the radiation protection of patients is the responsibility of the Minister for Health.

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

The Nuclear Safety and Radiation Protection Mission

The Nuclear Safety and Radiation Protection Mission, within the General Directorate for Risk Prevention at the Ministry for Ecological and Solidarity-Based Transition, 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 (HFDS)

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 Ecological and Solidarity-based Transition, with the support of the HFDS and more specifically its Nuclear Security Department. 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 decentralised State services

The decentralised services of the French State are those which locally implement the decisions taken by the central administration and which manage the State's services at the local level. These services are placed under the authority of the Prefects.

ASN maintains close relations with the Regional Directorates for the Environment, Planning and Housing (Dreal), the Regional and Interdepartmental Directorate for the Environment and Energy (Driee), the Regional Directorates for Enterprises, Competition, Consumer affairs, Labour and Employment (Direccte) and the Regional Health Agencies (ARS) which, although not strictly speaking decentralised services but public institutions, have equivalent powers.

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 intake, 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 analysis and expert assessment 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 technical regulations 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 authorises significant modifications to a BNI. 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.

Monitoring

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.

ASN issues the required approvals and certifications to the organisations participating in the verifications and in nuclear safety or radiation protection monitoring, as well as with regard to Nuclear Pressure Equipment (NPE).

Ordinance 2016-128 of 10th February 2016, issued pursuant to the TECV 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 field, the Ordinance of 10th February 2016 comprises provisions giving ASN competence to ensure that public research is tailored to the needs of nuclear safety and radiation protection. *"ASN keeps track of national and international research and development work on nuclear safety and radiation protection. It formulates any proposals or recommendations concerning research needs in nuclear safety and radiation protection. These proposals and recommendations are communicated to the Ministers and to the public stakeholders exercising the research duties concerned so that they can be taken into account in the orientations and the definition of the research and development programmes of interest for safety"* (Article L. 592-31-1 of the Environment Code).

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 a view to their integration by the licensees into their safety cases and impact assessments.

ASN takes part in IRSN's steering committee on research and draws on the expertise of 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 modified decision dated 8th July 2014, the ASN Commission renewed for a further four years the mandates of the nine members of the Scientific Committee, appointed for their expertise in the field of research. Under the chairmanship of Mr. Ashok Thadani, former head of research at the United States Nuclear Regulatory Commission (NRC), the committee comprises Mr. Bernard Boullis, Mr. Jean-Claude Lehmann, Mr. Michel Schwarz, Mr. Michel Spiro, Mr. Victor Teschendorff, Ms. Christelle Roy and Ms. Catherine Luccioni. The Scientific Committee met twice in 2017.

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.

In 2016, a map of the various nuclear safety and radiation protection research players was produced for an end-of-training course professional thesis entrusted by ASN to a trainee engineer. On the basis of this map, ASN established numerous contacts with public research organisations active in fields directly linked to those areas which it felt needed to be reinforced. This approach will be consolidated to enable ASN to inform these players of the research fields it considers to be priorities for improving nuclear safety and radiation protection.

The Fukushima Daiichi accident also highlighted the need for more research in the field of nuclear safety. A Call for Projects (AAP) 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.

A third ASN opinion under preparation on the research subjects to be taken further regarding nuclear safety and radiation protection should be published in 2018.

In addition, within the framework of the support given to Andra by the General Commissariat for Major Investments for research into nuclear waste, Andra decided to issue a Call for Projects entitled *"Optimisation of Decommissioning Radioactive Waste Management"*.

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 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 regulations and decisions. 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 rules of procedure which set out its organisation and working rules, as well as its ethical guidelines. The Commission's decisions and opinions are published in ASN's *Official Bulletin*.

In 2017, the ASN Commission met 86 times. It issued 17 opinions and 42 decisions.

ASN head office departments

The ASN head office departments 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 COMMISSION

From left to right: Sylvie Cadet-Mercier, Pierre-Franck Chevet, Lydie Évrard, Margot Tirmarche and Philippe Chaumet-Riffaud.

THE EXECUTIVE COMMITTEE

From left to right: Christophe Quintin, Olivier Gupta, Anne-Cécile Rigail, Ambroise Pascal and Julien Collet (1st January 2018).

The role of the departments is to manage national affairs concerning the activities under their responsibility. They take part in defining the general regulations and coordinate and oversee 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 the 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 the safety of pressure equipment installed in BNIs. It monitors the design, manufacture and operation of NPE 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", plus a "Source Security" section.

THE DIRECTORS

From left to right: Christophe Kassiotis, Alain Rivière, Remy Catteau, Fabien Feron, Simon Liu, Jean-Luc Godet, Frédéric Joureau, Céline Acharian and Daniel Delalande (Bénédicte Genthon, not in photo) (1st January 2018).

THE REGIONAL DIVISION HEADS

From left to right: Pierre Boquel, Marie Thomines, Pierre Bois, Remy Zmyslony, Aubert Le Brozec, Hélène Heron, Marc Champion, Jean-Michel Férat, Hermine Durand, Bastien Poubeau and Pierre Siefridt (1st January 2018).

THE REGIONAL REPRESENTATIVES

From left to right: Annick Bonneville, Vincent Motyka, Emmanuelle Gay, Patrice Guyot, Jérôme Goellner, Christophe Chassande, Patrick Berg, Françoise Noars, Thierry Vatin and Corinne Taurasi.

- 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 five Branches: "Radioactive Waste Management"; "Cross-disciplinary Laboratory-plant-waste-decommissioning and research facilities subjects"; "Fuel Cycle Installations"; "Reactors Decommissioning and Cycle Front-end"; "Office of decommissioning, Cycle back-end and Legacy Situations".

- 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 managing 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. It contributes to defining the framework of the organisation of the public authorities and nuclear licensees in the management of emergency situations. Finally, it defines ASN's oversight and regulation policy. The DEU comprises three Branches: "Safety and Emergency Preparedness", "Environment and Prevention of Nuisances" and "Development of Regulations".

- The International Relations Department (DRI) coordinates ASN's bilateral, European and multilateral actions on the international stage, both formal and informal. It develops exchanges with ASN's foreign counterparts in order to promote and explain the French approach and practices with regard to nuclear safety and radiation protection and to gain a greater understanding of practices abroad. It provides the countries concerned with useful information about the safety of French nuclear facilities, more specifically those which are located close to the borders. The DRI coordinates ASN representation in cooperative structures created under bilateral agreements or arrangements, but also within formal international bodies such as the European Union (ENSREG – European Nuclear Safety Regulators Group – which it chairs), the IAEA or the OECD's Nuclear Energy Agency (NEA). It ensures similar coordination in the more informal structures taking the form of associations (e.g.: WENRA – Western European Nuclear Regulators Association, INRA – International Nuclear Regulators Association) or cooperative groups under multilateral State-based initiatives (e.g.: NSSG – Nuclear Safety and Security Working group, under the G7).

- 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".

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 Interdepartmental Directorate for the Environment and Energy (Driee) in which the 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.

FOCUS

The State's regional reforms and ASN

Following the adoption by Parliament of Act 2015-991 of 7th August 2015 constituting the new 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 and defined the following orientations:

- maintain all of ASN's geographical sites;
- define an organisation and a working method such as to reinforce integration of the DEP within the head office departments and develop its relations, more specifically with the DCN and the DRC;
- have the Lille division take charge of radiation protection oversight within the perimeter of the former Picardie region;
- have the Bordeaux division take charge of radiation protection oversight within the perimeter of the former Limousin region;
- define new methods for ASN organisation and operation in the Grand Est region;
- examine the regulation and oversight of nuclear safety and radiation protection in the Occitanie region.

An oversight committee was set up to monitor the implementation of these orientations. This resulted notably in a modification to the resolution concerning the organisation of the ASN services (ASN resolution 2012-DC-0256 of 12th January 2012). The files handled by the "small-scale nuclear facilities" centre in Orleans for the Limousin region were transferred on 1st July 2017 to the Bordeaux division and those of Picardie, initially dealt with by the Châlons-en-Champagne division, to the Lille division on 1st January 2018.

With regard to the Occitanie region, the work led to the conclusion that the issue of the distance of the Marseille and Bordeaux divisions from stakeholders in the small-scale nuclear sector in Occitanie did not warrant creating an ASN division in Toulouse. However, steps were taken to improve operations to ensure effective oversight of nuclear activities, such as the development of grouped inspections for the locations most remote from the divisions.

With regard to the Grand Est region, the choice was taken to maintain two divisions, one in Châlons-en-Champagne and the other in Strasbourg. The issue was to harmonise the operation of the two sites, which represents a long-term undertaking. With regard to organisation and operation, this more particularly implies scheduling work across the two divisions.

Finally, with regard to the DEP, which is located in Dijon, in-depth work was carried out concerning its duties, its relations and its operating methods.

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 2017, the total ASN workforce stood at 508, divided between the head office departments (281 staff members), the regional divisions (225 staff members) and various international organisations (2 staff members).

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

ASN implements 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.

The 50 additional positions granted by Government and Parliament for the 2015-2017 three-year period, at a time of budget restrictions, were assigned to the priority issues identified by ASN. In parallel with these recruitments, ASN is continuing to implement the measures it has adopted for several years now, to reinforce its efficiency and enhance its performance.

Despite these efforts, ASN considers that its headcount remains insufficient. Furthermore, the detection in 2016 of irregularities in the Areva NP Creusot Forge plant requires the deployment of teams to examine the irregularities discovered and to carry out reinforced long-term monitoring of the licensees and their subcontractors, to prevent the occurrence of such situations. These needs led ASN, in its opinion dated 1st June 2017, to request the recruitment of an additional 15 Full-Time Equivalent (FTE) staff for the 2018-2020 three-year period, at a rate of 5 FTE each year. These expressed needs do not cover the examination of any new nuclear facility projects that would result from future energy policy decisions.

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 built primarily around a technical training programme tailored to each staff member, based on professional 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 2017, 39 ASN nuclear safety and radiation protection inspectors were senior inspectors, or nearly 12.5% of the 311 ASN staff members holding at least one accreditation.

In 2017, nearly 4,506 days of training were provided to ASN staff through 201 sessions forming part of 111 different courses.

Social dialogue

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

During 2017, the ASN Social Dialogue Committee (SDC) met on five occasions to discuss various subjects: relocation of the Caen and Bordeaux divisions, reorganisation of the head office entities, modification of the decision concerning the organisation of the ASN services further to the reform of the regions, travel charter, social audit, training audit, budget implementation, on-call duty system, etc.

Complementing the action of the ASN SDC, the Joint Consultative Commission (CCP) - which has competence for contract staff - met twice. In addition to prolonging the tenure system for contractual staff set out in Decree 2016-1085 of 3rd August 2016, the discussions mainly concerned the general situation of ASN contractual staff and their career prospects.

Finally, the ASN Health, Safety and Working Conditions Committee (CHSCT) met three times in 2017. The discussions with the personnel representatives mainly concerned the following topics:
- working of the CHSCT;
- actions carried out by the CHSCT and follow-up: prevention of psychosocial risks, first-aid worker training, preventive medicine and occupational health and safety inspectorate, etc.;

"NUCLEAR SAFETY" inspector training programme, Pressurised Water Reactor (PWR), Laboratories, Plants, Decommissioning and Waste (LUDD) and cross-disciplinary qualification(LUDD) et transverse

Mandatory qualification

"ASN core activities" basic training
Inspections at ASN
Sanctions
General knowledge of ASN personnel
Regulation radiation protection training for ASN staff likely to intervene in a regulated area
Introduction to general communication

Joint "nuclear safety" "qualifying" technical training
Nuclear licensee routine operations approach - Immersion
BNI technical regulations

Specific PWR training
Pressurised water reactor
Fire
"External hazards"
Ventilation
ESP1 staff
Monitoring of PWR safety

Specific LUDD training
Introduction to atomic engineering
Fire
External hazards
Ventilation

Specific cross-disciplinary training
Pressurised water reactor
Fire
External hazards
Ventilation

Qualifying professional experience

Joint nuclear safety inspectors qualifying experience
Has followed two inspections as an observer
Has played a hands-on role in three inspections

PWR inspectors qualifying experience (excluding Pressure Equipment - PE), LUDD
Has taken part in three notification investigations of Article 26
Has taken part in three significant event investigations (ASN regional divisions)

PWR inspectors qualifying experience with intervention limited to the PE field
Has taken part in investigating five PE-related files
Has taken part in three technical meetings on PE-related topics
A tutor's report produced following the training period

- progress of the actions in the 2016-2017 annual prevention programme: setting up a psychosocial risks unit, travel charter, etc.;
- annual audit of the general health, safety and working conditions situation at ASN;
- update of the unified occupational risks assessment document;
- CHSCT delegation visits;
- coordination of the network of prevention assistants…

Professional ethics

The legislative and regulatory texts concerning professional ethics issued since the end of 2011 comprise a number of obligations, implemented at ASN in the following way:

Declaration obligations:

- Public Declaration of Interests (DPI) stipulated in Article L. 1451-1 (derived from Act 2011-2012 of 29th December 2011 on strengthening the safety of drugs and health products) and Articles R. 1451-1 and following of the Public Health Code: the 4th July 2012 decision by the ASN Chairman applies the DPI requirements to the members of the Commission, the management committee and the GPMED (Advisory Committee for Radiation Protection for Medical and Forensic Applications of Ionising Radiation). These DPI were published until mid-July 2017 on the ASN website and are now accessible on the single electronic declaration site: *dpi-declaration.sante.gouv.fr*. There are 65 of them;
- Declarations of interests and assets to the High Authority for Transparency in Public Life (HATVP) derived from Act 2013-907 of 11th October 2013 on Transparency in Public Life:

since 1st October 2014, the members of the Commission have submitted their declarations on the HATVP website. The same applies to the Director General (DG), the Deputy Director Generals, the Secretary and assistant, since 15th February 2017 (modification of the Act of 13th October 2013 by Act 2016-1691 by 9th December 2016 extending the declaration obligations to the persons occupying these functions);
- "Civil service" declaration of interests introduced by Act 2016-483 of 20th April 2016 into Article 25 ter of Act 83-634 of 13th July 1983 and governed by Decree 2016-1967 of 28th December 2016 (see 2-3° for ASN): the decision defining ASN positions subject to the declaration of interests in this respect will be adopted jointly with the new internal rules of procedure;
- Management by the ASN Director General of his financial instruments in conditions which precludes all right of review on his part, pursuant to Article 25 quater of the 13th July 1983 Act and Decree 2017-547 of 13th April 2017: the ASN DG submitted substantiating data to the HATVP before 2nd November 2017.

Appointment of a professional ethics coordinator pursuant to Article 28 bis of the 13th July 1983 Act and Decree 2017-519 of 10th April 2017: in a decision of 6th November 2017, the ASN Chairman appointed Henri Legrand as ASN professional ethics coordinator.

Implementation of procedures for collecting internal ethics alerts from ASN personnel, pursuant to Act 2016-1691 of 9th December 2016 and Decree 2017-564 of 19th April 2017: these procedures will be defined in the ASN internal rules of procedure.

Over and above the implementation of the obligations recalled above, provision is also made for actions to raise personnel awareness in order to improve the internal professional ethics culture and prevent conflicts of interest, such as the posting of practical documents on the intranet (e.g.: information notice of 21st March 2017 on the prevention of conflicts of interest and the role of the civil service professional ethics commission), or a recent intervention on "rules of professional ethics applicable to ASN staff" during the "getting to know ASN" sessions organised for new arrivals.

Financial resources

ASN's financial resources are presented in point 3.

In its opinion of 1st June 2017, despite the efforts made by the Government and Parliament over the three-year period from 2015 to 2017, ASN considers that its headcount remains insufficient to deal fully with the unprecedented challenges previously identified.

ASN management tools

The Multi-year Strategic Plan

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 organisation and management. The PSP for the 2018-2020 period comprises the following five strategic points:
- reinforce implementation of a graded and efficient approach to our regulation and oversight;
- improve the running of technical assessments;
- reinforce the efficiency of our actions in the field;
- consolidate our operation to the benefit of regulation and oversight;
- promote the French and European safety approach on the international stage.

The PSP 2018-2020 is accessible on *www.asn.fr*.

FOCUS

ASN international audits (IRRS missions)

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. These audits are the result of the European Nuclear Safety Directive which requires a peer review mission every ten years.

In October 2017, the French system for the regulation of nuclear safety and radiation protection underwent an IAEA assessment of the steps taken following the review carried out at the end of 2014.

During the course of the 2017 assessment, the IRRS team observed that steps had been taken to address 14 of the 16 recommendations made by the 2014 mission. It considered that ASN had made significant progress in improving its management system and had drawn up general policy principles including safety culture aspects in training, self-assessment and management. It noted that ASN had increased its financial and human resources, while making efficiency savings across its activities and improving its resources planning. It underlined the need for ASN to continue concentrating on resources management to ensure that they enable future challenges to be met, more particularly the periodic safety reviews, the NPP operating life extension, the graded approach to issues and new responsibilities, such as supervision of the supply chain and the security of radioactive sources.

The reports for the 2006, 2009, 2014 and 2017 IRRS missions are available for consultation on *www.asn.fr*.

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.

The ASN internal management system

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 experience sharing 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 International Standard Organisation (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

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: ASN's internal communication, in the same way as human resources management, endeavours to foster the sharing of information and experience between teams and professions.

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 2017 are described in chapter 6.

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.

By Decree of 28th December 2016, the scope of competence of the CSPRT was again expanded. A standing sub-committee responsible for preparing the Council's opinions in the field of PE takes the place of the Central Committee for Pressure Equipment (CCAP). The role of this sub-committee is to examine non-regulatory decisions falling within this scope of competence.

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.

It must be referred to by the Government and by ASN for all questions affecting ministerial orders concerning pressure equipment. The accident files concerning this equipment are also copied to it.

2.4.4 Local Information Committees

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 département 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 trade union and 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 duties and activities of the CLIs are described in chapter 6.

2.5 ASN Technical support organisations

ASN benefits from the expertise of technical support organisations to prepare its decisions. IRSN is the main one. 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 setting up a French environmental health safety agency 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 expert assessment and research resources in these fields. These texts have since been modified, notably by Article 186 (V) of the TECV Act and Decree 2016-283 of 10th March 2016 concerning IRSN.

IRSN reports to the Ministers for the Environment, Defence, Energy, Research and Health respectively.

Article L.592-45 of the Environment Code specifies that IRSN is a State public industrial and commercial institution which carries out expert analysis and assessment 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 ionising radiation 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 2017, 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.

2.5.2 Advisory Committees of Experts

To prepare its decisions, ASN relies on the opinions and recommendations of seven Advisory Committees of Experts (GPE), with competence for waste, Nuclear Pressure Equipment (NPE), reactors, transport, laboratories and plants, medical radiation protection, radiation protection in non-medical sectors and the environment, respectively.

At the request of ASN, the GPEs 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 which can be backed up by recommendations.

TECV 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 2 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 analysis and assessment activities *"supported by research"*.
- It clarifies the relations between ASN and IRSN, indicating that ASN *"guides IRSN's strategic programming 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.

The GPEs consist of experts appointed individually for their competence and are open to civil society. Their members come from university and association backgrounds and from expert assessment and research organisations. They may 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.

Each GPE member produces a declaration of interest. Experts with a direct interest in the subject being addressed do not take part in establishing the position of the GPE.

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 summaries 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 35 experts appointed for their competence in the nuclear, geological and mining fields. In 2017, it held an information meeting and two plenary meetings, all three jointly with the "Laboratories and Plants" GPU, a bipartite three-day meeting with German experts in Germany, during which it visited the Konrad mine intended for radioactive waste disposal.

Advisory Committee for Nuclear Pressure Equipment (GPESPN)

Since 2009, the GPESPN has replaced the standing nuclear section of the CCAP, itself replaced since 28th December 2016 by the standing sub-committee of the CSPRT. The GPESPN is chaired by Sophie Mourlon and comprises 31 experts, following the changes made in 2017, appointed for their competence in the field of pressure equipment. It held one plenary meeting in 2017.

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

Chaired by Bernard Aubert, the GPMED comprises 36 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. The composition of the GPMED was renewed on 16th December 2016. It held three plenary meetings in 2017.

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 34 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. The composition of the GPRADE was renewed on 16th December 2016. It held three plenary meetings in 2017.

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. It held four plenary meetings in 2017.

Advisory Committee for Transport (GPT)

The GPT is chaired by Jérôme Joly and comprises 26 experts appointed for their competence in the field of transport. It held two plenary meetings in 2017.

Advisory Committee for Laboratories and Plants (GPU)

The Advisory Committee for Laboratories and Plants is chaired by Jérôme Joly and comprises 31 experts appointed for their competence in the field of laboratories and plants concerned by radioactive substances. In 2017, it held five plenary meetings, including three jointly with the GPD, and visited two BNIs before examining their file during a meeting.

2.5.3 The ASN's other technical support organisations

To diversify its expertise and benefit from other particular skills, ASN committed credits of €0.45 million in 2017.

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

In 2017, ASN more particularly continued or initiated collaborations with a group of several organisations approved for nuclear pressure equipment, for an analysis of the regulatory and standards reference system concerning the evaluation of the conformity of certain equipment items.

2.6 The pluralistic working groups

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

2.6.1 The working group on the National Radioactive Materials and Waste Management Plan (PNGMDR)

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, 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 General Directorate for Energy and the

Climate at the Ministry for Ecological and Solidarity-based Transition 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 an Interministerial Directive of 7th April 2005 on the action of the public authorities in the case of an event leading to a radiological emergency situation, ASN is tasked, together with the ministerial departments concerned, with defining, preparing for and implementing the necessary measures to manage 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 other pluralistic working groups

Considering that it was necessary to move forward with regard to the reflections and work being done on the contribution of humans and organisations to the safety of nuclear facilities, ASN therefore decided in 2012 to set up the Steering Committee for Social, Organisational and Human Factors (COFSOH). 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

TABLE 1: Advisory Committee meetings and visits in 2017

GPE	MAIN TOPIC	DATE
GPRADE	Kick-off meeting - Summary of previous mandate - Draft programme 2017-2020	31st January
GPR	OEF from EDF NPP reactors and foreign reactors over the 2012-2014 period	1st February
GPR	Stress tests - Accident prevention and management - Hardened safety core operations	2nd February
GPMED	Validation of opinions concerning radioactive human remains and dose constraints in a medical environment	28th February
GPU	Visit to BNIs 33, 38 and 47 (Areva) - La Hague	14th and 21st March
GPD/GPU	*Cigéo* technical information meeting	21st March
GPR	Draft guide presenting recommendations for the design of pressurised water reactors	24th March
GPD	C5 package - acceptability for deep disposal	28th March
GPRADE	Post-accident management of non-foodstuff products - 2017-2020 Programme	30th March
GPU	Areva NC plant at La Hague Request for final shutdown and complete decommissioning of BNIs 33 and 38 and periodic safety reviews	19th April
GPMED	2017-2020 Programme - Updating of 2015 medical imaging plan - 3rd version of draft opinion on the recommendations	12th May
GPD/GPU	*Cigéo* project safety options	18th and 19th May
GPT	Additional evaluations applied to the transport of radioactive substances	12th June
GPU/GPD	Visit to BNI 149 (Aube repository)	13th June
GPR	Strength criteria for nuclear fuel of pressurised water reactors	15th June
GPESPN	Analysis of the consequences of the anomaly in the Flamanville EPR reactor vessel head domes on their serviceability	26th and 27th June
GPT	New approval - TN G3 package model	6th July
GPD	Meeting between the GPD and its German counterpart in Hildesheim	11th and 13th September
GPMED	Dosimetry in on-board imaging - Quality controls during patient pre-treatment for radiotherapy	3rd October
GPRADE	OEF from the association of GPRADE with GPEs on nuclear safety - Radon in tap water Transposition of Directive 2013/59/Euratom	5th October
GPU	Visit to Areva BNI 63 (CERCA) in Romans-sur-Isère	14th November
GPU	Periodic safety review of BNI 63	21st November

on subjects that are insufficiently understood or which are lacking in clarity.

In 2015, the national committee responsible for monitoring the National Plan for Radon Risk Management, chaired by ASN, carried out an assessment of the 2011-2015 national action plan and in January 2017 published the third plan for the period 2016-2019 (see chapter 1).

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. The Institute and its activities are presented on its website: *www.e-cancer.fr*. An ASN-INCa convention was signed on 17th February 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 2017, the ASN budget amounted to €83.57 million in payment credits. It comprised €44.92 million in ASN payroll credits and €38.65 million in operating credits for the ASN central services and its eleven regional divisions.

The total IRSN budget for 2017 amounted for its part to €216.45 million, of which €84.95 million were devoted to the provision of technical support for ASN. IRSN credits for ASN technical support are covered in part (€41.60 million) by a subsidy from the State's general budget allocated to IRSN and inclusded 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 (€43.35 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, in 2017, the State's budget for transparency and the regulation of nuclear safety and radiation protection in France amounted to €179.27 million. €83.57 million for the ASN budget, €84.95 million for IRSN technical support to ASN, €10.6 million for other IRSN missions and €0.15 million for the working of the HCTISN.

TABLE 2: Breakdown of licensee contributions

LICENSEE	AMOUNT FOR 2017 (MILLIONS OF EUROS)			
	BNI TAX	ADDITIONAL TAXES WASTE AND DISPOSAL	SPECIAL ANDRA CONTRIBUTION	CONTRIBUTION TO IRSN
EDF	544.95	96.68	112.77	48.42
Areva Group	16.65	6.20	7.24	6.3
CEA	6.62	18.34	24.60	7.16
Andra	5.41	3.30	-	0.40
Others	3.26	1.68	-	0.70
TOTAL	**575.89**	**126.20**	**144.61**	**62.98***

** The amount allocated to IRSN is capped at €62.52 M*

TABLE 3: Budget structure of the credits allocated to transparency and the regulation of nuclear safety and radiation protection in France (January 2018)

				BUDGET RESOURCES				REVENUE
MISSION	PROGRAMME	ACTIONS	NATURE	INITIAL BUDGET ACT 2017		INITIAL BUDGET ACT 2018		BNI TAX 2016 (€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)	44.92	44.92	45.71	45.71	
			Operating and intervention spending	12.88	17.88	12.78	17.78	
			TOTAL	**57.8**	**62.8**	**58.49**	**63.49**	
		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	575.89
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	78.72	83.72	79.41	84.41	
Interministerial mission **Research and higher education**	**Programme 190:** Research in the fields of energy and sustainable development and spatial planning	**Sub-action 11-2 (area 3)**: IRSN	IRSN technical support activities for ASN (3)	42.00	42.00	41.60	41.60	
		Sub-action 11-2 (3 other areas): IRSN		131.1	131.1	129.4	129.4	
Annual contribution to IRSN instituted by Article 96 of Act 2010-1658 of 29th December 2010				43.35	43.35	42.7	42.7	
			SUB-TOTAL	216.45	216.45	213.7	213.7	575.89
			GRAND TOTAL	**295.17**	**300.17**	**293.11**	**298.11**	**575.89**

(1) Source: Budget Acts for 2013 and 2014 (annual performance project 2014 of programme 181).
(2) Source: 2006 Budget Act (after deduction of transfer made under 2008 Budget Bill).
(3) Source: Budget Acts for 2017 and 2018 (annual performance project 2018 of programme 190).

FUNDAMENTALS

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 €575.89 million in 2016. The proceeds go to the central State budget.

Furthermore, for nuclear reactors and spent nuclear fuel reprocessing plants, Act 2006-739 of 28th June 2006 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 Andra. The revenue from these taxes represented €126.20 million in 2017, of which €3.30 million were paid in 2017 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 €144.61 million in 2017.

Finally, Article 96 of Act 2010-1658 of 29th December 2010 creates an annual contribution to 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 €62.98 million in 2017.

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 2017 to €575.89 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.

4. Outlook

ASN will be implementing its new 2018-2020 Multi-year Strategic Plan, notably with reinforced implementation of a graded and efficient approach to its regulation and oversight, improved oversight of technical investigations and consolidation of its operations to enhance regulation and oversight.

In a context of unprecedented safety challenges, the ASN opinion of 1st June 2017 recalled that for the next three-year plan for 2018-2020, it has requested 15 additional full-time equivalent staff.

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.

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 regulations and decisions.

Finally, ASN will continue its efforts to address the recommendations issued following the IRRS evaluation mission in October 2017.

Regulations

03

Nuclear activites 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, depending on the nature of the activity and the associated risks, aims to guarantee that they will not be likely to be detrimental to public health and safety 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 for Protection of the Environment (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 Defence Basic Nuclear Installations (DBNI) 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 allow a renovation of the general legal framework for nuclear activities during the course of 2018.

1. The general framework for the legislation and regulation of 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. The body of legislative and regulatory texts is described in this chapter.

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 by various international organisations. The following in particular can be mentioned:

DIAGRAM 1: Drafting of radiation protection doctrine and basic standards

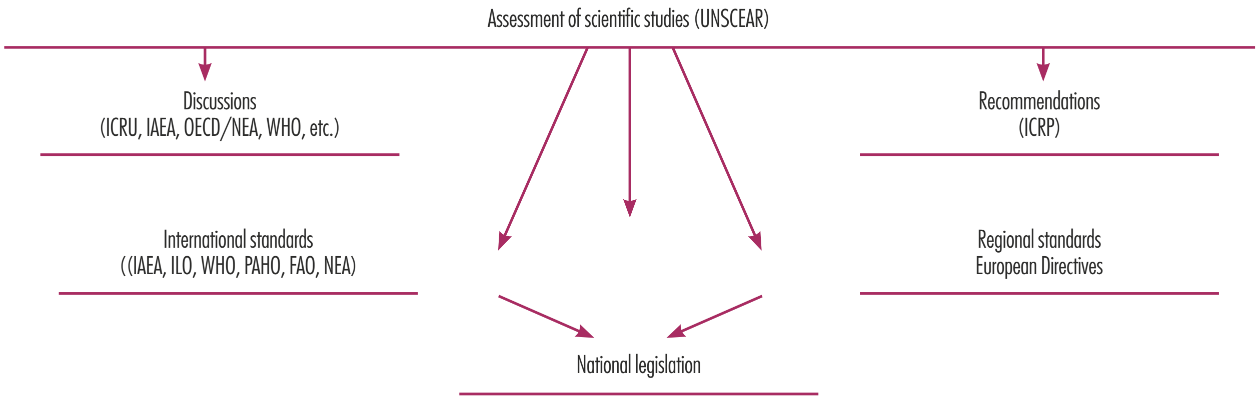


DIAGRAM 2: Various levels of regulation in the field of small-scale nuclear activities in France

ICRP, IAEA, WENRA	Orientation, Recommendations	**Not legally binding**
European Union	Directives and regulations	
Parliament	Acts	
Government	Decrees and Orders	**Legally binding**
ASN/ Government Approval	Technical Regulations	
ASN	Licensing decisions (Technical requirements)	
ASN	ASN guides/BSR*	**Not legally binding**

** Basic Safety Rules.*

- The International Commission on Radiological Protection (ICRP), a non-governmental organisation comprising international experts from various backgrounds, which publishes recommendations for the protection of workers, the population and patients against ionising radiation, based on the analysis of available scientific and technical knowledge and that published by the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR). The latest ICRP recommendations were published in 2007 in ICRP Publication 103.
- The International Atomic Energy Agency (IAEA), which publishes and regularly revises "standards" in the fields of nuclear safety and radiation protection. The basic requirements for protection against ionising radiation and the security of radiation sources, based on the latest ICRP recommendations (publication 103) were published in July 2014.
- The International Standard Organisation (ISO) which publishes international technical standards constituting a reference in the field of radiation protection.
- At the European level, the EURATOM Treaty, in particular 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. After transposition into national law, the corresponding Euratom Directives are binding on the various countries, such as new Council Directive 2013/59/Euratom of 5th December 2013. This Directive, published in the *Official Journal of the European Union* (OJEU) on 17th January 2014, repeals Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom and 2003/122/Euratom (see box).

1.1.2 The legal framework applicable to the regulation of nuclear activities in France

The legal framework for nuclear activities in France, which has been extensively overhauled since 2000, was updated with the transposition of Directive 2013/59/Euratom of 5th December 2013. At the legislative level, Ordinance 2016-128 of 10th February 2016 containing various nuclear safety provisions notably allowed a rewrite of the legislative

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The 2013/59/Euratom Directive of 5th December 2013

It repealed and replaced 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 the health protection of individuals against the dangers of ionising radiation in relation to medical exposure, repealing Directive 84/466/Euratom;
- 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 ICRP recommendations (ICRP 103) and the Basic Standards published by IAEA. The Member States had a period of four years in which to transpose this Directive after it entered force, the transposition deadline thus being set for 6th February 2018. In France, this transposition is carried out by Ordinance 2016-128 of 10th February 2016 containing various nuclear safety provisions as specified in Article 128 of the Energy Transition for Green Growth Act 2015-992 of 17th August 2015 (TECV Act), and by decrees currently being prepared concerning health protection against the dangers arising from exposure to ionising radiation and the protection of sources of ionising radiation against malicious acts and concerning worker protection against the risks arising from ionising radiation.

provisions of Chapter III of Title III of Book III of the first part of the Public Health Code concerning ionising radiation, while retaining the essence of the existing principles and requirements. At a regulatory level, the decrees under preparation, concerning worker protection against the risks arising from ionising radiation and concerning health protection against the dangers resulting from exposure to ionising radiation and the security of ionising radiation sources against malicious acts, are modifying the Labour Code, the Public Health Code, the Environment Code, the Defence Code and the Public Security Code.

The Public Health Code

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). These principles, described in point 2 of this chapter, underpin the regulatory measures for which ASN has responsibility.

The scope of application of Chapter III of Title III of Book III of the first part of the Public Health Code, concerning ionising radiation, 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. The decisions to take these steps must be justified. Their benefits must outweigh their risks and the optimisation principle is now applicable to them.

The administrative system 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. ASN technical decisions, based on a graded approach to risk, will be necessary to implement this new registration system but also to enable the existing licensing and notification system to be updated (see point 2.1).

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 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 (Article L. 591-1) defines the main concepts. Nuclear security comprises nuclear safety, radiation protection, prevention and combating of malicious acts, as well as 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 the Ordinance of 10th February 2016, 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, apply to the collective protection measures which are the responsibility of the licensee and are 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, requiring that it define the nuclear security regulations and implement 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*

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.*

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, European or Environment Code provisions concerning impact assessments, public information and consultation, and the regulations governing hazardous materials transport or pressure equipment.

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.

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. 123-19-1 and L. 123-19-2 of the Environment Code set the conditions and limits for implementation of the principle of public participation in the ASN regulations and licensing decisions 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 ASN regulations with an impact on the environment, Article L. 123-19-1 of the Environment Code requires that the draft regulation 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 licensing decisions with a direct or significant impact on the environment, Article L. 123-19-2 of the Environment Code, requires that the draft decision or, when the decision is issued on request, the corresponding 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 ensures that conditions favourable to participation of the public are created in the drafting of its regulations and decisions. (See chapter 6).

TECV Act

Act 2015-992 of 17th August 2015 on Energy Transition for Green Growth (TECV) comprises a title devoted to nuclear matters (Title VI - "Reinforcing nuclear safety and information of the public") and 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):

- the 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;
- the mandatory consultation of the CLI for any changes to the Off-site Emergency Plans (PPI);
- the 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

- New Article L. 593-6-1 of the Environment Code strengthens 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 setting out the general rules for BNIs 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 (see box "Fundamentals" Regulatory management of subcontracting, point 3.1.3).

Evolution in the BNI authorisation system

- Articles L. 593-14 and L. 593-15 of the Environment Code use the same terminology as the system of Installations Classified for Protection of the Environment (ICPE).
- The "substantial" modifications (previously referred to as "significant") are 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).
- An installation which has ceased to function for two consecutive years is considered to be finally shut down (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 security defined in Article L.591-1 of the Environment Code"*, therefore including 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 Act of 17th August 2015 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, pending 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 (GW) 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, following a period of two years at the latest, would thereby lead to its final shutdown pursuant to Articles L. 593-24 et seq. 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 by Article L.593-11 of the Environment Code) and, in any case, no later than 18 months before the commissioning date mentioned in its creation authorisation decree.

1.2 The legal framework 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 or not salaried, 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.

The legislative part was only little affected by the transposition of Directive 2013/59/Euratom. However, it does introduce a new requirement in that the authorisations issued by ASN in accordance with the BNI Systems and the Public Health Code must 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.593-42 of the Environment Code were thus introduced. They specify that the general rules, requirements, means and measures aimed at protecting the health of workers from ionising radiation, implemented pursuant to the Public Health Code and the legal framework applicable to BNIs, 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.

The regulatory part was entirely revised (Articles R. 4451-1 et seq.).

Articles R. 4451-1 et seq. of the Labour Code create a single radiation protection system for all workers (whether or not salaried) liable to be exposed to ionising radiation during the course of their professional activities. The changes are not limited to the transposition of the new provisions of the Directive of 5th December 2013 but also propose an overhaul of the existing provisions. They aim for improved efficiency. Grading more closely matching the risks run by the workers was adopted, along with closer harmonisation between the approach applicable to the "ionising radiation" risk and that adopted for the other risks. The main changes are described below.

Regulatory limits

The exposure limit for the lens of the eye is reduced to 20 millisieverts (mSv)/year (instead of 150 mSv/year) although with a transitional period during which the exposure limit is set at 100 mSv over five years, without exceeding 50 mSv/year: this change reinforces the implementation of the optimisation principle, more particularly in the medical field, in facilities where interventional procedures are carried out.

The other existing limits are maintained, in particular:
- the annual dose set at 20 mSv over 12 consecutive months, except in the case of exemptions granted to take account of exceptional exposure justified beforehand, or emergency professional exposure;
- the dose limits for pregnant women or more accurately for the unborn child (1 mSv for the period from the declaration of pregnancy up until birth).

Risk assessment

Risk assessment by the employer is a precondition to determining the prevention measures and means (collective and individual measures, zoning, etc.) and the conditions for employment of workers (classification, dosimetry monitoring of workers). A radiation protection organisation needs to be set up if a zone is restricted, if workers are classified, or if verifications are required. This is a change with respect to the prior situation in which it was mandatory for the workers to be subject to the provisions of the Labour Code concerning the radiation protection of workers when the activity was subject to one of the administrative systems applicable to nuclear activities.

Radiation protection advice

The employer advisory system is now based on a "radiation protection adviser" who may be, as chosen by the employer:
- either the Radiation Protection Expert-Officer (RPE-O), an employee of the facility or, failing which, of the contractor, who will continue to hold a certificate issued by a certified organisation;
- or a Radiation Protection Organisation (OCR) certified according to requirements to be determined in an order.

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ASN opinion of 2nd February 2017 on the new provisions concerning radiation protection of workers

Although its opinion was on the whole favourable, in its opinion 2017-AV-0286 of 2nd February 2017 on the draft decree for protection of workers against the risks arising from ionising radiation, ASN nonetheless drew attention to the risk of possible confusion regarding the nature of the regulation checks that were to be entrusted to a "radiation protection organisation" given that this same organisation could also be tasked with advising the employer regarding all questions concerning the radiation protection of workers. The decree under preparation takes account of this observation by making a clear separation between the new advisory system and the monitoring (verification) arrangements.

However, the outside RPE-O who intervenes only for activities requiring notification, may continue to exercise these duties for three years.

The duties of the RPE-O and the OCR are extended to questions concerning protection of the population and the environment, which is covered by additional provisions in the Public Health Code.

In the BNIs, an organisation based on "centres of expertise" grouping together the skills and qualifications necessary for acting as radiation protection adviser, takes the place of the RPE-O or the OCR. This internal organisation is subject to ASN approval within the framework of the existing procedures of the BNI System (Decree 2007-1557 of 2nd November 2007 concerning BNIs and the monitoring of the nuclear safety of the transport of radioactive substances, and was modified for this purpose with the creation of a new Title XII (Articles 63-6 and 63-8)).

The procedures for the training and certification of the radiation protection advisers (RPE-O, OCR, centres of expertise) will be defined in a new order to replace the Order of 6th December 2013, concerning the training conditions for the radiation protection expert-officer and for certification of the training organisations.

Regulation inspections and checks

The inspections performed by the organisations approved by ASN pursuant to the Labour Code are abolished. Initial regulation checks will however be performed by approved organisations at commissioning or in the event of a significant modification. They will concern certain working equipment defined by an order, in the workplace and on vehicles used for radioactive materials transport operations. Periodic checks, for which the conditions will be defined by means of an order, will be carried out by the radiation protection adviser.

Radon

The monitoring of exposure to radon is extended to all workplaces (basements and ground floors) within the priority zones (only underground environments were hitherto subject to mandatory surveillance). The reference level for radon in the workplace is lowered to 300 Bq/m^3 from 400 Bq/m^3. In the case of worker exposure exceeding 6 mSv/year, the employer shall set up a radiation protection organisation, "radon" zoning and individual dosimetry monitoring. The use of a specialist organisation is only required when this measurement reveals an exposure situation in excess of 6 mSv/year (organisation approved for radon by ASN or accredited). The results shall be communicated to IRSN when the radon activity concentration exceeds 300 Bq/m^3 after deployment of the prevention measures.

Workers in an emergency situation

The provisions of the Public Health Code dealing with occupational health and safety in a radiological emergency situation have been transferred in full to the Labour Code, to allow harmonised implementation of the provisions applicable to workers intervening in a radiological emergency

situation, whether on the site of the accident, within the perimeter of the facility, or outside in the areas in which special measures have been taken to protect the populations. The two intervening worker groups have been retained, but redefined as follows:
- the effective dose liable to be received by group 1 personnel is greater than 20 mSv;
- the effective dose liable to be received by group 2 personnel is greater than 1 mSv.

Monitored and controlled area

Some provisions of the Order of 15th May 2006 concerning the conditions for the demarcation and signage of monitored and controlled areas were introduced into the regulatory part of the Labour Code. A new order will nonetheless be needed to clarify its implementation. The system of monitored or controlled areas, identified by a "blue, green, yellow, orange or red" colour, giving a risk scale, is maintained, with the decree setting the effective doses to which the workers are liable to be exposed in each of these areas:
- the notions of regulated areas, specially regulated or intermittent or temporarily controlled areas have been abolished;
- "radon" zoning is put into place if the dose is liable to be greater than 6 mSv;
- "extremities" zoning is put into place if the monitored and controlled areas do not allow control of exposure of the extremities and guarantee compliance with the exposure limit values.

Approval of dosimetry organisations

ASN approval of dosimetry organisations is superseded by accreditation by the French accreditation committee. The accreditation baseline requirements will be reviewed to include particular requirements for example concerning the transmission of dosimetry results to the Ionising Radiation Exposure Monitoring Information System (SISERI). The approvals currently issued by ASN will continue to be valid for two years.

1.2.2 General protection of the population

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.

Justification

Any nuclear activity must now be justified (the principle has been in the legislative part of the Public Health Code since 2001 but its application to all nuclear activities was not the subject of regulatory provisions). In this respect, an order shall give a classification of the existing activities, per category, considered in principle to be justified. The demonstration of justification is binding on any party responsible for a nuclear activity and is included in the licensing application file. This demonstration may refer to the above-mentioned order if the activity in question is mentioned in it.

Optimisation

For nuclear activities, the party responsible for the nuclear activity and the competent authority may set a "dose constraint" for implementation of the optimisation principle on the emitting source, to ensure protection of the population and the environment. This requirement supplements the obligation of meeting the annual limit of 1 mSv/year (which takes account of the possible combined impacts of several nuclear activities).

Reference levels

The concept of the reference level was introduced by the Ordinance of 10th February 2016. When used in radiological emergency and post-accident situations, exposure situations following radiological contamination of the environment, or natural radiation exposure situations (radon for example), these reference levels constitute a "benchmark" in the

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ASN opinion of 23rd February 2017 on the new provisions concerning radiation protection of the population

In its opinion 2017-AV-0289 of 23rd February 2017 on the draft decree concerning health protection against the dangers arising from exposure to ionising radiation and the security of ionising radiation sources against malicious acts, ASN underlined the importance of the new measures more particularly applicable to implementation of the justification principle, the new authorisation, registration and notification system for small-scale nuclear activities and source security. ASN however wished to draw the Government's attention to several points of particular importance for the public, points on which its opinion had not been taken into account:
- the update of the system banning the addition of radioactive substances to consumer goods, foodstuffs, livestock feedstuffs and construction materials, should have enabled the list of products for which no waiver is accepted to be extended to clothing accessories and cosmetics and toiletries;
- for management of radiological emergency situations, it would have been preferable to align the reference level with the existing intervention level when deciding on evacuation of the populations, that is an effective dose of 50 mSv/year, to make this easier to understand for the decision-makers and the public;
- the process to define remediation measures for sites and soils contaminated by substances, coordinated by the Prefect, should systematically involve ASN so that it can continue to exercise its duty of protection of the populations.

optimisation process. The highest values given in the Euratom Directive are incorporated into the French legal framework:
- for emergency and post-accident situations, 100 mSv for exposure of the populations in a radiological emergency situation and 20 mSv the first year for management of the post-accident phase, with a gradual reduction in following years until 1 mSv/year is reached;
- for contaminated sites and soils, 1 mSv/year (excluding post-accident situation) and 300 Bq/m^3 for radon exposure.

Public dose limits

The effective annual dose limit (Article R.1333-11 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 for the skin are set at 15 mSv/year and 50 mSv/year respectively. These last limits have not been modified.

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 the Ministerial Order of 1st September 2003. This Order will soon be modified to take account of the ICRP publication of new dose coefficients (ICRP 137, January 2018).

Naturally occurring radioactivity

The new regulations reinforced the attention given to the exposure of persons to naturally occurring radioactivity. The notion of Naturally Occurring Radioactive Material (NORM) was thus introduced. This notion covers all substances containing one or more radionuclides with a potassium-40 concentration greater than 10 kiloBecquerel (kBq)/kg or for which the concentrations of uranium-238 or thorium-232 and their radioactive decay products are in excess of 1 kBq/kg.

Radioactivity in consumer goods and construction materials

The addition of natural or artificial radionuclides, including by activation, in addition to those naturally present, in all consumer goods, foodstuffs and livestock feedstuffs is prohibited (Article R. 1333-2 of the Public Health Code). The principle of this ban does not therefore concern radionuclides naturally present in the initial components or in the additives used for the preparation of foodstuffs (for example potassium-40 in milk).

The addition of artificial radionuclides and NORM is also prohibited in construction materials.

In addition, the use of substances from a nuclear activity is also banned if they are contaminated or liable to be contaminated by radionuclides utilised or generated by the nuclear activity.

This ban however makes provision for waivers which may be granted by the Minister responsible for Health after receiving the opinion of the French High Council for Public Health and ASN, except with respect to foodstuffs and materials placed in contact with them, livestock feedstuffs, 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 (see chapter 10).

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.

Radioactivity and the environment

A National Network for the Measurement of Environmental Radioactivity (RNM) was set up in 2002 (Article R. 1333-25 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 member laboratories of this network must meet approval criteria, which in particular include participation in inter-laboratory comparison tests.

A detailed presentation of the RNM (*www.mesure-radioactivite.fr*) 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 conditions for these inspections are specified by the Order of 12th May 2004 as amended, setting the conditions for the control of the radiological quality of waters intended for human consumption. They form part of the sanitary monitoring carried out by the Regional Health Agencies. The Order of 11th January 2007, as amended, concerning the quality limits and references for raw water and water intended for human consumption introduces four indicators (total alpha and beta activities, tritium and total dose) for the radiological quality of these waters. 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 to introduce a quality reference for radon in groundwater.

The 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 Order of 19th October 2017 concerning analysis methods used for the health checks on water regulates the use of analysis methods and sets detection limits for the various parameters measured.

The corresponding quality indicators and references are the total alpha activity (0.1 Bq/L), the residual total beta activity (1 Bq/L), the tritium activity (100 Bq/L) and the indicative dose (0.1 mSv/an). The quality reference for radon is 100 Bq/L.

The 13th June 2007 Circular from the General Directorate for Health, accompanied by ASN recommendations, specifies the doctrine associated with these regulations, in particular when these reference values are exceeded. It will be supplemented in 2018 to take account of the question of radon in water intended for consumption (work in progress).

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 nuclear accident, "automatic" application of this regulation cannot exceed a period of three months; specific measures would then enter into force (see the regulations 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 Commission Regulation 297/2011 of 25th March 2011 issued following the Fukushima Daiichi accident, the maximum permitted levels of cesium-134 and cesium-137 in milk were 1,000 Bq/L as provided for by 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 ICPEs is subject to the particular legislative and regulatory provisions concerning these installations (for BNIs, see point 3.4.4). For the management of waste and effluents from other establishments, including hospitals, 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). They must be managed by means of a specific route in order to ensure traceability. ASN considers that the use of clearance levels would have three major drawbacks:
- the difficulty in having internationally defined levels accepted nationally;
- the difficulty in controlling the clearance of this waste;
- and the incentive to dilute this waste in the environment.

1.2.3 Protection of persons in a radiological emergency situation

The protection of the population against the dangers of ionising radiation in a radiological emergency situation is guaranteed through the implementation of specific actions (or counter-measures) appropriate to the nature and scale of the exposure (evacuation, sheltering, restrictions on consumption of foodstuffs).

Reference values in a radiological emergency situation

The population protection measures in an emergency situation are decided on by taking account of reference values (called intervention levels in the previous regulations) used in the drafting of ASN's recommendations for the Prefect (Article D. 1333-84 of the Public Health Code) on the basis of predicted doses:
- sheltering, if the predicted effective dose due to discharges exceeds 10 mSv;
- evacuation, if it exceeds 50 mSv;
- administration of Thyroid Blocking stable Iodine (TBI) when the predicted equivalent dose to the thyroid from the releases is liable to exceed 50mSv.

Public information in a radiological emergency

The means of informing the population in a radiological emergency situation, which was the subject of a specific community directive (Directive 89/618/Euratom of 27th November 1989) were integrated into Council Directive 2013/59 Euratom of 5th December 2013. This Directive 89/618/Euratom 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. These provisions were taken up in Article R. 1333-86 of the Public Health Code.

The Order of 4th November 2005 concerning public information in the event of a radiological emergency situation clarifies these provisions.

2. *European regulation (EU) 297/2011 from the European Commission of 25th March 2011, setting specific conditions on the import of foodstuffs and livestock feedstuffs from Japan following the accident which struck the Fukushima nuclear power plant, then modified by regulations 351/2011, 506/2011, 657/2011, 961/2011, 1371/2011, 284/2012, 561/2012, 996/2012 and 495/2013.*

1.2.4 Protection of the general public in a long-term exposure situation

As defined in the French regulations, situations of lasting exposure to ionising radiation cover the situations following a radiological emergency situation which led to long-term contamination of the environment or property by radioactive substances on the one hand (post-accident situations) and any other situation of contamination by radioactive substances on the other (contaminated sites and soils).

For post-accident situations, the regulations set a reference effective dose level of 20 mSv for the first year after the end of the radiological emergency situation for anyone exposed to radioactive substances as a result of the situation, in order to define the initial management strategy for the contaminated land, which is then reassessed yearly, with the eventual aim of reaching a reference effective dose level over one year of 1 mSv added to the background level predating the situation.

For the other cases, 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 updated periodically and published 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).

For these situations, in accordance with the international texts, no population exposure limit is set by the regulations: management of these sites is primarily based on a case by case application of the optimisation principle, taking account of a reference level of 1 mSv/year.

A guide on the management of sites potentially contaminated 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 contaminated by radioactive substances.

2. Regulatory requirements applicable to small-scale nuclear activities

The expression "small-scale nuclear" refers to medical, industrial and research activities utilising sources of ionising radiation when not covered by the BNI or ICPE Systems. They in particular concern the manufacture, possession and utilisation, distribution of radioactive sources and devices containing said sources, as well as electrical devices emitting ionising radiation. They also concern import and export, as well as transport.

FOCUS

Update of the system of procedures applicable to small scale nuclear activities

The decree under preparation provides the clarifications necessary for the implementation of the new system of procedures applicable to small-scale nuclear activities, pursuant to Article L. 1333-7 of the Public Health Code. A more graded approach to regulation will make it possible to implement a third system, between notification and authorisation: this is a simplified authorisation system called the "Registration System". ASN is working on a breakdown of the various categories of nuclear activities among these three systems, on drafting the general requirements applicable to some of these activities and on defining the content of the notification and registration application files (justification of compliance with the general requirements) or authorisation application files (demonstration of protection of interests). This new breakdown will be gradually implemented as of 2018.

2.1 Procedures and rules applicable to small-scale nuclear activities

The procedures and rules applicable to small-scale nuclear activities, when they are not the beneficiaries of an exemption, are described in sections 6, 7 and 8 of Chapter III of Title III of Book III of the first part of the Public Health Code. ASN issues licenses and authorisations, carries out registration and receives notifications.

2.1.1 The existing licensing system and its changes

The licensing system applies to companies or facilities which have and use sources of ionising radiation, but also to those that trade in them or use them but without directly possessing them.

The ASN license may be issued for a limited period. In this case it can 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. 1333-119 to R1333-124 of the Public Health Code, are set out by ASN resolution 2010-DC-192 of 22nd July 2010, which establishes the content of the files enclosed with the license application. The requirements applicable to the medical and non-medical fields are harmonised.

It should be noted that the nuclear activities carried out in BNIs, ICPEs and facilities regulated under the Mining Code are not subject to the authorisation system of the Public Health Code (see chapter 10) but are however subject to the general regulations applicable to nuclear activities described in the Public Health Code.

Licenses in the medical field

ASN issues licenses for the use of radionuclides, products or devices containing them, used in nuclear medicine, brachytherapy, and for the use of particle accelerators in external radiotherapy and computed tomography devices.

Licensing of non-medical activities

ASN is responsible for issuing licenses for industrial and research applications. In these fields, this concerns:
- the manufacture, possession and utilisation, distribution of radionuclides, products or devices containing them, devices emitting ionising radiation, the use of accelerators of all types of particles;
- the import and export of radionuclides, products or devices containing them.

The licence exemption criteria are given in the appendix to the Public Health Code (Tables 1 and 2, appendix 13-8). They will be updated by decree.

2.1.2 The new registration system

The new Article L. 1333-7 of the Public Health Code introduces a simplified licensing 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 requires relevant regulations and, for the activities concerned, the drafting of general requirements.

Medical computed tomography and the use of certain categories of radioactive sources with moderate activity (currently subject to licensing) will henceforth require registration, as will fluoroscopy-guided interventional practices with radiation protection implications (currently require notification).

2.1.3 The notification system and its update

The list of activities requiring notification 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. In the same way as medical radiology, radiology in a veterinary practice is among the activities subject to notification.

The resolution of 16th July 2009 was modified in 2015 by a resolution of 10th November 2015 in order more specifically 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. A new notification is mandatory if significant changes are made (change or addition of a device, transfer or substantial modification of the premises, or change in the party responsible for the nuclear activity).

This list of activities requiring notification will be updated and broadened in 2018. It will be extended to activities with risks or detrimental effects that are moderate, or which could be prevented by compliance with the general requirements, without it being necessary to examine a licensing or registration application file. This change should enable ASN to focus its monitoring actions primarily on activities with the highest radiation protection risks.

This system will henceforth be extended to the use of certain categories of radioactive sources with limited activity, such as lead detection in paint (currently requiring licensing) and electrical devices generating ionising radiation offering high levels of operating safety (baggage inspection systems).

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 the products intended for industrial and research purposes, but also health products: drugs containing radionuclides (radiopharmaceuticals, precursors and generators), medical devices (telegammatherapy devices, brachytherapy sources and associated projectors, blood product irradiators, etc.) and *in vitro* diagnostic medical devices (for radioimmunoassay).

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. 1333-172 of the Public Health Code). The procedures for approval of these organisations are set by ASN resolution 2010-DC-0191 of 22nd July 2010. These approvals are issued by ASN. 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 the ASN resolution mentioned in point 1.2.1. This resolution will soon be repealed and replaced by an order.

2.1.6 The rules for the design of facilities

ASN technical decisions, 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 installations in which electrical devices are used for the production and utilisation of X-rays, for medical, veterinary, industrial and research purposes, ASN takes account of the lessons learned from the difficulty with implementing resolution 2013-DC-0349 of 4th June 2013. In 2017, it published a new resolution (ASN resolution 2017-DC-0591 of 13th June 2017) setting out the minimum technical design rules applicable to premises in which X-ray generators are used and repealed the previous resolution.

The minimum technical rules for design, operation and maintenance to be met by in vivo nuclear medicine facilities were defined by the resolution of 23rd October 2014. The new rules replacing the rules which existed since 1981, mainly concern the ventilation of the laboratory in which the

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The new ASN resolution of 13th June 2017

Experience feedback regarding the difficulties with implementing the resolution of 4th June 2013 showed firstly that the March 2011 version of standard NF C 15-160 mentioned in the resolution did not apply to all the existing situations, and secondly that the identification and justification of equivalent provisions - a possibility provided for in this resolution - posed technical application problems for the manufacturers, suppliers and users.

Given this situation, ASN worked on a revision of this resolution which is no longer based on standard NF C 15-160, but sets the radiation protection objectives to be achieved by adopting a graded approach according to the risk generated. In the new resolution, the requirements relative to the control of radiological risks remain similar but are written so as to meet more clearly formulated objectives. The draft text was posted on the ASN website for public consultation from 2nd August to 30th September 2016. More than forty or so contributions have been made. They are in favour of the new draft and more specifically enabled certain points to be clarified.

This new resolution entered into force on 1st October 2017, without introducing any additional requirements for the installations already compliant with the previous resolution. It is applicable:
- to workplaces in which at least one X-ray generator is used (whether or not intentionally), whether or not mobile and used permanently or frequently in the same room;
- chambers and conveyances within which such devices are used.

The resolution covers:
- the sizing of the biological protections of the premises for which the radiological zoning objectives are specified in the text;
- signalling of the risk at each access point and inside the premises;
- safety (emergency stop devices, devices interconnecting operation to points of access and access actuation systems);
- the content of the report guaranteeing compliance with the provisions of the resolution.

radiopharmaceutical drugs are prepared and the hospitalisation rooms for patients having received a therapeutic treatment (more particularly iodine-131).

2.1.7 Radioactive sources management rules

The general radioactive source management rules are contained in section 9 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 the IRSN is compulsory for the acquisition, 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.
- 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.
- All users of sealed sources are obliged to have the expired, damaged or end-of-life sources taken back by a qualified supplier, or by Andra.
- A supplier is required to recover any source it has distributed if the party in possession of said source so requests.

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).

FACILITIES conformity calendar

Handling a sealed source of gadolinium-153 used for activity meter quality controls. ASN inspection of Clémentville clinic, Montpellier, May 2017.

With regard to the recovery of sources, Decree 2015-231 of 27th February 2015 concerning the management of used sealed sources, which came into force on 1st July 2015, introduced the necessary provisions to enable those in possession of sources to have the expired or end-of-life used sealed radioactive sources recovered not only by their initial supplier, but also by any other authorised supplier of radioactive sources or, as a final resort, by Andra. This modification aims to address the difficulties experienced by those in possession of sources when seeking to find the original suppliers and to take account of the cost of recovery and the monopoly situation enjoyed by certain suppliers.

The conditions for the implementation and payment of the financial guarantees to be provided by the suppliers of radioactive sources are verified by ASN when it issues or renews the source distribution licenses.

2.2 Protection of persons exposed for medical purposes

The radiation protection of persons exposed for medical purposes is built around two principles mentioned in 1° and 2° of Article L. 1333-1 of the Public Health Code respectively: justification of procedures and optimisation of exposure, under the responsibility of 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. 1333-52 and R. 1333-56 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").

The decree under preparation introduces additional measures concerning the justification of categories of medical practices, called generic justification and based on the indication guides. Henceforth, these guides – proposed by the professionals – will be drawn up and distributed by the Minister responsible for Health (and no longer by ASN), given the possible links with the cost charged for the procedures.

FOCUS

Justification of new medical practices

If an innovative technology is used for radiotherapy, radiosurgery, diagnosis or fluoroscopy-guided interventional practices, or a new type of practice is carried out with an existing technology, the decree under preparation introduces special provisions to allow the collection and analysis of information concerning the expected benefits for the patient and the corresponding risks to be organised. If necessary, an ASN resolution could introduce specific requirements to ensure the radiation protection of patients, workers and the public.

Information will be collected and analysed in accordance with the recommendations of professional best practices. The information and the corresponding analysis will be transmitted to the High Authority for Health and to ASN.

These new provisions could also concern new radiopharmaceuticals which have received a license for release to market or for temporary utilisation and new implantable radioactive medical devices, provided that the radiation protection implications so warrant.

ASN is tasked with setting up an "intelligence watch" on new practices and new technologies. This mission will be entrusted to a new Advisory Committee reporting to the ASN Director General. It should be in place in 2018.

TABLE 1: List of 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	Indication guide	Indication and procedure guide	Procedure guide in external radiotherapy	Indication 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

2.2.2 Optimisation of exposure

In medical imaging (radiology and nuclear medicine) optimisation consists in delivering the lowest possible dose compatible with obtaining a quality image; that is an image that provides the diagnostic information being sought. In therapy (external radiotherapy, brachytherapy and nuclear medicine) optimisation consists in delivering the prescribed dose to the tumour to destroy cancerous cells while limiting exposure of healthy tissues to the strict minimum.

To facilitate the practical application of the optimisation principle, standardised procedure guides for the performance of procedures utilising ionising radiation are produced and regularly updated (Table 1).

Diagnostic reference levels

The Diagnostic Reference Levels (DRL) are one of the tools used for dose optimisation. As required in Article R. 1333-61 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 must be taken in each radiology and nuclear medicine unit. On the basis of the information received by IRSN, an update of these diagnostic reference levels is planned during the course of 2018 by an ASN resolution.

Dose constraints

In the field of research involving human beings to evaluate or use methods entailing exposure to ionising radiation, dose constraints to optimise the doses delivered must be established by the physician, according to the nature of the protocol and the risk/benefit trade-off for the participating subject.

Medical 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 use of a medical physicist has been extended to cover radiology. Pursuant to Ordinance 2017-48 of 19th January 2017 concerning the profession of medical physicist, the medical physicist, whose presence was already mandatory in radiotherapy and nuclear medicine, is now recognised as a health care professional.

The roles of the medical physicist were clarified by the Order of 19th November 2004 as amended, relative to the training, duties and conditions of involvement of medical physicists. Thus they 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 exposure to ionising radiation. More particularly in the field of radiotherapy, the medical physicist guarantees that the radiation dose received by the tissues being exposed 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.

The conditions regarding the presence of medical physicists in radiotherapy centres are defined by the National Cancer Institute, pursuant to Decree 2007-388 of 21st March 2007 on the layout conditions applicable to cancer treatment activities. This Decree notably makes the presence of the medical physicist mandatory during the treatment sessions.

Pursuant to the Ordinance of 19th January 2017, a decree should be published shortly to define medical physics procedures. It will repeal the modified Order of 19th November 2004.

Since 2005, heads of facilities have had to draw up plans for medical physics (Order of 19th November 2004, modified), defining the resources to be 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 the resources allocated to quality assurance and control.

The conditions of training of the medical physicists were updated by the Orders of 28th February and 6th December 2011.

In the same way as the physician or the radiographer, the medical physicist can be designated as the RPE-O 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 medical physicist, also contributes to reducing the doses received by the professionals performing the procedure.

Radiotherapy quality assurance

The quality assurance obligations of radiotherapy centres 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 assessment of the risks faced by the patients during the radiotherapy process, and the identification and handling of undesirable situations or malfunctions, whether organisational, human or equipment-related. The medical imaging quality assurance obligation also appears in the Public Health Code. Faced with the regular rise in the doses of ionising radiation delivered to patients over the past decade, ASN should be publishing a resolution in 2018 to clarify the corresponding requirements. The draft resolution was submitted for public consultation from 2nd December 2017 to 2nd February 2018. This action is part of Cancer Plan 3 adopted by the Minister responsible for Health in January 2014.

Maintenance and quality control of medical devices

The internal and external maintenance and quality control of medical devices using ionising radiation (Articles R. 5211-5 to R. 5211-35 of the Public Health Code) were made mandatory by the Order of 3rd March 2003 setting out the list of medical devices subject to the maintenance and quality control obligation. External quality control is entrusted to organisations approved by the Director General of the 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 can be consulted on *www.ansm.sante.fr*.

Training and information

Additional major factors in the optimisation approach are the training of health professionals and the information of patients.

ASN resolution 2017-DC-0585 of 14th March 2017 introduced new conditions for the continuous training of professionals in the radiation protection of persons exposed to ionising radiation for medical purposes. These new conditions replace those defined by the Order of 18th May 2004 concerning training programmes for the radiation protection of patients exposed to ionising radiation (this Order should soon be repealed). The new training system will be implemented after approval of the professional guides required by this resolution, scheduled for early 2018.

To ensure the traceability of information, the report on the procedure, written by the medical practitioner carrying out the examination, must provide information justifying the procedure and the operations carried out as well as the data used to estimate the dose received by the patient (Order of 22nd September 2006 on the dosimetry data to be included in the report of a procedure using ionising radiation).

Finally, with regard to information, 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 them, their friends and relations, the public and the environment. In the case of a therapeutic nuclear medicine procedure, this information - which is provided in writing – 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 Council for Public Health, learned societies) were sent out by ASN in January 2007, with the goal of harmonising the content of the information already given to patients by the nuclear medicine units.

2.2.3 Radiological examination with no direct medical indication

With the decree under preparation, the existing expression "forensic applications of ionising radiation" which was felt to be too vague, is replaced by the expression "radiological examination with no direct medical indication" (Articles R. 1333-75 to R. 1333-77 of the Public Health Code). The examination categories concerned are explicitly defined (examples: preventive examinations carried out for occupational medicine or sports medicine purposes, or for inspections to identify objects or narcotic products hidden in the human body). For this type of examination, the principles of individual and generic justification, and optimisation are applicable.

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 the management of the radon risk in premises open to the public will be overhauled by the decree under preparation:

- 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 (areas with high radon potential).
- The measurements are taken by organisations approved by ASN. They must be repeated every ten years and whenever works are carried out to modify the ventilation or radon-tightness of the building.
- The reference level is set at 300 Bq/m^3.

The geographical areas in which radon measurements are mandatory are the 31 *départements* mentioned in the Order of 22nd July 2004 concerning management of the risk related to radon in premises open to the public. A new map, showing individual municipalities, will be sent out by order during the first half of 2018 (see chapter 1).

The "premises open to the public" categories concerned are teaching establishments, including buildings for boarders, establishments accepting groups of children less than six years old, health care, social and medico-social facilities with in-patient capacity, spas and penitentiaries.

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 of the action levels of 400 and 1,000 Bq/m³ being 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 defines 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 specifies the conditions in which radon activity is measured.
- ASN resolution 2015-DC-0507 of 9th April 2015 sets 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. 1333-36 of the Public Health Code.

The list of approved organisations is published in the ASN *Official Bulletin* on *www.asn.fr*.

The Ordinance of 10th February 2016 also introduced new legislative provisions into 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

Activities using NORM. Activities utilising raw materials containing naturally occurring radioactive materials are now included in nuclear activities. They will henceforth be subject to the ICPE System once the quantity of radioactive materials exceeds one tonne.

This new regulation includes raw materials containing a naturally occurring radioactive material when the radionuclide concentrations exceed the regulation clearance levels (NORM, see point 1.2.2.).

Natural radioactivity of construction materials. New provisions have been introduced into the Public Health Code to regulate natural radioactivity in construction materials (Art. R. 1333-38 to R. 1333-44):

- A reference level of 1 mSv/year in terms of effective dose was introduced to regulate the exposure of persons to gamma radiation emitted by construction materials.
- The suppliers or producers of natural materials or industrial residues liable to create such exposure must provide a radiological characterisation of these materials or residues; these obligations apply only to materials or residues appearing on a list published by decree (see box opposite).
- The suppliers and manufacturers of construction products must provide the users with information about the natural radioactivity of the product they market, with the packaging stating the activity concentration index "I" (see box opposite).
- Depending on the value of I, specific requirements concerning the use of the product could be determined by means of an order.

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Lists of natural materials and industrial residues concerned by a radiological characterisation obligation and method for calculating the activity concentration index (I).

List of natural materials and industrial residues:

- Natural materials:
  - alum shale;
  - construction materials or additives of natural igneous origin, such as granitoid rocks (granites, syenite and orthogneiss), porphyries, tuff, pozzolan, lava.
- Materials containing residues from industries processing naturally radioactive materials, such as fly ash, phosphogypsum, phosphoric slag and residues from the primary production of metals (slag, dross, etc.).

Calculation formula for the activities concentration index (I)

$$I = \frac{C_{Ra226}}{300 Bq.kg^{-1}} + \frac{C_{Th232}}{200 Bq.kg^{-1}} + \frac{C_{K40}}{3000 Bq.kg^{-1}}$$

where C_{Ra226}, C_{Th232} and C_{K40} are the activity concentrations in Bq/kg of the corresponding radionuclides in the construction material.

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.

3.1 The legal bases

3.1.1 International conventions and standards

On proposals from Member States, the 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 the national legal framework.

Several legislative and regulatory provisions relative to BNIs are derived from or take up international conventions and standards, notably those of the 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, detailed 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 on 8th February 1987 and, as at 7th December 2016, it comprised 157 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 European Commission were integrated into Decree 2007-1557 of 2nd November 2007, 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 2.7).

Directive 2014/87/Euratom of 8th July 2014 modified Directive 2009/71/Euratom of 25th June 2009 and made the following substantial improvements:
- concepts converging with those of the 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 six years, the organisation of peer reviews by the European counterparts on specific safety topics, along the lines 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 2.3). 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 the Ordinance of 10th February 2016 constituting various nuclear provisions, issued on the basis of the authorisation given in the TECV Act.

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

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The regulation of subcontracting

Article L. 593-6-1 of the Environment Code, created by the TECV Act, stipulates that *"owing to the particular importance of certain activities for the protection of the interests mentioned in Article L. 593-1 of the Environment Code, a decree of the Council of State may regulate or limit their performance by contractors or subcontractors"* and that *"the licensee shall monitor activities important for the protection of the interests mentioned in the same Article L. 593-1 when they are performed by outside contractors. It shall ensure that these outside contractors have appropriate technical expertise for the performance of said activities. It may not delegate this monitoring action to a contractor."*

Decree 2016-846 of 28th June 2016 concerning the modification, final shutdown and decommissioning of BNIs and subcontracting clarified these provisions.

The principle whereby the licensee of a BNI is effectively responsible for its operation entails a ban on entrusting operational responsibility and oversight of the operation of a BNI to an outside contractor, including with regard to the handling of accidents, incidents and deviations, as well as preparedness for and management of emergency situations.

This Decree also specifies the conditions in which a BNI licensee may call on outside contractors for the performance of Activities Important for the Protection (AIP) of the interests mentioned in Article L. 593-1 of the Environment Code (public health and safety, protection of nature and the environment). The principle of the text is that the licensee must limit the number of subcontracting tiers as far as possible. This principle applies to all the phases in the life of a BNI, including during its construction. The need to resort to subcontracting shall be assessed in the light of the need for specific and exceptional skills.

In any case, the licensee shall retain the ability to manage the subcontracted activities. In its general operating rules, it shall describe the methods used to monitor the outside contractors.

The text also introduces a condition limiting to three the total number of successive subcontracting tiers, with the licensee's contractor being able to call on no more than two successive subcontractors. There are however the following two possibilities for a waiver to this limitation, provided that the licensee presents sufficient justifications:

- In the case of an unforeseeable event affecting the conditions of performance of the activity or requiring specific operations, the licensee must inform ASN beforehand and give the relevant reasons.
- When the use of an outside contractor or of more than two tiers of subcontractors ensures better protection of the protected interests, ASN may, at the request of the licensee, issue a waiver giving full reasons.

The limitation rule applies as of commissioning of the BNI and runs until delicensing, for all provision of services or works important for the protection of interests and performed within the perimeter of the BNI. It should be noted that simple compliance with the limit on the number of subcontracting tiers is not in itself sufficient justification that all attempts have been made to limit the number of subcontracting tiers as far as is possible.

In any case, the licensee shall monitor the AIP performed by outside contractors. To this end, it shall collect information from them, in particular for the purposes of operating experience feedback.

When a licensee intends to entrust the performance of an AIP to an outside contractor, it shall assess the proposals taking account of criteria giving priority to the protection of the above-mentioned interests; it shall first of all ensure that the companies it intends to call on have the technical capability to carry out the work and are able to manage the corresponding risks.

Finally, the licensee shall notify the outside contractors of the document containing its policy with regard to the protection of interests. The contract with the outside contractors shall specify the obligations necessary for application of the provisions of the BNI regulations incumbent upon each of the parties.

These provisions are now applicable to contracts following a call for tenders published after 1st January 2017.

sets various requirements for the States, the safety regulators and the licensees. This Directive was transposed in full into French law with the Ordinance of 10th February 2016.

For the drafting of these two Directives, the institutions of the European Union benefited from the work done by the WENRA association and ENSREG/WG2 (European Nuclear Safety Regulators Group) respectively (see chapter 7, point 2.7).

3.1.3 National texts

The legal system applicable to BNIs was revised in depth by Act 2006-686 of 13th June 2006 on Transparency and Security in the Nuclear field (TSN Act) and its implementing decrees, in particular Decree 2007-1557 of 2nd November 2007.

Since 6th January 2012, all the legislative measures specifically concerning BNIs – the TSN Act, the 28th June 2006 Programme Act and Act 68-943 of 30th October 1968 on civil liability in the field of nuclear energy – are codified in the Environment Code.

Title VI and a few provisions of Title VIII of the TECV Act and the Ordinance of 10th February 2016 constituting various nuclear provisions, made substantial modifications to the legislative framework for regulation of nuclear activities, BNIs in particular. ASN assists the Ministry responsible for Nuclear Safety in drafting regulatory texts clarifying these new legislative provisions: Decree 2016-846 of 28th June 2016 relative to the modification, final shutdown and decommissioning of Basic Nuclear Installations and to subcontracting and the draft decree relative to BNIs and nuclear transparency. This latter draft decree will create the regulatory part of the Environment Code relative to nuclear security and BNIs.

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 830-1557 of 2nd November 2007.

FOCUS

The draft decree concerning BNIs and transparency in the nuclear field

In 2017, ASN assisted the Ministry for Ecological and Solidarity-based Transition with the drafting of the regulatory part of the Environment Code concerning nuclear security and BNIs, which entails a draft decree codifying the following eight decrees in the Environment Code, essentially within the existing law:

- Decree 2007-830 of 11th May 2007 amended relative to the nomenclature of Basic Nuclear Installations;
- Decree 2007-831 of 11th May 2007 setting the procedures for appointing and qualifying nuclear safety inspectors;
- Decree 2007-1368 of 19th September 2007 concerning the secondment of certain civil servants to ASN on a part-time basis;
- Decree 2007-1557 of 2nd November 2007 concerning BNIs and the regulation of the transport of radioactive substances with respect to nuclear safety;
- Decree 2007-1572 of 6th November 2007 concerning technical inquiries into accidents or incidents concerning a nuclear activity;
- Decree 2008-251 of 12th March 2008 relative to Local Information Committees for Basic Nuclear Installations;
- Decree 2008-1108 of 29th October 2008 concerning the composition of the High Committee for Transparency and Information on Nuclear Security;
- Decree 2010-277 of 16th March 2010 concerning the High Committee for Transparency and Information on Nuclear Security.

The draft decree also updates the regulatory procedures concerning BNIs currently regulated by Decree 2007-1557 of 2nd November 2007 in order more particularly to interface them with the new regulatory requirements regarding the environmental assessment of projects.

It also:

- adds to the provisions concerning Local Information Committees (CLI) in order to include members from foreign States if the BNI site is located in a border *département* with provision made for the organisation of public meetings;
- allows definition of the conditions for the renewal of the ASN Commission pursuant to Act 2017-55 of 20th January 2017 concerning the general status of independent administrative authorities and independent public authorities;
- allows definition of the operation of the ASN sanctions commission and clarifies the procedures giving rise to administrative fines;
- allows clarification of the system applicable to BNIs, as a result of Directive 2010/75/EU of 24th November 2010 relative to industrial emissions or Directive 2012/18/EU of 4th July 2012 concerning control of the dangers linked to major accidents involving substances ("Seveso 3 Directive").

FOCUS

The centres of expertise (what will change)

Council Directive 2013/59/Euratom of 5th December 2013 imposes an obligation on companies to ask for the advice and opinion of a "radiation protection expert" with regard to questions concerning compliance with the applicable legal obligations, concerning occupational exposure (Article 34) and exposure of the public (Article 68). This expert, whose duties are specified in Article 82, must be qualified (Article 79). The Directive sets no particular provisions with regard to the status of this expert, who may be a natural or legal person, from inside or outside the company.

In French law, this expert, who already exists in the form of a natural internal or external person, referred to as the "radiation protection expert-officer" is only competent with regard to occupational radiation protection (Articles R. 4451-103 to R. 4451-114 of the Labour Code in force).

For the transposition of the Directive, the existing system should be consolidated by maintaining the radiation protection expert-officers and making it possible to outsource this role to radiation protection organisations, to be certified according to procedures set by means of an order.

For the BNIs defined in Article L. 593-2 of the Environment Code, for which the implications are the most significant, a particular system is planned, with the creation of a specific organisation within the company (centres of expertise), which will pool all the skills and qualifications necessary for acting as radiation protection adviser. The certification of these centres of expertise is entrusted to ASN.

The duties of the adviser now concern both occupational radiation protection and radiation protection of the population and the environment, so parallel and complementary provisions are created in the Labour Code on the one hand and in the Public Health Code on the other.

With regard to the centres of expertise, the arrangements will be as follows: in the operating rules of its installation, the BNI licensee will describe the main characteristics of the centre of expertise, the qualification requirements of the personnel and the means and resources allocated to it. As employer, the licensee will supplement its operating rules with aspects concerning the "occupational" centre of expertise.

The provisions of Chapter II of Title IV of Book V of the Environment Code (drawn in particular from the codification of the Act of 28th June 2006) introduce a coherent and integrated legislative framework for the management of all radioactive waste.

Decree 2007-1557 of 2nd November 2007

The Decree of 2nd November 2007 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 definition of the safety options, 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 defines the applicable procedures for adoption of the general regulations and the taking of licensing decisions concerning BNIs; it defines the conditions for application of the law with regard to inspection, policing measures and administrative and criminal sanctions; it finally defines the particular conditions for the application of certain administrative systems within the perimeter of BNIs.

This Decree, along with seven other decrees, more particularly concerning the BNI system and the transport of radioactive substances, CLIs, the HCTISN and nuclear safety inspectors, 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, 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 regulations, some of which are still being drafted.

3.2.1 Ministerial Orders

The Order of 7th February 2012 was a key milestone in the overhaul of the general technical regulations applicable to BNIs.

Order of 7th February 2012

Issued pursuant to Article L. 593-4 of the Environment Code, the Order of 7th February 2012 defines the essential requirements applicable to the BNIs to protect the interests listed in the Act: public safety, health and salubrity; protection of nature and the environment.

The 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 principle 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 order more specifically 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 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" drawn up by WENRA which defined 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 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 enter into force on the occasion of the first periodic review or the first substantial modification of the BNI, following the date of 1st July 2015, or at final shutdown and decommissioning of the facility.

3.2.2 ASN regulations

Pursuant to Article L. 592-20 of the Environment Code, ASN may issue regulations 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 regulations aimed at clarifying the Decree of 2nd November 2007 or the Order of 7th February 2012. Even before being required by law, ASN has from the outset submitted its

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The process of drafting general technical regulations for BNIs that are appropriate and proportionate to the issues

Following the adoption of the TSN Act, ASN and the Ministry responsible for Nuclear Safety initiated an overhaul of the regulations applicable to BNIs.

The BNI Order of 7th February 2012 made a fundamental but nonetheless gradual change in the technical regulatory framework applicable to BNIs, clarified by a number of ASN regulations.

As part of its role of drafting or contributing to the drafting of regulations, ASN's goal is to promote the adoption of clear, complete regulations reflecting the best safety standards, tailored to and proportionate to the actual 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, as a broader consultation makes a significant contribution to the adoption of regulations that are appropriate and easier to understand and implement.

Guide No. 25 Drafting of an *ASN regulation or guide - Procedures for consultation with the stakeholders and the public*, details the ways in which the licensees and industry players concerned, the public and the associations, contribute to the preparation of draft ASN regulations or guides concerning the BNIs.

This guide aims to:
- improve stakeholder involvement as early as possible in the process. Thus, the consultation of stakeholders and the public takes place as of the beginning of the process to draft the texts, concerning the orientations and the goals, and then throughout the process;
- provide a better analysis of the impact of the draft texts, with a reinforced framework for the drafts by means of the production of three documents: an orientation and justification document, an assessment of the impact of the draft text and experience feedback analysis, these documents themselves being subject to consultation;
- support and follow up the implementation of the regulatory texts by drafting guides intended for the licensees and industrial firms concerned and by integrating experience feedback after a few years of application of the texts.

Participation by the stakeholders and the public is either by means of consultation on the ASN website, or by means of exchanges with the stakeholders, or by consultation of consultative bodies which - depending on the subject or nature of the draft text - are the High Council for the Prevention of Technological Risks (CSPRT), the Advisory Committees of Experts, the CLIs or the HCTISN.

A specific heading has been created on *www.asn.fr* in which ASN makes a certain number of documents available.

draft regulations for public consultation on *www.asn.fr* (see chapter 6, point 2.3).

ASN proposed that some of its regulations also be presented to the CSPRT, more particularly those dealing with topics examined by the CSPRT with respect to the ICPE System, in order to ensure greater consistency between 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 2017, four resolutions were adopted to supplement the implementation procedures of the Order of 7th February 2012.

ASN resolution 2017-DC-587 of 23rd March 2017 relative to the packaging of radioactive waste and the conditions of acceptance of the radioactive waste packages in the disposal BNIs, approved by the Order of 13th June 2017

This resolution more particularly specifies the obligations of the radioactive waste producer, those of the licensee packaging it and those of the licensee of the disposal facility for which it is intended.

This resolution makes a distinction between the case of disposal facilities being studied and the case of disposal BNIs in operation.

It in particular sets out the general requirements concerning the packaging of radioactive waste, the packaging baseline requirements defined by the licensee of a packaging BNI, and the specifications for acceptance of radioactive waste packages defined by the licensee of a disposal BNI, along with the requirements applicable to packages intended for a disposal BNI under study.

ASN resolution 2017-DC-0588 of 6th April 2017 relative to the conditions for water intake and consumption, discharge of effluents and monitoring of the environment around PWR reactors, approved by order of 14th June 2017

This resolution contains the "generic" requirements concerning water intake, effluent discharges and their monitoring for NPPs, as well as those concerning information of the public and the authorities, which were previously contained in licensing decisions.

This resolution comprises no major change to the requirements, but the formulations are harmonised, using more recent and more informative terminology. It clarifies ASN's requirements and improves the consistency of the requirements applicable to French NPPs.

This resolution supersedes certain prior agreements contained in the licensing decisions concerning water intake and effluent discharges by NPPs for activities with no specific implications and which can be managed internally by the licensee. The licensee will continue to inform ASN of the performance of these activities.

This general regulatory foundation could be supplemented by licensing decisions specific to an NPP if additional requirements for management of water intake and discharges prove to be necessary in the light of the specific features of the site and its environment.

ASN resolution 2017-DC-0592 of 13th June 2017 concerning the obligations on BNI licensees in terms of preparedness for and management of emergency situations and the content of the on-site emergency plan, approved by Order of 28th August 2017

This resolution specifies the provisions of the Order of 7th February 2012 with regard to the licensees' obligations in terms of preparedness for and management of emergency situations and what ASN requires with regard to the contents of the BNI on-site emergency plans. It gives formal status to existing practices that had not yet been integrated into the regulations and introduces into French law certain reference levels established by the Western European Nuclear Regulators Association (WENRA), which take account of the lessons learned from the Fukushima Daiichi accident.

The resolution more specifically requires that the licensees:
- specify the content of the on-site emergency plan, while making it more operational and able to deal with emergency situations, even long-term ones;
- define the envisaged response to the complete or partial unavailability of the external resources on which the licensee had intended to call (for example the fire brigade);
- carry out an annual check on the content and pertinence of the alert and coordination agreements signed by the licensee with the authorities on the one hand and the external organisations and services (fire brigade, hospitals, etc.) on the other. These agreements must be updated at least every five years;
- define the headcount and skills of the emergency teams and carry out at least one exercise or simulation annually in order to train the personnel, including via emergency scenarios affecting several installations at the same time;
- in the event of an emergency, take steps to protect the persons present within the facility;
- provide for steps concerning the material resources needed to manage emergency situations (alert and communication means, instruments to characterise the state of the facility and any radioactive and chemical releases);
- together with ASN and its technical support organisation (IRSN), define the pertinent technical information for monitoring the development of the situation of the facility and its environment, along with the methods for transmission of this information;
- have emergency management premises meeting the characteristics defined in the resolution.

ASN resolution 2017-DC-0616 of 30th November 2017 concerning significant modifications to BNIs, approved by Order of 18th December 2017

This resolution is in response to a legislative change introduced by the 17th August 2015 Act and the Decree of 28th June 2016, leading to changes to the administrative system applicable to BNI modifications. The modifications subject to regulation and not leading to a modification of the authorisation decree, henceforth referred to as "noteworthy", are subject either to ASN licensing or notification of ASN depending on the general criteria set by these texts, which must be clarified by an ASN resolution.

In this respect, the wording of Article 27 of the Decree of 7th November 2007 derived from the Decree of 28th June 2016 states:

- *"Art. 27- Notification of ASN is required for the modifications mentioned in Article L. 593-15 of the Environment Code, which do not significantly call into question the safety analysis report or the installation impact assessment and the list of which is set by decision of this authority, taking account of the following criteria:*
  - *"1° The nature of the facility and the scale of its risks and detrimental effects on the interests mentioned in Article L. 593-1;*
  - *"2° The technical capabilities of the licensee and the internal oversight measures it puts in place to prepare for these modifications."*

Furthermore, as at 31st December 2017, these tests put an end to the internal licensing systems which hitherto had been used by certain licensees after approval by ASN and the scope of which had, until 31st December 2017, constituted the list of modifications requiring notification.

The resolution provides a regulatory framework for the management of all noteworthy modifications to BNIs, drawing on the provisions of the Order of 7th February 2012, which it clarifies.

The resolution stipulates that the management of noteworthy modifications of a BNI is an activity important for protection, that the licensee must define a management method for noteworthy modifications that is proportionate to the implications and that this management method must offer verification guarantees following on from those of the internal licensing system.

ASN reserves the right to restrict the scope of noteworthy modifications subject to notification if the licensee's internal monitoring proves to be insufficient.

The resolution sets the general criteria to be met by the noteworthy modifications subject to notification: procedural compatibility criteria, general fundamental doctrine criterion, general criteria which, in similar forms, appear in most internal licensing systems, criteria linked to consideration of the risks or drawbacks the modification is liable to create during the performance phase as well as criteria and provisions specific to certain types of modifications: documentary organisational modifications; incident and accident response strategies; temporary modifications to the technical operating specifications of the general operating rules for NPP reactors; waste zoning modifications; hardware modifications; modifications concerning the preparedness for and management of emergency situations; modifications of NPP reactor fuel and modifications concerning the transport of radioactive substances.

These resolutions supplement the legal framework made up of the regulations in force:

- **Resolution 2016-DC-0578 of 6th December 2016 on the prevention of risks resulting from the dispersal of pathogenic micro-organisms (legionella and amoeba) by PWR secondary system cooling installations.** The resolution reinforces the prevention of risks resulting from the dispersal of pathogenic micro-organisms. It sets requirements concerning the design, upkeep and monitoring of installations, the maximum legionella concentrations in the facility's cooling water and downstream, with regard to amoeba, the steps to be taken in the event of a proliferation of microorganisms in the systems or infection identified in the vicinity of the facility, as well as information of the public and the administrations in the event of proliferation of micro-organisms. To the extent possible, the resolution aims to align the requirements applicable to the NPP large cooling towers with those applicable to cooling towers of other industries with respect to legionella. However, owing to the considerable flow rates and volumes of water in the NPP cooling towers, certain requirements applicable to other industries would lead to an excessive environmental impact from biocidal treatments. Certain provisions were therefore adapted. Furthermore, the resolution also regulates the prevention of amoeba risks, already specified in the individual regulations of the NPPs.
- **Resolution 2016-DC-0571 of 11th October 2016 containing various provisions regarding nuclear pressure equipment conformity.** This was issued following changes to the Environment Code (Decree 2015-799 of 1st July 2015 concerning products and equipment entailing a risk) and the publication of the 30th December 2015 Order on nuclear pressure equipment. This resolution contains the provisions concerning the changes needed for application of the modules for assessment of conformity, the compliance notification model and the state of the art for the design and manufacture of category 0 nuclear pressure equipment.
- **Resolution 2016-DC-0569 of 29th September 2016 modifying resolution 2013-DC-0360 of 16th July 2013 relative to control of detrimental effects and the impact of basic nuclear installations on health and the environment.** It requests the implementation of an approach proportionate to the implications and takes account of recent changes to the regulations, in particular the entry into force on 1st June 2015 of Directive 2012/18/EU from the European Parliament and Council of 4th July 2012 concerning management of the hazards linked to major accidents involving hazardous substances, known as the "Seveso 3 Directive", as well as changes to the Environment Code resulting from the Ordinance of 10th February 2016 containing various nuclear provisions.
- **Resolution 2015-DC-0532 of 17th November 2015 concerning the BNI safety analysis report.** It specifies the contents of the safety analysis report the licensee is required to transmit to ASN in its BNI creation, commissioning or decommissioning authorisation application file. The main provisions of this resolution concern the objectives of the safety analysis report, the principles underpinning the drafting and updating of the safety analysis report, compliance with the legislative and regulatory requirements, the description of the BNI and provisions intended for management of the risks it presents, the nuclear safety case (management of the risks presented by the facility), the on-site emergency plan design study, particular operations such as BNI construction, management of radioactive sources and on-site transport operations, plus requirements specific to certain BNIs, more particularly BNIs for example comprising one or more nuclear reactors.

- **Resolution 2015-DC-0508 of 21st April 2015 concerning the study of waste management and the inventory of waste produced in the BNIs.** It specifies the rules applicable to the management of the wastes produced in BNIs, more particularly the content of the waste management study required by 3° of II of Article 20 of the Decree of 2nd November 2007 and Article 6.4 of the BNI Order of 7th February 2012, the procedures for the creation and management of the waste zoning plan mentioned in Article 6.3 of the BNI Order of 7th February 2012 and the content and procedures for drawing up the waste summary specified in Article 6.6 of the BNI Order of 7th February 2012.
- **Resolution 2014-DC-0462 of 7th October 2014 concerning the control of the criticality risk in BNIs.** It aims to set out 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 physically impossible. A guide for implementation of this resolution is being prepared.
- **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 defines the information to be transmitted to ASN by the licensee before, during and after shutdown of the reactor.
- **Resolution 2014-DC-0420 of 13th February 2014 concerning physical modifications to BNIs.** This resolution is repealed by resolution 2017-DC-0616 of 30th November 2017, which incorporates some of its provisions.
- **Resolution 2014-DC-0417 of 28th January 2014 concerning the rules applicable to BNIs with regard to the management of fire risks.** 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 of the regulatory authority and the public; it was modified by ASN resolution 2016-DC-0569 of 29th September 2016.
- **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 resolution is repealed by resolution 2017-DC-0616 of 30th November 2017. It clarified the conditions for application of the provisions of the Environment Code regarding consultation of the public, which were repealed (see chapter 6, point 2.3).
- **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 for the 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.** For the components, it defines the technical and manufacturing surveillance documentation in order to establish consistency between these provisions and those applicable to the manufacture of pressure equipment.

3.2.3 Basic Safety Rules and ASN guides

With regard to various technical subjects concerning BNIs, ASN has drawn up Basic Safety Rules (RFS), recommendations that specify the safety objectives and describe the practices that ASN considers 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 2017, it comprised thirty 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 design, construction and in-service monitoring 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 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 promotes 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.

With regard to Nuclear Pressure Equipment (NPE), AFCEN together with ASN is continuing sustained work to update its codes (RCC-M in particular) under a programme of work which will be completed at the end of 2018 and which aims to offer the entire sector improved control of regulatory requirements and equipment manufacturing.

3.3 Plant authorisation decrees and commissioning licenses

Chapter III of Title IX of Book V of the Environment Code contains a BNI creation authorisation procedure, followed by a number of licensing operations throughout its operating life, 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.

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. 121-8 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 (Articles R. 121-1 and R. 121-2 of this same Code).

The public debate looks at the need and suitability, objectives and characteristics of the project.

3.3.3 The Creation Authorisation

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.

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 BNI creation project is subject to an *"environmental assessment, [which] is a process consisting of the drafting, by the Owner, of a report assessing the consequences for the environment, […] "impact assessment", holding of consultations* [with the environmental authority as well as with local authorities and their groups interested by the project]*, as well as the examination by the authority with competence for authorising the project of all the information presented in the impact assessment and received within the framework of the consultations and from the Owner."* (III of Article L. 122-1 of the Environment Code)

The file presenting the project and comprising the impact assessment and authorisation application is submitted for approval to the environmental authority group of the General Council for the Environment and Sustainable Development, as well as to the local authorities and their groups concerned by the project.

The public inquiry

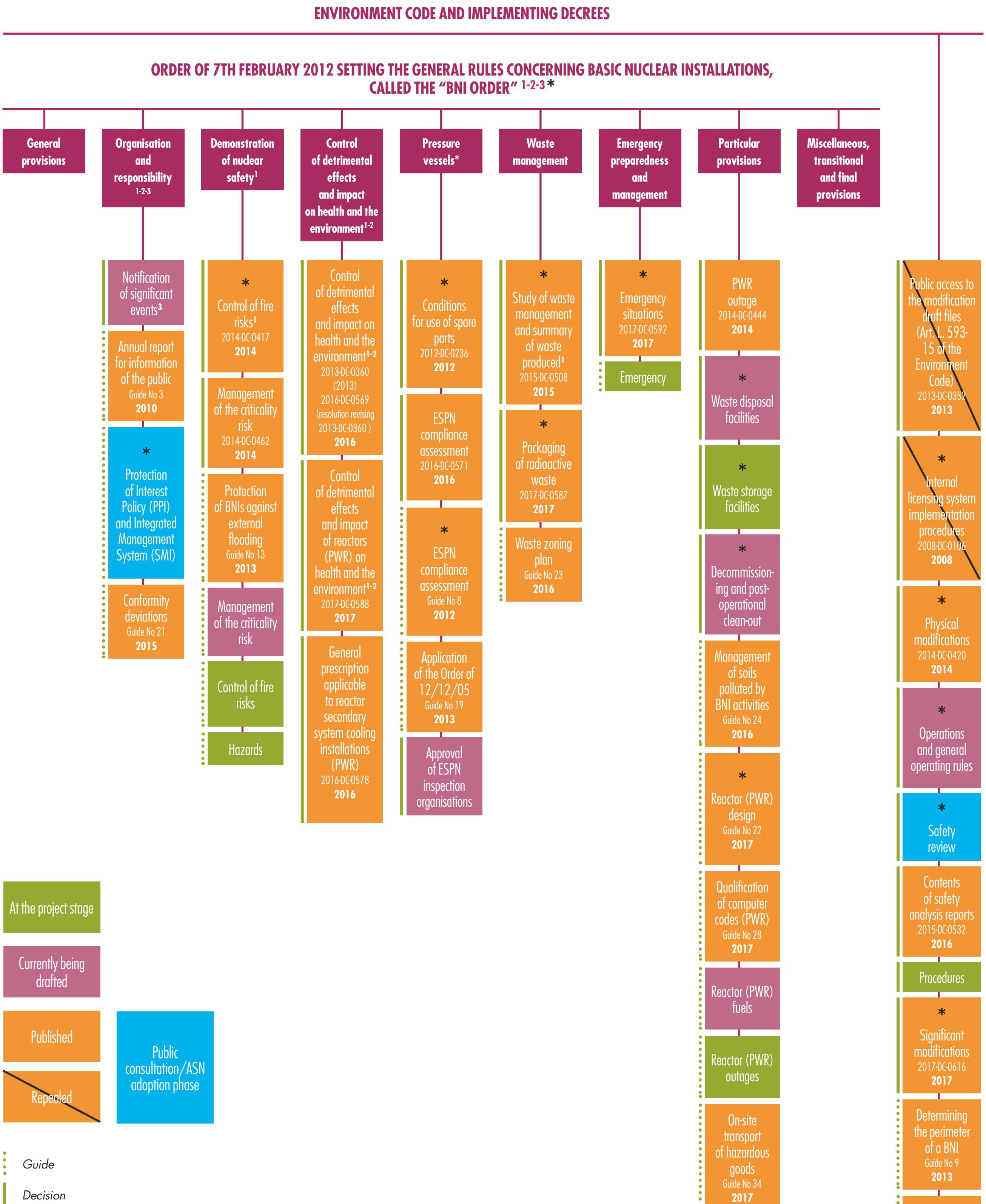
Article L.593-8 of the Environment Code stipulates that the authorisation can only be granted after holding a public inquiry. The purpose of the inquiry is to inform the public and collect their opinions, suggestions and counterproposals, in such a way as to provide the competent authority with all the 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. 123-18 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 (except if the inquiry is suspended or in the event of an additional inquiry). The dossier submitted by the licensee in support of its authorisation application is made available in the public inquiry dossier. The safety analysis report (document 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 supplemented by a risk control study, which itself comprises a non-technical summary of this study designed to make it easier to understand.

Since 1st January 2017, pursuant to the provisions of Article L. 123-12 of the Environment Code, the *"public inquiry file is placed on-line for the duration of the inquiry. It remains open for consultation, for this same period, on paper in one or more places determined as of opening of the public inquiry. Free access to the file is also guaranteed on one or more computer terminals in a place open to the public"*.

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 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."*

DIAGRAM 3: Status of progress of the overhaul of the general technical regulations applicable to BNIs, as at 1st January 2018



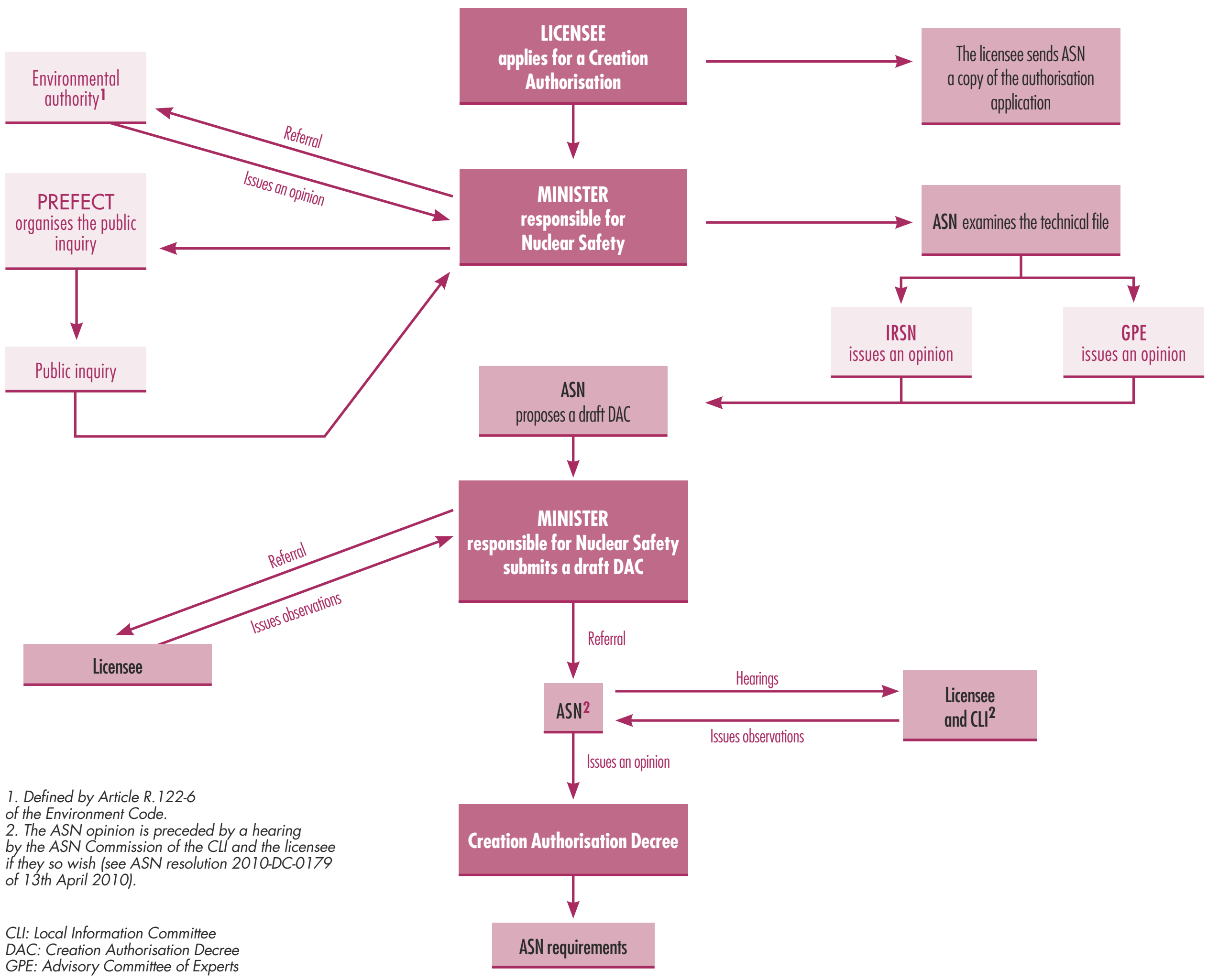
1. *Covering the scope of the Order of 31/12/1999*
2. *Covering the scope of the Order of 26/11/1999*
3. *Covering the scope of the Order of 10/08/1984*

* *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.

DIAGRAM 4: Creation authorisation procedure for a Basic Nuclear Installation (BNI) defined in Chapter III of Title IX of Book V of the Environment Code



1. Defined by Article R.122-6 of the Environment Code.
2. The ASN opinion is preceded by a hearing by the ASN Commission of the CLI and the licensee if they so wish (see ASN resolution 2010-DC-0179 of 13th April 2010).

CLI: Local Information Committee
DAC: Creation Authorisation Decree
GPE: Advisory Committee of Experts

The creation of a Local Information Committee (CLI)

The TSN Act of 13th June 2006, codified in Books I and V of the Environment Code, gave a legislative basis to 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 of 17th August 2015 are detailed in chapter 6. 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 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 to the Advisory Committees for examination, following a report from IRSN, as applicable.

After examining and analysing the results of the consultations, ASN proposes to the Minister in charge of Nuclear Safety the terms of a draft decree authorising or refusing the creation of the installation.

FUNDAMENTALS

General Operating Rules

The General Operating Rules are the "highway code" for BNIs. They are defined by the licensee and examined by ASN prior to commissioning of the facility and then with each modification affecting the protected interests. They constitute an interface document between design and operation. They determine a set of specific rules, for which compliance guarantees that operation of the facility remains within the range covered by the nuclear safety case.

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 issued by a decree from the Prime Minister 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 intake 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 Act of 17th August 2015, makes provision for two cases when dealing with modifications to the facility or its operating conditions:

- "Substantial" modifications to 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. A modification is considered to be "substantial" in the cases mentioned in Article 31 of the 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 having an impact on the protected interests 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 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 Act of 17th August 2015). This same Article states that these modifications may be opened up for public consultation.

Until 31st December 2017, pursuant to an interim provision of the Decree of 28th June 2016, the internal licensing systems of the licensees, approved by ASN, acted as the list of modifications subject to notification. This transitional situation came to an end with the adoption of ASN resolution 2017-DC-0616 of 30th November 2017 concerning noteworthy modifications to BNIs.

The other installations located within a BNI perimeter

The following co-exist within the perimeter of a BNI:

- equipment and installations necessary for operation of the BNI. Depending on its type, this equipment may technically be comparable to an ICPE, but because it is a part of a BNI, it is subject to the system and regulations applicable to BNIs;
- equipment and installations which are not linked to the BNI. These are the "not necessary" equipment and installations on the Installations, Structures, Works and Activities (IOTA) or ICPE lists, situated within or carried out within the perimeter of the BNI: they remain subject to these systems, with ASN retaining competence for individual

measures concerning this equipment and these installations and oversight thereof. Since 2017, ASN has competence for issuing the environmental license (which replaces the ICPE or IOTA licenses) for this equipment as an ICPE or as an IOTA with risks for the water resources and aquatic ecosystems. However, this equipment shall continue to be the responsibility of the Prefect with regard to other systems mentioned in the texts covering the environmental license (for example a land clearance license) and their licensees do not benefit from the integrated nature of the environmental license.

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) opened for signature on 22nd September 1992, is the mechanism whereby the European Commission and 15 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", which was adopted in 1991 and entered into force in September 1997, 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.

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 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 ASN licensing 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 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 ICPEs subject to licensing, in accordance with the provisions of the 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.

The resolution of 16th July 2013 was revised by the ASN resolution of 29th September 2016. This modification aims to clarify certain provisions more specifically concerning the content of the environmental monitoring programme to be put into place by the licensees, set out in appendix II to the resolution. It also updates the requirements to take account of regulatory changes in European Environmental Law (regulation 1272/2008 of the European Parliament and Council of 16th December 2008 concerning the classification, labelling and packaging of substances and mixtures, Directive 2012/18/EU of the European Parliament and Council of 4th July 2012 concerning the management of hazards linked to major accidents involving hazardous substances modifying and then repealing Council Directive 96/82/CE, known as the "Seveso 3 Directive").

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 in the impact assessment, the BNI creation authorisation application explains the licensee's choices in particular regarding the reduction at source measures and the decisions taken between confinement, treatment or dispersal of substances, based on safety and radiation protection criteria.

The optimisation efforts encouraged by the authorities and made by the licensees have - for "equivalent operation" - resulted in these emissions being constantly reduced. ASN sets discharge limit values in order to encourage the licensees to maintain their optimisation and discharge control 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. In 2017, ASN thus issued three licensing decisions updating the water intake and discharge limits and setting requirements applicable to water intake and discharges for the Gravelines NPP site as well as for all the facilities operated by CEA's Cadarache centre. In a regulation approved on 14th June 2017 by the Minister for Ecological and Solidarity-based Transition, ASN also defined the conditions for water intake and consumption, effluent discharges and environmental monitoring applicable to all NPP reactors.

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 Act of 13th June 2006 and more broadly the general technical regulations relative to 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 dealing with radioactive discharges.

ASN wants the impact of discharges of chemical substances 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 discharges lead to a localised rise in the temperature of the receiving environment, which generally remains moderate, but which can in certain circumstances reach several degrees, more particularly in low-water situations.

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 Order of 7th February 2012 and the ASN resolution of 16th July 2013 amended, concerning the control of detrimental effects and the health and environmental impact of BNIs, impose requirements 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 natural environment.

3.5 Requirements concerning radioactive waste and decommissioning

3.5.1 Management of BNI radioactive waste

The management of waste in the BNIs, whether or not radioactive, is regulated by ASN, notably to prevent and minimise the production and harmfulness of the waste – in particular at source – more specifically by acting on the design and operation of the installation, the sorting, treatment and packaging of the waste.

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 Decree of 2nd November 2007;
- the waste management study, which is part of the authorisation application file as described in Article 20 of the Decree of 2nd November 2007, the contents of which are specified in Article 6.4 of the 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 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.

In a resolution of 21st April 2015, ASN set requirements concerning the study of the management of waste and the summary of the waste produced in BNIs and specifies the operational procedures for waste management.

ASN Guide N° 23, published on 30th August 2016, gives recommendations for the definition and modification of the waste zoning plan for basic nuclear installations.

3.5.2 Decommissioning

Article L. 593-28 of the version of the Environment Code subsequent to the Act of 17th August 2015, 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.

The legal framework for BNI decommissioning, in particular the modifications made by the Act of 17th August 2015, is described in detail in chapter 15.

The final shutdown of a BNI is the responsibility of the licensee, which 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.

In a revised version of Guide No. 6, ASN specified the regulatory framework for the BNI decommissioning operations, following work to clarify the implementation of the administrative procedures (see chapter 15).

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, taking account of 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 of a BNI.

Guides N° 14 and N° 24 published on 30th August 2016 set out recommendations for the post-operational clean-out of structures, on the one hand and for management of soils contaminated by BNI activities, on the other.

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 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 the Decree of 23rd February 2007 concerning the secure financing of nuclear costs, modified by the Decree 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 these 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 facilities, 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 licensees 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.

In 2017, ASN issued its opinion on the consistency of the strategy submitted by the licensees in their three-yearly reports in 2016.

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, which integrates the principles of the "new European approach". New equipment must thus be designed and manufactured by its manufacturer in compliance with the essential safety requirements set out in the regulations and must undergo a conformity assessment by an ASN approved organisation.

These provisions are supplemented by requirements applicable to in-service monitoring of the equipment, set out in section 14 of Chapter VII of Title V of Book V of the Environment Code. These recommendations came into force on 1st January 2018. On this same date, Decree 99-1046 of 13th December 1999 relative to nuclear pressure equipment was repealed.

Pressure equipment specially designed for BNIs, known as "Nuclear Pressure Equipment" (NPE) is subject to both the BNI System and the pressure equipment system. For this equipment, specific Orders stipulate the provisions defined by the Environment Code. The Order in force is the 30th December 2015 Order on NPE.

ASN assesses the conformity of the NPE most important for safety and qualifies organisations for the other NPE. Once

TABLE 2: Regulations applicable to pressure equipment

	NUCLEAR PRESSURE EQUIPMENT		NON-NUCLEAR PRESSURE EQUIPMENT
	PWR REACTOR MAIN PRIMARY AND SECONDARY SYSTEMS	OTHER NUCLEAR PRESSURE EQUIPMENT	
GENERAL PROVISIONS	Chapter VII of Title V of Book V of the Environment Code		
	Titles I and IV of the Order of 30th December 2015		Chapter VII of Title V of Book V of the Environment Code
PROVISIONS CONCERNING NEW EQUIPMENT	Section 12 of Chapter VII of Title V of Book V of the Environment Code (regulatory part) Title II of the Order of 30th December 2015		Section 9 of Chapter VII of Title V of Book V of the Environment Code (regulatory part)
PROVISIONS CONCERNING IN-SERVICE MONITORING	Section 14 of Chapter VII of Title V of Book V of the Environment Code (regulatory part) Order of 10th November 1999	Section 14 of Chapter VII of Title V of Book V of the Environment Code (regulatory part) Title III of the Order of 12th December 2005	Section 14 of Chapter VII of Title V of Book V of the Environment Code (regulatory part) Order of 15th March 2000

in service, NPE 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 resolutions are available on *www.asn.fr*.

Furthermore, II of Article L. 593-33 of the Environment Code gives ASN competence to issue licensing decisions and check the in-service monitoring of non-nuclear pressure equipment installed in a BNI.

Table 2 presents regulations applicable to pressure equipment in BNIs.

4. Regulations governing the transport of radioactive substances

4.1 International regulations

The regulations applicable to transports of radioactive substances are based on the transport regulation called SSR-6, published by the IAEA. ASN takes part in the work by the IAEA committee tasked with drafting and updating this regulation.

ASN inspection on the topic of transport, Valognes, September 2015.

This regulation is not binding but its provisions, which are specific to radioactive substances, are integrated into the appendices of international agreements on the safety of the carriage of hazardous goods (which includes radioactive substances): the appendices of the European agreement on the International Carriage of Dangerous Goods by Road (ADR) for road transport, the regulation on the International Carriage of Dangerous Goods by Rail (RID) for rail transport, the appendices of the European agreement on the International Carriage of Dangerous goods by Inland Waterways (ADN) for river transport, the International Maritime Dangerous Goods Code (IMDG Code) for carriage by sea and the technical instructions of the International Civil Aviation Organisation (ICAO) for carriage by air.

France is a signatory to these various agreements, which are transposed in full into national law. For carriage by land (road, rail and inland waterways), European Directive 2008/68/CE of 24th September 2008 requires the application of the appendices to the ADR, RID and ADN within the European Union. This Directive is transposed into French law by a single order covering all carriage by land on the national territory. This is the Order of 29th May 2009 as amended concerning the carriage of dangerous goods by land, known as the "TMD" Order.

For carriage by sea, the Order of 23rd November 1987 concerning vessel safety, known as the "RSN Order" renders application of the IMDG code mandatory. Finally, for carriage by air, European regulation 859/2008 of 20th August 2008, known as "regulation EU OPS1", renders the ICAO's technical instructions directly applicable in French law and clarifies certain aspects.

The regulatory requirements applicable to the various modes of transport are all derived from IAEA regulation SSR-6. They more specifically concern package robustness, the reliability of transport operations, emergency management in accident situations and the radiation protection of workers and the public (see chapter 11).

4.2 National regulations

Issued pursuant to Articles L. 1252-1 et seq. of the Transport Code, the Order of 29th May 2009 transposes into French law the various international modal regulations and gives the nuclear safety inspectors appointed by ASN powers to oversee the application of its provisions concerning the transport of radioactive substances. It also states that ASN is consulted with regard to the modifications made to the Order of 29th May concerning its scope of competence and is asked to sit on the Interministerial Committee for the Carriage of Dangerous Goods (CITMD).

The Environment Code, more specifically its Article L. 595-1, and Article 62 of the implementing Decree of 2nd November 2007, state that ASN is the French Competent Authority to take licensing decisions and issue certificates for the carriage of radioactive substances. Pursuant to these provisions, the approvals required for the package models with the most significant potential consequences must be issued by ASN (see chapter 11).

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 companies transporting radioactive substances on French territory. This obligation entered into force in 2016. The notification is made on-line.

5. Requirements applicable to certain risks or certain particular activities

5.1 Sites and soils contaminated by radioactive substances

The tools and the approach to be followed for management of contaminated 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 contaminated by radioactive substances. ASN's prime objective is to achieve the most thorough cleanout possible, aiming for complete removal of the radioactive contamination to allow unrestricted use of the cleaned out premises and land. Nevertheless, when this objective cannot be technically and economically 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 TECV Act brought about a number of changes in this area, in particular in the Ordinance of 10th February 2016: the Government created a system of active institutional controls relating to radioactive substances, as already exists for 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, where necessary, to define restrictions on use or prescriptions governing future development or demolition work.

5.2 ICPEs utilising radioactive substances

Licensing by the Prefect, registration or simple notification is required for ICPEs depending on 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. Generally speaking, ASN is not involved in the oversight of ICPEs using radioactive substances, outside the perimeter of a BNI.

The list of classified installations (appendix to Article R. 511-9 of the Environment Code) which was modified at the beginning of 2018 with the transposition of Directive 2013/59/Euratom of 5th December 2013, defines the types of installations subject to this system and the applicable thresholds.

Four sections of the ICPE list concern radioactive substances:
- section 1716 for radioactive substances in unsealed form and naturally occurring radioactive substances utilised in an industrial or commercial facility and the total quantity of which exceeds one tonne, with the exception of particle accelerators and the medical sector subject to the provisions of the Public Health Code;
- section 2797 for the management of radioactive waste used in an industrial or commercial facility except for particle accelerators and the medical sector, when the quantity liable to be present exceeds 10 m^3 and the exemption conditions mentioned in 1° of I of Article R. 1333-80 of the Public Health Code are not met;
- section 2798 for transit installations for radioactive waste resulting from a nuclear or radiological accident;
- section 1735 for depots, 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 tonne.

It should be recalled that:
- 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 and naturally occurring radioactive materials are subject to the ICPE system; all sealed sources are subject to the Public Health Code.
- For waste disposal facilities which can contain naturally occurring radioactive materials, only those for which the activity of the natural radionuclides of the uranium and thorium series is greater than 20 Bq/g are subject to section 2797.
- Activities involving quantities of naturally occurring radioactive materials in excess of 1 tonne are subject to no particular system in accordance with the provisions of Article R. 1333-37 of the Public Health Code.

FUNDAMENTALS

List of natural materials and industrial residues concerned by the characterisation obligation (Article D. 515-110-1 of the Environment Code)

1° Extraction of rare earths from monazite, processing of rare earths and the production of pigments containing them

2° Production of compounds of thorium, manufacture of products containing thorium and the mechanical working of these products

3° Processing of niobium/tantalum and aluminium ore

4° Oil and gas production, except for exploratory drilling

5° Production of geothermal energy, except if carried out on a small scale

6° Production of titanium dioxide pigments

7° Thermal production of phosphorus

8° Zircon and zirconium industry, including the refractory ceramics industry

9° Production of phosphated fertilisers

10° Production of cement, including maintenance of clinker furnaces

11° Coal-fired power plants, including boiler maintenance

12° Production of phosphoric acid

13° Production of primary iron

14° Tin, lead, or copper foundry work

15° Treatment by filtration of groundwater circulating through igneous rocks

16° Extraction of natural materials of igneous origin such as granitoids, porphyries, tuff, pozzolan and lava, when intended for use as construction products.

In accordance with Articles L. 593-3 and L. 593-33 of the Environment Code, a facility on the ICPE list located within the perimeter of a BNI is subject to the BNI System if necessary for operation of the BNI and to the ICPE System otherwise.

Pursuant to 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 unsealed radioactive sources, take the place of the licences required under the Public Health Code. The legislative and regulatory provisions of the Public Health Code nonetheless apply to them, with the exception of those concerning procedures.

Finally in accordance with the provisions of Article R. 515-110 of the Environment Code, those responsible for industrial activities using naturally occurring radioactive sources, liable to cause gamma radiation exposure in excess of 1 mSv/year effective dose, are required to produce a radiological characterisation of the natural materials and industrial residues utilised. This characterisation shall be performed as of 1st July 2020 by an accredited organisation.

5.3 The regulatory framework for protection against malicious acts in nuclear facilities

Malicious acts include theft or misappropriation of nuclear materials, acts of sabotage and attacks from outside the BNIs.

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 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 of protection to facilities comprising a BNI *"when the destruction of or damage to (this BNI) could constitute a serious danger for the population"*. This system requires that the licensees take protection measures stipulated in an off-site emergency plan drawn up by themselves and approved by the administrative authority. These measures in particular include 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.

The Environment Code stipulates that, 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. In this case, the safety analysis report shall present the condition of the facilities after performance of the malicious act, in order to determine whether or not the creation authorisation can be issued, more particularly with regard to the emergency management measures taken. The most important risk prevention or mitigation measures can be the subject of ASN requirements.

Within a joint working group, ASN and the Defence and Security High Official 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. 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 of 17th August 2015, the Ordinance of 10th February 2016 and the implementing decree (see chapter 10, point 4.5)

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:
- Defence Basic Nuclear Installations (DBNI);
- 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 part of the provisions applicable to nuclear activities governed by ordinary law also applies 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 thus subject to particular information rules for protection of national defence confidentiality. Similarly, the nuclear facilities whose characteristics correspond to the BNI list but which are within the perimeter of a DBNI defined by decision of the Prime Minister, are not subject to the BNI System but to that of the special DBNI System defined by the Defence Code and implemented by the ASND (see section 2 of Chapter III of Title 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 DBNI has thus initiated a delicensing process, which should lead to registration by ASN of new BNIs, the first of which was registered on 1st December 2016.

ASN and ASND maintain close relations to ensure that the systems for which they are responsible are coherent and to ensure continuity of the oversight provided by the State on facilities making the transition from one system to the other.

6. Outlook

2018 will see the adoption of three decrees allowing the implementation of the legislative provisions adopted in 2015 and 2016 in the field of small-scale nuclear activities, as well as with regard to BNIs and the transport of radioactive substances. These decrees will renew the regulatory provisions of the Public Health Code, the Labour Code and the Environment Code. They will be followed by the adoption of the orders stipulated by the decrees, more particularly in the field of small-scale nuclear activities. In 2018, a new order will also be adopted concerning nuclear pressure equipment, which will be supplemented by several ASN resolutions and the revision of the Order of 7th February 2012 will be initiated.

ASN will be adopting or revising resolutions so that its regulation and oversight is more closely tailored to the issues, in particular with the implementation of rules applicable to noteworthy modifications to BNIs and the deployment of the new system of notification and registration of certain small-scale nuclear activities.

ASN will continue to draw up general technical regulations for BNIs and define the framework applicable to the protection of radioactive sources against malicious acts.

Appendix

The collection of ASN guides

No 1	Final disposal of radioactive waste in deep geological formations (February 2008)
No 2	Transport of radioactive materials in airports (February 2006)
No 3	Recommendations for drafting annual information reports for the public concerning Basic Nuclear Installations (October 2010)
No 4	Auto-assessment of risk exposure of patients receiving external radiotherapy (January 2009)
No 5	Management of radiotherapy safety and quality of treatment (April 2009)
No 6	Final shutdown, decommissioning and delicensing of Basic Nuclear Installations in France (August 2016)
No 7	Civil transport of radioactive packages or substances on the public highway: • Volume 1: Shipment certification and approval applications (February 2016). • Volume 2: Package models safety file, European “Package Design Safety Report” guide (December 2014). • Volume 3: Conformity of package models not requiring approval (November 2015).
No 8	Evaluation of nuclear pressure vessel conformity (September 2012)
No 9	Determining the perimeter of a BNI (October 2013)
No 10	Local involvement of CLIs in the 3rd ten-year outage of the 900 MWe reactors (June 2010)
No 11	Significant radiation protection event (excluding BNIs and radioactive material transports): notification and codification of criteria (July 2015)
No 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)
No 13	Protection of Basic Nuclear Installations against external flooding (January 2013)
No 14	Guide concerning the remediation of structures in BNIs (August 2016)
No 15	Control of activities in the vicinity of BNIs (March 2016)
No 16	Significant radiation protection event affecting a radiotherapy patient: declaration and classification on the ASN-SFRO scale (July 2015)
No 17	Contents of radioactive substance transport incident and accident management plans (December 2014)
No 18	Disposal of effluents and waste contaminated by radionuclides, produced in facilities licensed under the Public Health Code (January 2012)
No 19	Application of the Order of 12th December 2005 relating to nuclear pressure equipment (February 2013)
No 20	Drafting of the Medical Physics Organisation Plan (POPM) (April 2013)
No 21	Processing of non-compliance with a requirement defined for an Element Important for Protection (EIP) (January 2015)
No 22	Design of pressurised water reactors (July 2017) (Produced jointly with IRSN)
No 23	Definition and modification of the waste zoning plan for BNIs (August 2016)
No 24	Management of soils polluted by BNI activities (August 2016)
No 25	Preparation of an ASN regulation or guide Procedures for consultation with stakeholders and the public (October 2016)
No 26	*Control of the criticality risk in BNIs (draft)*
No 27	Tie-down of radioactive packages, materials or objects for transport (November 2016)
No 28	Qualification of scientific computing tools used in the nuclear safety case – 1st barrier (July 2017) (Produced jointly with IRSN)
No 29	*Radiation protection in radioactive substances transport activities (at project stage)*
No 30	*Protection of Interests Policy Integrated Management System (at project stage)*
No 31	Conditions for the notification of events during the transport of radioactive substances (April 2017 – applicable as of 1st July 2017)
No 32	*In vivo* nuclear medicine facilities: Minimum technical rules for design, operation and maintenance (May 2017)
No 33	*Intake and consumption of water, effluents discharge and monitoring of the environment of NPP PWR reactors (at project stage)*
No 34	Implementation of regulatory requirements applicable to on-site transport operations (June 2017)

Regulation exposure limits and dose levels

ANNUAL EXPOSURE LIMITS contained in the Public Health Code and in the Labour Code

REFERENCES	DEFINITIONS	VALUES	OBSERVATIONS
ANNUAL LIMITS FOR THE GENERAL PUBLIC			
Article R.1333-8 of the Public Health Code	• Effective dose	1 mSv/year	• 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.
	• Equivalent dose for the lens of the eye	15 mSv/year	
	• Equivalent dose for the skin (average dose over any area of 1 cm^2 of skin, regardless of the area exposed)	50 mSv/year	
WORKER LIMITS FOR 12 CONSECUTIVE MONTHS			
Article R. 4451-6-8 of the Labour Code	**Adults** • Effective dose • Equivalent dose for the hands, forearms, feet and ankles • Equivalent dose for the skin (average dose over any area of 1 cm^2 of skin, regardless of the area exposed) • Equivalent dose for the lens of the eye	20 mSv 500 mSv 500 mSv 150 mSv**	• 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.
	Pregnant women • Exposure of the child to be born	1 mSv	
	Young people from 15 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	6 mSv 150 mSv 150 mSv 50 mSv**	

** Only if covered by waivers, such as for apprentices.*
*** These limits will be modified by the decree under preparation concerning the protection of workers against the risks arising from ionising radiation (see point 1.2.1).*

MAXIMUM PERMITTED LEVELS 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 OU 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 ^{134}Cs and ^{137}Cs	400	1,000	1,250	1,000

Source: Council regulation 2016/52/Euratom of 15th January 2016.

Appendix

Regulation exposure limits and dose levels after

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.

OPTIMISATION LEVELS for patient protection (Public Health Code)

REFERENCES	DEFINITIONS	VALUES	OBSERVATIONS
DIAGNOSTIC EXAMINATIONS			
Diagnostic reference level Article R.1333-68, Order of 16th February 2004	Dose levels for standard diagnostic examinations	Ex.: entrance dose of 0.3 mGy or dose area product (DAP) of 25 $cGy.cm^2$ for a single incidence for a frontal posteroanterior chest X-ray)	• 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
Dose constraint Article R.1333-65, Order of 7th November 2007	Used when exposure offers no direct medical benefit to the person exposed.		The dose constraint can be a fraction of a diagnostic reference level, in particular for exposure in the context of biomedical research or forensic procedures
RADIOTHERAPY			
Target dose level Article R.1333-63	Dose necessary for a target organ or tissue in radiotherapy (experimentation)		The target dose level (the term target volume is used in radiotherapy) is used to calibrate the equipment

INTERVENTION TRIGGER LEVELS in cases of radiological emergencies (Public Health Code)

REFERENCES	DEFINITIONS	VALUES	OBSERVATIONS
PROTECTION OF THE POPULATION			
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 technical or medical intervention teams • 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

** The provisions concerning protection of workers in a radiological emergency situation will be introduced and modified in the Labour Code (see point 1.2.1).*

Regulation of nuclear activities and exposure to ionising radiation

04

In France, the party responsible for a nuclear activity must ensure that this activity is safe. 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.

Control and regulation of nuclear activities is a fundamental responsibility of ASN. Its aim is to verify that all licensees fully assume their responsibility and comply with the requirements of the regulations relative to nuclear safety and radiation protection, in order to protect people 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 substances. It consists in performing spot checks on the conformity of a given situation with regulatory or technical baseline requirements but may also include an assessment of the licensee's practices by comparison with current best practices. 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 non-compliance found during the inspection can lead to administrative or criminal penalties.

Nuclear activities are also regulated by ASN through various actions:
- authorisation, following analysis of the applicant's demonstration that its activities are satisfactorily managed in terms of radiation protection and safety;
- operating experience feedback, more specifically through analysis of significant events;
- approval of organisations and laboratories taking part in radioactivity measurements and radiation protection inspections and qualification of pressure equipment monitoring organisations;
- presence in the field, also frequently outside actual inspections.

ASN has a vision of control and regulation encompassing material, organisational and human aspects. Following safety and radiation protection assessments in each activity sector, its inspections lead to issue of resolutions, binding requirements, inspection follow-up documents, plus penalties as applicable.

In 2017, ASN decided to make the scope and depth of the inspections more adaptable, by taking account of both the risks inherent in the activities and the behaviour of those responsible for the activity. These changes will be implemented as of 2018.

1. Verifying that the licensee assumes its responsibilities

1.1 The principles of ASN's oversight duties

ASN oversight aims primarily to ensure that those responsible for an activity effectively meet their obligations. 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 human and environmental protection implications involved.

When applicable, this oversight can call on the support of the French Institute for Radiation Protection and Nuclear Safety (IRSN)

It applies to all the phases of 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 oversight includes an analysis of any justifications provided by the licensee.

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 oversight and the exchange of best practices with its foreign counterparts.

1.2 The scope of regulation of nuclear activities

Article L. 592-22 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;
- the manufacturers and users of Nuclear Pressure Equipment (NPE) used in the 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;
- the nuclear licensees, their suppliers, contractors or sub-contractors when they carry out activities important for the protection of persons and the environment outside the perimeter of the BNIs.

In this chapter, these persons or entities 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).

Although historically focused on verifying the technical conformity of installations and activities with regulations and standards, oversight now encompasses a broader dimension taking in social, human and organisational factors. It takes account of individual and group behaviours, management, organisation and procedures.

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 or qualification, contribute to the oversight of nuclear activities.

2.1 Definition of the implications

In order to take account of health and environmental issues on the one hand, and licensee safety and radiation protection performance on the other and the large number of activities for which it has oversight, ASN identifies and regularly reassesses its regulation and oversight priorities. It conducts regular 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 2017, the inspections focused on the following topics or activities:
- compliance of spare parts fitted to nuclear reactors;
- maintenance of steam generators;
- management of emergency situations and emergency management in BNIs other than reactors;
- removal of spent fuel, shipment from BNIs of packages not requiring approval, examination of package compliance at the moment of shipment, radiation protection of drivers and inspections on package stowage;
- interventional imaging;
- industrial radiography.

In order to identify these activities and topics, ASN relies on current scientific and technical knowledge and considers 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 and information resulting from checks by approved organisations. It adapts its priorities to take account of significant events occurring in France or around the world.

2.2 Oversight by ASN

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 oversight is achieved by examining files primarily concerning the licensing of nuclear activities, conducting pre-commissioning inspections of facilities and inspections, obtaining feedback from events and, finally, consulting professional organisations (trades unions, professional orders, learned societies, etc.).

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.

Regulation and monitoring of Basic Nuclear Installations

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 (see chapter 3). This notion 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, the Environment Code defines ASN as the organisation meeting these criteria, except for defence-related nuclear facilities and activities, which are regulated by the provisions of the Defence Code.

Ordinance 2016-128 of 10th February 2016 implementing the Energy Transition for Green Growth Act 2015-992 of

ASN inspection at the Chooz NPP, March 2017.

17th August 2015 (TECV Act) expanded the scope of ASN regulation to the suppliers, contractors and subcontractors of licensees, including for activities performed outside BNIs.

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 equipment

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 NPE (see chapter 3, point 3.6).

The Environment Code states that ASN is the administrative Authority with competence for issuing licensing decisions 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.

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 receipt at the final destination of the radioactive substance consignments and packages (see chapter 11).

The safety of the transport of radioactive substances is based on three successive barriers:
- primarily, the robustness of the packages;
- the reliability of the transport operations;
- 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 the role by drafting and monitoring technical regulations concerning radiation protection (see chapter 3, point 1).

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 for Protection of the Environment, 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 1. They will change with the publication of the decrees transposing European Directive 2013/59/Euratom of 5th December 2013 setting the Basic Standards for Health Protection against the dangers arising from exposure to ionising radiation, scheduled for early 2018.

Regulating the application of Labour Law in the nuclear power plants

ASN carries out labour inspectorate duties in the 58 reactors in operation (spread around the 19 nuclear power plants), the eight reactors undergoing decommissioning and the EPR reactor under construction at Flamanville. 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:
- checking application of all aspects of labour legislation (health, occupational safety and working conditions, occupational accident inquiries, quality of employment, collective labour relations);
- advising and informing the employers, employees and personnel representatives about their rights, duties and labour legislation;
- informing the administration of changes in the working environment and any shortcomings in the legislation;
- facilitating conciliation between the parties.

TABLE 1: Methods of ASN regulation of the various radiation protection players

	INSTRUCTION/AUTHORISATION	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 ASN labour inspectors have the same powers and the same prerogatives as common law labour inspectors. They belong to the labour inspectorate system for which the central authority is the General Directorate for Labour.

The duties of the labour inspectors are based on international standards (International Labour Organisation 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 (6.7 Full-Time Equivalent - FTE) in the field has increased 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.

2.3 Main 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).

2.3.1 BNI licensee internal oversight

In 2017, ASN adopted a resolution concerning operations taking place within the BNIs. This resolution identifies the administrative procedures to be implemented in the event of changes to a BNI, its authorised operating procedures, aspects which led to its authorisation or its commissioning authorisation, or its decommissioning conditions. This resolution more particularly identifies the organisational measures regarding internal oversight to be implemented by the licensee to guarantee management of the design and performance of the modifications eligible for the administrative system of notification.

ASN checks correct application of the provisions stipulated by the above-mentioned resolution.

The above-mentioned resolution replaces the internal authorisations system, which was regulated by Decree 2007-1557 of 2nd November 2007 and ASN resolution 2008-DC-0106 of 11th July 2008 concerning the procedures for implementation of internal authorisation systems within BNIs. This system was the subject of prior approval by an ASN resolution which defines:
- 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.

This system may last until 1st January 2019 for those facilities benefiting from such a resolution, the provisions of which are checked by ASN during inspections.

2.3.2 Internal monitoring of radiation protection by the users of ionising radiation sources

The current 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 Radiation Protection Expert-Officer (RPE-O), 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. As a result of the transposition of Directive 2013/59/Euratom of 5th December 2013, this system will inevitably change.

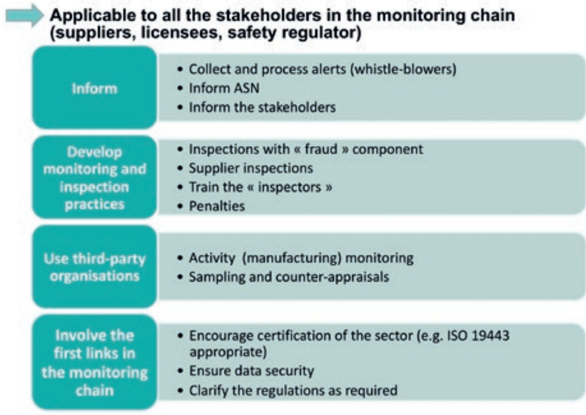
FOCUS

Prevention and detection of fraud

Since the end of 2015, a number of irregularities, one might even say falsifications, have been brought to light in France and other countries at known, monitored manufacturers and suppliers who have been working for the nuclear sector for many years. These anomalies call into question the entire control chain, at the top of which are the manufacturers, suppliers and licensees. ASN is examining ways of modifying the oversight and monitoring of the various stakeholders, in order to improve the prevention and detection of this type of irregularity.

The main aspects identified concern:
- information of the stakeholders, including implementation of a system for collecting alerts from whistle-blowers;
- changes to monitoring and inspection practices;
- the use of third-party organisations to take part in the inspection activities;
- the close involvement of the first links in the control chain.

The resulting action plan will be finalised in the first half of 2018.



2.4 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.

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 NPE conformity and inspection of pressure equipment in service.

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.

The checks carried out by these organisations contribute to ASN's overview of all nuclear activities.

In 2016, the Organisations Approved for Radiation Protection inspections (OARP) carried out 74,514 inspections, for which the breakdown per type of source and per field is given in Table 2 that follows.

The external inspection reports performed in each facility by the OARP are at the disposal of and examined by ASN personnel on the occasion of:
- licence renewals or modifications requiring ASN authorisation;
- inspections.

Examination of these reports on the one hand makes it possible to check that the external inspections have actually been carried out and, on the other, enables the licensees to be questioned about the steps taken to remedy any nonconformities.

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 the monitoring of:
- environmental radioactivity (see point 4);
- 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 2017, the following are approved by ASN:
- 41 organisations tasked with radiation protection checks; 11 approvals or approval renewals were delivered in 2017;
- 58 organisations tasked with measuring radon activity concentration in buildings. Nine of these organisations can also carry out measurements in cavities and underground structures, while 6 are approved to identify sources and means of radon ingress into buildings. In 2017, ASN issued 41 new approvals or approval renewals;

TABLE 2: Number of radiation protection inspections performed in 2016 by organisations approved for radiation protection inspections

TYPE OF SOURCE / FIELD	MEDICAL	VETERINARY	RESEARCH / TEACHING	INDUSTRY OUTSIDE BNIS	BNI	TOTAL
SEALED SOURCES	1,544	463	3,557	12,521	21,154	39,239
UNSEALED SOURCES	401	10	1,763	1,758	7,456	11,388
MOBILE GERI*	4,070	288	44	705	9	5,116
FIXED GERI	8,600	935	809	4,357	184	14,885
PARTICLE ACCELERATORS	472	2	69	120	17	680
DENTAL	3,206	0	0	0	0	3,206
TOTAL	18,293	1,698	6,242	19,461	28,820	74,514

** Generator of ionising radiation*

- 14 organisations tasked with the monitoring of worker internal dosimetry, 7 for external monitoring and 2 for monitoring exposure associated with natural radioactivity (one for internal exposure and one for external exposure). In 2017, ASN issued 6 new approvals or approval renewals;
- 5 organisations tasked with NPE inspections;
- 3 organisations qualified for Nuclear Pressure Equipment (NPE) and Simple Pressure Vessels (RPS) within the perimeter of BNIs (in-service monitoring);
- 19 inspection departments qualified for in-service monitoring of NPE and RPS within the perimeter of NPPs;
- 65 laboratories for environmental radioactivity measurements covering 880 approvals, of which 123 are approvals or approval renewals delivered during 2017.

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 tank trailers[1] ;
- the initial and periodic checks of tank trailers for transport of class 7 hazardous substances by land.

FOCUS

ASN reinforces the graduated approach for regulation of industrial small-scale nuclear activities

In 2016, ASN initiated work to examine the revision of its oversight system in the small-scale nuclear sector, at a time of changing regulations linked to the transposition of the European Directive on Basic Radiation Protection Standards. The purpose of this reassessment was to reinforce the efficiency of this system on the basis of an approach that is appropriate to and commensurate with the risks.

In 2017, this work led to:

- revision and adaptation of the inspection methods to the new administrative systems;
- redefinition of the categories of activities with inspection priority;
- improved targeting, for an inspection, of the essential points of the inspection.

3. Efficient regulation and oversight

3.1 Inspection

3.1.1 Inspection objectives and principles

The inspection carried out by ASN is based on the following principles:

- The inspection aims to verify compliance with the provisions that are mandatory under the regulations. It also aims to assess the situation with regard to the nuclear safety and radiation protection implications; it seeks to identify best practices, practices that could be improved and assess possible developments of the situation.
- The scope and depth of the inspection is adjusted to the risks inherent in the activity and the way they are effectively taken into account by those responsible for the activity.
- The inspection is neither systematic nor exhaustive, is based on sampling and focuses on subjects with the greatest potential consequences.

1. *For each new type of tank trailer, an organisation approved by ASN must issue a type approval certificate. This certificate confirms that the tank trailer 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 tank trailers is manufactured with no change to the design, the certificate is valid for the entire series.*

3.1.2 Inspection resources implemented

To ensure greater efficiency, ASN 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;
- technical inspections of approved organisations.

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;
- reinforced inspections, which consist in conducting an in-depth examination of a targeted topic by a larger team of inspectors than for a routine inspection;
- 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. With regard to both discharges and the environment of the facilities, these are designed to check 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.

Labour inspectorate duties in NPPs 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 (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;
- best practices or practices to which improvements could be made, even if not directly constituting requirements.

Some inspections are carried out with the support of an IRSN representative specialised in the facility checked or the topic of the inspection.

ASN inspectors

ASN has inspectors designated and accredited by its Chairman, in accordance with the conditions defined by Decree 2007-831 of 11th May 2007 setting the procedures for appointing and accrediting nuclear safety inspectors, subject to their having acquired the requisite legal and technical skills through professional experience, mentoring or training courses.

The inspectors take an oath and are bound by 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 several 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 experience to be shared 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. This choice also allows 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, 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 2017. 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 51% of the ASN inspectors. The 152 inspectors assigned to the departments take part in ASN inspections within their field of competence; they represent 49% of the inspector headcount and performed 17% of the inspections in 2017.

In 2017, 1,751 inspections were carried out, including 635 in the BNIs, 94 in activities linked to Pressure Equipment,

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 2017)

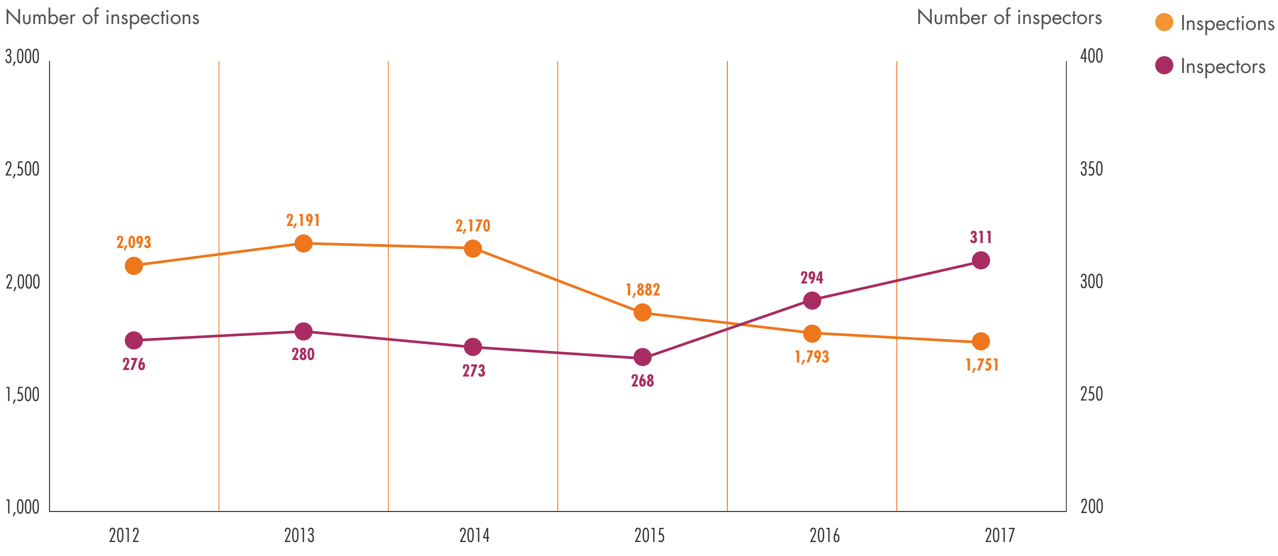
INSPECTOR CATEGORY (QUALIFICATION DOMAIN)	DEPARTMENTS	DIVISIONS	TOTAL
Nuclear safety inspector* (BNI)	130	103	**233**
of which nuclear safety inspector (transport)	*13*	*23*	***36***
Radiation protection inspector	39	104	**143**
Labour inspector	0	18	**18**
Number of inspectors all domains	152	159	**311**

* *Since 2016, the staff responsible for the inspection of nuclear pressure equipment have become nuclear safety inspectors*

TABLE 4: Trend in number of inspections performed from 2012 to 2017

	NUMBER OF INSPECTIONS CARRIED OUT					
YEAR	BASIC NUCLEAR INSTALLATION (BNI)	PRESSURE EQUIPMENT	TRANSPORT OF RADIOACTIVE SUBSTANCES	SMALL-SCALE NUCLEAR ACTIVITIES	APPROVED ORGANISATIONS AND LABORATORIES	TOTAL
2017	635	94	111	811	100	**1,751**
2016	561	88	106	911	127	**1,793**
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**

GRAPH 1: Trend in the number of ASN inspections and inspectors from 2012 to 2017



111 in radioactive substances transport activities, 811 in activities employing ionising radiation and 100 in approved organisations and laboratories. These 1,751 inspections represent 1,845 days of actual inspection in the field.

Graph 1 shows the trend in the number of inspections and inspectors between 2012 and 2017.

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, ASN drafts a forecast inspections schedule every year, taking account of the inspection implications (see point 2.1). This schedule is not communicated to the licensees or to those in charge of nuclear activities.

ASN monitors the performance of the programme and the follow-up given to the inspections, through periodic reviews. This enables the inspected activities to be assessed and contributes 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*.

3.1.3 Inspection of Basic Nuclear Installations (BNIs) and pressure equipment

In 2017, 729 inspections were carried out to check BNIs and PE, more than 25% of which were unannounced.

These inspections can be broken down into 359 inspections in the NPPs, 276 in the other BNIs (fuel cycle facilities, research facilities, facilities undergoing decommissioning, etc.) and 94 for pressure equipment. In 2017, an in-depth inspection was carried out on CEA's Cadarache site, on the subject of waste management.

The ASN labour inspectors also carried out 671 interventions during the 275 inspection days in the NPPs.

The inspection breakdown by family of topics is shown in Graph 2.

3.1.4 Inspection of radioactive substances transport

ASN carried out 111 inspections on transport activities, 39% of which were unannounced; their breakdown into topics is illustrated in Graph 3.

3.1.5 Inspection in the 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 2017, ASN carried out 811 inspections - 12% 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 (55%), industrial or research (37%) and veterinary (4.5%) sectors.

The breakdown of small-scale nuclear sector inspections according to the various activity categories is described in Graph 4.

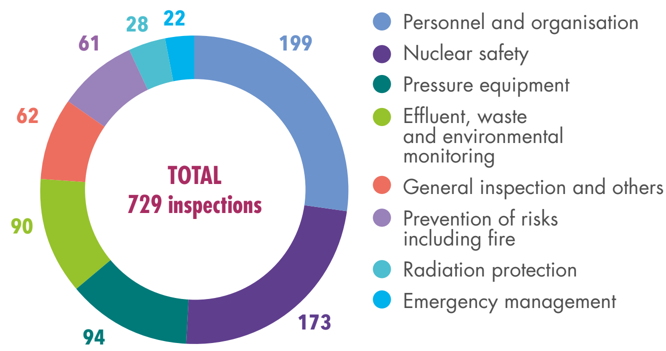
3.1.6 Inspection of ASN approved organisations and laboratories

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 actions such as:

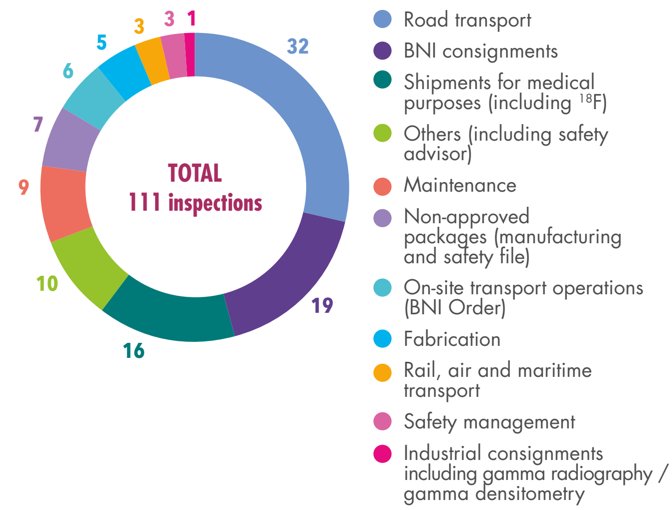
- approval audits (initial or renewal audit);
- checks to ensure that the organisation and operation of the entity concerned comply with the applicable requirements;
- checks, which are usually unannounced, to ensure that the organisation's staff work in satisfactory conditions.

In 2017, ASN carried out 100 inspections on approved organisations and laboratories, 38% of which were unannounced.

GRAPH 2: Breakdown of BNI inspections in 2017 by topic



GRAPH 3: Breakdown of radioactive substances transport inspections in 2017



GRAPH 4: Breakdown of small-scale nuclear activity inspections in 2017 per type of activity

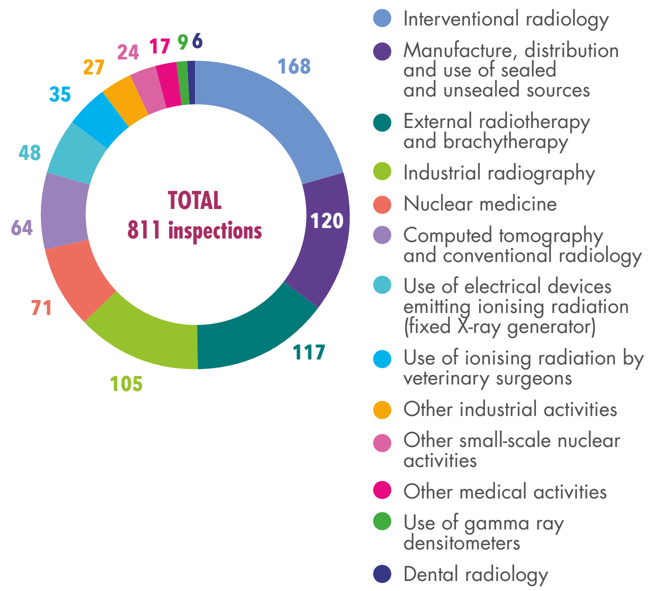


TABLE 5: Number of organisations approved for measuring radon levels

	APPROVAL UNTIL 15TH SEPTEMBER 2018	APPROVAL UNTIL 15TH SEPTEMBER 2019	APPROVAL UNTIL 15TH SEPTEMBER 2020	APPROVAL UNTIL 15TH SEPTEMBER 2021	APPROVAL UNTIL 15TH SEPTEMBER 2022
Level 1 option A*	19	5	8	15	11
Level 1 option B**	5	0	0	1	3
Level 2***	1	0	1	3	1

** Workplace and premises open to the public for all building types*
*** Workplace, cavities and underground structures (except buildings)*
**** Represents complementary investigations*

3.1.7 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 2017-2018 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 defined 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. In these activities, the materials used contain natural radionuclides 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.

3.2 Assessment of the demonstrations provided 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.

3.2.1 Analysing the files transmitted by (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 – assesses the safety analysis reports describing and justifying the design principles, equipment and system design calculations, utilisation rules and test procedures, and quality organisation provisions implemented by the prime contractor and its suppliers. It also analyses the facility's environmental impact assessment. ASN regulates and oversees the construction and manufacture of structures and equipment, in particular that of the main primary system and the main secondary systems of pressurised water reactors. 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 the environment, are notified to ASN or submitted to it for authorisation. 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 binding requirements for continued operation (see chapter 12 point 2.9.4).

The other files submitted by BNI licensees

There is a considerable volume of files on specific topics such as fire protection, PWR fuel management strategies, relations with contractors, and so on.

The licensee also periodically submits activity reports and summary reports on water intake, liquid and gaseous discharges and the waste produced.

3.2.2 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. Authorisations and renewals 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.

3.3 Lessons learned from significant events

3.3.1 Anomaly detection and analysis

History

The international Conventions ratified by France (Article 19vi of the Convention on Nuclear Safety of 20th September 1994; 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) 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. Ten years previously, the “Quality Order” of 10th August 1984 already required the adoption of this working method.

Based on thirty 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 three guides defining the principles and reiterating the obligations binding on the licensees with regard to notification of incidents and accidents:

- The Guide of 21st October 2005 contains the requirements applicable to BNI licensees and to on-site transport managers. It concerns significant events affecting the nuclear safety of BNIs, radioactive material transports taking place inside the perimeter of the BNI or an industrial site and without using the public highway, radiation protection and protection of the environment.
- Guide No. 11 of 7th October 2009, updated in July 2015, contains provisions applicable to those in charge of nuclear activities as defined in Article L. 1333-1 of the Public Health Code and to the heads of the facilities in which ionising radiation is used (medical, industrial and research activities using ionising radiation).
- Guide No. 31 which describes procedures for the notification of events relating to the transport of radioactive substances (see chapter 11). This guide has been applicable since 1st July 2017.

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. The regulations have defined a category of anomalies called “significant events”. These events 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 (Article 2.6.4), the Public Health Code (Articles L. 1333-3 and R. 1333-109 to R. 1333-111), the Labour Code (Article R.4451-99) and the regulatory texts applicable to the transport of radioactive substances (for instance, the Agreement on the carriage of dangerous goods by road).

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 players (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 from 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 compliance. The trend in the number of events does not therefore reflect any real trend in the safety level of the facility concerned.

ASN takes part in the INES consultative committee, a body comprising experts in the evaluation of the significance of radiation protection and nuclear safety events, tasked with advising the IAEA and the INES national representative of the member countries on the use of the INES scale and its updates.

3.3.2 Implementation of the approach

Event notification

The licensee of a BNI or the person responsible for the transport of radioactive substances is obliged to notify ASN and the administrative authority, without delay, of any accidents or incidents that occur on account of the operation of that installation or the transport activity and which could significantly prejudice the interests mentioned in Article L. 593-1 of the Environment Code.

Similarly, the party responsible for a nuclear activity must notify any event which could lead to accidental or unintentional exposure of persons to ionising radiation and liable to significantly prejudice the protected interests.

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.

The ASN 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 also carry out a more wide-ranging examination of the operating feedback from the events. The significant event reports and the periodic reviews sent by the licensees, as well as the assessment by ASN and IRSN, constitute the basis of operating experience feedback. The examination of operating experience feedback may lead to ASN requests for improvements to the condition of the facilities and the organisation adopted by the licensee, but also to 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 et seq. 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.

3.3.4 Statistical summary of events

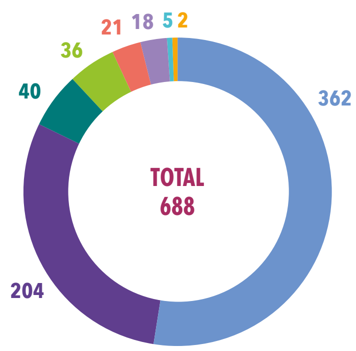
In 2017, ASN was notified of:
- 1,165 significant events concerning nuclear safety, radiation protection and the environment in BNIs; 1,040 of these events were rated on the INES scale (949 events rated level 0, 87 events rated level 1 and 4 event rated level 2). Of these events, 18 significant events were rated as "generic events" including 3 at level 1 on the INES scale and 3 at level 2;
- 66 significant events concerning the transport of radioactive substances, including 2 level 1 events on the INES scale;
- 655 significant events concerning radiation protection in small-scale nuclear activities, including 183 rated on the INES scale (of which 36 were level 1 events and 3 level 2).

2017 was marked by several events rated level 2 on the INES scale in the field of NPPs and in the medical field. Details are given on these events in chapter 2 with regard to the medical events and in chapter 12 with regard to events concerning the NPPs.

As indicated earlier, these data must 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.

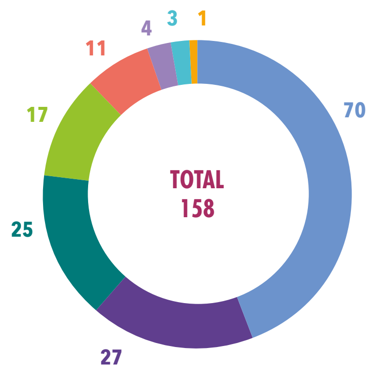
The distribution of significant events rated on the INES scale is specified in Table 6. As the INES scale does not apply to significant events concerning patients, the rating on the ASN-SFRO[3] scale of significant events affecting one or more radiotherapy patients is described in chapter 9.

GRAPH 5: Events involving safety in NPPs, notified in 2017



- Deviation from Operational Technical Specifications (STE) or event which could lead to a deviation
- Other significant events which could affect safety
- Transition to shutdown state in accordance with STE or accident procedures
- Automatic reactor trip
- Design, manufacturing or assembly anomaly
- Inadvertent start-up of a protection or safeguard system
- Occurrence of an internal or external natural hazard (flood, fire, etc.)
- 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 2017



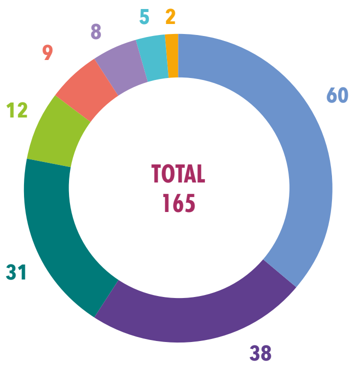
- Event which led to safety limit(s) being exceeded
- Event actually or potentially affecting the containment of hazardous materials
- Other significant events which could affect safety
- Fault, deterioration or failure which affected a safety function
- Inadvertent start-up of a protection or safeguard system
- Event which led to or which could have led to the dispersal of hazardous materials
- Internal or external hazard affecting the availability of important equipment
- Event affecting a safety function and potentially constituting an accident precursor

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 a radiotherapy medical procedure.*

TABLE 6: Rating of significant events on the INES scale between 2012 and 2017

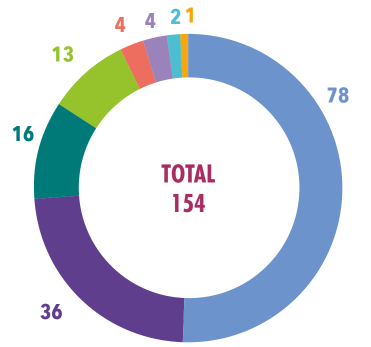
		2012	2013	2014	2015	2016	2017
Basic Nuclear Installations (BNIs)	Level 0	920	905	872	848	847	949
	Level 1	110	103	99	89	101	87
	Level 2	2	2	0	1	0	4
	Level 3 and +	0	0	0	0	0	0
	TOTAL BNI	1,032	1,010	971	938	948	1,040
Small-scale nuclear activities (medical and industry)	Level 0	118	130	157	126	111	144
	Level 1	33	22	34	25	30	36
	Level 2	1	2	4	2	0	3
	Level 3 and +	0	0	0	0	0	0
	TOTAL NPX	152	154	195	153	141	183
Transport of radioactive substances	Level 0	52	50	60	56	59	64
	Level 1	6	1	3	9	5	2
	Level 2	1	0	0	1	0	0
	Level 3 and +	0	0	0	0	0	0
	TOTAL TSR	59	51	63	66	64	66
	TOTAL	1,243	1,215	1,229	1,157	1,153	1,289

GRAPH 7: Significant environment-related events in BNIs notified in 2017



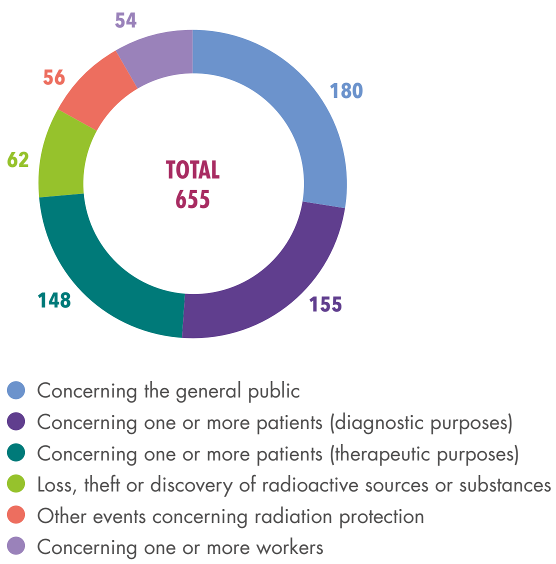
- Non-compliance with the Order of 31st December 1999
- Other significant events which could affect the environment
- Bypassing of normal discharge channels, with a significant impact due to chemical substances
- Non-compliance with an operational requirement which could lead to a significant impact
- Confirmation that a discharge or concentration limit has been exceeded
- Non-compliance with the site or facility waste study
- Bypassing of normal discharge channels, with a significant impact due to radioactive substances
- Discovery of a site significantly polluted by chemical or radioactive materials

GRAPHI 8: Events involving radiation protection in BNIs notified in 2017

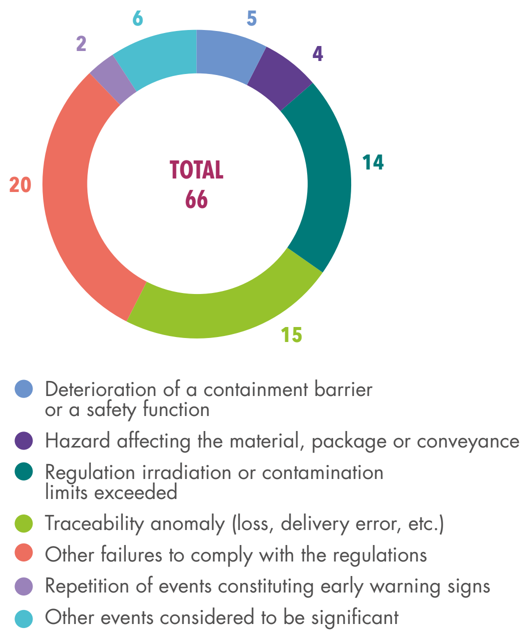


- Other significant event which could affect radiation protection
- Signage anomaly or failure to comply with zone access conditions
- Any significant deviation concerning radiological cleanness
- Abnormal situation affecting a source with activity higher than the exemption thresholds
- One quarter of the annual dose limit exceeded or event capable of leading to such a situation
- Radiological monitoring device inspection interval exceeded
- Activity with a radiological risk performed without risk assessment or ignoring its findings
- Uncompensated failure of radiological monitoring systems

GRAPH 9: Events involving radiation protection (other than BNIs and RMT) notified in 2017



GRAPH 10: Events involving the transport of radioactive substances notified in 2017



Likewise, 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 2017, 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 that 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 work by the ANSM, the medical activities inspectorate work 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, jointly with ASN.

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;
- approvals and accreditations it issues or rejects;
- incident notifications;
- the results of reactor outages;
- its publications on specific subjects.

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

The BNI Order of 7th February 2012 and ASN resolution 2013-DC-0360 of 16th July 2013, amended, set the general requirements applicable to any BNI with regard to their water intake and discharges. In addition to these provisions, in its resolution 2017-DC-0588 of 6th April 2017, ASN defined the conditions for water intake and consumption, effluent discharge and environmental monitoring applicable more specifically to pressurised water nuclear reactors. This resolution was approved by the Minister for Ecological and Solidarity-based Transition in an Order of 14th June 2017.

Apart from the above-mentioned general provisions, ASN resolutions set specific requirements for each facility, more particularly the water intake and discharge limits.

Monitoring discharges from BNIs

The monitoring of discharges from an installation is essentially the responsibility of the licensee. The requirements 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, water, 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 twenty inspections - with sampling- every year.

2016-2021 Micro-pollutants Plan

The 2016-2021 Micro-pollutant Plan[4] designed to preserve the quality of water and biodiversity, presented by the Minister for Ecology in September 2016, aims to protect surface waters, groundwaters, biota, sediments and waters intended for human consumption from all molecules liable to pollute the water resources, more particularly those previously identified during campaigns to Search for Hazardous Substances in Water (RSDE). This plan aims to meet the good water quality objectives set by the framework directive on water and contributes to those of the framework strategy directive for the marine environment, by limiting the input of pollutants into the marine environment from water courses.

For NPPs, the RSDE campaigns reached the conclusion that copper and zinc discharges in particular needed to be monitored. Under the Micro-pollutants Plan, the ASN actions initiated in 2017 comprise three parts:

- monitor the effective implementation of the action plan proposed by EDF to reduce discharges of copper and zinc (gradual replacement of the brass condenser tubes with stainless steel or titanium tubes);
- monitor the discharge trends for these substances;
- if necessary revise the individual requirements applicable to NPPs, setting emission limits for these molecules.

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 2016 relative to control of the detrimental effects and the impact of Basic Nuclear Installations on health and the environment, amended by the ASN resolution 2016-DC-0569 of 29th September 2016. These rules were set so as to avoid any under-estimation of the discharge values notified by the licensees.

For discharges of radioactive substances, accounting is not based on overall measurements, but on an analysis per radionuclide, introducing the notion of a "reference 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 page 145) are considered to be at the decision threshold level.

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 formulating recommendations to improve the efficiency of the regulations was presented in October 2016 to the Advisory Committee for Radiation Protection, for industrial and research applications of ionising radiation and the environment. ASN consulted the stakeholders on this subject in 2017 and will publish this report in 2018, along with its recommendations.

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

4. *A micro-pollutant can be defined as being an undesirable substance that can be detected in the environment in very small concentrations (microgram per litre or even nanogram per litre). Its presence is due, at least in part, to human activity (Industrial processes, agricultural practices or day to day activities) and it may, at these very small concentrations, create negative effects on living organisms owing to its toxicity, its persistence and its bioaccumulation.*

TABLE 7: Radiological impact of BNIs since 2011 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	REFERENCE GROUP MOST EXPOSED IN 2016	DISTANCE TO SITE IN km	ESTIMATION OF RECEIVED DOSES, IN mSv[a]					
			2011	2012	2013	2014	2015	2016
Andra / CSA	CD24	2.1	3.10^{-6}	1.10^{-5}	1.10^{-6}	2.10^{-6}	2.10^{-6}	2.10^{-6}
Andra's Manche repository	Hameau de La Fosse	2.5	4.10^{-4}	4.10^{-4}	3.10^{-4}	3.10^{-4}	2.10^{-4}	2.10^{-4}
Areva NP in Romans	Ferme Riffard	0.2	6.10^{-4}	6.10^{-4}	5.10^{-4}	3.10^{-4}	3.10^{-4}	3.10^{-4}
Areva / La Hague	Digulleville	2.8	9.10^{-3}	9.10^{-3}	2.10^{-2}	2.10^{-2}	2.10^{-2}	2.10^{-2}
Areva / Tricastin (Areva NC, Comurhex, Eurodif, Socatri, SET)	Les Girardes	1.2	[d]	3.10^{-4}	3.10^{-4}	3.10^{-4}	3.10^{-4}	2.10^{-4}
CEA / Cadarache [b]	Saint-Paul-Lez-Durance	5	3.10^{-3}	2.10^{-3}	2.10^{-3}	2.10^{-3}	1.10^{-3}	$<2.10^{-3}$
CEA / Fontenay-aux-Roses [b]	Achères	30	1.10^{-5}	3.10^{-5}	3.10^{-5}	1.10^{-4}	2.10^{-4}	$<2.10^{-4}$
CEA / Grenoble [c]	-	-	2.10^{-9}	2.10^{-8}	5.10^{-9}	[e]	[e]	[e]
CEA / Marcoule [b] (Atalante, Centraco, Phénix, Mélox, CIS bio)	Codolet	2	3.10^{-4}	2.10^{-4}	2.10^{-4}	2.10^{-3}	2.10^{-5}	$<2.10^{-3}$
CEA / Saclay [b]	Christ de Saclay	1	6.10^{-4}	1.10^{-3}	2.10^{-3}	2.10^{-3}	2.10^{-3}	$<2.10^{-3}$
EDF / Belleville-sur-Loire	Beaulieu-sur-Loire	1.8	8.10^{-4}	8.10^{-4}	7.10^{-4}	4.10^{-4}	5.10^{-4}	4.10^{-4}
EDF / Blayais	Braud et Saint-Louis	2.5	6.10^{-4}	2.10^{-4}	2.10^{-3}	6.10^{-4}	5.10^{-4}	5.10^{-4}
EDF / Bugey	Vernas	1.8	5.10^{-4}	6.10^{-4}	4.10^{-4}	2.10^{-4}	2.10^{-4}	9.10^{-5}
EDF / Cattenom	Koenigsmacker	4.8	3.10^{-3}	3.10^{-3}	5.10^{-3}	8.10^{-3}	7.10^{-3}	9.10^{-3}
EDF / Chinon	La Chapelle-sur-Loire	1.6	5.10^{-4}	5.10^{-4}	3.10^{-4}	2.10^{-4}	2.10^{-4}	2.10^{-4}
EDF / Chooz	Chooz	1.5	1.10^{-3}	9.10^{-4}	2.10^{-3}	7.10^{-4}	6.10^{-4}	6.10^{-4}
EDF / Civaux	Valdivienne	1.9	7.10^{-4}	9.10^{-4}	2.10^{-3}	8.10^{-4}	9.10^{-4}	2.10^{-3}
EDF / Creys-Malville	Creys-Mépieu	0.95	$7. 10^{-4}$	7.10^{-4}	2.10^{-4}	2.10^{-4}	2.10^{-6}	3.10^{-4}
EDF / Cruas-Meysse	Savasse	2.4	5.10^{-4}	4.10^{-4}	4.10^{-4}	2.10^{-4}	2.10^{-4}	2.10^{-4}
EDF / Dampierre-en-Burly	Lion-en-Sulias	1.6	2.10^{-3}	1.10^{-3}	9.10^{-4}	4.10^{-4}	5.10^{-4}	5.10^{-4}
EDF / Fessenheim	Nambshein	3.5	$8. 10^{-5}$	1.10^{-4}	1.10^{-4}	4.10^{-5}	4.10^{-5}	3.10^{-5}
EDF / Flamanville	Flamanville	0.8	2.10^{-3}	6.10^{-4}	7.10^{-4}	5.10^{-4}	2.10^{-4}	2.10^{-4}
EDF / Golfech	Golfech	1	8.10^{-4}	7.10^{-4}	6.10^{-4}	2.10^{-4}	3.10^{-4}	3.10^{-4}
EDF / Gravelines	Gravelines	1.8	2.10^{-3}	4.10^{-4}	6.10^{-4}	8.10^{-4}	4.10^{-4}	4.10^{-4}
EDF / Nogent-sur-Seine	Saint-Nicolas-La-Chapelle	2.3	8.10^{-4}	6.10^{-4}	1.10^{-3}	5.10^{-4}	4.10^{-4}	7.10^{-4}
EDF / Paluel	Saint-Sylvain	1.4	8.10^{-4}	5.10^{-4}	9.10^{-4}	9.10^{-4}	4.10^{-4}	3.10^{-4}
EDF / Penly	Biville-sur-Mer	2.8	1.10^{-3}	6.10^{-4}	7.10^{-4}	4.10^{-4}	4.10^{-4}	4.10^{-4}

LICENSEE/SITE	REFERENCE GROUP MOST EXPOSED IN 2016	DISTANCE TO SITE IN km	ESTIMATION OF RECEIVED DOSES, IN mSv[(a)]					
			2011	2012	2013	2014	2015	2016
EDF / Saint-Alban	Saint-Pierre-de-Bœuf	2.3	4.10^{-4}	4.10^{-4}	4.10^{-4}	2.10^{-4}	2.10^{-4}	3.10^{-4}
EDF / Saint-Laurent-des-Eaux	Saint-Laurent-Nouan	2.3	3.10^{-4}	2.10^{-4}	2.10^{-4}	2.10^{-4}	1.10^{-4}	1.10^{-4}
EDF / Tricastin	Bollène	1.3	7.10^{-4}	7.10^{-4}	5.10^{-4}	2.10^{-4}	2.10^{-4}	2.10^{-4}
Ganil / Caen	IUT	0.6	$<3.10^{-3}$	$<3.10^{-3}$	$<2.10^{-3}$	$<2.10^{-3}$	$<2.10^{-3}$	$<2.10^{-3}$
ILL / Grenoble	Fontaine (gaseous discharges) et Saint-Egrève (liquids)	1 et 1.4	5.10^{-5}	1.10^{-4}	2.10^{-4}	3.10^{-4}	2.10^{-4}	2.10^{-4}

a: until 2008, for installations operated by EDF, only "adult" figures were calculated. From 2010 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. The dose value indicated is the harshest value in the age classes.
b: for the Cadarache, Saclay, Fontenay-aux-Roses and Marcoule sites, the dose estimates entered in the table are the sum of the dose estimates transmitted by CEA. As these estimates comprise at least one term of less than 0.01 microsieverts, the values indicated are preceded by the "less than (<)" sign.
c: 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.
d: information not provided by the licensee
e: as the site has no longer had radioactive discharges since 2014, the radiological impact caused by radioactive discharges has been and continues to be nil since 2014.

FUNDAMENTALS

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).

More simply, LD ≈ 2 x SD.

For the measurement results on chemical substances, the Quantification Limit is equivalent to the Detection Limit 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, nickel-63, 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 (permanent discharges from ventilation networks, when draining "RS" effluent storage tanks and at decompression of reactor buildings), xenon-135 (permanent discharges from ventilation networks and at decompression of reactor buildings), xenon-131m (when draining "RS" tanks), krypton-85 (when draining "RS" tanks), argon-41 (at decompression of reactor buildings).

and their monitoring, which are subject to particular scrutiny during inspections.

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 represents 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.

Article 35 also states that the European Commission may access the monitoring facilities to verify their operation and their 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 the Manche repository of the National Radioactive Waste Management Agency (Andra) 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;

FOCUS

Fifth meeting of the "tritium" action plan follow-up committee in October 2017

Following the publication of the tritium White Paper, ASN set up a tritium action plan follow-up committee in 2010, which it convenes periodically.

ASN organised the fifth meeting of this committee on 4th October 2017. Significant advances in metrology were welcomed, such as the publication of a French standard and the development of new methods for measuring tritium traces in the environment. Identification of tritium levels in the environment has also progressed, in particular for the continental atmospheric and aquatic compartments. However, identification of the tritium levels in the soil, plants, biological matrices and living organisms in the marine environment needs to be investigated in greater depth. There are still gaps in our understanding of the behaviour of tritium bound with certain organic molecules, as well as the consequences on tritium transfer to the food chain. In 2017, IRSN published a report on this subject, entitled *Updating knowledge acquired on tritium in the environment.*

During this meeting of the committee, a number of licensees (EDF, CEA, Areva NC) presented the progress made in the work initiated to answer ASN's requests concerning the characterisation of the physico-chemical forms of tritiated waste. These various studies are in the process of being finalised and some deliverables are still to be transmitted to ASN during the course of 2018. All the documents will then be analysed by ASN.

Finally, ASN informed the committee members of the publication on its website of the White Paper *(www.asn.fr/sites/tritium/)*, the summary of all tritium discharges from BNIs and the corresponding dosimetric impacts declared by the licensees in France for the period 2012-2016. In addition, the ASN Research network produced a data sheet in 2017 on tritium measurements in the environment and the impact of this radionuclide. The recommendations of this sheet, presented to the ASN scientific committee in June 2017, should be taken up in the forthcoming ASN opinion on research.

The next meeting of the tritium action plan follow-up committee is scheduled for 2019.

- the CEA site at Cadarache in 2011;
- the environmental radioactivity monitoring facilities in the Paris area in 2016.

The next inspection planned by the European Commission will be in May 2018 on the Areva NC site at La Hague.

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 2016-283 of 10th March 2016 include participation in radiological monitoring of the environment), the Ministries (General Directorate for Health (DGS), General Directorate for Food, General Directorate for Competition Policy, Consumer Affairs and Fraud Control, 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-radioactivite.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 and in the individual requirements 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.

ASN environment inspection at CEA's Cadarache centre, July 2017.

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.

Following initial experience feedback from application of the above-mentioned resolution of 16th July 2013, the requirements concerning the environmental monitoring programme to be implemented by the licensees were clarified and updated by ASN resolution 2016-DC-0569 of 29th September 2016, approved by the Minister for the Environment, Energy and the Sea in the Order of 5th December 2016.

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 amended 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 the regulations.

Depending on specific local features, monitoring may vary from one site to another. Table 8 gives examples of the monitoring performed by the licensee of an NPP and of 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).

This monitoring is based on:
- 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;
- 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 state of the French environment. The first issue of this report, published at the beginning of 2013, covered the year 2010 and the first half

FOCUS

Detection of traces of ruthenium-106 in the ambient air in September and October 2017

During the course of its national radioactivity monitoring duties, IRSN measured the presence of very low levels (a few microbecquerels per cubic metre) of ruthenium-106 in the ambient air in the South-East of France, between the end of September and the beginning of October 2017.

As soon as this was detected, ASN contacted its European counterparts, who confirmed the detection of ruthenium-106 in the air over the same period in at least 14 European countries, with the highest values being measured in the countries of Eastern Europe. The end of this episode was confirmed as of the second half of October 2017.

As ruthenium-106 is not normally detected in the air, ASN considered that its presence could only be linked to an uncontrolled release, probably as a result of an accident.

However, at the time this report was written no country had informed the IAEA that it is the origin of this release, as required by the 1986 convention on the early notification of a nuclear accident.

IRSN carried out simulations to recreate the release from the measurement results observed in France and Europe. It compared its results with those of other expert assessment organisations in Europe, such as BFs (Germany), STUK (Finland) and NRPA (Norway).

On the basis of these simulations, IRSN determined that the most probable origin of this release was the southern Urals, without it being possible to be any more precise. The event causing this release probably occurred during the course of the final days of September.

The levels of atmospheric contamination by ruthenium-106 which were observed in France and the other European countries have no consequences for health and the environment and thus required no measures to protect the populations. ASN also examined the risk linked to the consumption of imported foodstuffs. The estimated radiological doses linked to the consumption of foodstuffs from the probable area in which the release originated, mushrooms in particular, showed that there was no identified health risk for consumers in France.

Following the invitation sent by IBRAE (Russian scientific committee), ENSREG, via its Chairman, jointly with the European Commission and together with the Russian safety regulator Rostechnadzor and IBRAE, determined the conditions for the participation in an international scientific commission tasked with determining the origin and circumstances of this release, as well as its local impact.

of 2011. The second issue, published at the end of 2015, corresponds to the period 2011-2014. The third issue is scheduled for publication at the end of 2018. In addition to this report, IRSN also produces regional radiological findings to provide more precise information about a given area.

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 are defined by the above-mentioned ASN resolution of 29th April 2008 amended.

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 PLANT AT LA HAGUE (ASN RESOLUTION 2015-DC-0535 OF 22TH DECEMBER 2015)
Air at ground level	• 4 stations continuously sampling atmospheric dust on a fixed filter, with daily measurements of the 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 ^3H	• 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 or $\beta_G > 1$ mBq/m^3 Monthly α (Pu) spectrometry 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 ^3H • 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 ^3H	• 2 continuous sampling stations including one under the prevailing winds with weekly measurement of α_G, β_G and ^3H. 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 ^3H • Continuous sampling in the river at the good mixing point ^3H measurement (average daily mixture) • Annual sampling in aquatic sediments, fauna and flora upstream and downstream of the discharge point with γ spectrometry, free ^3H measurement, and, on fish, organically bound ^{14}C and ^3H • Periodic sampling from a stream and in the dam adjoining the site with measurements of β_G, K, ^3H	• Daily seawater samples from 2 points on the coast, with daily measurements (γ spectrometry, ^3H) at one of these points and for each of the 2 points, α and γ spectrometry and β_G, K, ^3H and ^{90}Sr measurements • Quarterly seawater samples at 3 points offshore with γ spectrometry and β_G, K, ^3H 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 samples of water from 19 streams around the site, with α_G, β_G, K and ^3H measurements • Quarterly sampling of sediments from the 4 main streams adjacent to the site, with γ and α spectrometry • Quarterly samples of aquatic plants in 3 streams in the vicinity of the site with γ spectrometry and ^3H measurement
Groundwater	• Monthly sampling at 4 points, bi-monthly at 1 point and quarterly at 4 points with β_g, K and ^3H measurement	• 5 sampling points (monthly check) with α_G, β_G, K and ^3H measurement
Water for consumption	• Annual sampling of water intended for human consumption, with β_g, K and ^3H measurements	• Periodic sampling of water intended for human consumption at 15 points, with α_G, β_G, K and ^3H measurements
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, ^3H and ^{14}C measurements	• Monthly grass sampling at 5 points and quarterly at 5 other points with γ spectrometry and ^3H and ^{14}C measurements, • Annual campaign for the main agricultural crops, with α and γ spectrometry, ^3H, ^{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 ^3H measurement	• 5 sampling points (monthly check) with γ spectrometry, K, ^3H, ^{14}C and ^{20}Sr measurement

$\alpha_G = \alpha$ total; $\beta_G = \beta$ total
** Measurements of total concentration of potassium and by spectrometry for ^{40}K.*

This network is being deployed for two main reasons:
- 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;
- to ensure transparency 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 RNM website (see point 4.2).

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 is set by the above-mentioned ASN resolution of 29th April 2008 amended.

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 amended, specifies the organisation of the national network and sets the approval arrangements for the environmental radioactivity measurement laboratories.

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.

4.3.2 The approval commission

The approval commission is tasked with ensuring that the measurement laboratories have the organisational and technical competence to provide the RNM 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. It meets every six months.

The commission, chaired 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. During the course of 2018, ASN will be adopting a new decision to appoint members to the approval commission.

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.

In 2017, IRSN organised six ILTs. Since 2003, 70 ILTs have been carried out covering nearly 50 types of approval. The most numerous approved laboratories (57) 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. 31 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.).

In 2017, ASN issued 123 approvals or approval renewals. As at 1st January 2018, the total number of approved laboratories stood at 65, which represents 880 approvals of all types currently valid.

The detailed list of approved laboratories and their scope of technical competence is available on *www.asn.fr*.

5. Identifying and penalising deviations

ASN implements enforcement measures obliging a party responsible for an activity to restore compliance with the regulations, along with penalties.

5.1 Ensuring that penalty decisions are fair and consistent

In certain situations in which the licensee fails to comply with 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.

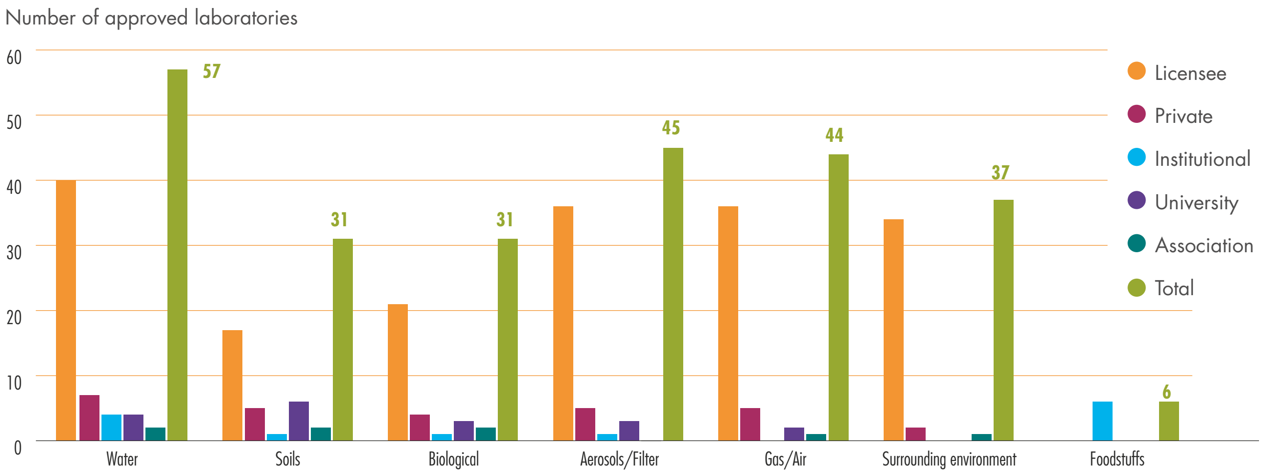
TABLE 9: Approval chart and forecast five-year inter-laboratory test (ilt) programme

Code	Radioactive measurements category	TYPE 1 – Sea water	TYPE 1 – Water		TYPE 2 – Soil and sediment matrices		TYPE 3 – Biological matrices		TYPE 4 – Aerosols on filter		TYPE 5 – Gas air		TYPE 6 – Ambient medium (soil/air)		TYPE 7 – Foodstuffs for health inspection	
..-01	Emitting radionuclides γ > 100 keV		○ 2nd half 2019	1_01	● 1st half 2020	2_01	○ 2nd half 2017	3_01	○ 2nd half 2019	4_01	● 1st half 2021	5_01		-	S (2017), L (2018), S (2019), L (2020), L (2021)	7_01
..-02	Emitting radionuclides γ < 100 keV		○ 2nd half 2019	1_02	● 1st half 2020	2_02	○ 2nd half 2017	3_02	○ 2nd half 2019	4_02	● 1st half 2021	5_02		-	S (2017), L (2018), S (2019), L (2020), L (2021)	7_02
..-03	Total alpha		○ 2nd half 2017 ● 1st half 2019	1_03		-		-	○ 2nd half 2017	4_03		-		-	-	-
..-04	Total beta	● 1st half 2018	○ 2nd half 2017 ● 1st half 2019	1_04		-		-	○ 2nd half 2019	4_04		-		-	-	-
..-05	^{3}H	● 1st half 2018	○ 2nd half 2017 ● 1st half 2019	1_05		2_05	○ 2nd half 2020	3_05		-		Cf. 1_05 5_05		-	-	-
..-06	^{14}C		● 1st half 2020	1_06		2_06	○ 2nd half 2018	3_06		-	● 1st half 2017	5_06		-	-	-
..-07	$^{90}Sr/^{90}Y$		● 1st half 2017	1_07	● 1st half 2021	2_07	○ 2nd half 2020	3_07	○ 2nd half 2019	4_07		-		-	-	-
..-08	Other pure beta emitters (^{63}Ni...)		^{99}Tc	1_08	○ 2nd half 2021 ^{99}Tc	2_08	● 1st half 2017 ^{99}Tc	3_08		-		-		-	-	-
..-09	U Isotopes		○ 2nd half 2018	1_09	● 1st half 2019	2_09	○ 2nd half 2021	3_09	○ 2nd half 2018	4_09		-		-	-	-
..-10	Th Isotopes			1_10	● 1st half 2019	2_10	○ 2nd half 2021	3_10	○ 2nd half 2018	4_10		-		-	-	-
..-11	^{226}Ra + desc.		○ 2nd half 2018	1_11	● 1st half 2019	2_11	○ 2nd half 2021	3_11		-		^{222}Rn : 5_11		-	-	-
..-12	^{228}Ra + desc.		○ 2nd half 2018	1_12	● 1st half 2019	2_12	○ 2nd half 2021	3_12		-		^{220}Rn : 5_12		-	-	-
..-13	Pu, Am, (Cm, Np) Isotopes		○ 2nd half 2020	1_13	○ 2nd half 2021	2_13	● 1st half 2018	3_13	○ 2nd half 2017	4_13		-		-	-	-
..-14	Halogenated gases			-		-		-		-	● 1st half 2021	5_14		-	-	-
..-15	Noble gases			-		-		-		-	● 1st half 2019 ^{85}Kr	5_15		-	-	-
..-16	Ambient gamma dosimetry			-		-		-		-		-	● 1st half 2018	6_16	-	-
..-17	Total uranium		○ 2nd half 2018	1_17	● 1st half 2019	2_17	○ 2nd half 2021	3_17	○ 2nd half 2018	4_17		-		-	-	-

L: Liquid
S: Solid

● 1st half year 2017 ○ 2nd half year 2017 ● 1st half year 2018 ○ 2nd half year 2018 ● 1st half year 2019 ○ 2nd half year 2019 ● 1st half year 2020 ○ 2nd half year 2020 ● 1st half year 2021 ○ 2nd half year 2021

GRAPH 11: Breakdown of the number of approved laboratories for a given environmental matrix as at 1st January 2018



The principles of ASN 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 risks associated with the deviation identified and also take account of factors relating to the licensee (past history, behaviour, repeated nature), the context of the deviation and the nature of the requirements contravened (regulations, standards, "rules of good practice", etc.);
- 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 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.

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 legislative and regulatory safety requirements, enforcement measures or sanctions can be imposed on the licensees, after an exchange of views in accordance with the right of defence and prior formal notice depending on the type of measures decided.

In the event of failure to comply with the applicable provisions and requirements, the Environment Code makes provision for graduated enforcement measures and administrative sanctions:

- 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 transport operation until the licensee has restored conformity;
- a daily fine (an amount set per day, to be paid by the licensee until full compliance with the requirements of the formal notice has been achieved);
- administrative penalty.

It should be noted that these last two measures, which have been available since the Ordinance of 10th February 2016, are proportionate to the gravity of the infringements observed. The administrative fine will be the competence of the future ASN Sanctions Committee.

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.

Any infringements observed are written up in reports by the nuclear safety inspectors and transmitted to the Public Prosecutor's Office that decides on what subsequent action, if any, is to be taken. The Environment Code and its implementing decrees and orders make provision for criminal penalties, with regard to the infringement or offence: a fine or even a term of imprisonment (up to €150,000 and three years in prison), depending on the nature of the infringement. For legal persons found to be criminally liable, the amount of the fine can reach €10M, depending on the infringement in question and the actual prejudice to the interests mentioned in Article L.593-1.

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.

In the field of pressure equipment, 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 enforcement and 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. This Chapter also includes provisions applicable to the manufacturers, importers and distributors of such equipment, aiming to ban the marketing, commissioning or continued operation of an equipment item and to serve the licensee with formal notice to take all steps necessary to ensure conformity with the legislative and regulatory provisions applicable to its activity.

5.2.2 For persons in charge of small-scale nuclear activities, approved organisations and laboratories

When ASN observes breaches of the legislative and regulatory provisions applicable to radiation protection (provisions of the Public Health Code and the Labour Code), administrative enforcement measures or sanctions may be taken against the parties responsible for a nuclear activity, after an exchange of views - in accordance with the right of defence - and prior formal notice.

If failure to observe the applicable provisions and prescriptions is detected, the Public Health Code makes provision for graduated enforcement measures and administrative sanctions:

- deposit in the hands of a public accountant of a sum corresponding to the cost of the work to be performed;
- have the work carried out without consulting the party responsible for the nuclear activity and at its expense (any sums deposited beforehand can be used to pay for this work);

- suspension of the activity until complete performance of the conditions imposed and the adoption of interim measures at the cost of the person served formal notice, in particular in the event of urgent measures to protect human safety;
- a daily fine (an amount set per day, to be paid by the party responsible until full compliance with the requirements of the formal notice has been achieved);
- administrative penalty.

It should be noted that these last two measures, which have been available since the entry into force on 1st July 2017 of the new provisions of the Public Health Code as stipulated by the Ordinance of 10th February 2016, are proportionate to the gravity of the infringements observed. The administrative fine will be the competence of the future ASN Sanctions Committee.

The Public Health Code also enables ASN to take decisions to temporarily or definitively revoke the administrative title (authorisation and soon registration) issued to the party responsible for the nuclear activity, after having informed the party concerned that it is entitled to submit observations within a given time, in order to comply with the exchange of views procedure.

The texts also make provision for criminal infringements. This will for example be non-compliance with the provisions concerning the protection of workers exposed to ionising radiation, non-compliance with formal notice served by ASN, performance of a nuclear activity without the required administrative title.

Infringements are written up in reports by the radiation protection inspectors and transmitted to the Public Prosecutor's Office that decides on what subsequent action, if any, is to be taken. The Public Health Code makes provision for criminal penalties in Articles L.1337-5 to L.1337-9: these consist of a fine of from €3,750 to €15,000 and a term of imprisonment of six months to one year, depending on the gravity of the infringement, with additional penalties being possible for legal persons.

5.2.3 For noncompliance with Labour Law

In the performance of their duties in NPPs, the ASN labour inspectors have at their disposal all the inspection, decision-making and enforcement resources of ordinary law inspectors (pursuant to Article R.8111-11 of the Labour Code). Observation, formal notice, administrative sanction, report, injunction (to obtain immediate cessation of the risks) or even stoppage of the works, offer the ASN labour inspectors a broad range of incentive and constraining measures.

5.2.4 2017 results concerning enforcement and sanctions

As a result of infringements observed, the ASN inspectors (nuclear safety inspectors, for BNIs, the transport of radioactive substances or nuclear pressure equipment, labour inspectors and radiation protection inspectors) transmitted twelve infringement reports to the public prosecutor's offices, five of which concerned labour inspections in the NPPs.

ASN issued three administrative measures, including two formal notices against contractors and parties responsible for nuclear activities. An administrative fine was proposed by the labour inspectors.

Table 10 shows the number of reports issued by the ASN inspectors since 2012.

TABLE 10: Number of infringement reports transmitted by the ASN inspectors between 2012 and 2017

	2012	2013	2014	2015	2016	2017
Report excluding labour inspection in the nuclear power plants	12	26	15	14	7	7
Labour inspection report in the nuclear power plants	11	10	9	3	1	5

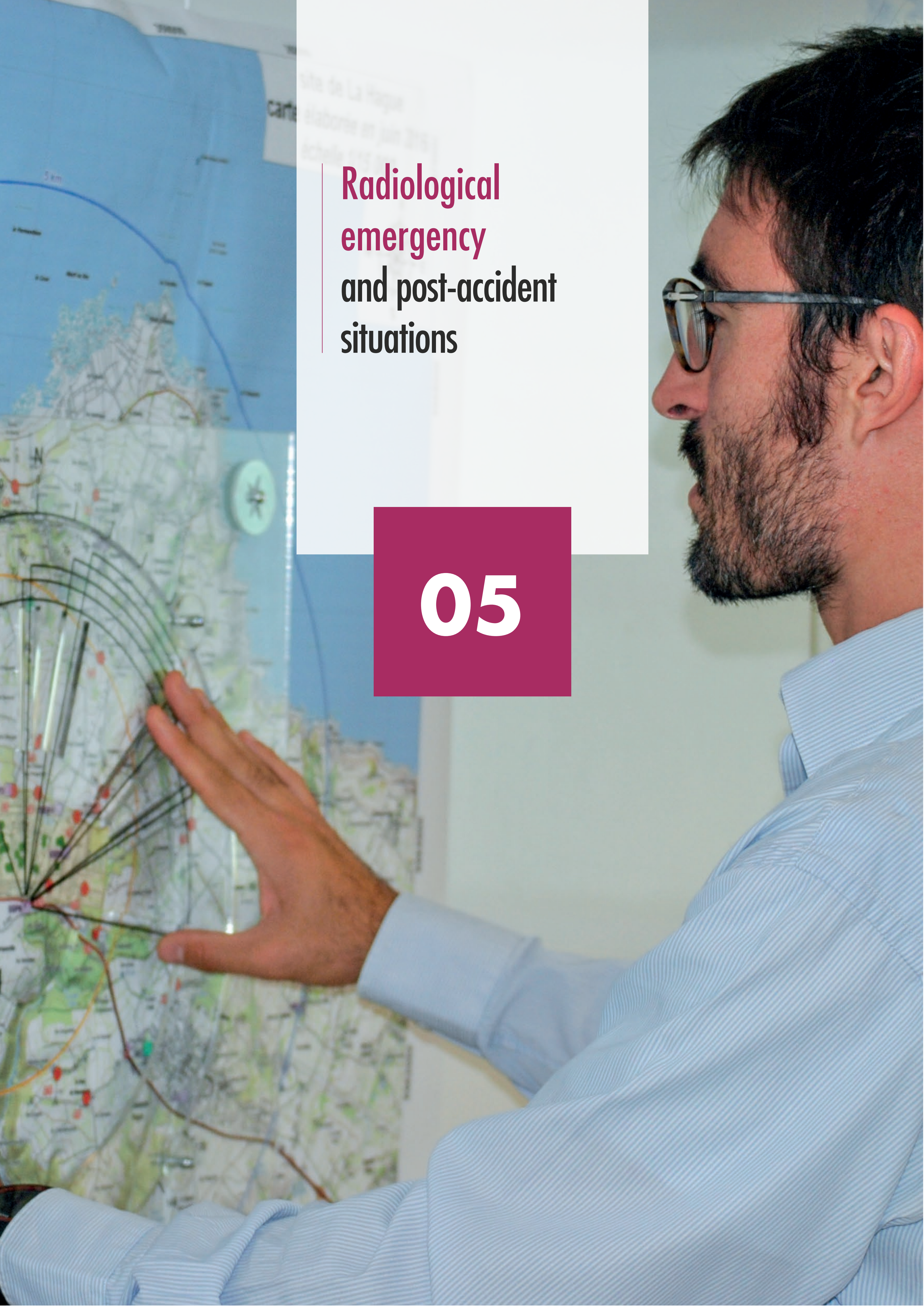
6. Outlook

In 2018, 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 and activities related to pressure equipment.

Further to the irregularities found in the manufacture of certain NPP equipment items, ASN has initiated a review of BNI licensee monitoring of their contractors and subcontractors. This review also concerned ASN's monitoring methods and alert mechanisms. In 2018, ASN will actually implement the actions it has identified.

In 2018, ASN will be implementing the conclusions of its review of the reinforced effectiveness of the oversight of small-scale nuclear activities. Furthermore, the revision of the Labour Code and the Public Health Code will enable ASN to finalise the revision of the criteria and procedures for the notification of significant radiation protection events.

In the field of environmental protection, ASN will continue with its regulatory work to implement the provisions of the TECV Act and the transposition to BNIs of the 24th November 2010 Directive 2010/75/EU on Industrial Emissions and the 4th July 2012 Directive 2012/18/EU concerning Major Accidents involving hazardous substances. Together with the Ministry for Ecological and Solidarity-based Transition, ASN will also restart work to revise the Order of 7th February 2012, more specifically to take account of recent changes to the general environmental regulations.



Radiological emergency and post-accident situations

05

Nuclear activities are carried out within a framework which aims to prevent accidents but also to mitigate their consequences. 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 and regularly tested and revised.

Radiological emergency situations, resulting from an incident or accident liable to lead to an emission of radioactive substances or to a level of radioactivity potentially affecting public health, include:
- emergency situations arising in a Basic Nuclear Installation (BNI);
- accidents involving the Transport of Radioactive Materials (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 contingency 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 more particularly by the expertise of its technical support organisation, the Institute for Radiation Protection and Nuclear Safety (IRSN), it has the following four key duties:
- check the steps taken by the licensee and ensure that they are pertinent;
- advise the authorities on population protection measures;
- take part in the dissemination of information to the population and media;
- act as Competent Authority within the framework of the international Conventions on Early Notification and Assistance.

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 published in November 2012 concerning the emergency phase exit, transitional and long-term periods, will be updated. Work is continuing on the management of waste and manufactured products as well as on the management of water and marine environments.

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 and contingency plans relative to accidents occurring in a BNI define the measures necessary for protecting site personnel, the general public and the environment, and for controlling the accident.

The Major Nuclear or Radiological Accident National Response Plan, published by the Government in February 2014, which ASN helped to draft, takes account of the lessons learned from the Fukushima Daiichi accident and the post-accident doctrine drafted by the Codirpa, specifies the national response organisation in the event of a nuclear accident, the strategy to be applied and the main steps to be taken. It includes 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.

In the vicinity of the facility, the Off-site Emergency Plan (PPI) is established by the Prefect of the *département* concerned pursuant to Articles L.741-6, R.741-8 et seq. of the Domestic Security Code, *"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 localised and fixed. The PPI implements the orientations of civil protection policy in terms of mobilisation of resources, information, alert, exercises* *and training"*. These Articles also stipulate 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 civil protection response organisation which describes the protective measures implemented by the public authorities in large-scale emergencies. Therefore, beyond the application perimeter of the PPI, the *département* or zone ORSEC plan is activated.

The On-site Emergency Plan (PUI), prepared by the licensee, is designed to restore the plant to a controlled and stable 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 concerning BNIs and the regulation of the nuclear safety of the transport of radioactive substances, the PUI is one of the items to be included in the file sent to ASN by the licensee for commissioning of its facility. The obligations of the licensee relative to the preparation for and management of emergency situations are defined in Title VII of the Order of 7th February 2012 setting the general rules for BNIs. The associated provisions were stipulated in ASN resolution 2017-DC-0592 of 13th June 2017 concerning the obligations of BNI licensees in terms of preparedness for and management of emergency situations and the content of the on-site emergency plan, known as the "emergency" resolution, approved by the Order of 28th August 2017.

FOCUS

The "emergency" resolution

ASN resolution 2017-DC-0592 of 13th June 2017 supplements the provisions of Title VII of the Order of 7th February 2012 setting the general rules relative to BNIs, by specifying the licensees' obligations regarding preparedness for and management of emergency situations, as well as ASN's requirements regarding the content of the PUI. Most of the provisions of this resolution give official status to existing practices which were not incorporated into the regulations. This resolution also transposes certain reference levels established by the Western European Nuclear Regulators Association (WENRA) and takes account of the lessons learned from the Fukushima Daiichi accident (emergency management premises, means of communication, exercises simultaneously affecting several facilities). It requires that the emergency crew members take part in at least one simulation or exercise per year and specifies the information that the licensee must transmit to the authorities.

This ASN resolution was the subject of a public consultation on the *www.asn.fr* website from 1st to 21st March 2017.

1.1.2 The accident response plans for the transport of radioactive substances

The transport of radioactive substances 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 the transport of radioactive substances. The content of these plans is defined in ASN Guide No. 17.

To deal with the possibility of a radioactive substances transport accident, each *département* Prefect must include in their implementation of the national response plan a part devoted to this type of accident, the ORSEC TMR (Transport of Radioactive Materials) 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.

1.1.3 The response to other radiological emergency situations

Apart from incidents or accidents affecting nuclear installations or a radioactive substances transport operation, radiological emergency situations can also occur:
- during performance of a nuclear activity, 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 limit the risk of human exposure to ionising radiation. Together with the Ministries and involved bodies, ASN drafted Circular DGSNR/DHOS/DDSC No. 2005/1390 of 23rd December 2005 relative to the principles of intervention in the case of an event that could lead to a radiological emergency, other than situations covered by a contingency plan or an emergency response plan. This Circular supplements the provisions of the Interministerial Directive of 7th April 2005 on the action of the public authorities in the case of an event leading to a radiological emergency situation presented in point 1.3 and defines the methods for the organisation of the State services in these radiological emergency situations.

Given the large number of those who could possibly issue an alert and the corresponding alert channels, all the alerts are centralised in a single location, which then distributes them to all the stakeholders: this is the fire brigade's centralised alert processing centre CODIS-CTA (*Département* Operational Fire and Emergency Centre – Alert Processing Centre), that can be reached by calling 18 or 112.

The management of accidents of malicious origin occurring outside BNIs are not covered by this Circular, but by the Government's NRBC (Nuclear, Radiological, Biological and Chemical) plan.

1.1.4 ASN role in the examination and monitoring of emergency plans and the drafting of contingency plans

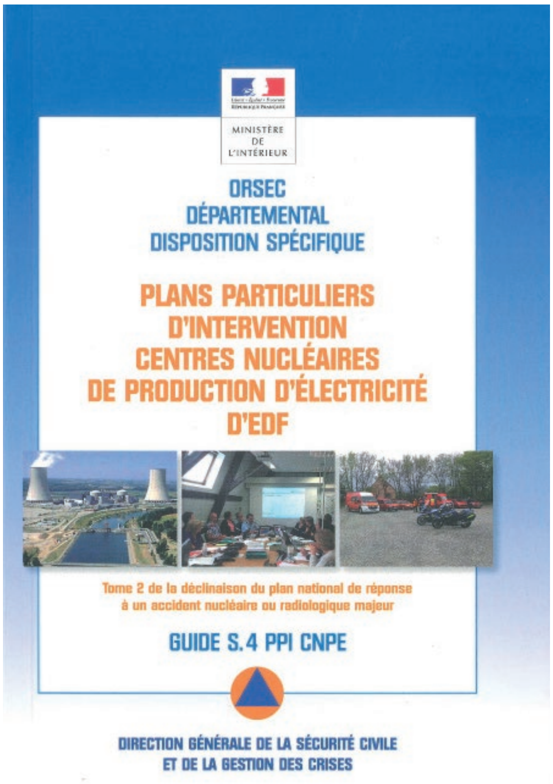
Examination of emergency plans for nuclear facilities or activities

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 and their updates.

Participation in drafting the contingency Plans

Contingency Plans, such as the PPI, identify the general public protection measures 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 the population in the event of the accident.

Pursuant to the Domestic Security Code, the Prefect is responsible for drafting 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.



| Ministry of the Interior guide for drafting PPIs around NPPs.

The PPI currently makes it possible to plan the public authorities' response in the first hours of the accident in order to protect the population living within the currently defined 10km radius around the affected reactor. On 3rd October 2016, the Ministry for the Interior published an instruction concerning the response to a major nuclear or radiological accident: Changes in national doctrine for the drafting or modification of PPIs around NPPs operated by EDF. In 2017, it published a guide intended for the offices of the Prefects in order to implement this instruction by updating the PPIs for the NPPs to take account of the changes, in particular the preparation for *"immediate"* evacuation within a 5km radius, the integration of consumption restrictions as of the emergency phase and the expansion of the PPI radius for NPPs to 20 km.

The PPI comprises a "reflex" phase which includes an immediate licensee alert of the populations within a 2 km radius of the facility, requiring them to take shelter and await instructions. The additional measures to be taken beyond the zone covered by the PPI are specified, as applicable, through a joint approach which can be based on the ORSEC arrangements, taking account of the characteristics of the accident and the weather conditions.

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

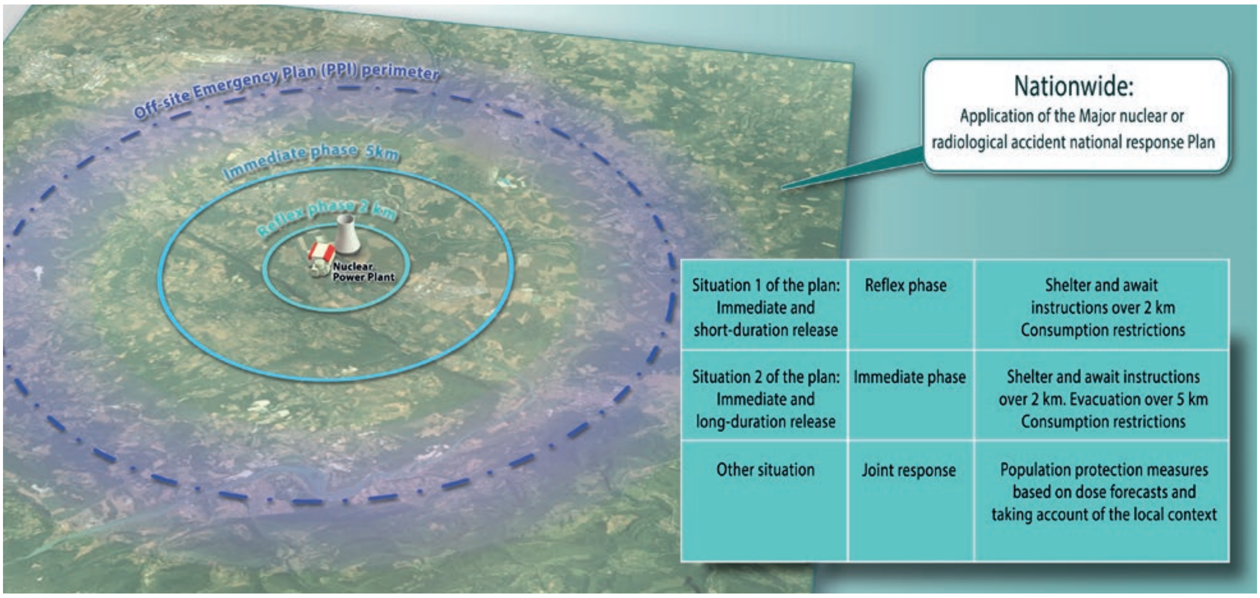
The aim of controlling urban development is to limit the consequences of an accident for the population and property. Since 1987, this type of approach has been implemented around non-nuclear industrial facilities and it has been reinforced since the AZF facility accident that occurred in Toulouse in 2001. Act 2006-686 of 13th June 2006 concerning transparency and security on nuclear matters (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. Given the specific nature of nuclear or radiological emergency management and of the corresponding risks, the steps taken for BNIs could be harsher than for installations classified for protection of the environment and lead to more stringent measures.

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.

The current approach to controlling activities around nuclear facilities exclusively concerns those subject to a PPI and

DIAGRAM 1: Major nuclear or radiological accident national response plan



primarily aims to preserve the operational nature of the contingency plans, in particular for sheltering and evacuation, limiting the population numbers concerned whenever possible. It focuses on the PPI "reflex" zones, determined by the Circular of 10th March 2000 revising the off-site emergency plans for BNIs, the pertinence of which was confirmed by the instruction of 3rd October 2016. In these "reflex" zones, immediate steps to protect the population are taken in the event of a rapidly developing accident. A Circular from the Ministry responsible for the Environment of 17th February 2010 concerning the control of activities in the vicinity of BNIs liable to present dangers off the site asked the Prefects to exercise increased vigilance with regard to urban development in the vicinity of nuclear facilities. 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 "reflex" zone. ASN is consulted on construction or urban development projects situated within this zone. The opinions issued are based on the principles explained in ASN Guide No. 15 on the control of activities around BNIs published in 2016. This guide, drawn up by 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), has the following basic objectives:
- preserve the operational nature of the contingency plans;
- prefer regional development outside the "reflex" zone;
- allow controlled development that meets the needs of the resident population.

1.3 Organising a collective response

The response by the public authorities to a major nuclear or radiological 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. 741-1 to L 741-32 of the Domestic Security Code, more specifically concerning the ORSEC plans and PPIs, clarified it in 2005.

How radiological emergency situations are dealt with is specified in the Interministerial Directive of 7th April 2005 on the action of the public authorities in the case of an event leading to a radiological emergency situation (see Diagram 1).

Thus, at the national level, ASN is actively involved in interministerial work on nuclear emergency management.

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. Better advance planning must be carried out for work done under ionising radiation and, in order to provide effective support for the country affected, international relations must be improved.

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 WENRA or HERCA (Heads of the European Radiological protection Competent Authorities) (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).
- ASN has a duty 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. Within the framework of the PPI, this comprises the ORSEC plans or the Off-site Protection Plan (PPE) in the event of a malicious act. The Prefect is thus responsible for coordinating the resources - both public and private, human and material - deployed in the plan. He/she keeps the population and the mayors informed of events. More specifically through its regional division, ASN assists the Prefect in managing the situation.
- The Prefect of the defence and security zone is responsible for coordinating reinforcements and the support needed by the Prefect of the *département*, for ensuring consistency between *départements* of the steps taken and for coordinating regional communication with national communication.
- 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, more particularly during iodine tablet distribution campaigns.

1.3.2 National response organisation

In a radiological emergency situation, each Minister - together with the decentralised State services – is responsible for preparing and executing national level measures within their field of competence.

In the event of a major crisis requiring the coordination of numerous players, a governmental crisis organisation is set up, under the supervision of the Prime Minister, with the activation of the Interministerial Crisis Committee (CIC). The purpose of this Committee is to centralise and analyse information in order to prepare the strategic decisions and coordinate their implementation at interministerial level. It comprises:
- all the ministries concerned;
- the competent safety Authority and its technical support organisation (IRSN);
- representatives of the licensee;
- administrations or public institutions providing assistance, such as *Météo-France* (national weather service).

1.4 Protecting the population

The steps to protect the populations 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 measures are mentioned in the PPIs.

1.4.1 General protective actions

In the event of a major nuclear or radiological accident, a number of measures can be envisaged by the Prefect in order to protect the population:
- sheltering and awaiting instructions: the individuals concerned, alerted by a siren, take shelter at home or in a building, with all openings 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 iodine tablets;
- evacuation: in the event of a 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.

The Prefect may also take measures to ban the consumption of foodstuffs liable to have been contaminated by radioactive substances as of the emergency phase (before the facility has been restored to a controlled and stable state).

The dose levels triggering implementation of population protection measures in a radiological emergency situation are 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 for a one year old child (age at which sensitivity to ionising radiation is highest) exposed to the releases.

In the event of the release of radioactive substances into the environment, measures are decided on to prepare for management of the post-accident phase; they are based on the definition of area zoning to be implemented as of the end of the releases on exiting the emergency phase and including:
- 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, as far as is reasonably possible (for example a ban on consumption of produce from the garden, restriction on access to wooded areas, ventilation and cleaning of homes, etc.);
- a Heightened Territorial Surveillance Zone (ZST), which is larger and which is more concerned with the economic management of the area, 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 The provision of 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 2017, the national campaign, supervised by ASN, for the distribution of iodine tablets to the populations situated in the zone covered by the PPIs around the NPPs operated by EDF, was completed by postal dispatch to persons who did not collect their tablets from the specified distribution points. Distribution was also carried out in 2017 around the sites of the Laue-Langevin Institute (ILL) in Grenoble and the CEA research centre in Saclay (see chapter 6).

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 *Santé Publique France* (more particularly including the Health Emergency Preparedness and Response Organisation). Each Prefect organises the procedures for distribution to the population in their *département*, relying in particular on the mayors for this. This arrangement is described in a Circular of 11th July 2011 concerning the storage and distribution of potassium iodide tablets outside the zones covered by a PPI. Pursuant to this Circular, the Prefects have drawn up plans to distribute stable 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. These persons shall be cared for by the emergency response teams duly trained and equipped for this type of operation.

Circular 800/SGDSN/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.

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 the information of use for the medical response teams in charge of collecting and transporting the injured, as well as for the hospital staff. Under the supervision of the SGDSN, a new version of this guide taking account of changes to certain practices is currently under preparation.

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, environmental and 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.

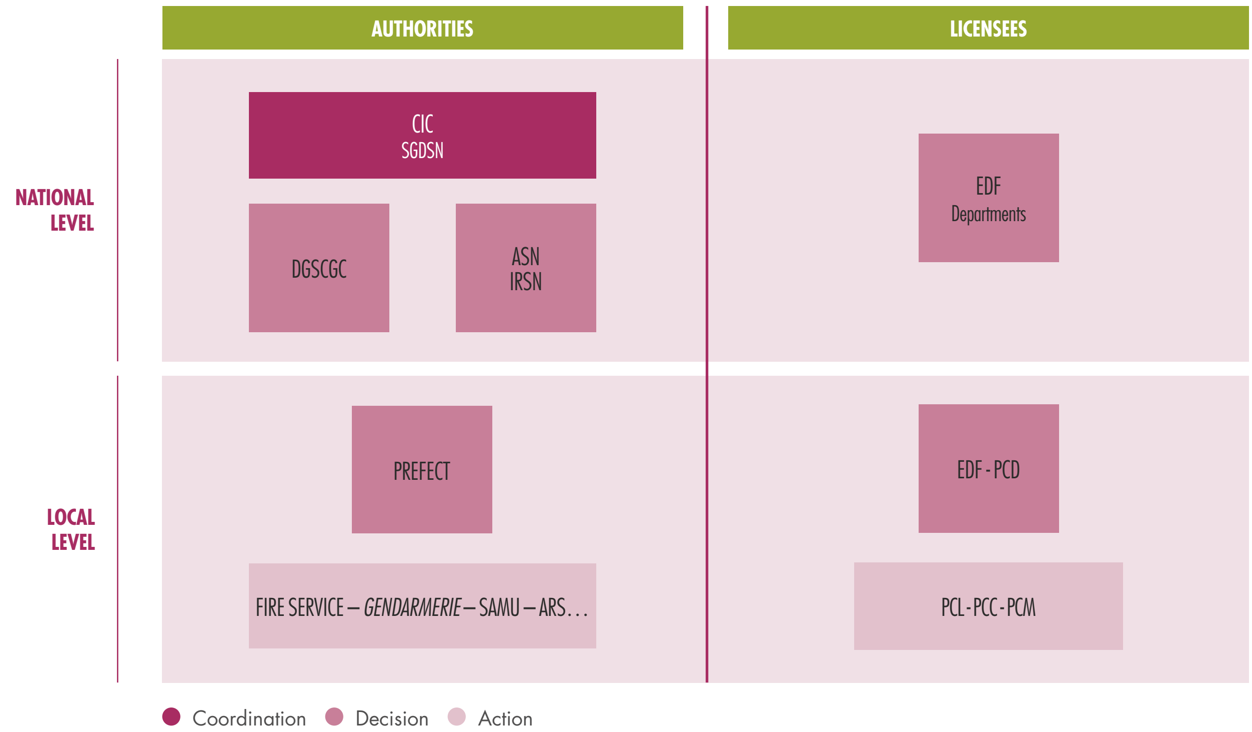
The conditions for reimbursement for the damage resulting from a nuclear accident are currently covered by Act 68-943 of 30th October 1968, amended, concerning civil liability in the field of nuclear energy. France has also ratified the protocols signed on 12th February 2004, reinforcing the Paris Convention 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 codified in the Environment Code (Section I of Chapter VII of Title IX of Book V). These provisions and the new liability thresholds set by the two protocols entered into force in February 2016, pursuant to Act 2015-992 of 17th August 2015 on Energy Transition for Green Growth (TECV Act). An Order of 19th August 2016 sets the list of sites with more limited risks which benefit from a reduced liability amount.

In order to determine the aspects of doctrine corresponding to the implementation of the provisions necessary for responding to post-accident situations following a nuclear accident, ASN in June 2005 created the Codirpa nuclear accident or radiological emergency steering committee and since then it has acted as its Chair and technical secretary. The ASN mandate was renewed in a letter from the Prime Minister dated 30th October 2014.

Numerous elements of the doctrine drawn up by the Codirpa were incorporated into the major nuclear or radiological accident national response plan, sent out in January 2014, such as post-accident zoning (see point 1.4.1).

The Codirpa is currently continuing with work to take account of the lessons learned from the post-accident management carried out in Japan following the Fukushima Daiichi disaster, but also experience feedback from emergency exercises. 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). Finally, work on the management of manufactured products, water and marine environments was started in 2017, along with initial consideration of a revision of the doctrine.

DIAGRAM 2: Emergency response organisation in an accident situation affecting a nuclear reactor operated by EDF



CIC: French Inter-ministerial Crisis Committee
SGDSN: General Secretariat for Defence and National Security
DGSCGC: General Directorate for Civil Protection and Crisis management (Ministry of the Interior)
ARS: Regional Health Agency

PCD: Command and Decision Post
PCL: Local Command Post
PCC: Supervision Command Post
PCM: Resources Command Post

2. Acting in emergency and post-accident situations

The emergency and contingency 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. 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 Organising to handle four essential duties

2.1.1 ASN roles and duties

In an emergency situation, the responsibilities of ASN, with the support of IRSN, are as follows:
- check the steps taken by the licensee and ensure that they are pertinent;
- advise the authorities on population protection measures;
- take part in the dissemination of information to the population and media;
- act as Competent Authority within the framework of the international Conventions on Early Notification and Assistance.

Checking the steps 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. It draws on IRSN's expertise and assessments and can at any time ask the licensee to perform appraisals and take the necessary actions, without however taking the place of the licensee in the technical operations.

Advising the département and zone Prefects and the Government

The decision by the Prefect concerning the general public protection measures to be taken in radiological emergency and post-accident situations depends on the actual or foreseeable consequences of the accident around the site. The law states that it is up to ASN to make recommendations to the Prefect and the Government, incorporating the analysis carried out by IRSN. This analysis covers both a diagnosis of the situation (understanding of the situation of the installation affected, analysis of the consequences for humans and the environment) and a prognosis (assessment of possible developments, notably radioactive releases). These recommendations more specifically concern the steps to be taken to protect the population in the emergency and post-accident phases.

Circulation of information

ASN is involved in informing:
- the media and the public: publication of press releases and organisation of press conferences; it is important that this action be carried out in close coordination with the other entities required to communicate (Prefects, licensees at both local and national levels, etc.);
- institutional and associative stakeholders: local authorities, ministries, offices of the Prefect, political authorities, general directorates of administrations, Anccli, Local Information Committees, etc.;
- 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, jointly with the Ministry for Foreign Affairs.

2.1.2 Organisation of ASN

Organising the response to accidents occurring in BNIs

The ASN emergency response organisation set up to deal with a nuclear accident in a BNI more specifically comprises:
- the participation of ASN staff in the various units of the CIC;
- 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/her representative acts as spokesperson, a role which is distinct from that of the head of the Technical Command Post.

FOCUS

Exercises in 2017: new challenges

In 2017, the programme of exercises comprised two unusual exercises for which the ASN emergency centre was activated: an NRBC exercise (malicious nuclear, radiological, bacteriological or chemical act) and a "zone" exercise.

The first was an opportunity for ASN to test its ability to respond to a complex subject unrelated to the safety of an installation and involving the use of rarely employed response frameworks.

The second, coordinated by the South-East Defence Prefect's office, was an opportunity for the *départements* of the Auvergne-Rhône-Alpes region, in particular those not containing a BNI, to practice implementing post-accident measures such as restrictions on the consumption and sale of local produce.

This emergency centre is regularly tested during national emergency exercises and is activated for actual incidents or accidents. At the local level, ASN representatives visit the *département* and zone Prefects to help them with their decisions and their communication actions. ASN inspectors may also go to the site affected; others take part in emergency management at the headquarters of the regional division involved.

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.

In 2017, the national emergency centre was activated on 14 occasions, for four actual situations and ten national exercises, two of which concerned defence BNIs or national defence sites regulated by the Defence Nuclear Safety Authority (ASND).

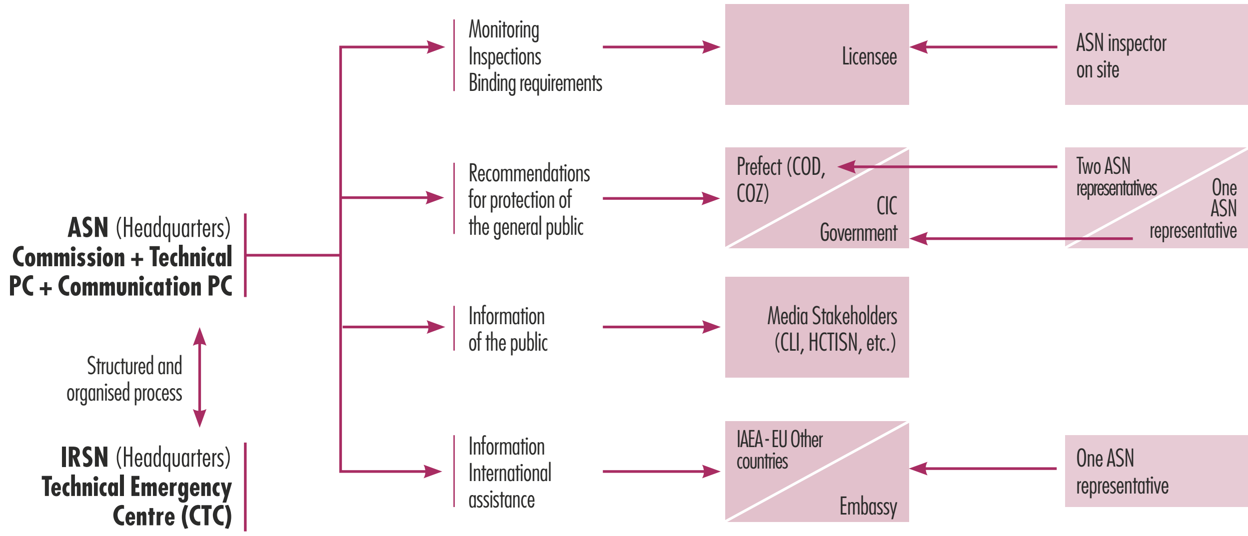
The actual situations concern two intrusions by Greenpeace on the Cattenom and Cruas-Meysse NPPs and two PUI activations on the Bugey NPP. The first concerned a fire on

TABLE 1: Positions of the various players in a radiological emergency situation

		DECISION	EXPERT APPRAISAL	INTERVENTION	COMMUNICATION
Authorities		Government (CIC) Prefect (COD, COZ)	/	Prefect (PCO) Civil protection	Government (CIC) 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
COZ: Zone Operations Centre - CTC: Technical Emergency Centre
PCO: Operational Command Post - PCT: Technical Command Post

DIAGRAM 3: The role of ASN in a nuclear emergency situation



COD: Departmental Operations Centre
COZ: Zone 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

a roof while work was being done in the controlled zone but had no consequences for the safety of the facilities and no environmental impact, as the fire was rapidly extinguished and was rated level 0 on the INES scale (International Nuclear and Radiological Event Scale). The second event concerned blockage of a valve on reactor 2, entailing manual shutdown of the reactor. The licensee implemented its incident management procedures, enabling a controlled state to be restored in a few hours. This event, rated level 1 on the INES scale, had no environmental impact. Following each of these events, ASN carried out inspections which confirmed that the licensee had taken the necessary steps. Lessons were learned from these events.

During exercises, or in the event of a real emergency, ASN is supported by an analysis team located at IRSN's Technical Emergency Centre.

ASN's alert system allows mobilisation of its emergency centre staff and those of the 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 SGDSN, the DGSCGC, the Interministerial Emergency Management Operations Centre (Cogic), *Météo-France* and the ministerial operational monitoring and alert centre of the Ministry for Ecological and Solidarity-based Transition.

The severity of the situation is evaluated by the various parties, who if necessary decide to activate their emergency management centres to manage the situation.

In 2017, the legal framework for implementing an on-call duty system at ASN was finalised, jointly with the Ministry of Ecology. The deployment of this system in 2018 aims to guarantee the robustness and reactivity of ASN staff mobilisation and intervention.

Diagram 3 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 coming from the ASN 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, intervention and communication, for which regular audio-conferences are held. The exchanges between the players 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 incident, 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.

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 incident, securing the zone and reducing the emission and, finally, clean-up.

The Prefect or the mayor coordinates the intervention response teams, and decides on the protective measures to be taken, on the basis of the plans they have drawn up (ORSEC for the Prefects, Local Safeguard Plans for the mayors). At the local level, the Prefects and 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 (in particular in the case of a radioactive substances transport incident).

2.2 ASN international duties

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 among to the tools used in ASN's emergency centre 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.

Two Interministerial Directives of 30th May 2005 and 30th November 2005 specify the procedures for 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, to rapidly provide the pertinent information about the situation, in particular to border countries, to enable them to take the necessary population protection measures and, finally, to provide the ministers concerned with a copy of the notifications and the information transmitted or received.

In 2017, ASN took part in several international exercises:
- the ConvEx 3 exercise organised by IAEA and concerning an accident at an NPP in Hungary;
- the major Swiss RAROS exercise to test information exchange and coordination of population protection measures;
- the national Trillo exercise organised by Spain;
- a table-top exercise with Germany on the coordination of population protection measures.

Finally, as part of the national exercise on the Cattenom NPP in October, the ASN emergency centre organised a coordination training session with the representatives of the German nuclear safety regulator and ministerial level representatives from Luxembourg.

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Observation of a "demonstration exercise" in the United Kingdom

The Office for Nuclear Regulation (ONR), ASN's counterpart in the United Kingdom, has for several years been carrying out in-situ inspections related to the ability of the licensees to implement the provisions of their PUI. Thanks to the commitment of one of its staff members, seconded to the ONR, ASN was invited to observe one such exercise at the Hinkley Point NPP, in June 2017. This type of "demonstration exercise" is comparable to an inspection during the course of an exercise. It mobilises between 4 and 10 ONR inspectors and is carried out every year on each nuclear site. The British inspectors record the best practices observed and the areas for improvement identified during the course of the exercise, without making any comments. They then send their remarks to the licensee during an analysis session held at the end of the demonstration. If too many anomalies are observed, the ONR may suspend the operation of the facility. This type of exercise usually leads to improvements in the licensee's arrangements or their implementation.

In 2018, ASN will initiate PUI implementation inspections along the same lines.

Simulation during the exercise with fire hoses.

2.2.1 Bilateral relations

Maintaining and strengthening bilateral relations with neighbouring and other European countries is one of ASN's priorities.

In 2017, 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.

ASN is continuing to develop bilateral relations in emergency management with many countries, Spain, Italy, Luxembourg, Germany, Switzerland and Belgium in particular. Meetings specifically dedicated to emergency management were in particular held in 2017 with these countries. Chinese, Turkish, Belarusian and Vietnamese delegations also visited ASN in 2017 to discuss emergency situation management and took this opportunity to visit the ASN emergency centre. The Chinese and Vietnamese delegations also took part as observers in a national emergency exercise at ASN.

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 and 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 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 General Safety Requirement (GSR) Part 7, published in November 2015. Two committee meetings, at which ASN represented France, were held in 2017. In 2018, ASN will organise a meeting with all the national emergency management stakeholders in France, to present the concept of the emergency situation protection strategy developed by IAEA.

ASN also collaborates with the NEA and takes part in the Working Party on Nuclear Emergency Matters (WPNEM).

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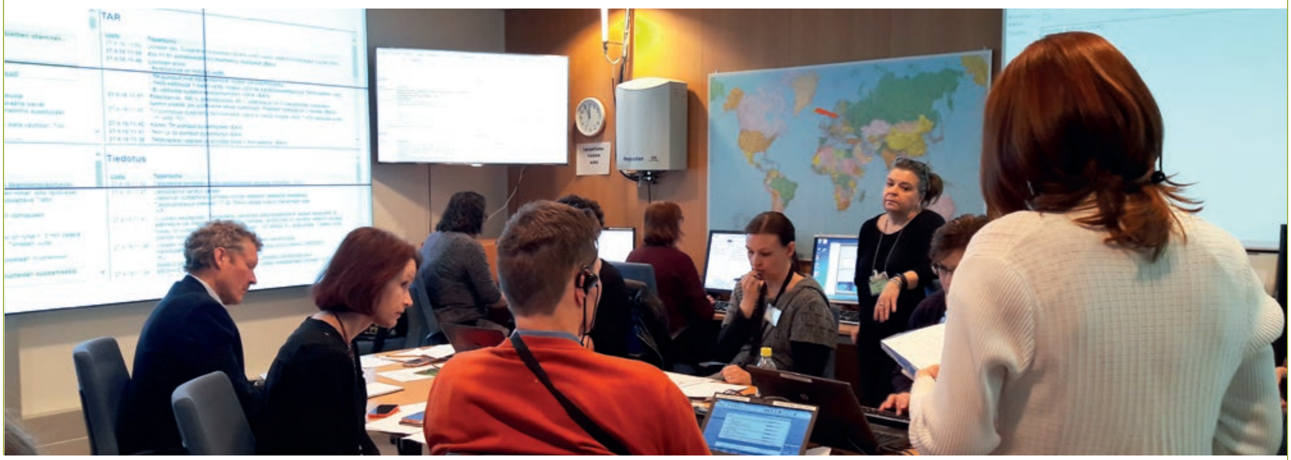
Observation of the "Olkiluoto 17" nuclear emergency exercise in Finland

This major exercise (the equivalent of a French Government SECNUC major exercise) was requested by the Finnish nuclear safety regulator (STUK, *Säteilyturvakeskus*) before commissioning of the Olkiluoto EPR, scheduled for 2018. The site also includes two other reactors. As in France, an emergency is managed at the local level by the emergency services, with the Government also being involved. In the emergency phase, the licensee may recommend population protection measures until the STUK is able to assume this responsibility (generally within two hours). These measures may include immediate evacuation within a 5 km radius. Emergency management is built around the principles described in the IAEA standards. The ASN observers found similarities in the response levels and roles, but also differences, notably concerning the status of STUK – which is both authority and expert – and the population protection measures implementation levels, explained by the lower population density.



Observation of an exercise in the emergency centre of the Olkiluoto NPP.

At the European level, ASN is a participant in the "Emergencies" working group reporting to 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 partly consists of members appointed by 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 measure the level of preparedness of all the entities involved (safety Authorities, technical experts, licensees);
- 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 alert and coordination procedures they contain are effective;
- to train those who would be involved in such a situation;
- to implement the various aspects of the organisation and the procedures set out in the Interministerial Directives: the emergency plans, the contingency plans, the local safeguard plans and the various conventions;
- to contribute to informing the media and develop a general public information approach so that everyone can, through their own individual behaviour, make a more effective contribution to civil protection;
- to build on emergency situation management knowledge and experience.

These exercises, which are the subject of an annual Interministerial review, involve the licensee, the Ministries, the offices of the Prefect and services of the *départements*, ASN, ASND, IRSN and *Météo-France*, which can represent up to 300 people when resources are deployed in the field. They aim to test the effectiveness of the provisions made for assessing the situation, the ability to bring the installation or the package to a safe condition, to take appropriate measures to protect the general public and to ensure satisfactory communication with the media and the populations concerned.

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 prepared a programme of national nuclear and radiological emergency exercises for 2017, concerning BNIs and RMT operations. This programme, announced to the Prefects in the Interministerial Circular of 2nd January 2017, took account of the lessons learned from Fukushima Daiichi and the emergency exercises performed in 2016.

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 2017.

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 and more specifically to test 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.

In 2017, in addition to the general objectives of the exercises listed earlier, additional objectives were introduced into the schedule, taking account of lessons learned and the results of the exercises and experimental training carried out in 2016.

Certain exercises were thus extended by one day devoted to a phase dedicated to civil protection subjects, with a view to optimising the preparedness of the offices of the Prefects for implementation of population protection measures or post-accident actions specific to the nuclear sector.

ASN is also heavily involved in the preparation and performance of 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 in charge of Energy) 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 2017, in accordance with the Interministerial Circular on nuclear and radiological emergency exercises. ASN activated its emergency centre to support the ASND in accordance with the agreement signed by both authorities on 5th July 2017.

TABLE 2: National civil nuclear and radiological emergency exercises conducted in 2017

NUCLEAR SITE	DATE OF THE EXERCISE	MAIN CHARACTERISTICS
Flamanville NPP	14th March	Decision-making process
Nuclear or radiological (Lyon)	18th May	Interfaces between office of Prefect and national stakeholders
Transport of radioactive substances (Pas-de-Calais)	23th May	Management of a nuclear emergency by a *département* without BNI, media pressure, interfaces between office of Prefect and national stakeholders
Regional zone exercise (South-East)	6th June	Management of a nuclear emergency by a defence zone, interfaces between the zone Prefect's office, the *départements* and national stakeholders
Cattenom NPP	17th October	Decision-making process, media pressure
Cadarache site - RES	14th November	Interfacing with ASND, Support with radiation protection and post-accident aspects
Saint-Alban/Saint-Maurice nuclear power plant	28th November	Decision-making process
Dampierre-en-Burly NPP	5th December	Decision-making process, media pressure
Ile Longue naval base	12th December	Interfacing with ASND, Support with radiation protection and post-accident aspects

This more particularly stipulates that:

- at the national level, ASN advises the ASND on aspects concerning the impact of releases on the environment and on preparation for post-accident management of the emergency;
- at the local level, a representative of the ASN regional division concerned goes to the office of the Prefect to advise the Prefect pending the arrival of the ASND representative.

The experience acquired during these many exercises enables ASN personnel to respond more effectively in real emergency situations.

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.

These assessment 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;
- the importance of communication in an emergency situation, in particular to inform the public and foreign authorities as rapidly as possible and avoid the spread of rumours liable to hamper good emergency management, in France and in other countries;
- the importance of providing the decision-makers with a clear view of the radiological impacts in the form of maps: the tool called Criter developed by IRSN gives a representation of the results of environmental radioactivity measurements.

In 2017, ASN also brought all the players together to review best practices to improve the response organisation as a whole. In the light of the lessons learned from the emergency exercises and actual emergency situations, ASN decided to study the possibility of adapting the activation of its emergency organisation to the situation actually encountered and the information sharing procedures. In addition, in order to improve the emergency organisation activation time, ASN will define criteria for triggering of the general alert by ASN when it becomes aware of an emergency situation and the licensee of the site concerned is late in triggering the alert.

4. Outlook

In accordance with the 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 continue to be tested in 2018 during exercises, in particular in those *départements* in which there is no BNI.

Following the Government's September 2016 adoption of the principle of extending the radius of the PPI perimeter around NPPs from 10 to 20 km, the preparation of immediate evacuation out to 5 km and the pre-distribution of stable iodine tablets out to 20 km, ASN will in 2018 contribute to continuation of the PPI update work done by the offices of the Prefects and to the new population information and iodine tablets distribution campaign for inhabitants in the zone between 10 and 20 km from the NPPs.

In 2018, ASN will continue to be actively involved in the continued work on the roadmap for the major nuclear or radiological accident national response plan, in particular the work coordinated by the Ministry of the Interior with regard to the PPI perimeters for BNIs other than NPPs. ASN will also take part in the revision, coordinated by the SGDSN, of the Interministerial Directive of 7th April 2005 on the action of the public authorities in the case of an event leading to a radiological emergency situation. It will also initiate the revision of the post-accident doctrine through the work of the Codirpa.

The implementation of an on-call duty system at ASN is a priority action for 2018 in order to reinforce ASN's ability to deal with a nuclear or radiological emergency situation.

The nuclear safety Authorities confirmed the need to continue with international work to improve the coordination of the respective approaches by each country in an emergency situation. In 2018, ASN will continue with the European initiatives taken with a view to harmonisation of actions to protect populations in an emergency situation on either side of a border 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 2018, in order to prepare the offices of the Prefects for the performance of public protection measures or post-accident actions, certain exercises will be prolonged, as in 2017, by a phase focusing on civil protection objectives or workshops concerning the post-accident phase.

In order to improve the control of urban development around nuclear sites, ASN will in 2018 be reinitiating a working group on the examination of active institutional controls, together with the services of the ministry responsible for the prevention of risks and urban development, as well as the Ministry of the Interior.

Finally, in 2018, ASN will be publishing a guide for a standard PUI template and its justification part, following on from the approval of ASN resolution 2017-DC-0592 of 13th June 2017 concerning the obligations of BNI licensees regarding preparedness for and management of emergency situations.

Informing the public and other audiences

06

At ASN, the French nuclear safety Authority, informing the public and other audiences is at the centre of its activities. The Acts of 2006 on Transparency and Security in the Nuclear field[1] and 2015 on Energy Transition for Green Growth[2] explicitly entrusted ASN with the mission of making a statement on the state of nuclear safety and radiation protection in France. Consequently, throughout the year ASN informs the citizens, the media, the institutional and professional audiences of the situation of the Basic Nuclear Installations (BNI) and small-scale nuclear activities with respect to the safety and radiation protection requirements. It presents its regulatory and oversight activity and the actions it takes in this respect, and widely disseminates its resolutions and position statements, explaining them where necessary. It publishes notices, guides and reports intended for professionals and informed audiences.

ASN also encourages the involvement of civil society in maintaining nuclear safety and radiation protection: for example, it consults the stakeholders and the public on its draft resolutions. To this end, it ensures that the principles of nuclear safety and radiation protection are understood by the widest possible audience: it produces explanatory documents and endeavours to render even the most technical issues understandable. In 2017, ASN also continued its work to enhance the nuclear risk awareness culture by developing, jointly with the Institute for Radiation Protection and Nuclear Safety (IRSN), the ASN-IRSN travelling exhibition.

1. Developing relations between ASN and the public

1.1 Raising awareness in the public at large and developing a "risk awareness culture" among citizens

ASN fosters the development of a "nuclear risk awareness culture" and the involvement of citizens in subjects relating to nuclear safety and radiation protection. To this end, ASN develops complete communication vectors combining printed publications, the website, the social networks, press relations and meetings and interchanges with the stakeholders. In 2017, ASN continued the information and iodine tablet distribution campaign in the vicinity of BNIs, by sending systematic reminders to those buildings open to the public which had not yet collected their stocks of iodine tablets. It also assessed the effectiveness of this national campaign and measured the progress made in its visibility, recognition and the collection of iodine tablets (see box).

1.1.1 The website - *www.asn.fr*

With more than 50,000 individual visitors per month on average, the *www.asn.fr* website is at the heart of the system for informing the public and other audiences. All the draft opinions and resolutions can be consulted on the website. A total of more than 3.2 million pages of the site were viewed in 2017. The website is also a reference source of information for the more informed audiences: expert citizens, members of environmental associations and professionals.

A new version of the website went on line in June 2017, simplifying access to the information and documents published and meeting the new browsing requirements (mappings, enriched content). Website frequentation has increased by more than 40% further to this overhaul.

To satisfy the needs for explanations inherent to a wide audience, the publication formats are varied and meet new expectations, particularly on the social networks (primacy of the image, simplified diagrams, computer graphics and illustrations). New educational content is also regularly put on line.

ASN takes care to translate into English the majority of the information notices, press releases, publications and content concerning major issues. These publications in English support ASN's work in large international organisations and foster a concerted world-scale vision of nuclear safety and radiation protection.

Lastly, ASN sends its two-monthly *Lettre de l'Autorité de sûreté nucléaire* (Nuclear Safety Authority Newsletter) to more than 4,000 subscribers. This publication provides a summary of the most noteworthy topical issues and information relative to ASN resolutions and actions, including on the international front. To subscribe to the ASN newsletter, simply register on *www.asn.fr*.

1.1.2 The social networks

The website content, which can be consulted on all digital media, is also shared on the main social media (primarily Twitter, Facebook and LinkedIn). The news feeds on the ASN social network accounts relay the main position statements and are followed by more than 8,000 subscribers on Twitter, more than 4,500 on LinkedIn and nearly 3,000 on Facebook. The major events in which ASN participates (parliamentary hearings, public meetings) are announced and can be followed in real time on the social networks.

Since 2011, social media have been integrated in the communication organisation set-up for the emergency exercises and participate in the "media pressure simulations". The issue at stake is to take into account factors such as the immediacy of the reactions, the

1. *Act 2006-686 of 13th June 2006 relative to Transparency and Security in the Nuclear Field (TSN Act)*
2. *Act 2015-992 of 17th August 2015 relative to Energy Transition for Green Growth (TECV Act)*

FOCUS

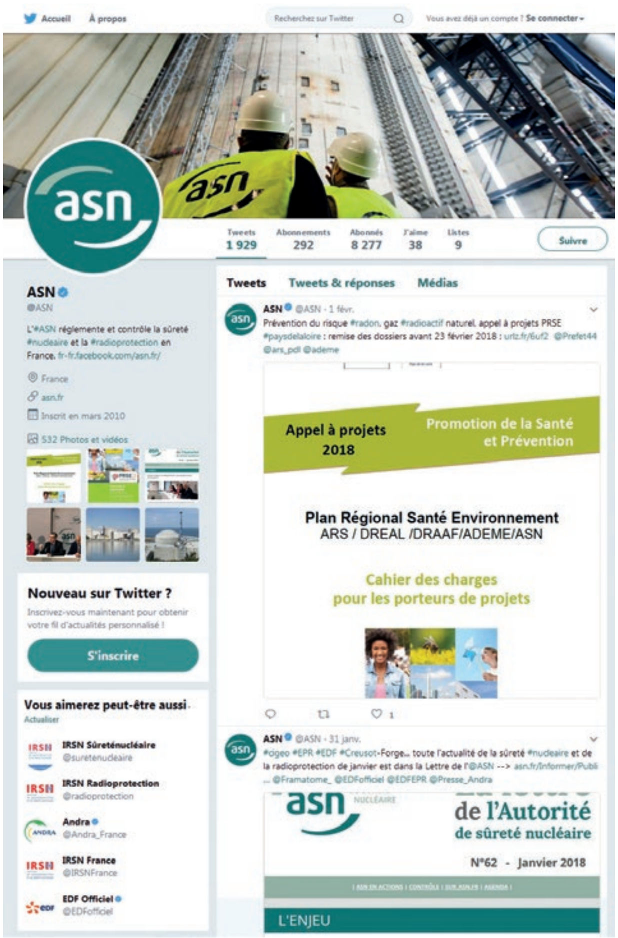
Significant progress in citizen mobilisation

The aim of the information and iodine tablet distribution campaign launched in 2016 and continued in 2017 was to develop a risk awareness culture among the populations living in the vicinity of the nuclear power plants. The number of iodine tablet collections from pharmacies by individuals, companies and buildings open to the public increased with respect to the previous campaign in 2009. Over and beyond that objective, the campaign also intended to develop citizens' awareness of the nuclear risk and knowledge of the means of protecting oneself against it. According to a survey by the BVA Institute in March-April 2017, the general public's memorisation of the campaign attains 93% and knowledge of the reflex protection actions in the event of a nuclear alert is widespread.

In 2018, taking account of the recent extension of the Off-site Emergency Plan (PPI*) radius from 10 to 20 km around the nuclear facilities, a campaign will be conducted in the new areas concerned to extend the risk awareness and the distribution of iodine tablets to the people living there. This campaign will be conducted by the local and national players (public authorities, health professionals, elected officials, EDF, Local Information Committees [CLIs], etc.). ASN will, on the strength its experience, assist the Ministry of the Interior in this procedure.

** The Off-site Emergency Plan ("PPI" is its French acronym) is a specific emergency plan drawn up by the State addressing risks associated with the existence and operation of specific installations or structures.*

urgency of the need for information and the speed of dissemination of incorrect or incomplete information, etc. In such emergency situations, whether simulated or real, ASN takes care to ensure the consistency, speed and clarity of the information delivered, including when it is delivered by other players.



The ASN Twitter account is followed by more than 8,000 subscribers: *twitter.com/ASN.*

1.1.3 The ASN/IRSN exhibition

As part of their duty to inform the public, ASN and IRSN have created an educational exhibition to develop knowledge of nuclear activities and radiation protection among high school pupils, students, employees, hospital personnel, patients, etc. and more generally the public at large.

Comprising some 80 display boards, it is designed to provide information on radioactivity - whether natural or artificial - its uses, its implications and its effects on humans and the environment. Some ten thematic sequences can be combined to meet more specific information objectives.

Through games, interactive media, videos, workshops, etc. the exhibition offers a comprehensive educational experience.

The exhibition is loaned free of charge. It is modular, light, readily transported and sufficiently flexible to adapt to the spatial constraints of the hosting venues.

In 2017, the exhibition was displayed in some sixty educational institutions and used as a support for conferences-debates, public meetings of Local Information Committees (CLIs), science fairs, etc.

Loan requests are to be made to *info@asn.fr*

1.1.4 The ASN Information Centre

Any citizen can address requests for information to ASN, either on-line (at the address *info@asn.fr*), by letter or by telephone. In 2017, the centre responded to more than 1,500 requests on diverse questions (technical questions, requests for administrative documents, information relative to the environment, publications, documentary searches, etc.).

1.2 ASN and the professionals

ASN produces specific publications, organises and takes part in numerous symposia and seminars to raise the professionals' awareness of the responsibilities and the implications of nuclear safety and radiation protection, to make known the regulations and to encourage the notification of significant events.

1.2.1 Making the regulations known and enhancing the safety culture

ASN considers that having clear regulations based on the best safety standards is an important factor in 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, while always being attentive to the clarity and completeness of the information delivered to the public concerning these regulations. The public is moreover increasingly involved in the rules development process.

ASN guides for concrete application of resolutions

The ASN guides give recommendations, present 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. Five ASN guides were created or updated in 2017, then published on the ASN website:

- In the medical field, ASN published a guide entitled *The minimum technical design, operating and maintenance rules applicable to in vivo nuclear medicine facilities*.
- Two guides concerning the transport of radioactive substances were published in 2017, one entitled *"The new procedures for notifying events relating to the transport of radioactive substances"*, the other *"Implementation of the regulatory requirements applicable to on-site transport operations"*.
- Two guides produced jointly with IRSN in 2017 provide recommendations for the design of BNIs. One is entitled *"Design of pressurized water reactors"*, the other *"Qualification of scientific computing tools used in the nuclear safety case - 1st barrier"* (the first barrier being the nuclear fuel).

A section for the professionals on www.asn.fr

The professionals can find all the regulatory texts and forms concerning their area of activity in a specific section, and they can create a personalised account. It also contains the data sheets, results by sector, presentations of regional seminars, letters on the regulations, etc.

Contrôle *magazine*

Following publication of issue No. 201(end of 2016), *Contrôle* magazine has been temporarily suspended pending a decision on the new form it should take (publication frequency, format). Distributed until then in several thousand copies, each issue provided an in-depth review of one of the major subjects relating to nuclear safety and radiation protection. The last one hundred issues of *Contrôle* magazine can still be consulted on *www.asn.fr*.

1.2.2 Radiation protection: a portal to notify significant events and a bulletin for sharing experience feedback

The notification of significant events is a key factor in reinforcing the safety and radiation protection culture. Since May 2017, all significant events concerning radiation protection have to be notified via ASN's new on-line services portal: *teleservices.asn.fr*. The possibility of notifying incidents on line, which has been operational since 2015 for radiotherapy, is now available for all medical applications that use ionising radiation: nuclear medicine, interventional and fluoroscopy-guided practices, computed tomography and conventional and dental radiology.

The *www.mesure-radioactivite.fr* website gives the public access to the 300,000 radioactivity measurements taken each year in France in the various compartments of the environment (air, water, soils, fauna and flora) and in food products.

The *www.asn.fr* website receives more than 50,000 individual visitors per month on average.

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 healthcare safety. Two new issues were published in 2017, addressing the protraction and fractionation of the delivered dose, and the place of the patient in treatment safety.

1.2.3 Professional symposia and seminars

ASN participates very regularly in the congresses of the French Association of Radiographers (AFPPE), the French Radiology Days and the days of the French Society for Radiation Protection (SFRP) devoted to Radiation Protection Officers-Experts.

These events provide the opportunity to interchange with specialised audiences, to enhance knowledge of the regulations (regulatory sheets and guide to the regulatory provisions relative to medical and dental radiology), to present the inspection results (*in vivo* nuclear medicine, computed tomography) and to share the analysis of significant radiation protection events.

In 2017, ASN organised in Paris the first meeting of occupational physicians on account of their role in radiation protection and control of radiation doses in medical imaging. The other medical seminars focused on interventional radiology.

On the initiative of ASN, a first meeting of holders of high-activity sealed sources (HASS) was held in Dijon to share experience feedback and take stock of the regulatory changes associated with integration of the security of sources.

1.3 ASN and the media

ASN maintains regular relations with the regional, national and foreign media throughout the year. ASN spokespersons responded to more than 600 press queries in 2017 and gave some twenty local and national press conferences.

The main subjects relating to specific facilities addressed in the press in 2017 were:
- the follow-ups to the detection of irregularities at the Creusot Forge plant;
- the EPR and the outage of Fessenheim reactor 2;
- the Fessenheim nuclear power plant;
- the safety situation of the Bugey NPP;
- the outbreak of fire that led to detonation on a turbine at Flamanville;
- the follow-ups to the fall of a steam generator at the Paluel NPP;
- the earthquake resistance of the facilities;
- the provisional shutdown of the Tricastin NPP.

And for the more recurrent or general subjects:
- the position of ASN on the extension of operation of the NPPs ;
- decommissioning;
- the security of the NPPs following the intrusions by Greenpeace.

FOCUS

The ASN barometer

In 2017, ASN conducted the 14th wave of its annual "barometer". This opinion survey was carried out from late October until early December 2017 on representative samples of the general public and of the informed and professional audiences. Moreover, a sample of people living in the Off-site Emergency Plan (PPI) zone near a BNI was constituted in order to get a better grasp of the issues associated with the risk awareness culture. The results of this survey will be issued in spring 2018.

1.4 ASN's relations with elected officials and institutional bodies

In 2017, ASN was heard on some ten occasions before Parliament with respect to its activities and subjects relating to nuclear safety and radiation protection and with regard to the budget bill for 2018.

On 30th November, ASN presented its *Report on the state of nuclear safety and radiation protection in France in 2016* to the Parliamentary Office for the Evaluation of Scientific and Technological Choices (OPECST). This report, which constitutes the reference document on the state of the activities regulated by ASN, is effectively submitted each year to the President of the Republic, to the Government and to the Parliament. It is also sent out to more than 2,000 addressees: heads of administrative authorities, elected officials, licensees and persons/entities in charge of regulated activities or installations, associations, professional unions and learned societies.

ASN also maintains regular contact with the national and local elected officials and interchanges with its institutional contacts on subjects relating to nuclear safety and radiation protection.

Participation of ASN and IRSN at the 21st Mayors and Local Authorities Exhibition

For the fourth year running ASN was present at the Mayors and Local Authorities Exhibition which ran from 21st to 23rd November, sharing a stand with IRSN, its technical support organisation. The urban planning -related issues were widely discussed with the mayors of municipalities situated in off-site emergency plan zones.

It also provided an opportunity to present the changes in the *www.mesure-radioactivite.fr* website created by ASN and IRSN in 2010.

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 in informing the public. In 2017, ASN continued its participation in the Communication Working Group (WGPC) coordinated by the Nuclear Energy Agency. ASN took part in a cooperation mission financed by the European Commission to help the Vietnamese nuclear regulator establish an information policy that meets the best international standards (see chapter 7). Each year ASN receives foreign delegations wishing to find out more about its practices.

1.6 ASN staff and information

In order to issue 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 has a duty to inform the public in the event of an emergency situation[3]. In order to prepare for this, ASN staff receive specific training and take part in emergency exercises. In 2017, eight emergency exercises included simulated media pressure from journalists, designed to assess and strengthen ASN's responsiveness to the media, as well as the consistency and quality of the messages put across by the various stakeholders, both nationally and locally (see chapter 5).

2. Reinforcing the right to information and participation of the public

ASN is extremely vigilant in the application of all the legislative and regulatory provisions governing transparency and access of the various audiences to information. ASN also ensures they are applied by the licensees under its oversight, and it endeavours to facilitate interchanges between the stakeholders.

2.1 Information provided by the licensees

The main licensees of nuclear activities implement 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 as detailed below.

The annual public information report 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 regard to the prevention of risks for public health and the environment.[4] In 2010 ASN published a guide containing recommendations for the drafting of these reports (ASN Guide No.3, *Recommendations for drafting the annual public information reports relative to basic nuclear installations*). The reports are often presented to the CLIs.

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.

In application of the Environment Code, licensees must communicate to any person who so requests, the information they hold on the risks their activity presents for public health and the environment and on the measures taken to prevent or mitigate these risks.

This right to information on the risks also concerns those responsible for the transport of radioactive substances when the quantities involved exceed the thresholds set by law.

3. *Pursuant to the provisions of Article L. 592-32 of the Environment Code.*
4. *See Article L. 121-15 of the Environment Code.*

The Commission for Access to Administrative Documents (CADA)

In the event of refusal by a licensee to communicate information, the applicant can refer the matter to the Committee for Access to Administrative Documents (CADA), an independent administrative Authority, which gives an opinion on whether the refusal is justified or not. 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 can be communicated. ASN is heavily committed to the application of this right to information and regularly encourages the public to exercise it.

2.2 Information given to populations living in the vicinity of basic nuclear installations

The TECV Act has instituted an obligation to regularly inform the populations living in the vicinity of a BNI of the nature of the accident risks associated with that installation, the envisaged consequences of such accidents, the planned safety measures and the action to take in the event of an accident. This information is provided at the expense of the licensee.

2.3 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 decisions taken by ASN or in which it participates by formulating opinions (draft decrees and orders issued by the Government in particular).

2.3.1 Public consultation on draft ASN regulations

Article L. 123-19 of the Environment Code provides for a procedure of consultation of the public via the Internet on draft regulatory texts having an impact on the environment.

ASN has decided to apply this widely. Consequently, all draft ASN regulations 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 ASN regulations relative to the transport of radioactive substances that ASN adopts.

ASN's regulations relating to radiation protection are also submitted to public participation if they concern activities involving significant releases 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 ASN regulations and guides having an impact on the environment is updated every three months on *www.asn.fr*.

FOCUS

Public inquiry on the periodic safety reviews

A public inquiry is planned at the periodic safety review of nuclear reactors which have been in operation for more than 35 years.

This provision will start to apply in the coming months with the fourth periodic safety reviews of the 900 MWe reactors operated by EDF. In view of the stakes these reviews represent, of the importance of ensuring a good level of public participation in this process, and of the complexity of the process (with a "generic" phase concerning all the reactors and phases specific to each reactor), the HCTISN (French High Committee for Transparency and Information on Nuclear Security) has set up, further to an ASN proposal, a working group tasked with proposing practical methods of public participation in these various phases.

The public participation procedure consists in posting the draft ASN regulation on the website 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 regulation are published on *www.asn.fr* at the latest on the date of publication of the regulation. During 2017, three consultations concerned draft ASN regulations and three concerned draft guides.

2.3.2 Public consultation about draft ASN licensing decisions

The ASN licensing decisions 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, the BNI creation authorisation and decommissioning procedures form the subject of a public inquiry.

Since 1st June 2012, in an ongoing experiment, the files of projects that are subject to a public inquiry and which could affect the environment are available on line. The BNIs, whether for their creation or their decommissioning, are included in this experiment.

Disclosure of drafts on www.asn.fr

The ASN licensing decisions which are not subject to public inquiry and which could have a significant effect on the environment are disclosed for consultation on the Internet. These are mainly individual requirements 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 is open for at least fifteen days on *www.asn.fr*.

During 2017, seventy-five (75) draft ASC licensing decisions were 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). It now supplements the general consultation procedure via the ASN website.

2.3.3 Consultation of particular bodies

The BNI authorisation procedures also include consultation of the departmental council, the municipal councils and the CLIs for their opinion (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 Departmental Council for the Environment and for Health and Technological Risks are consulted on the draft ASN requirements 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.

2.3.4 Consultation: for ever wider and more varied participation of the various audiences

ASN ensures that these consultations allow the public and the associations concerned to express their views, in particular by verifying the quality of the licensee's files and by trying to develop the CLI's resources so that they can express an opinion on the files.

The framework of the public consultation has greatly evolved over the last few years. It is now necessary to make the practical conditions of these consultations evolve to make them more effective aids to public participation.

2.4 The other actors in the area of information

2.4.1 High Committee for Transparency and Information on Nuclear Security (HCTISN)

The 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 organised four plenary meetings in 2017 during which major topical subjects were detailed and discussed: all the presentations can be consulted on *www.hctisn.fr*. The HCTISN made three opinions public: "The intentional addition of radionuclides to consumer goods or construction products", "Public information and transparency concerning the construction anomalies of the Flamanville 3 EPR reactor" and "The carbon concentration anomalies on certain steam generators of the EDF reactors".

2.4.2 Institute of Radiation Protection and Nuclear Safety (IRSN)

IRSN implements a policy of information and communication that is consistent with the objectives agreement signed with the Government.

The IRSN presents its activities in an annual report which is distributed to its supervisory ministers, to the HCTISN, the French High Public Health Council (HCSP) and the Working Conditions Guidance Council (COCT).

The TECV Act obliges IRSN to publish the opinions it gives to the authorities who referred matters to it. Thus since March 2016, IRSN publishes twice a month on its website all the opinions it issues at the request of ASN. These opinions are the synthesis of the appraisal carried out by IRSN in response to ASN's request.

Alongside this, in 2017 - as in the previous years - IRSN made public the results of its research and development programs, with the exception of those concerning national Defence.

IRSN continued to develop its "multichannel" information policy and its educational approach to nuclear and radiological risks with new files on its website and increased presence on the social networks (professional and general public), not to mention the exhibition on nuclear and radiological risks created by ASN and IRSN for all audiences (see point 1.1.2).

FUNDAMENTALS

High Committee for Transparency and Information on Nuclear Security

The HCTISN comprises 40 members appointed by decree for six years. They include:

- two members of the National Assembly appointed by the National Assembly and two members of the Senate appointed by the Senate;
- six representatives of the CLIs;
- six representatives of environmental protection associations and approved health system users associations;
- six representatives of persons in charge of nuclear activities;
- six representatives of representative employee labour organisations;
- six "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 chair of the HCTISN is appointed by the Prime Minister from among Members of Parliament, members of the CLIs or qualified public figures.

Marie-Pierre Comets has chaired the HCTISN since 2015.

2.4.3 The Local Information Committees (CLI)

The CLIs have a general duty of monitoring, informing 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 nuclear site around which they have been created.[5]

Operating framework

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 State services, including ASN, and of the licensee have an automatic right to participate in the work of a CLI in an advisory capacity. The TECV Act provides for the participation of foreign members in the CLIs of border *départements*.

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. They receive the information they need to function from the licensee, from ASN and from other State services. They may request expert assessments or have measurements taken on the installation's discharges into the environment.

Further to the redefining of the Off-site Emergency Plan (PPI) zones, the decree relative to BNIs and transparency in the nuclear field provides for the adaptation of the composition and competencies of the CLIs.

ASN considers that the good functioning of the CLIs contributes to safety. ASN aims to ensure that the CLIs receive information that is as complete as possible. Representatives of the ASN regional divisions regularly attend CLI meetings. The ASN regional divisions also invite CLI representatives to take part in inspections. At present, only the ASN inspectors have an enforceable right of access to the licensee's facilities. This means that the consent of the licensee is necessary for observers from CLIs to participate in inspections. ASN encourages BNI licensees to facilitate CLI access to the files concerning procedures in which the CLI's opinion will be required.

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.

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 reflections 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 of 13th June 2006, to add to the budget of the CLIs with association status (there are about ten of them) with a matching contribution of funds drawn from the BNI Tax; however, this provision has not yet been implemented.

Poster for the meeting of the Normandie CLIs: retrospective on the lessons learned from Fukushima, six years after the accident.

All BNI sites have a CLI, except for the Ionisos facility in Dagneux in the Ain département. This means that there are 35 CLIs governed by 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.

The 35 CLIs count nearly 3,000 unpaid members, including 1,500 elected officials.

For the nuclear sites concerning Defence, which are regulated by the delegate to nuclear safety and radiation protection for defence-related activities and installations, 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 CLIs organise plenary meetings and set up specialist commissions.

The TECV Act obliges each CLI to hold at least one public meeting per year. The majority of the CLIs have applied this provision, either by opening one of the CLI meetings to the public, or by organising an event designed especially for the

5. *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 29th Conference of Local Information Committees brought together 260 participants on 15th November 2017 in Paris at the initiative of ASN and in partnership with Anccli.

public. The audience attending these shared moments can be very variable. Exchanges of good practices should allow these results to be improved upon so that the CLIs can better fulfil their primary role, namely informing the local population.

About thirty CLIs have a website or have pages on the website of the local authority that supports them. Some twenty CLIs publish a newsletter (sometimes as inserts in the news bulletin 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.

ASN informs the CLIs regularly about the files concerning the nuclear facilities. The CLIs are always informed of the launching of public consultation procedures by ASN.

2.4.4 National association of local information committees and commissions (Anccli)

The Environment Code[6] provides for the constitution of a federation of CLIs and the Decree of 12th March 2008 details the missions of this federation. Anccli groups the 35 CLIs that exist in France. It is currently chaired by Jean-Claude Delalonde. The Anccli has a scientific committee and has set up five thematic advisory groups (“Radioactive materials and waste”, “Post-Accident - territories”, “Safety”, “Decommissioning”and “Health”). It is also heavily involved in the discussion and interchange bodies set up by its partners (HCTISN, ASN, IRSN, etc.).

In 2017, these advisory groups published three white papers intended for CLI members and the institutions: *“Planning emergency management and post-accident management”*, *“Reversibility and retrievability”* and *“Under what conditions can the CLIs and Anccli participate influentially in the regional and national monitoring of decommissioning work sites?”*.

Anccli coordinates the network of CLIs and leads national reflections on questions of nuclear safety within dedicated working groups.

Partnership with ASN

Anccli interchanges with ASN very regularly and participates in several of its permanent or occasional working groups. In 2017, Anccli representatives took part in meetings of the Advisory Committees of Experts, of several working groups of the Codirpa (on post-accident management), of the Steering committee for social, organisational and human factors, and lastly of the working group on the PNGMDR (French National Radioactive Material and Waste Management Plan).

Anccli consolidates its expertise by organising thematic seminars jointly with IRSN. It also participates in the meetings of the HCTISN and in its working groups. Anccli, with ASN and IRSN, maintains a technical dialogue on the high-stake issues and takes part in the public consultations on nuclear questions.

6. *In accordance with Article L. 125-32 of the TSN Act.*

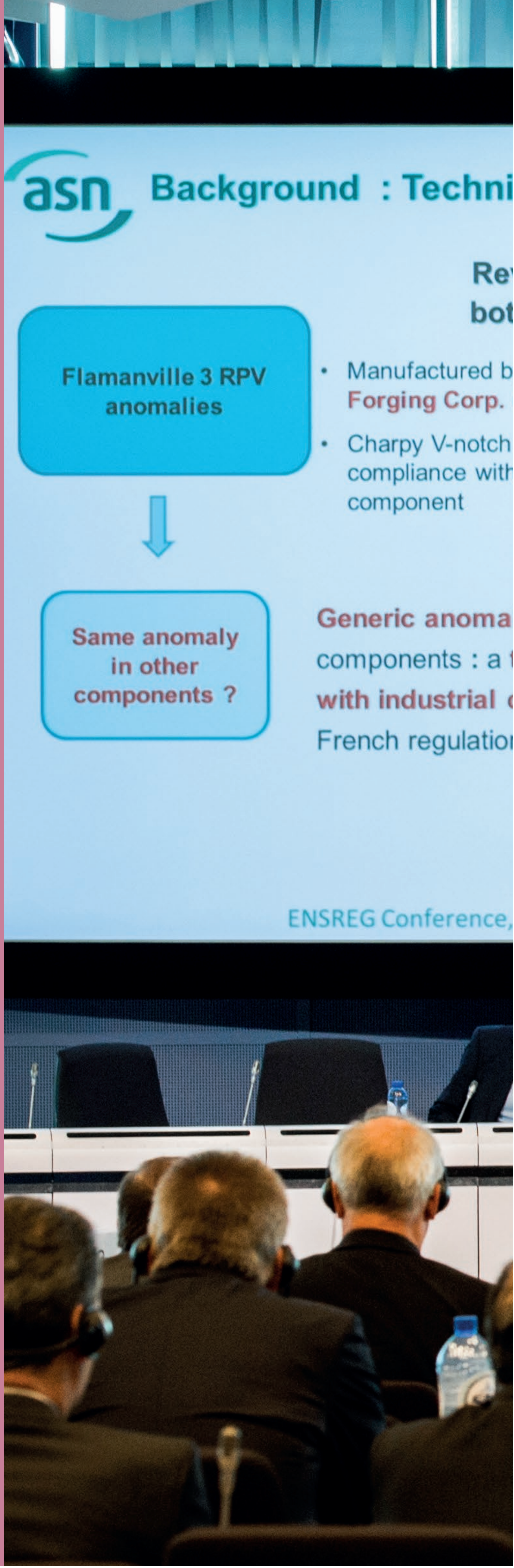
3. Outlook

In 2018, ASN will further develop its information actions targeting the general public, endeavouring to make the technical subjects it presents clearer and more accessible. It will continue its action to foster transparency and information in the nuclear field. It will improve in particular the conditions in which members of the public can be consulted on the draft opinions and regulatory texts.

It will assist with the organising of measures to inform the populations situated in the Off-site Emergency Plan (PPI) zones, which have had their radius extended from 10 to 20 km around the nuclear installations; it will ensure correct implementation of the obligations to regularly inform the populations situated in these zones.

In 2018, ASN will develop the information it gives to the public on its duties, its areas of competence and its oversight activity. It will interchange with the elected officials and stakeholders and place itself at their disposal to clarify any questions relating to nuclear safety and radiation protection.

ASN will continue to support the CLI's in their activities – particularly in their role of informing the public and other audiences – and to maintain high-quality interchanges with them.



asn
Background
Flamanville 3 RPV
anomalies
Forging Corp.
component
Same anomaly
in other
components ?
ENSREG Conference,

International relations

07

Through a range of bilateral, European and multilateral cooperation frameworks, ASN aims to promote the adoption of ambitious international requirements to make known French positions and doctrines which could contribute to this promotion and to draw on the best practices from around the world to advance nuclear safety and radiation protection. This helps make ASN an international benchmark.

This process of sharing, harmonisation and improvement of knowledge and practices also includes cooperation on any significant nuclear events or accidents (for example Chernobyl and Fukushima Daiichi) in which France has played a key post-accident management role since 2011.

This action is based on the legislative provisions of the Environment Code, which states that within its scope of competence, ASN proposes France's positions to the Government for international negotiations and must represent France in international and community organisations in this field.

1. ASN objectives in Europe and worldwide

The approach for sharing, harmonisation and improvement of knowledge and practices requires that ASN work in three complementary consecutive circles.

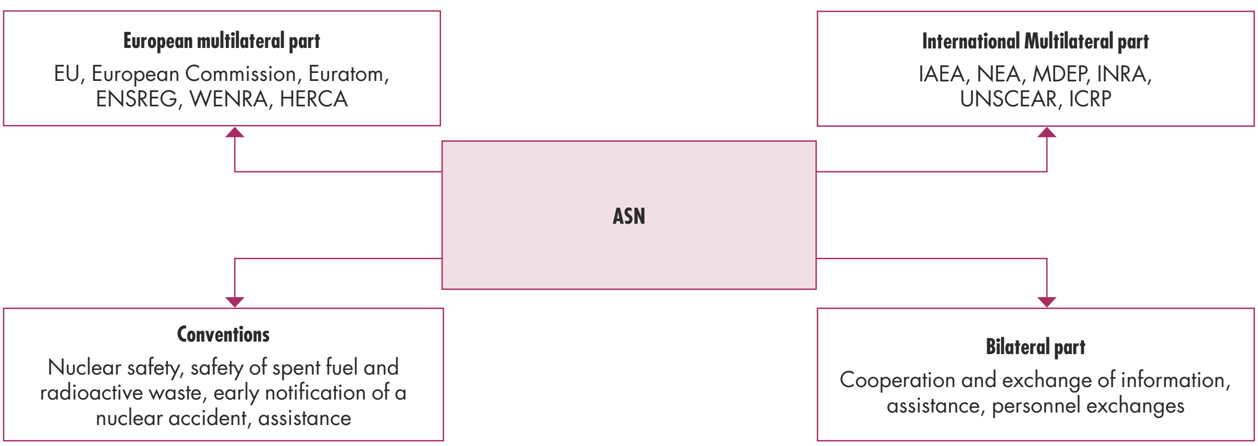
At a bilateral level, ASN first of all cooperates with numerous countries under bilateral agreements, which can be governmental agreements or administrative arrangements. Bilateral relations allow direct exchanges on topical subjects and the rapid implementation of cooperation measures, sometimes on behalf of joint initiatives within a European or multilateral framework, which can lead to the drafting of new safety or radiation protection baseline requirements. They are also essential in the management of emergency situations.

At a European level, the regulatory context has changed in recent years, with the adoption and updating of three European Directives on nuclear safety (Council Directive 2009/71/Euratom of 25th June 2009 creating a community framework for the nuclear safety of nuclear facilities/revised 2014), waste legislation (Council Directive 2011/70/Euratom of 19th July 2011 creating a community framework for the responsible and safe management of spent fuel and radioactive waste) and radiation protection (Council Directive 2013/59/Euratom of 5th December 2013 setting basic standards for health protection against the dangers arising from exposure to ionising radiation and repealing Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom and 2003/122/Euratom).

In the construction of this legal framework concerning nuclear safety, the European Commission is supported by ENSREG (European Nuclear Safety Regulators Group) which brings together experts from the European Commission and member countries of the European Union.[1]

1. The national delegations are made up half by heads of safety Regulators and half by representatives from Ministries for the Environment or Energy.

ASN ACTION on the international stage



The safety regulators also set up voluntary associations, such as the Western European Nuclear Regulators Association (WENRA), the Heads of the European Radiological protection Competent Authorities (HERCA) and the European Association of Competent Authorities (EACA) for the transport of radioactive materials.

At a multilateral level, cooperation takes place within the framework of the International Atomic Energy Agency (IAEA), a UN agency founded in 1957, and the OECD's Nuclear Energy Agency (NEA), created in 1958. These two agencies are the most important inter-governmental organisations in the field of nuclear safety and radiation protection.

1.1 Giving priority to Europe

Europe is one of the priority areas for ASN's international actions. The aim is to contribute to sharing, harmonisation and improving knowledge and practices in the fields of nuclear safety, the safety of waste and spent fuel management and radiation protection.

With regard to nuclear safety and the safe management of waste and spent fuel, ASN takes part in two informal organisations working more specifically in favour of European harmonisation: ENSREG and WENRA.

ENSREG was created in 2008 and 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.

WENRA was created in 1999 and is an association of the heads of nuclear regulatory authorities in European countries with power reactors, with the other countries being observers. This association is based 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, HERCA, which was founded in 2007, aims to create an informal forum for heads of radiation protection authorities, along the lines of WENRA. Its aim is to reinforce European cooperation in radiation protection and the harmonisation of national practices.

1.2 Cooperation in the fields of nuclear safety and radiation protection outside Europe

ASN multiplies its initiatives to share nuclear safety and radiation protection best practices and regulations outside Europe.

Within the 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

Presentation by Pierre-Franck Chevet, ASN Chairman, at the opening of the ENSREG conference in Brussels, 28th-29th June 2017.

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), along with OSART (Operational Safety Review Team) audits of nuclear power plants in operation.

ASN also contributes actively to the MDEP (Multinational Design Evaluation Programme) the aim of which is to discuss and compare the experiences of safety regulators with regard to the evaluation of new reactors, including the EPR. This programme, started in 2006 by ASN and the American Nuclear Regulatory Commission (NRC), currently brings together 16 safety Authorities and aims to develop innovative approaches for sharing the resources and knowledge of the safety regulators in charge of regulatory evaluation of new reactors, in order to contribute to the harmonisation of safety standards and their implementation.

In the field of radiation protection, ASN monitors the progress of the work done by 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.

FUNDAMENTALS

Extensive sharing of operating experience feedback: manufacturing anomaly in nuclear reactor components

Within its various circles of cooperation, ASN aims to benefit from the operating experience feedback of its counterparts and also share its own.

As of mid-2015, ASN began discussions with its counterparts on a bilateral and multilateral (MDEP) basis concerning the anomalies found in the composition of the steel in the centre of the Flamanville EPR reactor pressure vessel closure head and bottom head. This analysis of manufacturing anomalies was at the same time extended to the fleet in service and revealed the presence of positive carbon macrosegregations in some of its components. As of the autumn of 2016, ASN met its main counterparts whose NPP fleets could be affected by similar anomalies. It also presented this subject at a plenary meeting of the WENRA association and the 7th review meeting of the contracting parties to the Convention on Nuclear Safety. At the plenary meeting of WENRA in April 2017, ASN was tasked with setting up an ad hoc group to define coordinated measures for checking large components and making changes to the manufacturing codes.

2. Relations within Europe

European harmonisation of nuclear safety and radiation protection principles and standards has always been a priority for ASN. In this context, ASN participates actively in exchanges between the national nuclear safety and radiation protection authorities of the Member States.

2.1 The EURATOM Treaty

The Treaty creating the European Atomic Energy Community (EURATOM) was signed on 25th March 1957 and constitutes the primary law in the field. It has allowed 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.

2.2 European Nuclear Safety Regulators Group (ENSREG)

ASN chairs the work of ENSREG, which supports the European Commission's European legislation initiatives. ENSREG is supported by three working groups, devoted to installations safety (WG1), the safe management of radioactive wastes and spent fuels (WG2) and transparency in the nuclear field (WG3) respectively. A fourth group (WG4) dealing with international cooperation was restored to the mandate of WG1 and more specifically focuses on the European Commission's Instruments for Nuclear Safety Cooperation (INSC) (evaluation and programming).

ENSREG and the European Commission created the stress tests initiative for the European NPPs, organised in 2012 in the wake of the Fukushima Daiichi accident.

A further exercise to follow up the recommendations of the stress tests was carried out in 2015. ASN sent ENSREG its updated action plan, as did the other Member States.

ENSREG is also organising the first peer review of ageing management for power reactors and research reactors with a power of greater than 1 MWth. Each of the 19 countries taking part in this review is thus in charge of drafting a national report devoted to an assessment of ageing management for the reactors concerned. The closure date for on-line publication of this report on the ENSREG website was set at the end of December 2017. The first meeting devoted to the topical peer review will be held from 14th to 18th May 2018 in Luxembourg, while the second – to present the conclusions, including to the stakeholders – will be on 6th and 7th June 2018.

In 2017, ASN chaired the steering committee for the 4th ENSREG conference, a two-yearly event held in June in Brussels. This conference was an opportunity to bring all the stakeholders together (licensees, industry, NGOs, European Commission, Member States) around the European nuclear safety regulators and some of their counterparts from outside the European Union, to discuss nuclear safety progress and challenges. Radioactive waste management, the process for licensing new facilities, reactor operations beyond forty years and oversight of the supply chain were all covered during the course of four thematic sessions.

2.3 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 (see chapter 3).

Directive 2014 modifies Directive 2009 and more specifically requires additional measures concerning peer reviews, safety reassessments every ten years, greater transparency and safety objectives incorporating the notion of defence in depth.

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.

This Directive was extensively transposed into the Energy Transition for Green Growth Act 2015-992 of 17th August 2015 (TECV Act) and Ordinance 2016-128 of 10th February 2016 containing various nuclear-related provisions. With the help of ASN, France also notified complete transposition of the 2014 Directive in August 2017, in accordance with the deadlines set by the Commission. Consistently with this transposition, ASN supports actions aiming to define the technical safety objectives being sought.

2.4 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 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

FUNDAMENTALS

Irregularities and falsifications: adapting ASN oversight to a context of fraud

Changing ASN's approach taking account of lessons learned around the world and sharing the conclusions of its work

Following the discovery of irregularities in the manufacturing files for components manufactured by the Creusot Forge plant, ASN set up an in-house working group at the beginning of 2017 to adapt its oversight processes. This work drew on the existing IAEA guides and the work of the NEA (CNRA/WGOE) and questioned its counterparts by means of the various multilateral forums. As of mid-2017, ASN presented the initial results of this work and chaired a session devoted to oversight of the supply chain, at the 4th ENSREG conference (28th and 29th June in Brussels).

Studies in France about prevention and detection measures relating to safety culture, data integrity, or the use of information obtained from whistle-blowers, served as input for the initial ENSREG work programme, which will be continuing. In the autumn of 2017, ASN presented the conclusions of its work to WENRA and to the MDEP. The latter decided to take the work done by ASN further in order to share the best practices.

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. These aspects constitute significant progress in reinforcing the safety and accountability of spent fuel and radioactive waste management in the European Union. The TECV Act and the Nuclear Ordinance enabled the provisions of the Directive to be transposed.

2.5 The Euratom European Directive on Radiation Protection "Basic Standards"

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. The Member States were required to transpose the provisions of this Directive before 6th February 2018.

Starting in 2013, ASN was leader and technical secretary for the transposition committee for this Directive. ASN also made sure that it played an active part in the work of the HERCA association to facilitate transposition. ASN more specifically focused on the subjects of the medical applications of ionising radiation, preparedness for emergency situations, the training of "radiation protection experts" and "radiation protection officers".

2.6 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).

2.7 The Western European Nuclear Regulators Association (WENRA)

WENRA continues to develop a joint approach to nuclear safety and its regulation, more notably within the European Union. WENRA created two working groups with the role of harmonising safety approaches in the fields of:
- nuclear power reactors (Reactor Harmonisation Working Group - RHWG);
- radioactive waste, spent fuel disposal and decommissioning (Working Group Radioactive Waste and Decommissioning - WGWD).

In each of these fields, the groups defined the reference levels for each technical topic, based on the IAEA's most recent standards and on the most stringent approaches adopted within the European Union.

In 2017, WENRA held two plenary meetings, in April in Berne and in October at The Hague. These meetings produced the following major contributions:
- validation of an analysis document (ad hoc group on Article 8 of the 2014 Directive) concerning safety improvements to existing nuclear facilities, in response to the general objectives set by the 2014 Directive;
- finalisation of the technical specification allowing the start of the Topical Peer Review (TPR) in accordance with the 2014 Directive;
- continued technical examination of types of possible improvements, related to the first orientations of the *ad hoc* group;
- continued work on the reference levels concerning waste management;
- ASN oversight of a working group for technical anomalies (macrosegregation) on nuclear pressure equipment for Pressurised Water Reactors (PWR). This group enabled the French technical analysis to be shared and a draft recommendation to be prepared;
- initial examination of the need to develop reference levels for research reactors, more particularly by reviewing the levels developed for PWRs.

2.8 The Association of the Heads of the European Radiological Protection Competent Authorities (HERCA)

HERCA, the Association of the Heads of the European Radiological Protection Competent Authorities, was created in 2007 at the initiative of ASN in order to organise close consultation between the heads of the European Authorities with competence for radiation protection. In now comprises 56 Authorities, 32 of which come from European countries.

Five expert groups are currently working on the following topics:
- practices and sources in the industrial and research fields;
- medical applications of ionising radiation;
- preparation and management of emergency situations;
- veterinary applications;
- sources of naturally occurring radiation;
- education and training.

ASN has been the technical secretary for this association since it was created and takes part in all the working groups. Moreover, in 2018 and 2019, ASN will chair the working group on medical applications.

As early as 2014, HERCA approved an action plan to facilitate the transposition of Directive 2013/59/Euratom of 5th December 2013 (see point 2.5).

In 2017, HERCA closed its action plan with the publication of six important documents concerning the transposition work and the implementation of the requirements of the Euratom Directive on radiation protection basic standards in the following fields:
- training of "radiation protection experts" and "radiation protection officers";
- justification of new types or categories of practices in the medical field;
- involvement of scanner manufacturers in the optimisation of imaging procedures;

- accidental and involuntary exposure in the medical sector;
- radiation protection training of veterinary sector professionals;
- radon, radiation protection activities (NORM) and construction materials.

These documents were published on the HERCA website (*www.herca.org*).

In the field of preparedness for and response to emergency situations, HERCA monitors the implementation of the HERCA-WENRA approach by the member countries. It should be recalled that this approach, approved in 2014, aims to coordinate population protection measures with those measures decided on by the country in which the accident occurred, in order to create a coherent response in the countries affected by the accident. HERCA is continuing its work to facilitate the effective implementation of this approach. It is in particular working on the definition of a common situation report, on transboundary coordination of population protection measures and on the production of country sheets for management of emergency situations.

The Board of HERCA met twice in 2017.

At the last HERCA board meeting (2nd and 3rd November 2017), the working groups presented an update of their mandates and of their action plan for the next three years.

2.9 ASN participation in the European Horizon 2020 programme

In 2017, 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 II (Sustainable Network of Independent Technical Expertise for Radioactive Waste Disposal) project, carried out under the European Horizon 2020 Programme.

The aim of the SITEX I project (2012-2013) 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.

The project continued from June 2015 to November 2017. Its main goal was to set up a platform dedicated to technical expertise in the field of geological disposal facilities. It more specifically looks at questions of research, training, and examination of files by the safety regulators and experts and the involvement of civil society.

2.10 Assistance programmes under the Instrument for Nuclear Safety Cooperation (INSC)

In 1991, the Commission launched the "nuclear safety" part of the TACIS programme to address the concerns raised by the Chernobyl accident. From 1991 to 2006, more than €1.3 billion were committed to nuclear safety projects. Since 2007, the actions of the European Union with regard to assistance and cooperation in the field of nuclear safety have continued under the Instrument for Nuclear Safety Cooperation (INSC).

Three priority areas for assistance to the countries of Eastern Europe were defined under these programmes, 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.

Regulation 237/2014/Euratom 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 236/2014/EU 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.

These actions are supplemented by other international technical assistance programmes, in accordance with resolutions adopted by the G8, or by the IAEA, to improve nuclear safety in third party countries, and which are funded by contributions from donor States and the European Union.

The tangible assistance actually provided by ASN via the INSC mainly took the form of aid for the nuclear safety authorities. Thus, in 2017, ASN took part in regulatory assistance projects on behalf of the safety regulators of China (second phase) and Vietnam. It also took part in calls for bids and notably won the Turkey project.

3. Multilateral International Relations

3.1 The International Atomic Energy Agency (IAEA)

The International Atomic Energy Agency (IAEA) is a United Nations organisation based in Vienna. It comprises 168 Member States (November 2017 data). The IAEA's activities are focused on two main areas: one of them concerns the control of nuclear materials and non-proliferation and the other concerns 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.

Following on from the action plan approved by the IAEA Board of Governors in September 2011 and with the aim of reinforcing safety worldwide by learning the lessons from the Fukushima Daiichi accident, the 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 CSS, set up in 1996. The CSS consists of 24 representatives from the highest levels of safety regulator organisations, appointed for four years and has been chaired since early 2012 by the Director General of the Czech regulatory body, Dana Drabova. In 2017, the CSS held its 41st and 42nd meetings. An ASN deputy Director General is the French representative sitting on this commission, which coordinates the work of five committees. These committees are tasked with drawing up documents in their respective fields: 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, WASSC (Waste Safety Standards Committee) for safe radioactive waste management and EPReSC (Emergency Preparedness and Response Safety Standards Committee) for preparation and coordination in the event of a radiological emergency. 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 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 mandates of the national representatives on these various committees came to an end at the end of 2017; they will be updated in 2018.

A specific committee for security (Nuclear Security Guidance Committee - NSGC) was created and an interface designed to improve the analysis of the interaction between safety and security was set up between the committees working in these fields. For the longer term, an expansion of the scope of the CSS to security-related subjects overlapping with safety is being envisaged, in order to allow greater synergy between these fields.

- **The rise in the number of peer review missions requested** from the IAEA by the Member States and their increased effectiveness.

Of the observed missions, ASN hosted the ARTEMIS mission (Integrated Review Service for Radioactive Waste and Spent Fuel Management, Decommissioning and Remediation) at the beginning of 2018. The auditors assessed the French system for radioactive waste management in the light of the IAEA safety guides and technical recommendations, as well as the best practices in place internationally.

Along the same lines, the IRRS and OSART missions are carried out using the IAEA safety standards as their point of reference.

The IRRS missions

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 Directive 2009/71/Euratom on the safety of nuclear facilities, revised in 2014, the Member States of the European Union are already subject to periodic and mandatory peer reviews of their general nuclear safety and radiation protection oversight arrangements.

The IRRS missions are devoted to analysing all aspects of the framework governing nuclear safety and the corresponding activities of a regulatory Authority.

Further to the IRRS mission hosted in France in 2014, following which 46 recommendations and suggestions were made by the team of auditors, ASN developed an action plan to take appropriate measures and change certain practices.

The IRRS follow-up mission took place from 1st to 9th October 2017 and was chaired by William Dean from the American Nuclear Regulatory Commission (NRC). This mission reviewed the progress made since the 2014 mission, more particularly in the fields which had been the subject of recommendations and suggestions. The team of auditors concluded that France had significantly reinforced the framework of its regulation and oversight of nuclear safety and radiation protection, but it did however point out that ASN needed to demonstrate vigilance with regard to the question of human resources, in the light of the safety issues facing nuclear facilities in France. A total of 40 recommendations and suggestions were closed or are considered to be closed *"subject to implementation of the ongoing measures"*. During the closing session of this follow-up mission, the IAEA, represented by Greg Rzentkowski, head of the nuclear installations safety division, underlined ASN's efficiency in its role as regulator and also recalled that France is so far the first country to have completed two full IRRS cycles, after the missions in 2009 and 2014 respectively.

In 2017, ASN took part in several IRRS missions, in Nigeria, Romania, Botswana, Macedonia and Belgium, respectively.

The OSART missions

The OSART missions are carried out by a team of experts from third party country licensees who, for two to three weeks, examine 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 30th OSART mission carried out in France (in other words one OSART mission per year) was held at the Bugey NPP in October 2017. As for the previous missions, the report drafted afterwards is published on *www.asn.fr* after validation by the parties. Moreover, an OSART follow-up mission to Dampierre-en-Burly was organised in February 2017.

The next OSART mission will take place on October 2018 and will concern the Flamanville EPR reactor. This mission is being intentionally carried out prior to commissioning of the reactor. It will take place after those carried out on the EPR reactors in Taishan (China) and Olkiluoto (Finland).

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 in assistance missions. The beneficiaries are generally countries of the French-speaking community. Thus, in 2016, ASN representatives went to Algeria, Democratic Republic of Congo, Madagascar and Morocco in turn. ASN also welcomed trainees from Romania and Montenegro.

Harmonisation of communication tools

ASN remains closely involved in the work on the INES (International Nuclear and radiological Event Scale).

In 2006, at France's request, a working group on the rating of radiation protection events involving patients was set up. In July 2012, a draft technical document was produced and the consolidated methodology was presented in October 2014 to all the countries using the INES scale and then sent out to all the INES national correspondents at the end of 2015. The implementation of this new scale in France is scheduled for 2018.

Generally speaking, ASN is closely involved in the various actions carried out by the IAEA, providing significant support for certain initiatives, notably those which were developed following the Fukushima Daiichi accident, including the complete report on the accident. For information, this report was presented to the Board of Governors in September 2015 and was published at the end of 2015.

Finally and still under the supervision of the IAEA, ASN also participated in the RCF (Regulatory Cooperation Forum) chaired by a deputy Director General of ASN. This forum, created in 2010, aims to bring those safety regulators in countries adopting 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, while ensuring that the fundamental nuclear safety objectives can be met (independence of the regulator, appropriate legal and regulatory framework, etc.). This year, in addition to a close examination of the situation of the regulatory authorities in Belarus, Jordan, Poland and Vietnam, the RCF reinforced its cooperation with the European Union (INSC) and with "regional" forums such as ANNuR (Arab Network of Nuclear Regulators), FNRBA (Forum of Nuclear Regulatory Bodies in Africa) and ANSN (Asian Nuclear Safety Network). Finally, the RCF examined the request from Bangladesh for active assistance, which should be effective in 2017.

3.2 The OECD's Nuclear Energy Agency (NEA)

The NEA, created in 1958, now comprises 33 members from Europe, North America and the Asia-Pacific region, with the inclusion of Argentina and Romania in 2017. Its main role is to assist the member countries in maintaining and developing the scientific, technological and legal bases

IRRS mission: conclusions of the follow-up mission, Montrouge, 1st to 9th October 2017.

essential for safe, environmentally-friendly and economic utilisation of nuclear energy.

Within the NEA, ASN mainly takes part in the work of the Committee on Nuclear Regulatory Activities (CNRA), but also 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).

Also noteworthy is the upcoming creation of a standing technical committee on the decommissioning of nuclear facilities and management of legacy matters, within which ASN will play a role.

The CNRA supervises the work done by four working groups covering a variety of fields to which ASN makes an active contribution: Working Group on Operating Experience (WGOE), Working Group on Inspection Practices (WGIP), Working Group on Public Communication (WGPC) and Working Group on the Regulation of New Reactors (WGRNR). Also of note is the creation at the end of 2017 of two new working groups (now making a total of six); the Working Group on Safety Culture (WGSC) and the Working Group on Digital Instrumentation and Control (WGDIC), this latter being the result of the transfer of the MDEP/DICWG to the NEA (see point 3.3).

In 2017, ASN devoted particular efforts to informing the members of the CNRA, and indeed all international bodies, of the carbon segregation problem and the suspicion of falsification at Areva's Creusot Forge plant.

More information about NEA/CNRA activities can be found at the following address: *www.oecd-nea.org/nsd/cnra/*

3.3 The Multinational Reactor Design Evaluation Program (MDEP)

The MDEP, 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, the NEA is responsible for the technical secretariat of this programme. An ASN staff member is seconded to NEA to help with this task.

Members of the programme

With the inclusion of Argentina in 2017, the MDEP now comprises 16 national safety regulators: AERB (India), ARN (Argentina), 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 (STC). Since February 2015, the STC has been chaired by an ASN Deputy Director General. The work is performed by working groups which meet periodically to deal on the one hand with specific projects for nuclear reactors - the Design Specific Working Groups (DSWG) and on the other with 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).

Also worth noting is the September 2017 decision by the Strategy Committee to create an additional working group specifically for the design of the Chinese HPR1000 (Hualong One).

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

Concerning the MDEP activities in 2017, particularly noteworthy is the organisation of its 4th conference in September 2017. This is a forum for discussions about new nuclear reactor designs by the leading international nuclear safety regulators and representatives of the nuclear industry and international standards development organisations.

2017 thus enabled MDEP to observe the performance of an FPOT (First Plant Only Test) concerning vibration on the Taishan 1 reactor vessel internals (March 2017).

The ongoing studies of the transfer of the working groups dedicated to MDEP cross-cutting subjects to the NEA led first of all to the creation of a new Working Group on Digital Instrumentation and Control (WGDIC) within the NEA's Committee on Nuclear Regulatory Activities (CNRA).

Finally, the MDEP makes sure that it maintains its interactions 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 The 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 topical matters in these various countries and the positions adopted 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, Spain in 2016, United States in 2017 and South Korea in 2018).

3.5 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 compiles 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 experts, including an ASN Commissioner, Margot Tirmarche.

3.6 The International Commission on Radiological Protection (ICRP)

The ICRP, a non-governmental organisation, was created in 1928 with the aim of assessing the state of knowledge about the effects of radiation, in order to ensure that it does not call current protection rules into question. The ICRP bases its findings on the results of the research work carried out around the world and examines the work of other international organisations, notably that of UNSCEAR. It issues general recommendations on the protection rules to be adopted and on the exposure levels to be complied with.

Margot Tirmarche is a member of the "Health effects of radiation" C1 Committee of the ICRP and chairs a working group evaluating cancer risks linked to alpha emitters.

4. International agreements

ASN acts as the national point of contact for the two Conventions dealing on the one hand with nuclear safety (the Convention on Nuclear Safety) and on the other with spent fuel and wastes (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).

40th INRA meeting: Foreground and background, left to right: Stephen Burns (NRC), Fernando Marti Scharfhausen (CSN), Mats Persson (SSM), Pierre-Franck Chevet (ASN), Mina Golshan (ONR), Ramzi Jammal (AIEA), Jeng K. Nam (NSSC) and Masaya Yasui (CNRA), Chicago, 17th-18th May 2017.

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.[2]

The objectives of the Convention on Nuclear Safety are to reach and maintain a high level of nuclear safety worldwide; to establish and maintain effective defences in nuclear facilities against potential radiological risks and to prevent accidents which could have radiological consequences and mitigate their consequences should they occur. 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. Since 1999, six review meetings of the Convention on Nuclear Safety have been held, including one chaired by ASN in 2014.

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

2. *This Convention sets a certain number of nuclear safety objectives and defines measures for achieving them. France signed it on 20th September 1994 and approved it on 13th September 1995. The Convention on Nuclear Safety entered into force on 24th October 1996 and, as at 31st December 2017, there were 80 contracting parties.*

resources so that it can participate in the review meetings and be present at the various presentations and discussions.

The Vienna Declaration on nuclear safety was adopted on 9th February 2015 by the contracting parties to the Convention on Nuclear Safety, who met on the occasion of the diplomatic conference tasked with reviewing a proposal to amend the Convention on Nuclear Safety.

At the 7th review meeting, Ramzi Jamal (Canada) was appointed Chairman of the 7th review meeting and Georg Schwarz (Switzerland) and Geoffrey Emi-Reynolds (Ghana) were appointed Vice-Chairmen.

Several months before the review meeting is held, each contracting party submits a national report describing how it meets the obligations of the Convention. The French national report was drafted and made public on 11th August 2016, on the IAEA and ASN websites respectively. 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 review 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.

After publication of the national report before the deadline, set for 15th August 2016, the next phase began, involving an analysis by each contracting party of the foreign reports made public. The questions and comments resulting from this analysis by ASN were published and shared on the IAEA website before the deadline of 28th November 2016. This was followed by a new phase to draw up answers to the questions asked of France concerning its national report, which were transmitted to the IAEA before 20th February 2017. France asked 311 questions for the 7th review and received 267 questions from the other contracting parties.

The final phase of the review process for the Convention on Nuclear Safety concerned the holding of the 7th review meeting from 27th March to 7th April 2017 in Vienna. The 8th review meeting of the Convention on Nuclear Safety is scheduled for 23rd March to 3rd April 2020.

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 2017, there were 77 contracting parties.

The 6th review meeting of this convention will be held at the IAEA headquarters in Vienna, from 21st May to 1st June 2018.

ASN coordinated the drafting of the 6th report for France, which it submitted to the IAEA on 23rd October 2017. All the French stakeholders in the field take part in the drafting of this three-yearly report which presents the latest progress made in France's programme with regard to its obligations under the Joint Convention: ASN, General Directorate for Energy and Climate and Nuclear Safety and Radiation Protection Mission of the Ministry for Ecological and Solidarity-based Transition, Andra, Institute for Radiation Protection and Nuclear Safety (IRSN), Areva, EDF, CEA, ILL and ITER. Since 23rd October, French experts with an ASN mandate have been examining the reports from the other contracting parties and drawing up questions and comments, which were submitted on 23rd February 2018. ASN collects the questions and comments about the French report from the other contracting parties and will forward them to the stakeholders concerned. The responses to these questions and comments shall be submitted to the IAEA by 23rd April 2018. This peer review process will end with the review meeting during which each contracting party will present its national report. France's report will be presented by Olivier Gupta, ASN Director General, and by the Director General of Andra, on 23rd May 2018.

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 121 contracting parties as at 31st December 2017.

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 the 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 2017, there were 115 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. 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 155 contracting parties in 2017. An amendment to this convention, which entered into force in 2016, was ratified by 115 of them.

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 and its counterparts hold discussions on subjects which frequently concern topical national safety and radiation protection matters (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 to enhance staff training. One of the means used to achieve this is to develop personnel exchanges, notably with the ONR (Office for Nuclear Regulation) and the NRC.

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 2016, about 30 peer observations of inspections in the field of nuclear safety and radiation protection were organised with Germany, Belgium, Luxembourg, Netherlands, United Kingdom, Russia, Sweden 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 activities and operations of foreign nuclear safety and radiation protection regulators. Whenever possible, this type of exchange should be reciprocal.

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. Below is a summary of the key moments of 2017:

South Africa

9th November 2017: steam generators replacement, decommissioning, emergency management and relations with the technical support organisation (IRSN).

Bilateral Franco-American meeting in the margins of the public annual conference of the American nuclear safety regulator (Regulatory Information Conference, RIC) 2017. In the centre, Olivier Gupta, ASN Director General, and Victor McCree, Director General of the NRC, Washington, 15th March 2017.

Germany

15th-16th June 2017: discussions concerning topical aspects related to border NPPs: Fessenheim and Cattenom for France and Neckarwestheim and Philippsburg for Germany.

Belgium

31st May 2017: safety of nuclear facilities and transports, discussions on the monitoring of installations such as the *Institut national des radioéléments* in Belgium or CIS bio international in France.

China

4th April 2017: renewal in 2014 of the overall nuclear safety and radiation protection cooperation agreement, expanding the scope of this agreement to radioactive waste management and to fuel cycle facilities. The specific cooperation agreement on the EPR was also extended by five years.

Discussions on progress in the construction of the EPR in the two countries and on the first start-up tests of the Taishan EPR, as well as monitoring of equipment manufacturing. A list of actions in fields of interest to the two safety regulators was drawn up.

ASN is head of a three-year European assistance project, which started in February 2017 with the aim of reinforcing the development of the Chinese authority, the NNSA (National Nuclear Safety Administration) and its technical support organisation, the NSC (Nuclear Safety Center) on the following topics: management of radioactive waste, decommissioning, preparedness for emergency situations, radioactive material transports, fuel reprocessing, seismic evaluation and development of nuclear safety R&D skills.

Spain

28th September 2017: discussions on topical nuclear safety and radiation protection subjects in our two countries, on progress in previously defined cooperation measures and updating of the roadmap for this cooperation between the two authorities for the next two years. This future cooperation will more particularly cover:
- operating experience feedback from the licensing of a proton-therapy centre, notably with a forthcoming visit to Nice;
- the holding of cross-inspections to compare and discuss nuclear waste transport rules;
- continued discussions on intermediate level, long-lived waste management issues.

United States

19th May 2017 : variety of topics (decommissioning, pressure equipment manufacturing anomalies).

Russia

15th june 2017: recent organisational and regulatory changes and an inventory of nuclear facilities in the two countries. The latest cooperation measures were also reviewed and the upcoming actions were identified (observation of inspections, seminars, etc.). The day before the meeting, a workshop was held on the oversight and regulation of fuel cycle facilities, followed by a visit to the Elektrostal nuclear fuel fabrication plant.

Finland

25th-26th September 2017: bilateral meeting between ASN and STUK *(Säteilyturvakeskus)* in Montrouge, followed by a visit to the Flamanville 3 construction site on 27th September 2017.

Japan

14th-15th November 2017: latest regulatory topics in the two countries, discussions on the seismic resistance of facilities and equipment, fraud and irregularities in the manufacture of components and monitoring the safety of spent fuel reprocessing plants. This meeting was rounded off by a visit to the Areva plant at La Hague.

Norway

9th may 2017 : discussions on the monitoring of research reactors, the radon risk, the management of emergency situations and radioactive waste management.

United Kingdom

24th April 2017: meeting on LUDD (Laboratories, Plants, Waste and Decommissioning) and visit to Sellafield concerning waste management.

Sweden

28th September: the Orleans division took part in an inspection carried out by the SSM *(Strål Säkerhets Myndigheten)* in the Forsmark NPP, after a preparatory meeting the previous day in Stockholm.

Switzerland

19th-20th December 2017: regular relations with the IFSN (Federal Nuclear Safety Inspectorate) on a variety of subjects such as the safety of nuclear facilities, radiation protection in the medical field, radon, preparedness for and management of emergency situations, transport, etc.

5.3 ASN bilateral assistance

In 2017, at their request, ASN had contacts with several safety regulators in countries looking to find out about the steps involved in creating a nuclear safety regulatory and oversight infrastructure.

ASN responds to these approaches by means of bilateral actions with the safety regulator of the country concerned, in addition to the instruments, both European (INSC) and international (IAEA's 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

COMPETENCIES of the main civil nuclear activity regulatory Authorities*

COUNTRY/ REGULATORY AUTHORITY	STATUS			ACTIVITIES						
	ADMINIS-TRATION	GOUVERN–MENT AGENCY	INDEPENDENT AGENCY	SAFETY OF CIVIL INSTALLATIONS	RADIATION PROTECTION			SECURITY (PROTECTION AGAINST MALICIOUS ACTS)		SAFETY OF TRANSPORT
					LARGE NUCLEAR FACILITIES	OUTSIDE BNIs	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	•			•	•	•		•	•	•
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 came into force on 1st July 2017.*

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 competence in terms of safety, safety and regulatory culture and management of radiological emergency situations.

Vietnam

In 2017, ASN oversaw the second assistance programme for Vietnam under the INSC, in order to develop the safety, safety culture and regulatory capabilities of the Vietnamese nuclear regulator, VARANS. This assistance project, which started in May 2016, is scheduled to last for three years.

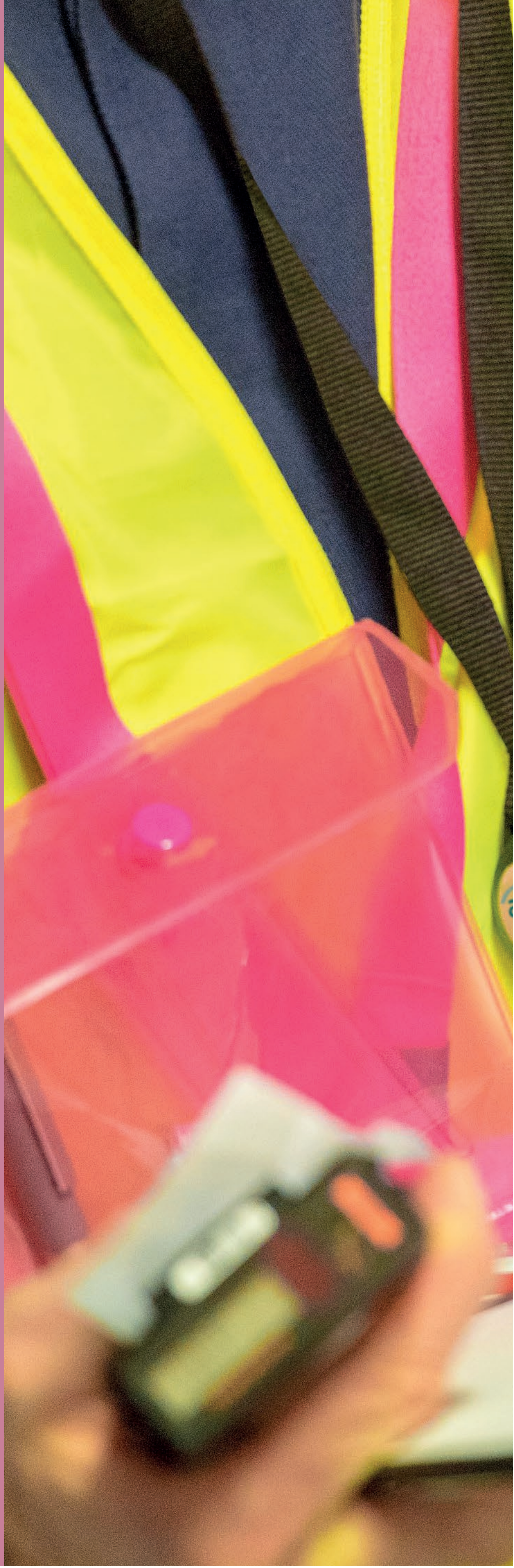
ASN is also involved in assistance to Vietnam via the RCF, the forum for exchanges between safety regulators, created under the aegis of the IAEA. In this context, a meeting was held on 14th and 15th June 2017 in Brussels, with a view to facilitating the sharing of experience between regulators and rationalising the assistance given to those countries looking to develop nuclear energy.

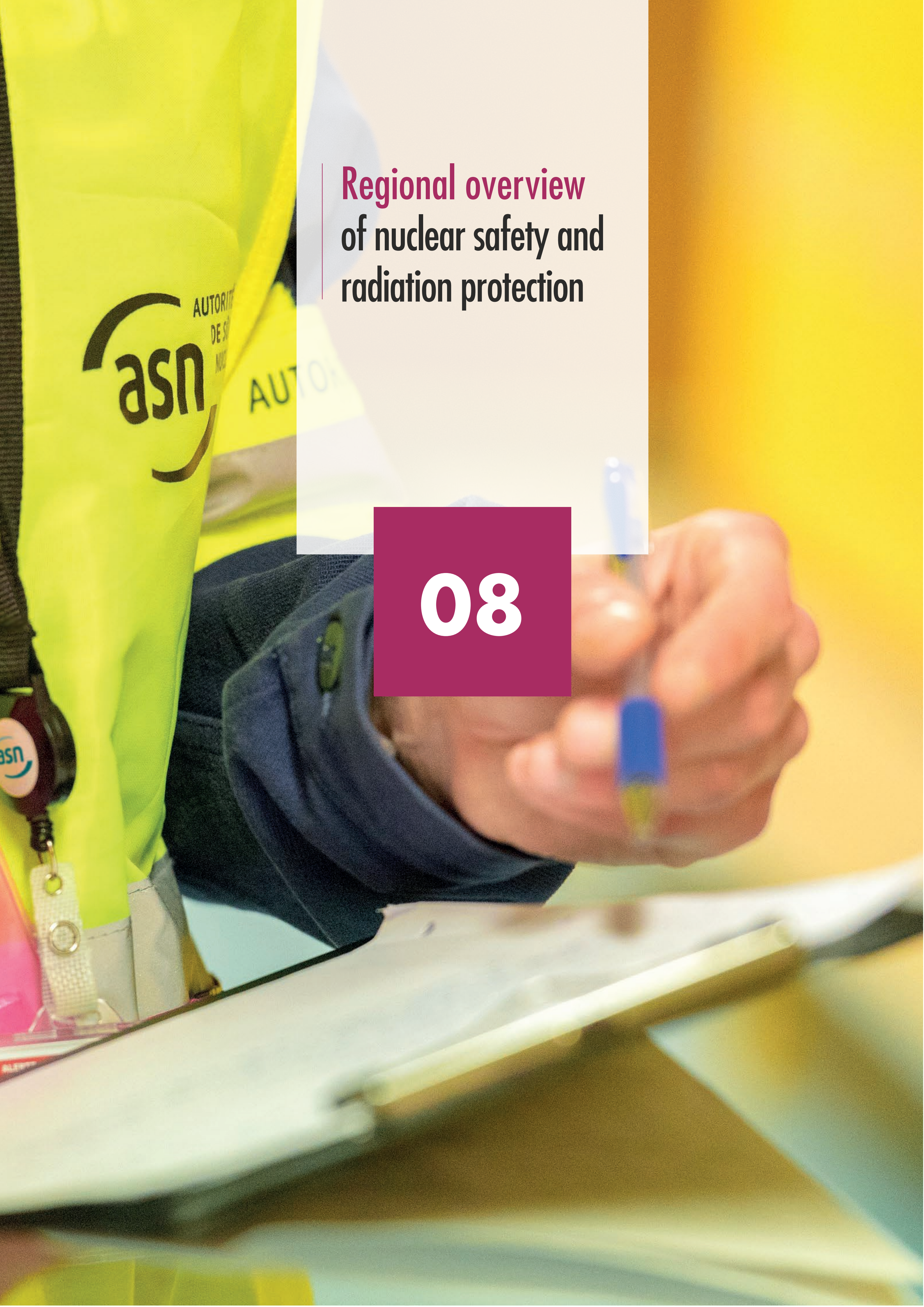
6. Outlook

ASN will continue its actions within a European framework, with regard to nuclear safety and radiation protection, more particularly through bilateral cooperation agreements, but also and above all by influencing the work of ENSREG of which it is the chair. Particular attention will be paid to the thematic review on the management of the ageing of nuclear power reactors and research reactors with a power of more than 1 MWth, a review which led to the production of a national report published in December 2017. ASN will also aim to ensure that its policies and positions are influential within multilateral frameworks, notably those involving the IAEA.

To this end, ASN:
- will continue bilateral exchanges with foreign safety regulators on regulatory practices and on priority subjects such as monitoring of the manufacture of nuclear pressure equipment;
- will actively take part in the work of HERCA, WENRA, the IAEA, the NEA and INRA;
- will present the national report to the 1st thematic peer review of ageing management (ENSREG) to be held from 14th to 18th May 2018 in Luxembourg;
- will contribute to the performance of stress tests on the Ostrovets NPP in Belarus;
- will contribute to examining the definition of technical objectives to improve safety, as related to Article 8 of the 2014 Directive;
- will be a driving force behind the WENRA task force which is to define a strategy document;
- will examine the possibility of holding a transboundary "Greater Region" conference on nuclear safety and radiation protection, in order to achieve more balanced cooperation;
- will present the national report within the framework of the Joint Convention (2018);
- will continue its involvement in the European cooperation instruments assisting third party countries in the field of nuclear safety.

2017 regional overview of nuclear safety and radiation protection:





Regional overview of nuclear safety and radiation protection

08

Regional overview of nuclear safety and radiation protection

ASN has 11 regional divisions through which it carries out its regulatory responsibilities throughout metropolitan France and in the French overseas *départements* and collectivities. Several ASN regional divisions can be required to coordinate their work in a given administrative region. As at 31st December 2017, the ASN regional divisions totalled 225 employees, including 159 inspectors.

Under the authority of the regional representatives (see chapter 2, point 2.3.2), the ASN regional divisions carry out on-the-ground inspections of the Basic Nuclear Installations (BNIs), of radioactive substance transport operations and of small-scale nuclear activities; they examine the majority of the licensing applications submitted to ASN by the persons/entities responsible for nuclear activities within their regions. They check application within these installations of the regulations relative to nuclear safety and radiation protection, to pressure equipment and to Installations Classified for Protection of the Environment (ICPEs). They ensure the labour inspection in the nuclear power plants.

In radiological emergency situations, the ASN divisions check the on-site measures taken by the licensee to make the installation safe and assist the Prefect of the département, who is responsible for protection of the population. To ensure preparedness for these situations, they help prepare the emergency plans drafted by the Prefects and take part in the 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.

This chapter presents ASN's overall assessment by broad sector of activity and its assessment of nuclear safety and radiation protection in each region. It also reports on the local issues and procedures that are particularly representative of the regional action of ASN, especially with regard to informing the public and cross-border relations.

Auvergne-Rhône-Alpes

The Lyon division regulates nuclear safety, radiation protection and the transport of radioactive substances in the 12 *départements* of the Auvergne-Rhône-Alpes region.

The installations and activities to regulate comprise:

- 4 NPPs operated by EDF:
  - Bugey (4 reactors of 900 MWe);
  - Saint-Alban/Saint-Maurice (2 reactors of 1,300 MWe);
  - Cruas-Meysse (4 reactors of 900 MWe);
  - Tricastin (4 reactors of 900 MWe);
- the nuclear fuel fabrication plants of Areva NP (now called Framatome) in Romans-sur-Isère;
- the nuclear fuel cycle plants operated by Areva NC (now called Orano) and its subsidiaries 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 and the Bugey Inter-Regional Warehouse (MIR) 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 SICN in Veurey-Voroize, waiting to be delicensed;
- the CEA (French Alternative Energies and Atomic Energy Commission) reactors and plants in Grenoble, decommissioned and waiting to be delicensed;
- the CERN international research centre located on the Swiss-French border;
- small-scale nuclear activities in the medical sector:
  - 22 external-beam radiotherapy departments;
  - 6 brachytherapy departments;
  - 23 nuclear medicine departments;
  - about 200 centres performing fluoroscopy-guided interventional procedures;
  - 120 computed tomography scanners;
  - some 10,000 medical and dental radiology devices;
- small-scale nuclear activities in the industrial and research sectors:
  - one synchrotron;
  - 700 veterinary structures (practices or clinics);
  - about 30 industrial radiology agencies;
  - about 600 users of ionising radiation in the industrial sector;
  - about 100 research units;
  - 3 head offices and 8 agencies of approved bodies.

In 2017, the Lyon division carried out 334 inspections in the Auvergne-Rhône-Alpes region, of which 111 were in the nuclear power plants of Bugey, Saint-Alban/Saint-Maurice, Cruas-Meysse and Tricastin, 95 in other nuclear plants and facilities undergoing decommissioning, 118 in small-scale nuclear activities and 10 in the transport of radioactive substances.

ASN also carried out 42 days of labour inspections in the four nuclear power plants and on the Creys-Malville site.

ASN was notified of 22 significant events rated level 1 on the INES scale, of which 21 occurred in BNIs and 1 in small-scale nuclear activities.

One event was rated level 2 on the INES scale; this is due to the fact that the embankment protecting the Tricastin facilities against flooding would not withstand the Safe Shutdown Earthquake (SSE).

In the small-scale nuclear activities, 13 events concerning radiotherapy patients were rated level 1 on the ASN-SFRO scale and one was provisionally rated level 2.

1. Assessment by domain

1.1 The nuclear installations

Nuclear power plants

Bugey nuclear power plant

ASN considers that the nuclear safety, radiation protection and environmental protection performance of the Bugey NPP is in line with its general assessment of EDF's performance. Although progress was observed in 2017, the control of certain particular operating conditions must be improved. Shortcomings in the fire prevention culture led to one of the two activations of the on-site emergency plan in June 2017.

With regard to nuclear safety, the Bugey NPP made progress in 2017 in the areas of reactor control, serenity in the control room and compliance with procedures. The site must nevertheless remain vigilant in the configuring of systems, an area in which EDF encountered difficulties in 2017, and in the management of the baseline requirements applicable to the periodic tests. The year 2017 was marked by the activation of two radiation safety emergency plans within the space of ten days, the first due to a fire which broke out on a section of the roof of the reactor 5 general auxiliary building on19th June 2017: this shows that the Bugey NPP can improve its control of fire-related risks.

Noteworthy maintenance work in 2017 included the repair of the reactor 5 containment and the performance of a containment pressure test to requalify the repair. The result is that leakage rates for the Bugey NPP reactor 5 containment are once again in compliance with the general operating rules. The Bugey NPP reactor 5 restarted in July 2017, but EDF will have to demonstrate that the repair remains effective over the long term.

With regard to environmental protection, ASN notes that the Bugey NPP adequately controls its discharges. The problem of the containment of liquid substances remains a major issue for the site, as witnessed by the event that led to the detection of tritium in the water table in December 2017.

The Bugey NPP also showed a significant improvement in its occupational radiation protection results in 2017.

Saint-Alban/Saint-Maurice nuclear power plant

ASN considers that the nuclear safety performance of the Saint-Alban/Saint-Maurice NPP is above average for the plants operated by EDF, and that environmental protection and radiation protection performance levels on the whole are in line with the general assessment for EDF.

The nuclear safety results for the SaintAlban/Saint-Maurice NPP are satisfactory. In certain areas (compliance with operating technical specifications, configuring the systems), the 2017 results consolidate the progress EDF has made in the last few years. The Saint-Alban/Saint-Maurice NPP does however show below average results in the areas of reactor trips and control of fire-related risks.

Concerning maintenance work, the third ten-yearly outage of reactor 1 was an overall success for EDF, particularly with regard to the integration of modifications.

Considering environmental protection, the operational results for discharges are satisfactory. The site must nevertheless improve its waste management and the monitoring of the service providers in charge of the premises in which the waste is stored.

On the subject of worker protection, the operational results for radiation protection were satisfactory on the whole, particularly during the ten-yearly outage of reactor 1.

The work health and safety results are also satisfactory: no serious accident occurred during the ten-yearly outage.

Cruas-Meysse nuclear power plant

ASN considers that the performance of the Cruas-Meysse NPP with regard to nuclear safety, environmental protection and radiation protection is, on the whole, in line with the general standard of EDF plant performance.

With regard to nuclear safety, ASN has noted that the number of deviations notified is down in comparison with the preceding years, reflecting progress which is moreover observed in several areas of activity such as system configuring and reactor control. In 2017, ASN nevertheless found shortcomings in the application of the process to guarantee that certain components which are essential to safety and whose position cannot be seen from the control room are kept in the required position.

ASN observes that the maintenance situation at the Cruas-Meysse NPP is still tenuous when the work load increases, particularly during the reactor refuelling and maintenance outages. The reactor 1 outage during which the steam generators were replaced was prolonged due to poor management of the personnel working on certain phases of this job.

ASN also notes that the control of fire-related risks is below the standard of the preceding years: the NPP had two fire outbreaks in premises situated in controlled areas. Even though the rapid intervention of the site response teams enabled these fires to be brought under control, it is vital for EDF to improve fire risk prevention.

With regard to environmental protection, progress can still be made in waste management, but the site has made improvements in the containment of liquid substances.

In terms of radiation protection, the collective dosimetry is still well managed and the radiological cleanliness of the site's facilities has been significantly improved.

Tricastin nuclear power plant

ASN considers that the overall nuclear safety performance of the Tricastin NPP is slightly below average for the plants operated by EDF, and that environmental protection and radiation protection performance levels on the whole are in line with the general assessment for EDF.

2017 was marked firstly by the question of carbon segregation zones in the steam generators and secondly by the inadequate earthquake resistance of the embankment protecting the Tricastin NPP against flooding. These two factors led ASN to oblige EDF to carry out specific reactor shutdowns at this facility.

Although ASN finds that management of the reactor outage phases was satisfactory in these two situations, it does note that spring and summer were marked by significant events highlighting shortcomings in the monitoring of the facility's control rooms. These factors led ASN to initiate a tightened inspection on this theme.

With regard to maintenance and the initial reactor outage programme, finally only reactors 2 and 3 were shut down for scheduled maintenance and partial refuelling: these two outages went satisfactorily on the whole.

With regard to protection of the environment, while the radioactive and chemical discharges are well managed, the Tricastin NPP must further improve its waste management and the containment of liquid radioactive substances.

As far as radiation protection is concerned, and despite the improvements with respect to last year, there are still some shortcomings in radiological cleanliness.

Labour inspection on the nuclear power plants of the Auvergne-Rhône-Alpes region

Thirty four labour inspections were carried out during 2017, along with 21 days of presence in the region's nuclear power plants for meetings, discussions with employees and staff representatives, and participation at the meetings of the Committees for Health, Safety and Working Conditions (CHSCT).

The inspections are divided between inspections conducted on the sites of maintenance work carried out during the reactor outages and thematic inspections (chemical, electrical, asbestos risk). Work on the conformity of the loading machines and the safety of the ultimate backup diesel generator set construction sites was moreover carried out on the four sites in the region. Lastly, inspections were also carried out further to serious workplace accidents.

ASN notes the substantial preparation work carried out to control the risks associated with the lifting operations involved in the replacement of steam generators of reactor 1 of the Cruas-Meysse NPP.

Broadly speaking, what emerges from 2017 is:
- Compliance work on the loading machines needs to be continued.
- Difficulties were encountered in the management of some asbestos-removal work sites.
- Continued efforts are required in radiation protection.
- The quality of work site operations risk analyses must be improved.

Fuel cycle installations

Areva NP nuclear fuel fabrication plants in Romans-sur-Isère (Drôme *département*)

In 2017, the licensee Areva NP continued its work to improve the safety of its facilities, which have been under tightened ASN surveillance since 2014.

The inspections carried out in 2017 confirmed the improvements with regard to compliance with the safety requirements and operating rigour, particularly in the control of the criticality risk, equipment qualification and maintaining qualification, and the performance of periodic inspections and tests.

The site has increased its personnel numbers in various areas: safety, radiation protection, projects and support services. This increase in manpower and the reorganising of the safety teams are helping to improve the way operational safety and the safety of the ongoing projects on the site are taken into account.

With regard to environmental protection, Areva NP must further improve its control of the waste management routes, particularly with regard to the distinction between radioactive waste and conventional waste. Improvements can still be made in radiation protection, but the site is nevertheless actively engaged in a progress strategy.

The majority of the compliance and reinforcement work on the facilities of BNI 98 (fuel manufacture for the nuclear power plants) is complete. The examination of the periodic safety review file for this facility showed that further improvements must be made in earthquake and fire resistance and in the management of the risks associated with hazardous substances. The first commitments made by the licensee have been met. ASN will rule on the conditions for continued operation of BNI 98 in 2018. Another phase of reinforcement work on the recycling unit is also expected.

The licensee suspended operation of BNI 63 (manufacture of fuels for research reactors) until June 2017 in order to carry out compliance work required by ASN resolution 2015-DC-0485 of 8th January 2015 to improve the containment of radioactive substances and control of the earthquake and fire risks in the main building. In 2018, in its examination of the periodic safety review file submitted by the licensee, ASN will rule on the conditions for continued operation of BNI 63. Moving forward with the new uranium handling zone project must be a priority in this respect.

Areva NC nuclear fuel cycle plants situated on the Tricastin industrial platform (Drôme and Vaucluse *départements*)

In 2017, Areva's Tricastin site senior management was inspected on the themes of occupational radiation protection and environmental monitoring, and the inspections found the practices to be satisfactory. ASN also conducted a series of unannounced inspections on the theme of retention devices for preventing environmental pollution. These inspections revealed the existence of a base of common requirements, but their monitoring and verification can be further improved.

In 2016, Areva presented a project to ASN that aims to continue pooling the organisation of licensees in order to achieve a fully integrated site based on cross-structural functional departments. This modification would lead more specifically to the reorganising of the department responsible for safety and the environment. At the end of 2016, ASN considered that the file initially submitted was not admissible because it did not demonstrate how the nuclear licensees, who are responsible for the safety of their installations, will be able to exercise this responsibility. The new version of the file submitted by the licensee is currently being examined. ASN will adopt a position on this application in the first half of 2018.

Areva's uranium chemistry plants TU5 and W in Pierrelatte (Drôme *département*)

ASN considers that the safety of operation of the TU5 and W plants is satisfactory. Relations with the licensee are nurtured and constructive.

The conclusions of the periodic safety review early in the year were of major importance for the TU5 plant in 2017. Areva made 66 commitments in this context. The commitments for 2017 have been implemented. In 2018, ASN will rule on the conditions for continued operation of this facility.

With regard to EM3, the new uranium hexafluoride (UF_6) emission unit of the W plant, which is scheduled for commissioning in 2018, the work has continued with the completion of equipment installation and starting of tests. This new unit will meet the safety requirements set by ASN in the wake of the Fukushima nuclear accident and will ensure better containment in the event of a UF_6 leak and greater resistance to internal and external hazards.

More generally, the licensee must continue to improve operating rigour and more specifically the detection and management of deviations. ASN will therefore remain attentive to see that sufficient rigour is maintained in the operating and maintenance actions, in the management of anomalies detected during the periodic verifications and tests and in the tracking of deviations and the resulting actions.

In addition to this, an unannounced inspection on waste management revealed that Areva was not adequately organised to process the large streams of waste during technical outages and to ensure compliance with the interim storage management requirements and the segregation, packaging and traceability of the different categories of waste. ASN asked for a plan of action combined with verification and monitoring measures to be put in place; it will check the results of this in 2018.

Areva's uranium fluorination plants in Pierrelatte (Drôme *département*)

The functioning of the Comurhex 1 fluorination plant was affected by several unforeseen events in 2017. Several events – with no off-site consequences – were notified further to nonconforming discharges and losses of containment, particularly the dispersion of potash that was slightly contaminated with uranium over the facility. In accordance with the ASN requirement, the plant definitively stopped production before 31st December 2017.

In October 2017, ASN actually suspended operation of the plant further to anomalies affecting the embankment protecting the site from the Donzère-Mondragon Canal. ASN prescribed the reinforcement of the water curtain systems designed to mitigate the consequences of a discharge of gaseous hydrofluoric acid, so that they remain operational in the event of a flood resulting from a breach in the embankment caused by an earthquake.

At the same time, the licensee has made significant progress in the tests of the new Comurhex 2 production units, which will start production in 2018 to reach nominal level in 2019. ASN will be watchful to ensure that the licensee draws the lessons from the operation of the Comurhex 1 plant to establish a high level of operating rigour in the Comurhex 2 plant.

Alongside this, the licensee continued its programme to prepare for final shutdown of the old installations of BNI 105, prior to their decommissioning. ASN discovered an unsatisfactory situation in a legacy storage area on the site and asked that a plan of action be implemented to improve the safety of this storage area until the material it contains is removed.

ASN continued the examination of the decommissioning file. The file was submitted to a public inquiry in early 2017 and the decommissioning decree should be signed in 2018.

Eurodif's Georges Bess I enrichment plant in Pierrelatte (Drôme *département*)

The gaseous diffusion rinsing of the enrichment cascade equipment at the Georges Besse I plant was finished at the end of 2015 and achieved the uranium-removal objectives for the circuits and diffusers under conditions of safety deemed satisfactory by ASN.

Operations to prepare for the decommissioning phase have been in progress since 2017. The licensee has submitted to ASN an authorisation file for the shut down facilities to enter a monitoring phase which is to last until the start of the decommissioning operations, scheduled as from 2028. Before issuing its authorisation, ASN asked the licensee to draw up a precise inventory of the last potential risks, which arise in particular from the operational waste that remains to be removed. The licensee must also continue removing this waste and treating the residual pollution of the facilities.

Following a fire response exercise which was organised during an unannounced inspection and which put Eurodif in difficulty, ASN obtained the reinforcement of the response team that intervenes in the event of fire in these facilities.

Furthermore, following the discovery in 2016 of shortcomings in waste management, radiation protection and environmental protection, ASN notes that in 2017 Eurodif put in place many measures to improve these issues. ASN notes in particular the action plan deployed to improve the monitoring of the areas delegated to the joint services of the Areva Tricastin platform.

Alongside this, a procedure to modify the authorisation decree is in progress to provide a framework for the decommissioning of the facility. The licensee's file underwent a public inquiry in early 2017. The decommissioning challenges concern the volume of waste produced (including 160,000 tonnes of metallic waste) and the decommissioning time frame which must be as short as possible (currently estimated at 30 years). ASN will issue a position statement on this file in 2018.

SET's Georges Bess II enrichment plant in Pierrelatte (Drôme *département*)

The Georges Besse II (GB II) plant operated by *Société d'Enrichissement du Tricastin* (SET), displayed a satisfactory level of safety in 2017. The technologies utilised in the facility enable high targets for safety, radiation protection and environmental protection to be achieved.

Ramping the plant up to full production was slowed down to maintain the skills currency of the centrifuge installer's teams. It was completed at the end of 2017.

ASN identified in 2017 two areas requiring particular attention. The first concerns the discovery of a water presence detector which was not connected to the instrumentation and control system, an anomaly which had failed to be detected by both the commissioning tests and the periodic tests. The second concerns the process for assessing the physical changes made to the facility by the licensee, which requires reinforcement.

Lastly, the SET must maintain the progress initiative undertaken to control leaks of refrigerant gases.

Socatri's maintenance, effluent treatment and waste packaging facilities in Bollène (Vaucluse *département*)

ASN considers that Socatri's level of operational safety in 2017 was satisfactory and that operating rigour was improved.

The licensee also made significant improvements in the safety of the facilities, further either to ASN instructions or commitments made by the licensee in the follow-ups to the periodic safety review of the facilities. ASN nevertheless drew the licensee's attention to the next periodic safety review, scheduled for 2018.

The licensee conducted tightened inspections of the retention structures identified as being priorities for safety, as required by ASN resolution CODEP-CLG-2017-014344 of 7th April 2017. ASN expects the licensee to repair the nonconforming retention structures detected by these inspections as rapidly as possible.

Socatri has applied for authorisation to substantially modify its facility in order more specifically to install a site waste processing unit baptised Trident. At the end of the public inquiry conducted in 2016, the licensee was consulted in 2017 on a draft decree. In 2017, ASN gave its consent to start the work to set up the unit. Commissioning this unit will require the prior consent of ASN.

Areva Tricastin analysis laboratory (Atlas) in Pierrelatte (Drôme *département*)

Atlas constitutes BNI 176, a new installation of laboratories authorised by Decree 2015-1210 of 30th September 2015. Atlas brings significant improvements in safety compared with the old laboratories.

In 2017, ASN conducted inspections to check compliance with the facility commissioning conditions, which formed the subject of ASN resolution 2017-DC-0584 of 7th March 2017. On completion of these inspections, ASN found that a number of commitments made by the licensee had not been fulfilled by the stated deadlines and asked Areva to fulfil them before 30th October 2017.

Installations undergoing decommissioning

EDF Superphénix reactor at Creys-Malville (Isère *département*)

ASN considers that the safety of the Superphénix reactor decommissioning operations and of operation of the fuel storage facility is on the whole ensured satisfactorily. ASN's inspections have nevertheless revealed several deficiencies in the monitoring of subcontracted activities. ASN therefore expects the licensee to make improvements in this area in 2018.

Inspections also revealed deterioration in the processes for managing deviations and monitoring the commitments the licensee made to ASN. ASN reminded the licensee of the regulatory requirements concerning these activities which are important to safety and asked it to comply with them.

As concerns emergency situation management, the fire that broke out on sodium-contaminated waste on 4th July 2017 and the exercise organised by ASN during an unannounced inspection on 4th August 2017 showed that the site's organisation for emergency management outside working hours was unsatisfactory. Site management submitted a corrective action plan to ASN. ASN will be particularly attentive to this issue in 2018.

With regard to environmental protection, ASN surveyed EDF's work to ensure the tightness of what EDF considers to be ultimate retention structures, and to improve the management of the mobile retention structures and the transfer of liquid effluents.

EDF performed the periodic safety review on the site's two installations. ASN has started the technical examination of the submitted files, and once completed, it will specify the reinforcement work to perform on the installations.

EDF Bugey nuclear power plant reactor 1 undergoing decommissioning

ASN considers that decommissioning of the Bugey 1 reactor is proceeding under satisfactorily safe conditions. The licensee has a robust organisation and monitors the decommissioning equipment and work with rigour.

EDF presented a project to ASN to modify the decommissioning strategy for the gas-cooled reactors which would result in the Bugey 1 installation decommissioning schedule being pushed back by several decades. ASN is examining the files it requested to justify the change of strategy, as much in the scenario (decommissioning in air as opposed to under water as initially planned) as in the timing, by choosing to decommission Chinon A2 (or A3) as first in series instead of Bugey 1. The decommissioning completion date for the Bugey 1 containment structure in this case would be around 2080. If this new strategy and the corresponding time frame were implemented, the decree governing reactor decommissioning would have to be revised.

In 2017, ASN also examined the periodic safety review guidance file provided by EDF for the Bugey 1 reactor. The safety review conclusion report is to be submitted by EDF before the end of 2018.

CEA Grenoble reactors and plants undergoing decommissioning (Isère *département*)

The LAMA (Active Materials Analysis Laboratory) and the STED (Effluent and Solid Waste Treatment Station) decommissioning operations are now completed.

Having achieved the clean-out objectives, ASN delicensed the LAMA laboratory – BNI 61 – through ASN resolution 2017-DC-0602 of 24th August 2017.

ASN also conducted an inspection of the STED, the last installation on the site remaining to be delicensed, and took soil samples from it. The installation delicensing application file will be sent to ASN in 2018. In view of the presence of a residual chemical and radiological marking, ASN will make delicensing of the STED dependent on the implementation of active institutional controls.

The other installations on the site – the experimental reactors Siloé, Siloette and Mélusine – have been cleaned out and delicensed.

The other industrial and research facilities

High Flux Reactor (RHF) in the Laue-Langevin Institute (ILL) in Grenoble (Isère *département*)

Despite having observed several deviations from the safety management regulations, ASN considers that the facilities of the ILL display a satisfactory level of safety. Consequently, ASN expects the ILL to reinforce its organisation with respect to the requirements of the regulations.

In 2017, the ILL continued putting in place backup systems and making reinforcements to its facility. These works correspond to ASN instructions or commitments made as part of the lessons learned from the Fukushima nuclear accident. The main works concern reinforcing the sealing of the openings in the reactor building containment (particularly in the case of extreme flooding) and the installation or modification of backup systems to protect against the risks associated with loss of cooling (systems for resupplying the reactor with water, including after an extreme earthquake and extreme flooding).

In May 2017, the ILL gave notification of a significant safety-related event involving the jamming of a spent fuel element in its handling cask during operations to transfer it to the non-exposable part of the storage pool, and which was rated level 1 on the INES scale. This event had no immediate consequences on either the facility, the workers or the environment. The recovery of the spent fuel element did take several weeks however, as it was necessary to modify the winch used to handle the transfer cask. During this period the fuel element was in secure condition and cooled normally. The analysis of the event identified the causes and enabled corrective measures to be put in place to prevent it from recurring.

With regard to occupational radiation protection, one significant event led to minor contamination of one level of the reactor building and of a few operators. This event was rated level 0 on the INES scale.

ASN expects the ILL to make significant improvements in its management of the periodic verifications and tests required by the regulations or by its operating baseline requirements. Indeed, since 2016 the ILL has notified 7 significant events relating to safety and concerning the incomplete and delayed accomplishment of periodic verifications or tests.

On 6th February 2018, ASN gave the ILL formal notice to change its organisation in order to comply with the regulatory requirements concerning the modifications of its facility. ASN will pay particular attention in 2018 to the implementation of the ILL's new integrated management system, deployment of which began in 2017. Significant improvements are required in the management of the equipment modifications management process in particular, with the setting up of a classification system for equipment modifications and reinforcing of the corresponding prior risk analyses.

Lastly, the ILL submitted the ten-yearly safety review file for the facility in 2017. After examining it, ASN will make a statement on the conditions of continued operation of the facility.

The EDF Activated Waste Packaging and Interim storage Installation (Iceda) at Bugey (Ain *département*)

The purpose of the Iceda facility – BNI 173 –, authorised by Decree on 23rd April 2010, will be to process and store activated waste from operation of the EDF reactors in service and from the decommissioning of the first-generation reactors and of the Creys-Malville NPP.

The last finishing operations and the pre-commissioning tests were continued in 2017. ASN notes that the test programme is running significantly behind schedule. EDF now envisages commissioning the facility in the second half of 2018.

During the 2 inspections it carried out in 2017, ASN found the rigour of EDF's organisation and of the temporary grouping of contractors for equipment installation and test monitoring in the facilities to be adequate. The inspectors noted the good overall upkeep of the work site.

The EDF Inter-Regional fuel Warehouse (MIR) at Bugey

The Inter-Regional Warehouse (MIR – BNI 02) operated by EDF at Bugey is a storage facility for fresh nuclear fuel intended for the nuclear power plant fleet in operation.

The level of safety of MIR was satisfactory in 2017.

The periodic safety review of the facility is in progress, as are the stress tests required by ASN in the wake of the Fukushima Daiichi nuclear accident. The facility has more specifically been modified to improve control of the risk of flooding. After examining the periodic safety review file submitted by the licensee, ASN will rule on the conditions for continued operation of the facility.

Ionisos irradiator in Dagneux (Ain *département*)

The Dagneux irradiator – BNI 68 – operated by the company Ionisos, displayed a satisfactory level of safety in 2017.

In accordance with its commitment, Ionisos submitted a conclusion report on the periodic safety review of the facility at the end of October 2017. This report, which must integrate the lessons learned from the safety reviews of the Ionisos sites of Pouzauges and Sablé-sur-Sarthe, is being examined by ASN.

Tricastin Operational Hot Unit (BCOT) in Bollène (Vaucluse *département*)

On completion of its inspections, ASN considers that the level of safety of the BCOT is satisfactory on the whole.

In 2017, the BCOT continued the cutting up of the used control rod guide tubes from the pressurised water reactors operated by EDF. The operations should be completed in 2020 at the latest.

The examination of the facility's periodic safety review file resulted in ASN imposing several improvement measures, particularly concerning occupational radiation protection, through its resolution CODEP-CLG-2017-034825 of 28th August 2017.

In a letter dated 22nd June 2017, EDF declared the final shutdown of the BCOT by 30th June 2020 at the latest. The storage and maintenance operations shall be carried out on the Saint-Dizier maintenance base (Bamas). Transfer of the activities and the start of decommissioning are scheduled for 2018. ASN will be particularly attentive to these points.

CERN accelerators 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.

In 2017, ASN and the OFSP thus continued the examination of the safety files submitted by CERN to demonstrate the safety of the new facilities, particularly the Medicis facility designed to produce radioisotopes for medical research purposes.

The French and Swiss authorities conducted a joint inspection in 2017 on the theme of waste management. This inspection found the practices to be satisfactory.

1.2 Radiation protection in the medical field

Radiotherapy and brachytherapy

In 2017, ASN conducted inspections in 14 of the 22 radiotherapy centres of the Auvergne-Rhône-Alpes region and two inspections in brachytherapy centres.

All the radiotherapy 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.

Consequently, since 2016 ASN has turned its inspections towards assessing the risk management capability of the centres. In 2017, 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 the centres that implement innovative treatment technologies and those whose staffing levels are considered potentially vulnerable. The inspections reveal in particular that the centres must focus more attention on new techniques in their risk analyses and maintain efforts to increase experience feedback.

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 19 events in 2017 and is making sure that the centres concerned draw the appropriate lessons from these events. Of these 19 significant events, one was provisionally rated level 2 and thirteen were rated level 1 on the ASN-SFRO scale, which comprises eight levels from 0 to 7.

Fluoroscopy-guided interventional procedures

In the light of the 23 inspections carried out in 2017, ASN recurrently observes large disparities between the services performing these procedures.

Improvements are required in operating theatres in particular, where ASN has observed, among other things, deficiencies in personnel training and the wearing of dosimeters.

With regard to interventional practices, the optimisation of doses delivered to patients and medical personnel is not yet sufficiently developed. The time medical physicists devote to this activity is still insufficient. Furthermore, the training of practitioners in good patient and worker radiation protection practices, and in the use of medical devices, must be continued.

Nuclear medicine

The six inspections carried out in 2017 reveal that radiation protection of workers, patients and the public is on the whole taken into consideration in the nuclear medicine facilities in the Auvergne-Rhône-Alpes region.

Improvements are nonetheless required in performing in-house technical radiation protection controls, in assessing the risk of worker internal contamination, in the management of radioactive effluents and the analysis of significant events.

In 2017, ASN was notified of 12 significant radiation protection events.

1.3 Radiation protection in the industrial, research and veterinary sectors

Industrial radiography

In the industrial radiography sector in the Auvergne-Rhône-Alpes region, ASN considers that radiation protection is ensured relatively satisfactorily, be it in the agencies or during worksite operations.

The fourteen inspections carried out in 2017 indicate that the main regulatory requirements concerning radiation protection of workers and the public are satisfied. The doses recorded by the workers are generally low in the case of operators working in bunkers, and seem to be well controlled on work sites.

ASN notes however that satisfactory performance of radiation protection controls is strongly dependent on the means allocated to the radiation protection expert-officer and it detects a degree of overstretching of these means.

ASN observes an improvement in the marking out of the work areas on work sites.

Lastly, improvements must still be made in order to bring the facilities into compliance with standard NF M62-102 and demonstrate compliance in the various operating configurations of the facilities.

Universities and laboratories or research centres

In 2017, ASN carried out eight inspections in the field of public research.

The inspections carried out in this area since 2014 have shown that, on the whole, radiation protection in research laboratories is satisfactory.

Particular attention must nevertheless be focused on the retrieval of contaminated waste and expired sources, which require substantial budgets.

Veterinary

In 2017, ASN carried out three inspections in the field of veterinary activities. The purpose of these inspections was, among other things, to monitor certain structures whose situation was found to be unsatisfactory in the remote oversight operations conducted in 2016. The inspections revealed relatively satisfactory integration of ASN's demands.

1.4 Radiation protection of the public and the environment

Radon

In 2017, 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 Auvergne-Rhône-Alpes region, particularly in schools, detention centres and spas.

ASN carried out 5 inspections in private educational institutions concerned by the radon exposure risk and in spas.

1.5 Nuclear safety and radiation protection in the transport of radioactive substances

ASN carried out 10 inspections in the field of radioactive substance transport in the Auvergne-Rhône-Alpes region in 2017, including one inspection of a nuclear medicine department, 3 unannounced inspections of radioactive package carriers and 4 inspections on this theme in BNIs.

During these inspections, ASN checked the organisation put in place by the licensees and carriers to comply with the regulations relative to the transport of radioactive substances and for the operations relating to the shipping and reception of packages in these installations.

The inspections on the transport of radioactive substances carried out by ASN in the Auvergne-Rhône-Alpes region in 2017 revealed no situations giving cause for concern.

2. Additional information

2.1 Informing the public

Press conference

On 20th September 2017, ASN held a press conference in Lyon on the situation of nuclear safety and radiation protection in the Auvergne-Rhône-Alpes region.

Information and preventive iodine tablet distribution campaign around the High Flux Reactor (RHF) of the Laue-Langevin Institute (ILL) in Grenoble (Isère département*)*

This campaign concerned both the replacement of the iodine tablets distributed in 2011, which were reaching their expiry date, and the development of the radiation protection culture of the people living or working in the vicinity of the facility. It followed on from the campaign conducted in 2016 around the EDF nuclear power plants.

The campaign was organised by the State departments, ASN, the ILL and the Council of the Order of Pharmacists. The iodine tablets were sent directly to the entities and people residing within the perimeter of the off-site emergency plan, that is to say within a radius of 500 metres around the facility.

A public meeting was held on 25th January 2017 to inform the populations concerned.

Work undertaken with the Local Information Committees (CLI)

All nuclear facilities in the Rhône-Alpes region apart from the Ionisos irradiator in Dagneux (Ain *département*) have a CLI.

These CLIs, whose activity has developed significantly through the coordination and implementation of working groups and public information meetings, met regularly in 2017. The Lyon division thus took part in 18 CLI meetings in 2017. The subjects addressed concerned the ongoing issues in the nuclear installations, such as the anomalies affecting primary system components, or the revisions of installation water intake and discharge authorisations. Lastly, the tightened vigilance applied to the Areva NP site of Romans-sur-Isère and the progress of the licensee's safety improvement plan are always presented at each meeting of the CLI.

In application of the new provisions of the Act No. 2015-992 of 17th August 2015 relative to Energy Transition for Green Growth, the CLIs of Bugey, Saint-Alban/Saint-Maurice, Cruas-Meysse, Romans-sur-Isère and Tricastin organised public information meetings on nuclear activities and on their work.

The Lyon division and the CLIs of the Auvergne-Rhône-Alpes region participated in the meeting of the Rhône Valley CLIs held on 18th and 19th May in Marseille. This event brought together about ten CLIs and the stakeholders (local authorities, departmental and regional councils, ASN, IRSN, licensees, etc.). Three themes (relations between the public, the licensee and ASN; the performance of independent analyses and expert assessments; waste management) were adopted with a view to sharing experience, and should lead to the creation in 2018 of a national working group on the management of very low level radioactive waste.

2.2 International action

The Lyon division continued its bilateral exchanges with the NRA (Japan's Nuclear Regulation Authority) on inspection practices and the actions deployed further to the Fukushima Daiichi accident.

A delegation of NRA inspectors was received in Lyon on this account. The exchanges focused on the organisational changes made at the NRA to reform oversight of the nuclear installations, and the conditions of putting the Japanese reactors back into service. The NRA inspectors visited the Bugey, Saint-Alban/Saint-Maurice and Areva NP Romans sites and took part in discussions with the licensees. A visit to the Bugey site was organised.

The Lyon division also received a delegation of inspectors from the Norwegian nuclear regulation Authority, which took part in a joint waste management inspection at the ILL in Grenoble in July 2017. The two Authorities discussed inspection practices on the sidelines of this inspection.

Lyon division inspectors visited a nuclear fuel manufacturing facility in Russia in order to compare the safety standards of that facility with those of the Areva NP plant in Romans-sur-Isère.

One inspector also participated in a working group with the U.S. Nuclear Regulatory Commission (NRC), on decommissioning practices, the objectives of post-operational clean-out, and the management of nuclear waste in the United States. A visit was organised to the decommissioning worksite of the Zion NPP (Illinois), whose installations are very similar to those of the French pressurised water reactors.

The Lyon division also continued its cross-inspection practices with the Swiss nuclear safety and radiation protection Authorities. Inspectors from the Swiss safety Authority (ENSI) took part in inspections on the Tricastin and Cruas-Meysse sites in April 2017. Inspectors from the Lyon division took part in an inspection at the Swiss Leibstat NPP and the Paul Scherrer Research Institute in September 2017. The Lyon division also continued its joint oversight actions with the Swiss Federal Office of Public Health, which is responsible for radiation protection oversight, and monitoring CERN in particular.

Broadly speaking, these exchanges have permitted the sharing of good practices in the oversight of nuclear activities and radiation protection and in methods of decommissioning.

2.3 The other notable events

ASN deployed its emergency organisation for 2 notable events that occurred on the Bugey NPP, namely a fire in the roof of a nuclear building and the failure of a reactor control component, neither of which had any consequences on the installation or the environment. These two situations demonstrated ASN's ability to deploy its organisation to support the public authorities.

In contrast, the national emergency exercise, planned to take place on the Saint-Alban/Saint-Maurice NPP on 28th and 29th November 2017, was partially cancelled due to the intrusion of an association on the Cruas-Meysse site. Only the post-accident management phase could be played out, on the second day.

Bourgogne-Franche-Comté

The Dijon division regulates nuclear safety, radiation protection and the transport of radioactive substances in the 8 *départements* of the Bourgogne-Franche-Comté region.

The installations and activities to regulate comprise:

- small-scale nuclear activities in the medical sector:
  - 8 external-beam radiotherapy departments (21 accelerators, 2 contact therapy devices);
  - 4 brachytherapy departments;
  - 14 nuclear medicine departments, 3 of which practice internal vectorised radiotherapy;
  - 37 centres performing fluoroscopy-guided interventional procedures;
  - 51 computed tomography scanners;
  - about 800 medical radiology devices;
  - about 2,000 dental radiology devices;
- small-scale nuclear activities in the veterinary, industrial and research sectors:
  - 208 veterinary practices;
  - 390 industrial and research establishments, including 28 companies exercising an industrial radiography activity, 166 users of devices for detecting lead in paint, 1 cyclotron accelerator for research and the production of medical imaging drugs and 2 industrial accelerators for radiography and polymer cross-linking;
- approved laboratories and organisations:
  - 3 organisations approved for radiation protection controls, with 6 agencies;
  - 5 organisations approved for radon monitoring and 1 laboratory approved for measuring radioactivity in the environment.

In 2017, ASN conducted 71 inspections in the Bourgogne-Franche-Comté region, comprising 28 inspections in the medical sector, 30 inspections in the industrial research and veterinary sectors, 3 inspections concerning radon exposure, 3 oversight inspections of the activity of approved organisations and laboratories and 7 inspections on the transport of radioactive substances.

Among the significant events notified and analysed to draw lessons, 4 events concerning radiotherapy patients were rated level 1 on the ASN-SFRO scale.

The manufacturing plants of Areva NP situated in the Bourgogne-Franche-Comté region were also the subject of particular scrutiny by ASN in 2016 and 2017 following the discovery of irregularities in components manufactured by Creusot Forge. The steps taken by ASN in this respect are described in chapter 12.

1. Assessment by domain

1.1 Radiation protection in the medical field

Radiotherapy and brachytherapy

ASN performed 5 inspections of radiotherapy and brachytherapy activities in 2017. Three commissioning inspections of new items of equipment were also carried out. On the whole, the inspected departments have complied with ASN resolution 2009-DC-0150 requiring the setting up of a specific organisation to ensure treatment safety and quality. Two of the inspected departments must however make improvements, particularly in the studies of the risks for patients. The inspections revealed a continued dynamic approach to adverse event analysis and significant event notification.

In 2017, 4 significant events concerning the radiation protection of radiotherapy patients were rated level 1 on the ASN-SFRO scale. Three of these events concerned errors in the medical procedure while the fourth was due to equipment failure.

ASN had placed the University Hospital of Besançon (CHRUB) under tightened monitoring since the second quarter of 2015 on account of substantial changes in its organisation and being significantly behind schedule in radiation protection in the areas of radiotherapy and interventional practices.

This led more specifically to inspections conducted in May 2015, February 2016 and October 2017. In the course of these inspections, ASN observed strong resolve on the part of general management and the departments concerned to meet the regulatory requirements. The inspection of the radiotherapy department in October 2017 showed that the required improvements in documentation, in the organisation to ensure treatment quality and safety and in the organisation of the medical physics unit, had been achieved. ASN therefore decided in November 2017 to lift the tightened monitoring of the CHRUB and will now be particularly attentive to the completion of the improvement measures that are still in progress.

Fluoroscopy-guided interventional practices

The opening of the private Dijon-Bourgogne Hospital in Valmy during the summer of 2017 resulted in the grouping of interventional practices previously carried out in the Chenôve and Fontaine-les-Dijon Clinics. At the early stages of this project, ASN verified that the radiation protection requirements were effectively taken into account, particularly regarding compliance with the design standards applicable to the premises.

ASN focused particular attention in 2017 on centres that use image intensifiers in the operating theatre, carrying out 6 inspections in this area, 4 of them in private clinics and 2 in public hospitals. Two of the inspected centres were found to be below standard.

With regard to patient radiation protection, all the inspected centres have initiated a process to optimise doses delivered to patients, using the skills of medical physicists, often external to the centre. The dosimetric data are thus collected to establish internal reference levels for the procedures involving the highest doses. The obligation to control the quality of the images delivered by the devices is well respected on the whole. There is nevertheless still a need for more widespread training of physicians in patient radiation protection, in the use of imaging devices and the recording of information on the radiation doses delivered to patients in the procedure reports.

With regard to occupational radiation protection, it is often necessary to update the workstation/environment analysis to take into account developments in the activities. The premises zoning signs often indicate a permanent risk when in fact it is intermittent. The use of personal protective equipment is increasing, but must continue in this direction, as must the wearing of dosimeters, compliance with the frequency of occupational radiation protection training and coordination of radiation protection measures with outside workers.

Two significant radiation protection events concerning workers were notified in 2017. ASN considers that progress must be made in the notification of events in the area of interventional practices.

Nuclear medicine

In 2017, the majority of the nuclear medicine departments in the region asked ASN for authorisation to introduce changes in their way of functioning. The requests concerned the replacement of old equipment by higher-performance equipment, as well as the moving of nuclear medicine activities to the new Nord Franche-Comté Hospital, which opened in Trevenans in January 2017.

In 2017, ASN carried out six inspections in nuclear medicine departments. Two inspections also concerned the opening of new departments. They showed that patient and personnel radiation protection is satisfactory, but further progress is still required.

With regard to the radiation protection of health professionals, radiation protection must be better coordinated in the structures that use private practitioners.

As for patient radiation protection, the involvement of a medical physicist must become standard practice to achieve a high level of optimisation of delivered doses. Work must moreover be undertaken in the next few years to take fully into account the regulatory requirements applicable to the fitting out of nuclear medicine premises.

Half of the significant events relating to patient radiation protection notified to ASN in Bourgogne-Franche-Comté in 2017 concern nuclear medicine procedures. The most frequent causes are errors in examination preparation or performance, leading to patients being injected with an inappropriate radiopharmaceutical preparation.

1.2 Radiation protection in the industrial and research sectors

Industrial radiography

ASN carried out 7 inspections in industrial radiography in 2017, of which 4 were on worksites using radioactive sources or X-ray generators. These inspections revealed overall compliance with radiation protection requirements, and more specifically compliance with the principle of exposure optimisation through the use of collimators.

The main areas for improvement are the justification of the safety perimeters and their correct application on the ground, the completion of job studies and the drawing up of guidance documents for incident situation management. In addition, efforts are to be made to bring all the fixed radiology facilities into compliance with the applicable standards.

The jamming of a radioactive source outside a gamma ray projector was notified as a significant event in 2017. This event took place in a protected enclosure and had no consequences for the personnel. Generally speaking, one or two events of this type occur per year in France.

Universities and laboratories or research centres

In 2017, ASN carried out three inspections in university laboratories that use unsealed sources. These inspections revealed satisfactory compliance with radiation protection requirements and rigorous management of radioactive sources and waste. This being said, dosimetric monitoring that is appropriate for the manipulated radionuclides (tritium and carbon-14) must be implemented.

In 2017, ASN also monitored the legacy radioactive waste management procedures at the Franche-Comté University.

Veterinary

In 2017, ASN carried out three inspections in specialised veterinary facilities. Two of these inspections specifically targeted owners of scanners whose administrative situation is currently being regularised. These inspections revealed a satisfactory radiation protection situation in both inspected facilities. The third facility will be inspected again in 2018, in cooperation with the labour inspectorate, to check that the requested actions have been taken.

Installations Classified on Environmental Protection grounds (ICPEs)

In 2016, ASN began a three-year inspection campaign of sites with Installation Classified for Protection of the Environment (ICPE) status which, because they use sealed radioactive sources, will have to meet the radiation protection requirements of the Public Health Code by 2019. ASN carried out 8 inspections as part of this campaign in 2017. They confirmed the first trends found in 2016. The inspected facilities have a good safety culture but efforts must be made to integrate all the radiation protection requirements that will apply to them in 2019. The main areas for improvement concern the assessment of radiological risks, the radiation protection technical controls and coordination of radiation protection with the service providers.

1.3 Monitoring approved organisations and laboratories

ASN conducted an inspection of approved organisations to assess the conformity of nuclear pressure equipment. The steps taken by ASN in this respect are described in chapter 12. ASN also carried out two inspections of organisations approved for radiation protection controls. ASN observed that these organisations carry out their controls in accordance with the reference system that was approved when they received their accreditation. The operators were nevertheless reminded of their obligation to transmit their control intervention schedules in advance. The aim of this is to enable ASN to conduct unannounced oversight actions.

1.4 Radiation protection of the public and the environment

Exposure to radon

In 2017, ASN continued its inspections of the administrators of lower and upper secondary schools in the five *départements* with priority status for management of the radon risk. The actions taken in the private lower and upper secondary schools to measure the level of exposure to radon and, if necessary, initiate remediation actions were assessed. ASN also conducted inspections in two spas.

These inspections on the whole showed lateness in meeting the regulatory requirements.

ASN continued its collaboration with the ARS (Regional Health Agency) and the Dreal (Regional Directorate for the Environment, Planning and Housing) for the management of situations of exposure to a high level of radon in certain places open to the public and in dwellings close to former mining sites.

ASN also participated 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. It contributed to the Franco-Swiss JURAD-BAT project which aims at establishing, by 2019, a cross-border platform to improve management of the radon exposure risk in buildings situated in the Jura Arc.

Contaminated sites and soils

Work has been in progress since 2014 to clean out a former watchmaking factory in the Haut-Doubs where traces of radium and tritium were found. In 2016, the CNAR (National Commission for Aids in the Radioactive Field) adopted a scenario for finalising the cleaning out of this site. In 2017, ASN helped to prepare the prefectural order that will govern this work.

Mining sites

In 2016, Areva proposed solutions to the State services for remedying the radiological anomalies resulting from the reuse of mining waste rock on three sites in the Saône-et-Loire *département* and two sites in the Nièvre *département*. The Dreal asked ASN to help assess these proposals. ASN will issue an opinion on this subject in early 2018.

ASN is particularly attentive to the monitoring of two other sites situated in the Saône-et-Loire *département* 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 tailings from the treatment of uranium-bearing ores have been stored in a former uranium mine (Bauzot site). In 2016, the prefectural authority asked Areva to supplement the assessment of radioactive substances present on the site and the monitoring of the site environment. In 2017, ASN helped the Dreal assess the responses provided by Areva, which led to the formulation of new requests.

In Gueugnon, waste from a uranium ore processing plant which operated between 1955 et 1980 is stored in an ICPE. In 2015, during the process to inventory mining waste rock, Areva discovered five plots of land near this ICPE which display radiological contamination from ore processing residues. In September 2016, Areva began the remediation of a first site accommodating a residential house. ASN kept track of the progress of the first two phases of the radiological remediation in 2017. The work carried out so far by Areva has allowed extensive remediation of the site and restored a situation approaching the natural radiological state.

In 2017, at the request of the Dreal and in cooperation with IRSN, ASN also contributed to the updating of the provisions for environmental monitoring around the ICPE repository for waste from the former uranium ore processing plant.

1.5 Nuclear safety and radiation protection in the transport of radioactive substances

ASN carried out 7 inspections in the area of radioactive substance transport in the Bourgogne-Franche-Comté region in 2017. These inspections concerned radioactive package consignors and consignees, road transport carriers and one nuclear medicine department.

The inspections showed that the companies or departments without a transport safety advisor lacked knowledge of the regulations. For the majority of package consignors and consignees, the inspections highlighted poor knowledge of the regulatory requirements and margins for improvement in their quality management systems. The situation was found to be more satisfactory with the road transport carriers, who complied with all the regulatory requirements to ensure the safety of transport.

2. Additional information

2.1 Informing the public

Press conference

On 6th September 2017, ASN held a press conference in Dijon on the state of nuclear safety and radiation protection in the Bourgogne-Franche-Comté region.

2.2 The other notable events

ASN organised a seminar held on 28th November 2017 in Dijon for manufacturers and actors in the medical sector in the Bourgogne-Franche-Comté region which focused on radiation protection in industrial radiography activities and the security of high-activity sources. Attended by over 80 participants, this seminar gave the operators the opportunity to share experience feedback and review the regulatory changes under preparation.

Bretagne

The Nantes division regulates radiation protection and the transport of radioactive substances in the 4 *départements* of the Bretagne region. The Caen division regulates the nuclear safety of the Monts d'Arrée NPP (Brennilis), currently undergoing decommissioning.

The installations and activities to regulate comprise:

- the Monts d'Arrée site NPP undergoing decommissioning, regulated by the Caen division;
- the facilities and activities using ionising radiation in the medical, industrial and research sectors:
  - medical services: 8 external-beam radiotherapy departments; 5 brachytherapy departments; 11 nuclear medicine departments; 37 centres performing interventional procedures, 54 computed tomography scanners and some 2,500 medical and dental radiology devices;
  - industrial and research uses: one cyclotron, 20 industrial radiography companies, including 3 gamma radiography contractors and about 450 licences for industrial and research equipment, including more than 325 users of devices to detect lead in paint;
  - 6 radiation protection technical control agencies, 7 radon screening agencies and 4 head offices of laboratories approved for taking environmental radioactivity measurements.

In 2017, ASN carried out 36 inspections: 2 at the Monts d'Arrée NPP undergoing decommissioning and 34 in small-scale nuclear activities.

Among the notified events, one was rated level 1 on the INES scale and 4 events in radiotherapy were rated level 1 on the ASN-SFRO scale.

1. Assessment by domain

1.1 The nuclear installations

Mont d'Arrée NPP - Brennilis

During 2017, EDF continued the effluent treatment station decommissioning operations and the reactor containment "recovery" operations following the September 2015 fire on the heat exchanger decommissioning worksite.

In 2017, the heat exchanger worksite teardown operations continued under satisfactory conditions of safety and radiation protection. ASN remained vigilant with regard to EDF's accompanying and monitoring of outside contractors, particularly regarding control of the fire risk.

As far as the Effluent Treatment Station (STE) is concerned, the basemat demolition work continued in 2017. The discovery of an asbestos pipe in the basemat led to a two-month suspension of the worksite. As at the end of 2017, the basemat was 95% demolished. ASN will publish a position statement in 2018 on the plan proposed by EDF for management of the subjacent soils.

The inspections carried out by ASN n 2017 show that the management of deviations and the performance of the periodic checks and tests are satisfactory. This being said, the management of events occurring outside opening hours can be improved. Corrective actions were made during the year further to ASN inspections.

In August 2017, ASN issued a resolution making the taking of samples from the reactor block subject to prior ASN consent. ASN is also examining the periodic safety review guidance file. Lastly, EDF will transmit a new complete decommissioning file in July 2018.

1.2 Radiation protection in the medical field

External-beam radiotherapy

Three external-beam radiotherapy accelerator replacements were registered for Bretagne in 2017. The change in equipment is accompanied by the development of new techniques (primarily stereotaxy) which lead to new risks. Three of the eight external-beam radiotherapy centres in Bretagne were inspected in 2017. Risk management and the implementation of new treatment techniques were verified in depth.

Following a phase of consolidation of the quality approach, the inspections in 2017 confirm that the sites are now all resolutely engaged in a phase of quality management and continuous improvement. Although the "quality" objectives are regularly updated by the centres' respective governing bodies, their monitoring and assessment can still be improved in some cases.

The risks induced by the new techniques are integrated in the a priori risk analysis with the putting in place of new requirements or defence barriers. However, deadlines and the people responsible for their implementation are not always specified.

The organisation for detecting and analysing adverse events is effective on the whole and contributes to the development of the risk analysis. A total of 12 significant patient radiation protection events were notified to ASN in 2017, and 4 of them were rated level 4 on the ASN-SFRO scale. After analysing the events, improvement measures have been implemented but their effectiveness is still insufficiently assessed in some centres.

Lastly, despite the efforts made over the last few years to recruit medical physicists, dosimetrists and physical measurement technicians enabling all the centres to comply with the skills presence requirements during treatment time slots, most of the centres should define their medical physics needs more precisely.

Interventional practices

Oversight of interventional practices has figured among the priority objectives of the Nantes division since 2014[1].

Despite the effort made over the last few years in the number of inspections and their prioritisation, the division has not yet inspected each centre at least once, emphasis having been placed on monitoring the sites presenting the most serious radiation protection implications. However, to raise radiation protection awareness within the centres and to reinforce the prioritisation approach, a survey was carried out in 2017 with the centres that had never been inspected and with a few centres that have a very low level of activity in this area but whose practices nevertheless were considered to merit monitoring in view of the findings of the first inspection. This initiative moreover allowed the volume of activity of these centres to be updated and the two sites which in the first survey had declared they did not carry out fluoroscopy-guided interventional procedures to be identified. This instrument was also used to refine the targeting of the inspections on the 2018 schedule.

In 2017, ASN inspected 3 of the 37 institutions identified by the division.

Among these inspected institutions, the Brest University Hospital has made steady progress over the years, underpinned in particular by the strong involvement of the various professionals, including within the medical community, thanks to which the professional practices audits have more specifically allowed an objective review of the deviations detected by ASN and the implementation of appropriate measures to correct them.

This being said, the findings for the institution inspected for the first time in 2017 – relatively similar to the findings for first-time inspected institutions in previous years – reveal considerable room for improvement in worker and patient radiation protection. For the third institution inspected in 2017, closer monitoring shall be implemented in view of the little progress observed with regard to the serious radiation protection implications associated with intensive cardiology-related activities.

Nuclear medicine

Two inspections were carried out in 2017 before new facilities started operating, due in one case to the addition of a Positron Emission Tomography (PET) scanner, and in the other to the relocating of a PET unit in new premises.

The number of significant radiation protection event notifications remains relatively stable (up from 3 events in 2016 to 4 in 2017).

Computed Tomography

Two centres were inspected in 2017. The inspections focused more particularly on patient radiation protection, which is implemented satisfactorily in these centres. The personnel concerned are correctly trained, the facility quality controls have been carried out and patient dose optimisation protocols have been established.

The medical monitoring of workers, the coordination of the resources of private practitioners and outside companies and the periodic refreshing of occupational radiation protection training, still constitute the three areas for improvement in occupational radiation protection.

1.3 Radiation protection in the industrial sector

Industrial radiography

ASN carried out 4 inspections concerning industrial radiography in Bretagne in 2017, of which 2 were on gamma radiography

1. *62 inspections carried out in the Bretagne – Pays de la Loire regions in the 2014-2017 period, out of a total of 77 centres (82 sites).*

worksites. The results show that the inspected companies on the whole comply with the regulatory requirements regarding the organisation of radiation protection, operator training and monitoring, equipment maintenance and the general preparation of industrial radiography work.

Improvements must nevertheless be made in the implementation of marking-out plans, the utilisation of Sentinelle radiation monitors, the consistency of the worksite documents with the equipment used, the risk assessments, the analysis of received doses and the transmission of worksite schedules.

1.4 Nuclear safety and radiation protection in the transport of radioactive substances

ASN did not carry out any inspections that exclusively addressed the transport of radioactive substances in 2017. During an industrial radiography inspection however, the examination of the requirements relating to transport led ASN to point out the requirements applicable to the securing of the gamma ray projector transport package and the conditions of transport of the gamma ray projector control key.

1.5 Radiation protection of the public and the environment

Radon

After being a source of proposals in 2016 in the working groups tasked with developing the 3rd Regional Health/Environment Plan (PRSE3), this plan was validated on 4th July 2017. At the end of 2017, in collaboration with the Regional Health Agency (ARS), ASN drew up the action sheet for communicating to the Bretagne populations on the radon risk.

Furthermore, ASN continued – again in collaboration with the ARS – to check compliance with the radiation protection requirements relative to radon in the state-run schools (kindergartens and primary schools) of two municipalities[2]. These inspections confirmed that these establishments, which are concerned by the Order of 22nd July 2004, are subject to regular monitoring. However, after several years and despite the implementation of simple corrective measures, some institutions still display radon concentrations above the levels set by the regulations at which action is required (400 and 1,000 Bq/m^3). These establishments will have to undergo further work to reduce the radon contents to below the reference levels.

Mining sites

For several years now ASN has been attentive to 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.

After having validated the 12 work sheets concerning the sites of waste rock reuse in 2016, ASN monitored, with the Dreal (Regional Directorate for the Environment, Planning and Housing), the progress of the work which started in late 2017 and will continue in 2018. In this same context, in November 2017 ASN and the Dreal conducted an inspection of the former mining site of Prat Mérien which had been chosen and authorised to accept the mining waste rock from the work in the sector of the former Lignol concession. This inspection showed that Areva complies with the radiation protection provisions of the Prefectural Order of 19th June 2017 governing the disposal of these materials.

With regard to sites of mining waste rock reuse situated near living areas (dwellings or enterprises), Areva, at the request of the State, conducted a first radon screening campaign by sending radon dosimeters to all the property owners concerned. Despite a return rate of less than 50%, this campaign did reveal two dwellings in which the radon concentrations exceed 2,500 Bq/m^3. The complementary studies of these two dwellings found that the radon did not originate from uranium-bearing mining waste rock. ASN also asked for dosimeters to again be distributed to the populations concerned. Reflections have moreover been initiated with the Dreal and the ARS to take into consideration dwellings with radon concentrations of between 300 and 2,500 Bq/m^3.

Lastly, ASN has issued favourable opinions on the projects to remove the radiologically marked sludge and sediments from the former Breton mining sites. These materials will have to be excavated and transported to the former Écarpière mining site situated in the Loire-Atlantique *département*, on which the disposal of these materials has been authorised by a Prefectural Order of 21st August 2017.

2. Additional information

2.1 L'action d'information du public

Press conference

On 26th September 2017, ASN held a press conference in Rennes on the situation of nuclear safety and radiation protection.

Work with the Local Information Committees (CLI)

ASN participated in two general assemblies of the CLI for the Brennilis NPP; it presented, among other things, its assessment of the safety situation of the Brennilis NPP. ASN also provided information on the management of soils polluted by a nuclear installation to the technical group set up by the Brennilis CLI to analyse the licensee's file concerning management of the soils beneath the Effluent Treatment Station (STE). In accordance with the provisions introduced by Act 2015-992 of 17th August 2015 relative to Energy Transition for Green Growth, the Brennilis CLI organised a public meeting on the dismantling of the NPP.

2. *Quimper in Finistère* département *and Saint Brieuc in Côtes d'Armor* département.

Centre-Val de Loire

The Orléans division regulates nuclear safety, radiation protection and the transport of radioactive substances in the 6 *départements* of the Centre-Val de Loire region.

The installations and activities to regulate comprise:

- BNIs:
  - 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);
- small-scale nuclear activities in the medical sector:
  - 8 external-beam radiotherapy departments;
  - 3 brachytherapy departments;
  - 10 nuclear medicine departments;
  - 35 centres performing fluoroscopy-guided interventional procedures;
  - 43 computed tomography scanners;
  - some 2,700 medical and dental radiology devices;
- small-scale nuclear activities in the industrial and research sectors: 10 industrial radiography companies, including 4 gamma radiography contractors, about 330 industrial, veterinary and research radiography devices.

In 2017, ASN carried out 130 nuclear safety and radiation protection inspections: 98 inspections of the nuclear installations on the EDF sites of Belleville-sur-Loire, Chinon, Dampierre-en-Burly and Saint-Laurent-des-Eaux, and 39 inspections in small-scale nuclear activities in the Centre-Val de Loire region.

ASN carried out 71 days of labour inspections in the nuclear power plants.

Eight significant events rated level 1 on the INES scale were notified by the licensees of the EDF nuclear installations in the Centre-Val de Loire region in 2017. In small-scale nuclear activities, 8 significant events of level 1 and one of level 2 on the ASN-SFRO scale were notified in the Centre-Val de Loire region.

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 in radiation protection is on the whole in line with the general assessment of EDF, but its performance in safety and the environment has regressed.

With regard to nuclear safety, there are still many significant events resulting from a lack of rigour in the management and monitoring of the facilities, and the improvement that was tangible in the first half of the year failed to be maintained. Consequently, in September 2017 ASN decided to place the Belleville-sur-Loire NPP under tightened monitoring. This decision was motivated firstly by recurrent deficiencies in the identification and analysis of the consequences of the anomalies affecting certain items of equipment important to safety. ASN also observed the apparent degraded condition of several items of equipment after successive postponements of maintenance operations. ASN will closely monitor application of the action plan put in place by EDF.

With regard to the environment, and despite a positive organisational assessment, there are still deviations in the application of the rules concerning the containment of liquids and control of the discharge measuring facilities. NPP management has started taking measures to overcome the deteriorated state of certain facilities that can have an impact on the environment; these measures must be continued and maintained over the longer term. Lastly, ASN has also observed an increase in cooling fluid discharges into the atmosphere and significant deviations in control of the explosion risk and lightning protection.

In the area of radiation protection, ASN notes that improvements are required in the control of the risk of contamination dispersion, particularly during reactor outage periods.

Chinon site

ASN considers that the safety and environmental protection performance of the Chinon NPP on the whole is in line with ASN's general assessment of EDF, and that the radiation protection performance is above the national average.

With regard to nuclear safety, the site is maintaining a satisfactory level, as illustrated by the good management of the general operating rules and the temporary safety instructions. Nevertheless, many of the notified significant events are linked to a lack of rigour on the part of the operators and anomalies in the content of the documents used. Reactor outage management can manifestly also be improved, given the numerous findings from the inspections carried out in 2017, particularly concerning management of the risk analyses and of the work tracking documents.

The organisation of radiation protection is deemed satisfactory, giving the site good results in dosimetry and radiological cleanness. The risk prevention department is particularly involved in these areas and its field response times are short. Raising the awareness of service providers to radiation protection, and in particular to the rigorous application of the rules for work in radiological environments must however be continued in view of the notified events, albeit few in number.

Environmental performance, while comparable with the national average, was down with respect to preceding years. Although gaseous and liquid effluent discharge values remain within limits and few significant events concern the environment, numerous deviations relating to management of the lightning risk and of waste were observed during the inspections in 2017.

In June 2017, ASN gave EDF a hearing on its change in decommissioning strategy for the gas-cooled reactors, decided in 2016. This new strategy involves decommissioning the Chinon A2 reactor pressure vessel first, in air rather than under water, before starting decommissioning of the other GCR pressure vessels (see chapter 15). In 2018, ASN will examine the files requested for the examination of this strategy. ASN will also prescribe submission of the decommissioning file for the Chinon A1 and A2 reactors under the Decree of 28th June 2016. Lastly, ASN will examine the periodic safety reviews of the Chinon A1 and Chinon A2 reactors, for which the conclusions reports were received at the end of 2017.

ASN considers that the level of safety of the Chinon site nuclear installations undergoing decommissioning (Chinon A1, A2 and A3) is satisfactory in the short term. The inspections carried out in 2017 confirmed the licensee's involvement in the safety initiative. This being said, waste management – particularly the tracking of interim storage times and waste removal – must be improved.

Decommissioning of the Chinon A3 heat exchangers was resumed in August 2017 after developing a new handling system and cleaning out the parts containing asbestos. ASN will be particularly attentive to EDF's monitoring of the outside contractors who perform the decommissioning operations. With regard to the Chinon A2 reactor, further to the results of the first analyses of the components removed from the reactor systems, additional analyses will be carried out to determine the treatment strategy for this waste.

The treatment of chemically polluted soils is in progress. The measures to reinforce groundwater monitoring have been taken and the additional characterisation of the gaseous discharges was finalised in January 2018.

The analysis and expert assessment activities of the Irradiated Material Facility (AMI) have stopped and the decommissioning preparation operations are in progress. Since early 2017 the facility has been operated by a new structure that depends on the EDF department in charge of decommissioning.

The management of waste treatment operations and the monitoring of equipment in service are satisfactory. Particular attention must however be focused on operating rigour. In a context where the facility's activities are changing significantly, ASN will be attentive to the management of these changes and compliance with the baseline requirements.

The decommissioning authorisation application file was submitted to the environmental authority in the last quarter of 2016 and to a public inquiry in early 2017. ASN is continuing its examination of the decommissioning file.

Pending issuing of the decommissioning decree, ASN will be attentive to the progress of the decommissioning preparation operations to reach the initial state planned for when the decree takes effect.

In addition, as required by the Decree 2007-1557 of 2nd November 2007 relative to BNIs, EDF transmitted its report on the conclusions of the periodic safety review at the end of 2017. ASN will examine this report and develop its opinion for the Ministry responsible for Nuclear Safety.

ASN considers that the operating organisation of the Chinon Inter-regional Fuel Warehouse (MIR) seems robust and ensures efficient monitoring of the commitments made further to the inspections and significant events. Several physical improvements have thus been made in protection against the risks of fire and flooding. The validity of the criteria applied for the inspection of the cranes remains an issue.

In November 2017, further additions were made to the periodic safety review file which was initially submitted in 2015 and received its first supplement in June 2016. To compensate for the insufficient earthquake resistance of the handling crane detected in this review, the licensee, as of 2016, put into service two gates to protect the halls against the risk of flooding induced by an earthquake.

Dampierre-en-Burly nuclear power plant

ASN considers that the nuclear safety performance of the Dampierre-en-Burly NPP is on the whole in line with the general assessment of the EDF plants. It considers that the radiation protection and environmental protection performance is below the national average.

The nuclear safety performance is considered satisfactory on the whole. The strong involvement of the independent safety organisation in the follow-up to events is to be maintained. ASN does however note that deviations in maintenance activity scheduling, procurement deficiencies or nonconformities in spare parts led to several significant events and caused reactor outage extensions in 2017. ASN also notes that the site must regain its grip of the management of fire, explosion and lightning risks to bring the facilities into compliance with the associated regulations.

With regard to radiation protection, the action plan deployed by the site in 2017 has not yet demonstrated its effectiveness. Recurrent deviations are still observed and the site has attained few of its set targets. Strong measures tailored to situations in the field are expected in 2018.

As regards environmental protection, the site's performance is yet again found to be somewhat below ASN's assessment of the preceding years. Recurrent events were notified in 2017. They are related essentially to organisational deficiencies and reflect the lack of effectiveness of the corrective measures taken by the site since 2016.

Saint-Laurent-des-Eaux site

ASN considers that the performance of the Saint-Laurent-des-Eaux NPP is on the whole in line with the general assessment of EDF in the areas of the environment and radiation protection, but its safety performance is down compared with preceding years.

With regard to nuclear safety, ASN observes that several deviations in operation of the installations occurred during the reactor restarting periods. The action plan implemented by NPP management has not yet produced any significant improvement in the management of the periodic tests – already a weak spot in 2016 – which remain the cause of several significant event notifications. The in-depth analyses of these events reveal deficiencies in the technical analyses, quality assurance and training. Furthermore, the NPP's organisation for detecting deviations and justifying their remediation time frames, in accordance with the applicable regulations, is not sufficiently robust and must be improved. ASN nevertheless notes the good overall upkeep of the worksites and the efforts to update the maintenance documentation with respect to the baseline requirements.

ASN considers that the radioprotection organisation of the Saint-Laurent-des-Eaux NPP is satisfactory. The site's culture in this area meets expectations. The radiation protection rules are generally well integrated in the preparation and performance of work in controlled areas, even if a few deviations, including 2 significant events, were detected.

The performance of Saint-Laurent-des-Eaux with regard to the environment seems satisfactory on the whole. ASN underlines the commitment of the organisation and the robustness of the measures taken to manage activities involving high environmental risks. On the other hand, the long-term integration of the environmental requirements must still be improved.

ASN considers that the level of safety of the old Saint-Laurent-des-Eaux NPP is satisfactory for the short term.

In 2016, EDF announced a change in the decommissioning strategy for its gas-cooled reactors, and in 2017 it submitted the elements requested by ASN which will be examined in 2018 (see chapter 15). ASN will also examine the periodic safety review for the Saint-Laurent-des-Eaux reactors A1 and A2 in 2018, for which the conclusions report was received at the end of 2017.

The liquid and solid waste removal operations continued as part of the decommissioning of the reactors of Saint-Laurent-des-Eaux A. An action plan specifically targeting the legacy waste of the installation was prepared and presented to ASN. In this context, EDF plans to create a new legacy waste characterisation area and is seeking an interim storage solution for "legacy waste with projected disposal route" and "legacy waste without disposal routes". ASN will be vigilant regarding compliance with the proposed deadlines and the actions undertaken.

The worksites involving an "alpha" contamination risk had been suspended since 2016 following the discovery of confirmed internal contamination of persons, which had been incurred on such worksites. These activities were resumed in June 2017. ASN has verified that all the corrective actions defined by EDF further to the discovery of the contamination have been correctly accomplished. An action plan focusing on work rigour has been initiated and presented to ASN. ASN will continue to implement the defined measures and corrective actions in 2018.

Labour inspection in the nuclear power plants

During 2017, as in the preceding years, the ASN labour inspectors conducted various worksite inspections on all the nuclear power plants of the Centre-Val de Loire region in the areas of health and safety at work, particularly during maintenance outages. Specific inspections were also carried out on the following themes: explosion risk, operation of ventilation, conformity of loading – unloading machines, etc. These inspections focused on the periodic verifications as well as the conformity of the facilities or work equipment with the applicable regulations.

Worksite inspections were also carried out on the ultimate backup diesel generator set construction sites (post-Fukushima project) and on tertiary building worksites.

Several workplace accidents have given rise to specific inspection operations to determine the exact causes and the corrective actions implemented by the licensees of the NPPs concerned.

In addition, regular meetings took place with the bodies representing the personnel at the meetings of the Committee for Health, Safety and Working Conditions and when the personnel representatives made specific requests on subjects essentially addressing application of the labour laws.

1.2 Radiation protection in the medical field

Radiotherapy and brachytherapy

The Centre-Val de Loire region has 8 external-beam radiotherapy departments and 3 brachytherapy departments. The two regional hospital centres of Tours and Orléans implement advanced treatment techniques in external-beam radiotherapy such as tomotherapy and stereotactic treatments.

The oversight action conducted in 2017 endeavoured to integrate the new inspection guidelines set out by ASN for the 2016-2019 period relative to risk management (prospective and retrospective risk analysis), experience feedback (management of internal notifications, continuous improvement of treatment quality and safety in radiation therapy) and the deployment of new techniques (management in project mode).

In view of the findings of the 2017 inspections, ASN considers that patient radiation protection is generally properly catered for in the radiotherapy centres of the Centre-Val de Loire region. These inspections did nevertheless highlight significant disparities between external-beam radiotherapy centres in the safeguarding of the patient care pathway.

Fourteen significant events in external-beam radiotherapy were notified to ASN in 2017. These events were mainly caused by patient positioning errors. Eight of these events were rated level 1 on the ASN-SFRO scale, while one was rated level 2. The level-1 rating is assigned to events having consequences as regards the administered dose but no expected clinical consequences for the patient. The level-2 rating is assigned to events that could cause moderate alteration of a function. In the present case, this event was associated with a palliative treatment.

Fluoroscopy-guided interventional practices

In the light of the 5 inspections carried out in interventional imaging in the Centre-Val de Loire region, ASN considers that occupational radiation protection still gives cause for concern even if there is a tendency towards improvement, particularly thanks to the observed hands-on investment of the Radiation Protection Expert-Officers. ASN still notes a lack of occupational radiation protection culture, more particularly in the operating theatres (procedure reports only partially completed, regulatory training not carried out or lacking traceability, failure to systematically wear personal protective equipment and dosimeters). With regard to patient radiation protection, it is still not adequately integrated in the operating theatres due to medical physics resources that are insufficiently directed towards interventional practices, whether this concerns the internal resources of large institutions or of service providers in the smaller healthcare centres.

No significant radiation protection event concerning interventional imaging was notified in the Centre-Val de Loire region. In view of the number of centres or departments using these techniques, the absence of event notifications reveals the necessity to continue putting in place tools to identify and analyse abnormal situations.

Nuclear medicine

ASN inspected two of the ten centres practising nuclear medicine in the Centre-Val de Loire region. The overall findings are positive with regard to the measures taken in response to the radiation protection challenges. Findings regarding the optimisation of doses delivered to patients and the medical monitoring of personnel were nevertheless notified and were subject to particular monitoring by ASN.

Alongside this, ASN continued its inspections relating to the transport of unsealed sources. The need for the inspected centres to continue upgrading their organisation in this area was observed.

One significant event was notified for the Centre-Val de Loire region in 2017. This incident, which concerned repeated failures affecting a PET-CT scanner (positron emission tomography scanner combined with a computed tomography scanner) had no clinical consequences for the patients or personnel.

1.3 Radiation protection in the industrial and veterinary sectors

Industrial radiography

ASN carried out four inspections in companies using X-rays for the Non-Destructive Testing (NDT) of industrial parts, particularly in the weapons industry. Occupational radiation protection is satisfactory despite some shortcomings in the application of the installation standards in effect. The personnel assigned to NDT tasks are trained and have an appropriate understanding of the radiation protection issues.

Two inspections of worksites using gamma radiography, one in a nuclear power plant, were carried out in 2017. As one of these inspections revealed shortcomings in worksite preparation (marking out, verification of exposure in actual situation), these points are now examined systematically and brought to the attention of service providers.

Veterinary

ASN carried out 2 inspections in veterinary facilities in 2017 (1 inspection was in a facility equipped with a CT scanner). Occupational radiation protection is satisfactory and takes into account the implications in this respect.

1.4 Nuclear safety and radiation protection in the transport of radioactive substances

ASN performed 4 inspections in BNIs, one inspection of a nuclear medicine centre and one inspection of a road transport carrier in 2017.

The inspections focused primarily on the quality management systems, the operational measures applied, compliance with the package approvals (particularly for spent fuel transport operations), and radiological verifications. Transport operations within BNI sites were also inspected.

These inspections showed that the regulations applying to road transport are correctly applied. The main areas for improvement concern the management of deviations, radiological verification procedures, the auditing of subcontracted activities, training course tracking, operations traceability in compliance with the quality assurance provisions and the marking of packages.

The significant events had no notable impacts. They primarily concerned labelling and placarding anomalies, package classification errors resulting from insufficient radiological verifications, incomplete shipping documents and noncompliance with organisational provisions.

1.5 Monitoring of approved organisations

Radiation protection technical controls

Two organisations approved for radiation protection controls have their head office in the Centre-Val de Loire region. ASN kept up its oversight action in 2017 by conducting one in-depth inspection of an agency and one unannounced supervisory check. The main findings concerned the conditions of performance of agency audits and the exhaustiveness of the points checked in the technical controls conducted with customers.

2. Additional information

2.1 Informing the public

Press conference

ASN held a press conference in Orléans on 14th September 2017 to present the situation of nuclear safety and radiation protection in the Centre-Val de Loire region. It included a presentation of the conditions of tightened surveillance of the Belleville-sur-Loire NPP.

Work with the Local Information Committees (CLIs)

The ASN Orléans division supported the work of the Centre-Val de Loire CLIs by participating in their plenary meetings. It also took part in the public meetings organised in 2017, which addressed more specifically the improvements in safety further to the Fukushima Daiichi accident, the management of radioactive waste and an overview of the emergency exercise carried out at Dampierre-en-Burly in December 2017.

2.2 International action

2017 saw a further meeting between ASN's Orléans division and the Swedish Safety Authority (SSM, *Strål Säkerhets Myndigheten*) to discuss oversight practices.

On this occasion, a team of inspectors from ASN participated in an SSM inspection of the Försmark NPP in Sweden.

Corse

The division Marseille regulates radiation protection and the transport of radioactive substances in the Corse territorial collectivity.

The installations and activities to regulate comprise:

- small-scale nuclear activities in the medical sector:
  - 2 external-beam radiotherapy departments;
  - 2 nuclear medicine departments;
  - 9 centres performing fluoroscopy-guided interventional procedures;
  - 8 computed tomography scanners;
  - some 330 medical and dental radiology devices;
- small-scale nuclear activities in the industrial and research sectors:
  - 11 industrial establishments licensed to hold or use sources of ionising radiation;
  - 23 users of lead detectors;
  - some 20 veterinary surgeons using diagnostic radiology devices.

n 2017, ASN carried out three inspections in Corse. Two "out of INES scale" significant events were notified by Corse health institutions in 2017.

1. Radiation protection in the medical field

External-beam radiotherapy

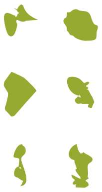
ASN performed 2 inspections in external-beam radiotherapy in 2017 and considers on the whole that the inspected institutions have a satisfactory grasp of worker and patient radiation protection. The same goes for treatment quality and safety and risk control. It must nevertheless be pointed out that the limited staff numbers, radiation oncologists in particular, can create vulnerabilities in treatment quality and safety, therefore ASN remains aware in this respect.

With regard to the project to put in place a new radiotherapy technique in the radiotherapy department of the Maymard Polyclinic in Bastia, the inspectors emphasised that today the project could benefit from existing experience feedback and a structure organised and coordinated by a formally appointed project manager.

2. Radiation protection in the industrial and research sectors

X-ray generators

ASN conducted an inspection in an industrial facility that uses electrical generators of ionising radiation and considers that the radiation protection measures adopted are on the whole satisfactory. ASN noted in particular that the Radiation Protection Expert-Officer was well involved on a daily basis.



DROM-COM

The regulation of radiation protection and the transport of radioactive substances in the 6 overseas *départements* and regions (Guadeloupe, Martinique, Guyane, La Réunion, Mayotte, Saint-Pierre-et-Miquelon) is ensured by the Paris division. It also fulfils duties as expert to the competent authorities of French Polynesia and New Caledonia.

The installations and activities to regulate comprise:

- small-scale nuclear activities in the medical sector:
  - 4 external-beam radiotherapy departments;
  - 3 brachytherapy departments;
  - 4 nuclear medicine departments;
  - 26 centres performing fluoroscopy-guided interventional procedures;
  - about 35 centres in possession of at least one Computed Tomography (CT) scanner;
  - about 100 medical radiology centres;
  - about 1,000 dental radiology devices;
- small-scale nuclear activities in the industrial and research sectors:
  - more than 70 users of veterinary radiology devices;
  - 2 industrial radiography companies using gamma radiography devices;
  - 2 cyclotrons, of which 1 is currently being installed.

In 2017, 22 inspections were carried out in the small-scale nuclear activities sector in the DROM (French Overseas *Départements* and Regions). Three on-site inspection campaigns were carried out by the ASN Paris Division.

One event involving an external-beam radiotherapy patient was rated level 1 on the ASN-SFRO scale.

1. Assessment by sector in the DROM

The inspections revealed the DROM to be somewhat behind in the application of patient radiation protection measures. This is due primarily to a lack of means dedicated to medical physics in radiotherapy and to fluoroscopy-guided interventional practices. While the centre which was served formal notice in 2016 for not having a medical physicist is now compliant, another centre was served formal notice for the same reason in 2017. Tightened oversight will be exercised in 2018.

The year 2017 was marked by the construction of an imaging centre using PET-CT (Positron Emission Tomography combined with a Computed Tomography scanner) and including a cyclotron for the local production of radiopharmaceutical products. The centre will undergo a pre-commissioning inspection in 2018.

2. ASN's action in New Caledonia and French Polynesia

During 2017, ASN continued its cooperation work with French Polynesia and New Caledonia as part of their local installation oversight operations 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.

With regard to French Polynesia, ASN provided its support in the examination of the license application files for nuclear activities submitted by French Polynesia in 2017. ASN also assisted in the handling of a significant radiation protection event that occurred in the nuclear medicine department concerning the overflow of a tank of contaminated effluents in the radioactive iodine therapy department.

In 2017, ASN carried out another mission in New Caledonia. Five inspections were carried out with the local authorities in the medical and industrial sectors on the basis of the regulatory baseline requirements applicable in metropolitan France. The training actions for the local authorities were continued. The problem of emergency situation management and the medical projects envisaged in the Caledonian territory, including a project for a nuclear medicine centre, were addressed more specifically in 2017. ASN also contributed its expertise in the ongoing reflection in New Caledonia concerning the creation of a unit dedicated to radiation protection and ultimately tasked, among other things, with examining license applications, oversight of inspections and management of emergency situations.

Grand Est

The Châlons-en-Champagne and Strasbourg divisions are jointly responsible for regulating nuclear safety, radiation protection and the transport of radioactive substances in the 10 *départements* of the Grand Est region.

The installations and activities to regulate comprise:

- BNIs:
  - the Cattenom NPP (4 reactors of 1,300 MWe);
  - the Chooz A NPP (currently being decommissioned);
  - the Chooz B NPP (2 reactors of 1,450 MWe);
  - the Fessenheim NPP (2 reactors of 900 MWe);
  - the Nogent-sur-Seine NPP (2 reactors of 1,300 MWe);
  - 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 intermediate-level long-lived radioactive waste (*Cigéo* project);
- small-scale nuclear activities in the medical sector:
  - 14 external-beam radiotherapy departments;
  - 5 brachytherapy departments;
  - 19 nuclear medicine departments;
  - 93 computed tomography scanners;
  - about 76 centres carrying out fluoroscopy-guided interventional procedures;
  - some 2,100 medical and dental radiology devices;
- small-scale nuclear activities in the industrial and research sectors:
  - about 85 veterinary clinics;
  - about 500 licensed industrial activities, with more than half of the licenses being for possession of devices to detect lead in paint;
  - about 50 research laboratories situated primarily in the universities of the region;
- 5 head offices of organisations approved in radiation protection.

In 2017, ASN carried out 161 inspections, of which 76 were in Nuclear Power Plants (NPPs), 4 in radioactive waste disposal facilities, 74 in small-scale nuclear activities and 7 in the transport of radioactive substances.

ASN also carried out 17 days of labour inspections in the NPPs.

During 2017, seventeen significant events rated level 1 on the INES scale were notified by nuclear installation licensees. Two generic events were rated level 2 on the INES scale, one related to the earthquake resistance of the anchoring of the auxiliary systems of the emergency diesel generator sets on the Cattenom, Nogent-sur-Seine and Fessenheim sites, the other related to a risk of loss of the heat sink for the reactors of the Cattenom and Nogent-sur-Seine NPPs in the event of an earthquake. In small-scale nuclear activities, 6 significant events were rated level 1 on the ASN/SFRO scale.

1. Assessment by domain

1.1 The nuclear installations

Cattenom nuclear power plant

ASN considers that the nuclear safety, radiation protection and environmental protection performance of the Cattenom NPP is in line with ASN's general assessment of EDF's performance.

With regard to the operation of the reactors, ASN considers that the site's performance is slightly down. For example, the need for greater vigilance on the part of the licensee, which became apparent at the end of 2016, was confirmed in 2017: although significant events appear to be managed efficiently on the whole, given the way they are handled and the associated analyses, the increase in their number due to errors resulting from carelessness reveals an unfavourable trend which must be remedied. The licensee is implementing an action plan in this respect.

This trend is found in the routine maintenance operations, where the licensee's rigour in their preparation or performance has been found deficient on several occasions. Operations of significant scale, however, such as the replacement of a monophase unit of the reactor 1 main transformer and the temporary replacement of the combustion turbine, were carried out competently.

In the area of environmental protection, ASN considers that the efforts made in the preceding years are showing satisfactory results, particularly with regard to the management of waste and compliance with the limit values for aqueous discharges, in a sometimes complex context of managing compatibility between the chemical treatments of the cooling tower water and the prevention of the legionella risk. In this respect, the licensee's environmental monitoring and transparency are to be underlined.

With regard to occupational radiation protection, ASN sees a positive dynamic in the management of radiation protection which has resulted in encouraging signs in day-to-day behaviour in the field.

Chooz nuclear power plant

ASN considers that the radiation protection and environmental protection performance of the Chooz NPP is on the whole in line with the general assessment of EDF plant performance, but that its nuclear safety performance is below the average.

In the area of nuclear safety, 2017 was marked by numerous unforeseen incidents during the reactor outages resulting in a large number of significant events related to noncompliance with the general operating rules. These events once again reflect a lack of rigour in behavioural attitudes and in the documenting of practices, as well as the vulnerability of the resources available for the management of the installations.

With regard to maintenance, the unexpected incidents during the reactor outages revealed the site's difficulties in restoring correct operation of the equipment concerned, in particular its difficulty in mobilising sufficient human skills and resources, including among service providers.

In the area of radiation protection, shortcomings were observed in the optimisation of occupational radiological exposure; several internal contaminations of workers occurred due to the non-integration in the prevention plan of safety recommendations resulting from the activity preparation phase. Several events moreover reflect a lack of radiation protection culture when entering worksites. The site must also remain vigilant with the process for analysing radiation protection deviations.

Lastly, ASN considers that the site's organisation for environmental protection is satisfactory. A number of events have nevertheless revealed shortcomings in the embracing of the regulatory requirements that govern some installations on the site.

Fessenheim nuclear power plant

ASN considers that the nuclear safety and environmental protection performance of the Fessenheim plant is stable and above the average of the plants operated by EDF and that the radiation protection performance is in line with the general assessment for EDF.

2017, like 2016, was marked by shortened reactor operation because reactor 2 was kept shut down pending a decision on the fitness for service of the steam generator with an anomaly in one of its parts manufactured by the Creusot Forge plant. The operating and maintenance operations went smoothly on the whole, given this particular context.

The site's organisation of environmental protection and the corresponding level of performance remain satisfactory. The obligations resulting from the new resolutions concerning water intakes and discharges are properly integrated and applied.

Occupational radiation protection, which showed occasional weaknesses in 2016, has reached a satisfactory level again.

EDF's confirmation in late 2017 of its intention to proceed with final shutdown of the Fessenheim NPP when the Flamanville EPR is commissioned marks the beginning of a singular period. Although ASN observed no demotivation of the personnel or shift in the site's maintenance strategy in 2017, the consideration of organisational and human factors and the defining of an industrial roadmap corresponding to the phases of end of operation, of site shutdown and of scheduling the decommissioning operations now represent pivotal points for the management of the site's safety challenges.

Nogent-sur-Seine nuclear power plant

ASN considers that the nuclear safety performance of the Nogent-sur-Seine site is on the whole in line with the general assessment of EDF, while its performance in radiation protection and environmental protection is below average.

With regard to nuclear safety and maintenance, ASN considers that the scheduled outages of the two reactors were properly managed. ASN does nevertheless note a lack of oversight of outside contractors' activities and that deficiencies in communication between the actors involved in the management of equipment modifications caused several events.

With regard to radiation protection, ASN considers that the site has not corrected the shortcomings in radiation protection culture already seen in 2015 and 2016 during the scheduled maintenance work on the reactors. The deficiencies in the optimisation of radiological exposure of workers and compliance with radiological zoning must produce a firm response from the licensee in reinforcing the radiation protection culture of all the personnel, including outside contractors' personnel.

With regard to environmental protection, ASN considers that the site must improve its performance by increasing its skills and resources in this area in order to be capable of implementing adequate decisions. ASN considers in particular that the management of both nuclear and conventional waste must be significantly improved to comply with the rules in effect.

Labour inspection in the nuclear power plants

ASN performed 21 inspections and took part in 11 meetings or surveys on the sites and continued its oversight actions in the area of occupational safety, particularly during reactor outages.

The measures taken by the licensee in terms of occupational safety remain satisfactory on the whole. ASN does nevertheless observe, as in the preceding years, shortcomings in application of prevention measures, and that the approach of the licensee and its service providers to the risk analyses is too theoretical, leading to work conditions that do not always take the identified risks into account. On the subject more specifically of the electrical risk, ASN has also observed shortcomings in the regulatory obligations in the context of specific inspections and severe accident inquiries.

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 2017, Andra, the French National Radioactive Waste Management Agency, continued deployment of the package inspection facility designed to provide the CSA site with more powerful means of checking the quality of the packages it receives. The commissioning authorisation application for this facility, planned for 2018, is currently being reviewed by examined ASN.

In 2017, ASN continued the examination of the CSA periodic safety review file which is intended, among other things, to assess the safety of the facility with regard to the planned development of its activities over the next ten years. It will also detail the strategy for decommissioning, closing and monitoring the facility once it has stopped receiving waste.

ASN considers that experiments and scientific work conducted by Andra in the underground laboratory at Bure continued in 2017 with a good standard of quality, comparable with that of the preceding years. After examining the safety options file for the *Cigéo* deep geological waste repository (see chapter 16 of this report), ASN issued its opinion on 11th January 2018. ASN considers that this file is documented and supported and represents significant progress with respect to the preceding files on which it gave an opinion; at this stage it expresses reservations concerning the disposal of the bituminous waste.

Chooz A reactor undergoing decommissioning

The work to decommission the Chooz A reactor under water has begun.

With regard to the environment and nuclear safety, ASN considers that the decommissioning operations have been carried out satisfactorily.

In the area of radiation protection, ASN observes the reappearance of deficiencies in the consideration of internal contamination risks, which have been the cause of 2 significant events. The licensee will have to increase its vigilance in 2018 with the continuation of the decommissioning worksites on which this risk is present.

Lastly, ASN has started examining the reactor periodic safety review report which it received in September 2017.

1.2 Radiation protection in the medical field

External radiotherapy and brachytherapy

ASN inspected eight radiotherapy centres in 2017, two of which were commissioning a new accelerator. The inspections therefore focused more on risk management and analysis.

These inspections targeted the functioning of certain centres, and in particular their computerised patient care management systems, which are sometimes pooled if the centres are structured as a national network.

Despite the fact that the centres now have treatment quality and safety management systems, these inspections still revealed the need to continue improving management of the risks to which patients are exposed and the integration of experience feedback. The management system upgrades must also take better account of the development of new techniques and the replacement of equipment by putting in place an appropriate organisation, including prior to the planned changes. These changes have a significant impact on the needs for medical physics resources, which are highly mobilised in these new projects.

Fluoroscopy-guided interventional practices

ASN carried out 15 inspections in operating theatres and dedicated interventional radiology rooms (neurology, cardiology) in the region in 2017. Interventional techniques are growing fast, with significant implications for radiation protection, but the resources of the radiation protection services and the means available to the medical physics teams are generally insufficient to guarantee compliance with all the radiation protection requirements, except in the centres practising the most complex procedures, which involve the highest risks.

Consequently, the observations expressed over the past years concerning the training of personnel in patient and worker radiation protection and the technical controls of the devices are often still pertinent.

Furthermore, the embracing of risk management by the intervening teams must be further improved, particularly in the protection of practitioners: while the risk assessments are satisfactory, the job and work environment analyses do not give sufficient consideration to exposure of the extremities or the lens of the eye.

Lastly, improvements are still required in the monitoring and analysis of doses delivered to patients.

Nuclear medicine

ASN inspected ten nuclear medicine departments in 2017. These inspections have shown that, save exceptions, the overall extent to which the centres take radiation protection requirements into account is good for patients and personnel alike. More specifically, the analyses of jobs and work environments taking into consideration all modes of exposure and the training of medical personnel in patient radiation protection are found to be satisfactory. The situation regarding the performance of technical controls and the implementation of prevention plans with the outside contractors or private practitioners nevertheless remains varied. Improvements have been observed in setting up and applying procedures for managing significant events. This has moreover revealed a substantial rise in significant events associated with patient injection errors. Lastly, the regular updating of the licenses issued by ASN should be better anticipated by the centres.

Computed tomography and dental radiology

ASN conducted 6 inspections of CT scanners in 2017, keeping its attention focused on reviewing the patient radiation protection measures taken by the centres in a context where occupational radiation protection is improving. This situation nevertheless fits in with the continuous development, over the long term, of this type of examination which represents a significant cause of exposure of the French population to ionising radiation.

ASN has observed that more arguments are given to justify procedures and that effective optimisation of procedures and the defining of examination protocols have become widespread practices. The regulatory controls (quality controls, technical controls) are in place, but the possible nonconformities merit being taken into consideration more rapidly. The fact remains that contrasted situations exist, particularly with regard to organisation on the scale of a given centre or economic interest groupings combining teams from the public and private sectors.

A remote inspection campaign focusing on dental radiology confirmed the conformity of certain facilities and identified the additional inspections required in others.

1.3 Radiation protection in the industrial, research and veterinary sectors

Industrial radiography

ASN carried out 20 inspections in industrial radiography and gamma radiography activities in 2017 and found extremely varied situations. Some companies rigorously apply the radiation protection rules, while for others ASN has been obliged to put in place tightened monitoring. As in 2016, the main deviations observed concerned the signalling and cordoning off of work zones with, in addition, a poor predicted dose estimate. It also emerges that worksite preparation is insufficient.

ASN drew up and transmitted to the Public Prosecutor a violation report following the observation of an unacceptable lack of rigour in the preparation of a job and the application of the radiation protection rules by the operators responsible for handling the radiography device.

Universities and laboratories or research centres

The 3 inspections ASN carried out in the research centres of the region show that these centres usually have very high level skills and are fully conversant with the radiation protection issues from the operational viewpoint, with a good degree of involvement of the Radiation Protection Expert-Officers (RPE-O). Shortcomings are however regularly observed in the rigour with which the regulations are applied, and some nonconformities are recurrently observed: technical controls lacking or incomplete, inadequate management of sources surplus to requirements and of legacy waste, weaknesses in the radiation protection training of personnel and shortcomings in job and work environment studies, administrative deviations with respect to the authorised scope of activity.

The substantial work initiated by the research clusters of the region to bring the administrative situation of all their entities into compliance must be continued, particularly when licensed nuclear activities are transferred or stopped. The strong involvement of the RPE-O is to be underlined, despite their often undervalued positioning in the organisation of the licensees' departments.

1.4 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 dealing with the legacy radioactive contamination resulting from operation of the former Orflam-Plast plant in Pargny-sur-Saulx (Marne *département*). After the work to render safe the main areas impacted, the management of the last plots accommodating dwellings continued in 2017.

A one-off case mobilised ASN and the Dreal inspectors for ICPEs (Installations Classified for Protection of the Environment) following the discovery of low-level radioactive waste stored without precautionary measures in the vicinity of a scrap metal collection site at the port of Strasbourg, causing local contamination of the soils. The licensee placed the waste in safe-keeping and decontaminated the land without delay; the inspectors informed the Public Prosecutor, and conducted a further inspection to verify that things were back to normal.

1.5 Nuclear safety and radiation protection in the transport of radioactive substances

In the area of small-scale nuclear activities, ASN carried out 7 inspections focusing on radioactive substance transport operations. They reveal varying situations in the implementation of the European regulatory provisions (ADR regulations) by the carriers. The requirements coming under the responsibility of the supplier or user enterprises appear to be poorly known.

2. Additional information

2.1 Informing the public

Press conferences

ASN held press conferences on the status of nuclear safety and radiation protection in the Grand Est region in Châlons-en-Champagne, Metz and Strasbourg on 3rd, 4th and 5th October 2015 respectively.

Work with the Local Information Committees (CLIs)

ASN took part in meetings of the Cattenom, Chooz, Fessenheim, Nogent-sur-Seine and Soulaines CLIs. During these meetings, ASN presented its assessment of the safety of these nuclear installations and its work on these sites and on the publication of the French National Radioactive Material and Waste Management Plan (PNGMDR) 2016-2018.

Each of these CLIs organised a meeting open to the public, and those situated near borders received representatives from Belgium, Luxembourg and Germany, in accordance with the provisions of Act 2015-992 of 17th August 2015 relative to the Energy Transition for Green Growth.

The agenda of the Cattenom CLI included in particular the new resolution relative to the prevention of the "legionella" risk and the presentation of the Anccli white paper "Emergency situation and post-accident management".

The Chooz CLI examined the organisation adopted for the extension of the radius of the public authority's Off-site Emergency Plan (PPI) in an emergency situation and the change in the population protection measures.

The Local Information and Monitoring Committee of Fessenheim examined in greater depth the subjects relating to the manufacturing and quality assurance anomalies at the Le Creusot forge and the problem of carbon segregations in forged parts. The implications of the announced shutdown of the NPP were also discussed.

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 inspections and started looking into the monitoring of the next 10-yearly outage of reactor 1, scheduled for early 2019.

ASN also took part in the general assemblies and meetings of the Bure Local Information and Follow-up Committee (CLIS) where it contributed to informing the local populations and to the initiative of discussions with civil society led by IRSN on the safety options file submitted by Andra.

Lastly, ASN participated in the meeting of the regional network of PCRs of the Grand Est region.

2.2 International action

The Châlons-en-Champagne division continued to maintain regular relations with the Belgian nuclear regulator, the AFCN. The cross-inspections continued in the areas of small-scale nuclear activities and nuclear industry facilities on the sites of Chooz and Tihange (Belgium). The division took part in the management committee meetings and the Franco-Belgian working group on nuclear safety.

The Strasbourg division is actively involved in the bilateral relations with its German counterparts through the work of the Franco-German Commission (DFK) on the subjects of reactor safety and emergency situation preparedness; the subjects of joint interest relating to decommissioning and waste management have been introduced into the scope of the bilateral work. The Strasbourg division also participated actively in the work of the Franco-Swiss Commission and the Franco-Luxembourg Commission.

2.3 The other notable events

A national emergency exercise was organised around the Cattenom NPP on 17th and 18th October 2017, mobilising the local, national and cross-border emergency management organisations. This exercise provided the opportunity to test the deployment and functioning of the emergency management systems and to study the operational procedures for the new 5-km evacuation radius, which will shortly be integrated in the off-site emergency plans.

Hauts-de-France

The Châlons-en-Champagne and Lille divisions jointly regulate nuclear safety, radiation protection and the transport of radioactive substances in the 5 *départements* of the Hauts-de-France region.

The installations and activities to regulate comprise:

- BNIs:
  - the Gravelines NPP (6 reactors of 900 MWe) operated by EDF;
  - the Somanu *(Société de maintenance nucléaire)* site operated by Areva in Maubeuge (Nord *département*);
- small-scale nuclear activities in the medical sector:
  - 19 external-beam radiotherapy departments;
  - 3 brachytherapy departments;
  - 27 nuclear medicine departments;
  - 92 centres performing fluoroscopy-guided interventional procedures;
  - 126 computed tomography scanners;
  - some 4,600 medical and dental radiology devices;
- small-scale nuclear activities in the veterinary, industrial and research sectors:
  - 600 industrial and research establishments, including 31 companies exercising an industrial radiography activity, 3 particle accelerators of which 2 are cyclotrons, 38 laboratories situated mainly in the universities of the region, 19 companies using gamma ray densitometers and 280 users of devices for detecting lead in paint;
  - 340 veterinary surgeries or clinics practising diagnostic radiology;
- organisations approved by ASN:
  - 4 agencies of approved organisations in the area of small-scale nuclear activities.

In 2017, ASN carried out 101 inspections in the Hauts-de-France region, comprising 27 inspections in the Gravelines Nuclear Power Plant (NPP), one at Somanu in Maubeuge, 67 in small-scale nuclear activities and 6 in the transport of radioactive substances.

ASN also carried out 14 days of labour inspection in the Gravelines NPP.

During 2017, 11 significant events rated level 1 on the INES scale were notified by the Gravelines NPP. In small-scale nuclear activities 5 events were rated level 1 on the INES scale (in particular loss or theft of devices for detecting lead in paint and irradiation by customs authority scanners), plus 10 events involving radiotherapy treatments rated level 1 on the ASN-SFRO scale.

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 the general assessment of EDF plant performance, but its nuclear safety results are below the general average.

The improvement in nuclear safety performance seen in 2016 did not continue in 2017, on the contrary, results got worse, including in areas in which the NPP had shown no weaknesses until now. The site must in particular pursue its continuous improvement measures in the detection and correction of deviations and adherence to operating instructions.

With regard to maintenance, ASN observes that the downturn in results is partly due to the cascading of several maintenance outages during the summer, on one pair of reactors in particular. ASN was obliged to intervene to speed up the diagnosis and repair of pipes with increased corrosion susceptibility due to their seaside location, and of supporting structures whose earthquake resistance could not guarantee availability of the heat sink under all circumstances.

With regard to environmental protection, the compliance work on the tanks for storing effluents from the reactor primary and secondary cooling systems was completed at the end of 2017. The site must continue to improve the environmental conformity of its facilities with the licenses delivered by ASN. On 19th October 2017 ASN issued a resolution governing the use of certain devices for discharging liquid effluents into the environment, for which the site had been found noncompliant during an inspection.

Concerning management of the fire risk, ASN considers that the site must improve the quality of storage areas and fire sectorisation, particularly during reactor maintenance operations, even though there were no significant fire outbreaks in 2017.

With regard to radiation protection, ASN continues to note shortcomings in the access control of some areas presenting risks of radiological exposure. Progress is required in particular in the training of security agents in the interpretation of radiation portal monitor activation parameters at the exit from controlled zones, and in improving the process for dealing with any potentially contaminated worker.

On 19th October 2017, ASN issued a resolution imposing requirements relative to the continued operation of reactor 3.

Labour inspection in the Gravelines nuclear power plant

ASN carried out 14 days of labour inspection duties at the NPP.

ASN remains attentive to worker compliance with the safety rules. The labour inspectors investigated two severe accidents which occurred at the year end and three near-accidents on the worksite of the ultimate backup diesel generator sets.

Société de Maintenance Nucléaire (*Somanu*) *in Maubeuge*

ASN considers that operation of Somanu's facilities is satisfactory on the whole. Somanu maintained a good standard of operating performance in 2017. However, given the many technical, regulatory and organisational challenges facing Somanu, the ongoing efforts will have to be maintained over the long term.

The performance in radiation protection was maintained at the level of the previous year. ASN asks that the efforts be maintained, particularly in the management of radioactive waste, in order to optimise the doses received by the operators responsible for sorting the waste and putting it into drums.

With regard to the environment, the licensee places great importance on controlling the environmental impact of its facilities. It has produced instructions to follow in the event of pollution; the operators however are not always familiar with the instructions and the required resources are not always available near the potentially impacted areas.

The actions relating to the periodic safety review are continuing and will require Somanu to maintain its efforts in this respect in the coming years. Examination of the creation authorisation decree modification file and of the modification request concerning the associated discharge resolutions has, since 2016, given rise to several technical discussions between the licensee, ASN and its technical support agency IRSN. Complementary studies should allow the files to be updated so that ASN can set requirements that are appropriate for the facilities' risk issues.

1.2 Radiation protection in the medical field

Radiotherapy

The Hauts-de-France region counts 19 external-beam radiotherapy departments and 3 brachytherapy departments under ASN oversight. These departments use 46 linear accelerators (including 2 contact radiotherapy machines), most of which are recent. Some of these centres use innovative techniques, more specifically with three CyberKnife® robotic radiosurgery machines (a fourth machine will enter service in early 2018 and a project for a fifth machine is envisaged for the end of the year). In addition, the GammaKnife® system (multiple-source machine) in service at the Lille CHRU (Regional University Hospital) since 2001 is currently being replaced.

ASN carried out fifteen inspections in the radiotherapy centres in 2017 to check the radiation protection of patients and workers. The inspections focused on examining the quality policy and management, through processes such as prospective risk management, management of the analysis of adverse events or the implementation of new techniques and change management. With regard to brachytherapy (on inspection in 2017), the additional subjects of source management and emergency situation management were addressed. These inspections also provided a better understanding of the functioning of certain centres with a group structure which have pooled their resources; this situation made it easier to help teams embrace new techniques. Five inspections were conducted to verify the presence of the required minimum contingent of personnel during radiotherapy treatments at particular times of the day (early morning, mid-day break and late afternoon) and the measures taken for the forecast vacation periods. None of the inspections revealed any deviations.

In 2017, as in 2016, ASN's findings were mixed regarding the development of the process of continuous improvement in practices in which the centres have been engaged for the last few years. Further to human or organisational changes, several centres have to upgrade their quality management system and the associated coordination tools. ASN still notes disparities between the centres in the region and a lack of consistency over time. This situation moreover resulted in tightened monitoring (inspection frequency higher than the national average between 2016 and 2018) of 10 centres in the region.

The procedure for collecting and analysing adverse events is generally in place. ASN nevertheless observes, as in the preceding two years, a loss of momentum in the recording and analysis of adverse and precursory events. At the same time, the number of significant radiation protection event notifications remains relatively low and involves the personnel to different extents. Furthermore, monitoring of the action plans resulting from these analyses can generally be improved. These analyses are effectively often limited to the human causes without working back to the organisational causes.

The initiative of placing the patient treatment process under strict quality assurance procedures, after having progressed strongly in the past years, must now be maintained over time through lasting and resilient systems which can withstand changes of environment and organisation in a context of rapidly evolving techniques. Radiotherapy is effectively a field that increasingly calls upon innovative technologies which bring, among other things, greater precision in treatments (stereotactic treatments, for example). ASN asks that in-depth reflection be carried out on the appropriation of these technologies by the teams of the departments on a project management basis and with the support of adequate human and technical resources. ASN will continue to give priority to good integration of these prerequisites in 2018.

Fluoroscopy-guided interventional practices

ASN observes an ever-increasing use of fluoroscopy-guided interventional practises and that they have evolved considerably in the last few years, bringing significant radiation exposure risks for medical teams and patients alike, particularly during long or repeated procedures. ASN carried out 8 inspections in the Hauts-de-France region in 2017 in fluoroscopy-guided interventional practices in the operating theatre, particularly for cardiac surgery procedures.

ASN sees progress, particularly in the increased provision of human and material resources, such as the time allocated to the Radiation Protection Expert-Officer, the use of physicists or the purchase of personal protective equipment, thanks to heightened awareness of the radiological risks. Further efforts must nevertheless be made to effectively meet the commitments made to ASN further to preceding inspections. Improvements are required in particular in 1) the effective wearing of dosimeters, more specifically by the practitioners who often minimise the exposure risk, particularly for the extremities and the lens of the eye, 2) training in occupational and patient radiation protection, 3) the optimisation of doses delivered to patients by putting in place appropriate and updated protocols, and 4) the coordination of prevention measures.

Nuclear medicine

ASN conducted 5 inspections in nuclear medicine in 2017, including one commissioning inspection of a new technical platform and one unannounced inspection.

These inspections reveal greater integration of occupational and patient radiation protection in the practices of the departments, correlated in particular with the involvement of the Radiation Protection Expert-Officers. They moreover confirm an improvement, albeit slower than ASN expected, in the integration of certain regulatory provisions. Progress is expected in the internal technical radiation protection controls, in the coordination of prevention measures with practitioners and outside contractors, and in the compliance with the requirements of ASN resolution relative to the design of the premises.

Among the reported events, 4 concern a problem associated with the preparation and administration of radiopharmaceuticals.

Lastly, several department redevelopment projects to be implemented in 2018 were presented to ASN.

Computed Tomography

ASN's inspections in computed tomography facilities in 2017 concerned four centres in the Hauts-de-France region. The relatively satisfactory situation in this area remains fairly stable. In the course of its oversight actions ASN has found that although the rules concerning the radiation protection of workers and patients are now applied in general, improvements must still be made, particularly with regard to exposure of the extremities in interventional practices, and to equipment quality control and the optimisation of protocols for certain categories of patients. Greater traceability of application of the principle of procedure justification is also required.

Lastly, ASN notes that managing facilities through Economic Interest Groupings (EIG) combining teams from the public and private sectors can bring beneficial synergies.

1.3 Radiation protection in the industrial, research and veterinary sectors

Industrial radiography

In 2017, 10 inspections were carried out in industrial radiography, including 4 inspections of agencies and 2 of own-account users.

ASN observes continued improvement in the organisation of radiation protection and the monitoring of workers within companies, even if particular vigilance is still required in conducting worksites, especially in the management of work areas.

With regard to the agency inspections, ASN focused in particular on the radiography bunkers. Measures are required to ensure compliance with the standards in effect and should enable worksite inspections to be focused solely on parts that cannot be readily transported.

Since 2009, ASN, in partnership with DIRECCTE (Regional Directorate for Enterprises, Competition, Consumption, Work and Employment) and CARSAT (Retirement and Occupational Health Insurance Fund), has instituted a charter of good practices in industrial radiography for the Hauts-de-France region. The aim of this charter is to optimise the use of ionising radiation in this area of activity; at present it has been signed by 19 companies (ordering customers and service providers) who have undertaken to limit the committed doses further than the levels required by the regulations.

Universities and laboratories or research centres

The research units in the Hauts-de-France region use a wide variety of ionising radiation sources (sealed and unsealed sources, electric generators); nevertheless, the radiation risks in these units remain low. ASN's oversight duties led to the performance of two inspections in 2017 on the subjects of occupational radiation protection and the management of radioactive sources and waste. ASN considers that in the majority of research units, radiation protection has on the whole been improving for several years. The management and the procedures for removing the sources and stored radioactive waste found in certain universities are still major issues, as they were in 2016.

Veterinary

ASN carried out 3 inspections in the veterinary sector in 2017, 2 concerning more specifically the use of an X-ray generator in an equine field diagnostic situation and the third in a veterinary clinic practising nuclear medicine, radiotherapy and brachytherapy.

These inspections revealed relatively good integration of occupational radiation protection in the work practises, including in field situations. ASN highlighted areas for improvement in terms of job and work environment studies and zoning, in medical monitoring and training of exposed workers, and in the organisation for reporting adverse events to ASN.

Devices for detecting lead in paint

A campaign of 10 inspections in the Nord and Pas-de-Calais *départements* targeted holders of devices for detecting lead in paint who did not have license and who, in the majority of cases, had failed to return their radioactive sources. Further to this campaign, ASN drew up 6 violation reports for unlicensed holding of radioactive sources. This measure prompted the majority of the operators to put their administrative situation in order, either by submitting a license application file or by having the radioactive source supplier take back the sources.

In the other three *départements*, ASN renewed its remote oversight action in 2017 which concerned 33 holders of devices for detecting lead in paint and aimed to check the designation of a Radiation Protection Expert-Officer and performance of the radiation protection technical controls. In the majority of cases the device holders' situation was satisfactory.

1.4 Nuclear safety and radiation protection in the transport of radioactive substances

ASN conducted 6 inspections concerning the transport of radioactive substances in 2017, in small-scale nuclear activities and in the Gravelines NPP. These inspections revealed no major deviations from the regulations.

In the small-scale nuclear activities sector, the inspections focused in particular on the dispatching of a cyclotron to check compliance with the main provisions applicable to the carriers.

As part of the international exchanges with the Belgian Federal Agency for Nuclear Regulation (AFCN) and its technical support agency (BEL V), an inspector from BEL V accompanied ASN during an inspection at the Gravelines NPP on the theme of compliance with the regulations applicable to the transport of radioactive substances.

2. Additional information

2.1 Informing the public

Press conference

ASN's annual press conference on the situation of nuclear safety and radiation protection in the Hauts-de-France region was held on 13th September 2017 in Lille.

Work with the Local Information Committees (CLIs)

ASN regularly presented files in progress concerning the Somanu facility in Maubeuge and the Gravelines NPP to their CLIs. Public meetings were held on 14th December 2017, organised by the Somanu CLI, on the theme "Nuclear issues: how should our environment be monitored and what is the impact on our health", and on 15th December, organised by the Gravelines CLI, on the ageing of nuclear installations.

Professional gathering

ASN contributed to the "Radiation protection in the medical environment" gathering held on 14th November 2017 in Lille, and which was organised by the association Environment and Alternative Development in partnership with the Hauts-de-France Health Quality Network. This third edition, following those of 2013 and 2015, brought together 150 people including hospital personnel – many of them radiographers, veterinary surgeons and students. The talks and discussions addressed subjects such as the protection to be provided for personnel and patients throughout the care pathway in both the centres and the home, the importance of information in teamwork and of having constant communication between practitioners and patients, and lastly on research into the radiosensitivity of irradiated tissues with the aim of predicting any long-term effects of the ionising radiation on healthy tissues.

2.2 International action

Within the framework of international exchanges, 6 joint inspections were carried out with the AFCN and the BEL V, and one with the ANVS (*Autoriteit Nucleaire Veiligheid en Stralingsbescherming*), the Dutch nuclear safety authority. Six inspections were carried out in the Gravelines NPP on the themes of the environment, radiation protection, management of installations (including the start of an unannounced inspection outside opening hours), containment, maintenance and transport. Two ASN inspectors travelled to Borselle in the Netherlands for a cross-inspection on theme of refuelling and maintenance outages.

2.3 The other notable events

The Lille division took part in the national emergency exercise of May 23rd 2017 simulating a radioactive substance transport accident on a railway line near the A1 motorway in the Pas-de-Calais *département*. 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 radiological emergency situation management.

Ile-de-France

The Orléans and Paris divisions jointly regulate nuclear safety, radiation protection and the transport of radioactive substances in the 8 *départements* of the Ile-de-France region.

The installations and activities to regulate comprise:

- BNIs regulated by the Orléans division
  - the 8 BNIs in the CEA Saclay centre, including the Osiris and Orphée 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.
- small-scale nuclear activities in the medical sector regulated by the Paris division:
  - 26 external-beam radiotherapy departments;
  - 13 brachytherapy departments;
  - 59 nuclear medicine departments;
  - about 170 centres performing fluoroscopy-guided interventional procedures;
  - more than 200 centres in possession of at least one Computed Tomography (CT) scanner;
  - about 850 medical radiology centres;
  - about 8,000 dental radiology devices;
- small-scale nuclear activities in the industrial and research sectors under the oversight of the Paris division:
  - about 650 users of veterinary radiology devices;
  - 9 industrial radiography companies using gamma radiography devices;
  - more than 200 licenses concerning research activities involving unsealed radioactive sources;
- organisations approved by ASN:
  - 11 organisations approved for radiation protection controls.

ASN carried out 205 inspections in the Ile-de-France region in 2017, of which 39 were in the field of nuclear safety, 146 in small-scale nuclear activities and 20 in the transport of radioactive substances.

Five Safety-related Significant Events (ESS) in BNIs in Ile-de-France were rated level 1 on the INES scale. In small-scale nuclear activities, 10 Significant Radiation Protection Events (ESR) were rated level 1 and 3 events were rated level 2 on the INES scale.

In addition to these, 14 events involving radiotherapy patients were rated level 1 and one event rated level 2 on the ASN-SFRO scale.

1. Assessment by domain

1.1 The nuclear installations

CEA's Saclay Centre

ASN considers that the safety of operation of the CEA Saclay Centre BNIs is satisfactory.

In 2017, the Saclay and Fontenay-aux-Roses centres were brought together within a single centre (CEA Paris-Saclay). ASN points out that particular attention must be paid to the control of safety and radiation protection in the Saclay BNIs during the consolidation of this new organisation.

As no decommissioning authorisation application file had been submitted for the Osiris reactor, ASN issued resolution 2017-DC-0599 of 1st August 2017 requiring submission of this file before 29th June 2018. Pending its decommissioning authorisation, operations to remove radioactive and hazardous substances and to prepare for decommissioning are in progress with an organisation adapted to the new status of the reactor. The schedule for these operations was detailed at the end of 2016 and is giving rise to technical examinations by ASN.

The CEA moreover stated on 7th October 2017 that it wished to push back the shutdown of BNI 72, in which the solid waste from the Saclay centre facilities is treated, from 31st December 2017 to 31st December 2022 in order to continue its activities during the transition phase between the initially planned shutdown date and the date the decommissioning decree takes effect. When it examines the periodic safety review and the decommissioning file, ASN will decide whether BNI 72 can continue to operate in complete safety. ASN will also check that the decommissioning preparation operations, particularly those relative to the removal of radioactive and hazardous substances, are carried out under optimum conditions of safety and radiation protection and with adequate means.

ASN is moreover extremely attentive to the change in the management of the liquid effluents from the BNIs in the current context of local padlocking of the BNI 35 front-end tank room and the continued removal of the effluents to Marcoule under satisfactory conditions.

More generally, the CEA must maintain the presence of its personnel in the field for the monitoring of outside contractors.

ASN notes compliance with the deadlines of ASN resolution 2015-DC-0508 of 21st April 2015 for transmission of the update to the Saclay site "waste" study and the chapters of the general operating rules specific to the waste from the BNIs as a whole. ASN nevertheless observes disparities between the BNIs in the application of the waste regulations. ASN will ensure that the good practices are disseminated to all the installations.

The review of the stress tests performed by the CEA led ASN to require the implementation of an emergency management hardened safety core in 2016. CEA complied with the initial deadlines of this resolution and forwarded additional studies and justifications concerning its ability to activate its emergency organisation in extreme situations. ASN is currently examining these elements and will remain attentive to the availability, maintenance and upgrading of the specific means of communication and alert of the Saclay site and its facilities.

The periodic safety review files for BNIs 18, 35, 49 and 72 were submitted to ASN at the end of 2017 as expected and are currently being examined.

CEA's Fontenay-aux-Roses Centre

In the light of its inspections and the incidents reported in 2017, ASN considers that the standard of safety of the Fontenay-aux-Roses BNIs is improving.

The in-depth diagnosis of the Social, Organisational and Human Factors (SOHF) carried out in 2016 is beginning to produce results. Waste management has improved and performance of the operational management operations is satisfactory. ASN notes the satisfactory monitoring of deviations and the involvement of the personnel.

ASN takes positive note of the removal of the high-level effluents by the CEA in 2017.

The organisation and implementation of emergency situation management can nevertheless be improved. ASN will closely monitor the CEA's commitments in terms of manpower and training in this respect.

ASN also regrets that revising of the On-site Emergency Plan (PUI) has still not been completed and that the files currently being examined (decommissioning, clean-out, etc.) are falling successively behind schedule. Given the ongoing reorganisation of the centre and staff vacancies, ASN observes that it has not been possible to catch up the delays.

Control of the fire risk remains a major issue. The CEA has carried out specific studies to assess the fire resistance of its facilities. These studies however, which are part of the substantiation documents to be provided to finalise the revision of the on-site emergency plan, were not conclusive and need to be supplemented.

The CEA submitted the periodic safety review files to ASN in early November, within the required times. Lastly, in 2018 ASN will analyse the new version of the application files to extend the decommissioning authorisation of the Fontenay-aux-Roses nuclear facilities.

The CIS bio international plant in Saclay

Broadly speaking, ASN considers that the safety of the facility operated by CIS bio needs to be significantly improved. To this end, ASN observes the efforts made by CIS bio international to render the safety management of the facility more efficient by reinforcing and modifying its organisation and its operating processes. However, despite some visible improvements, ASN considers that the results are still not good enough. The increase in significant events, the causes of which almost always include organisational and human failures, reflects an unsatisfactory situation of operating safety. The recurrence of certain events indicates shortcomings in taking operating experience feedback into account.

The deviations observed during inspections reveal persistent weaknesses in the monitoring of actions and commitments, in operating rigour and in the application of the baseline requirements. More specifically, waste management and the in-service monitoring of pressure equipment must be significantly improved.

With regard to the periodic safety review follow-ups which have fallen increasingly behind schedule in the last few years despite the efforts made since the end of 2016, CIS bio international is still having difficulty in managing and meeting within deadlines the 50 additional requirements set by an ASN resolution. The shortcomings concern equally well the time frames for performing the studies and actions as to their content. Consequently, ASN has asked the licensee to commit itself to deadlines for ensuring compliance and it will be able to apply enforcement measures.

The many projects, studies and work in progress – for several years in some cases – to improve the safety of the facility, have not been completed. Generally speaking, the large-scale actions initiated by CIS bio international are not completed within reasonable time frames. The implementation of new regulatory provisions is not adequately prepared for, resulting in lateness in their application.

Complementary studies concerning the consequences of accident situations are currently being appraised. The inconveniences the facility creates for the protected interests should be significantly reduced in the medium term. This significant change in activities, concerning the sealed sources and iodine inventory held in the facility, will be examined at the same time as the next periodic safety review which is to be submitted before 31st July 2018.

To conclude, ASN expects to a see lasting improvements at CIS bio international. The operating rigour, the safety culture, optimisation of the organisational structure and the staff, the monitoring of operations, the cross-functionality of the organisation, and compliance with the baseline requirements of the facility and of the resolutions and regulations must all be improved.

1.2 Radiation protection in the medical field

External radiotherapy and brachytherapy

ASN carried out 13 inspections in external-beam radiotherapy departments and 7 in brachytherapy departments in the Ile-de-France region in 2017. One inspection was carried out in 2017 further to an ESR (Significant Radiation Protection Event) in 2016 involving a laterality (wrong-side) error and rated level 2 on the ASN-SFRO scale. This inspection provided a better understanding of the succession of steps that led to the event, and allowed the quality of the analysis, the relevance of the corrective measures implemented and the methods of assessing these measures to be reviewed.

ASN considers that the departments have on the whole progressed. Most of them now have a complete documentary baseline and have deployed computerised tracking of the patient care pathway, thereby improving treatment safety. One department found to have organisational vulnerabilities in 2017 will be subject to tightened monitoring in 2018. The inspections in 2017 focused mainly on the practical implementation of these procedures and the involvement of all the players in the culture of risk management. Further progress is required in taking SOHFs into account, particularly through experience feedback from adverse events. Furthermore, the renewal of equipment and the implementation of new treatment techniques can create tensions in the organisational setups, which can foster the occurrence of errors.

The two brachytherapy departments displaying shortcomings in the application of the regulations have implemented the majority of the corrective actions needed to meet the demands formulated in 2016. In 2017, ASN inspected the brachytherapy departments in order to have a complete view of the way worker and patient radiation protection is applied and of the safety of transport operations.

Fluoroscopy-guided interventional practices

ASN performed 37 inspections in the area of fluoroscopy-guided interventional practices in Ile-de-France in 2017.

Three significant radiation protection events rated level 2 on the INES scale involving exceeding of the regulatory maximum dose at the extremities for workers performing fluoroscopy-guided interventional procedures were reported at the end of 2017. The centres concerned will undergo a specific inspection at the beginning of 2018, conducted by a radiologist expert designated by the French Professional College of Radiology (G4) for one and an IRSN expert for the other, in order to better understand the practices of the centres that reported the events. In view of the observed shortcomings in the wearing of extremity dosimeters by the workers in many centres, ASN wonders whether other similar cases might have gone undetected.

The inspections performed in 2017 confirmed the major radiation protection implications for patients and workers during interventions involving ionising radiation. ASN observed that radiation protection was 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 risks than in specialities in which the practitioners carry out interventional procedures in operating theatres. ASN observes a lack of involvement of the medical physicists in the operating theatre and insufficient presence in the field.

Five significant radiation protection events that occurred during interventional procedures were reported to the Paris division. Three concerned workers, one concerned a patient and one concerned the theft of a decommissioned mobile surgical C-arm unit.

Nuclear medicine

ASN carried out 12 inspections in nuclear medicine departments in Ile-de-France in 2017.

ASN found that the design or layout of the ventilation systems in several departments did not fully meet regulatory requirements.

Twenty significant radiation protection events were reported by nuclear medicine departments. Twelve events involved errors in the preparation or administration of radionuclides to patients, leading to either administration of the wrong radiopharmaceutical or an error in the administered activity. One event concerned the potential external exposure of patients and workers in a conventional room through which passed a pipe carrying contaminated liquid effluents from the nuclear medicine department.

1.3 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, performing 11 inspections in Ile-de-France in 2017. Six of these inspections were unannounced and carried out under worksite conditions.

One inspection was carried out as a follow-up to an ESR rated level 1 on the INES scale in which workers performing on-site gamma radiography work were exposed to a dose to the extremities exceeding one quarter of the regulatory annual limit. This inspection more specifically allowed an assessment of the extent to which social, organisation and human factors contributed to the incident.

Universities and laboratories or research centres

ASN carried out 14 inspections in research facilities in the Ile-de-France region in 2017. Particular attention was paid to the monitoring of removal of sources and checks of non-contamination of premises when the laboratories ceased their activity. ASN was also attentive to the design conformity of facilities that use particle accelerators.

Ten significant events were reported in this area in 2017, of which two concerning lost sources were rated level 1 on the INES scale.

1.4 Radiation protection of the public and the environment

Contaminated sites and soils

In 2017, as part of its remit to inform the public and assist the Prefects in radiation protection oversight for the management of polluted sites and soils, ASN continued its oversight of sites contaminated by radioactive substances. These are mainly orphan sites which in the past carried out research work on natural radioactivity. Other sites are associated with legacy activities of the CEA.

The former CEA site of Fort de Vaujours, on which experiments involving natural and depleted uranium were carried out, was purchased by the Placoplatre Company with the aim of operating an open pit gypsum quarry. Following on from its oversight actions carried out at the request of the Prefects of Seine-et-Marne and of Seine-Saint-Denis, ASN performed 2 on-site inspections, one further to the discovery of radioactive objects buried in an area considered to have been remediated according to the sampling verifications and the legacy information provided by the CEA. Further measurements were taken on site by the third-party expert designated by the Prefectural departments. Site radiation protection management was found to be satisfactory, although ASN remains vigilant given the extent of the worksite and the inherent difficulties in detecting manufactured uranium. All the actions taken were presented at meetings of the Site Monitoring Committee (CSS).

One inspection was carried out on the site of the former Curie laboratories in Arcueil to check the characterisation and packaging of legacy waste, operations which were resumed after setting up a mobile analysis laboratory.

Finally, the Radium Diagnosis operation which began on 21st September 2010 is continuing in Ile-de-France. This operation, which is placed under the responsibility of the Prefect of the Ile-de-France region and the Prefect of Paris, and is coordinated by ASN. Twenty-one diagnoses revealed traces of radium in premises that are undergoing rehabilitation. The rehabilitation work, which is financed by the State, has been completed on 15 sites, is in progress on 3 sites and under preparation on 3 others. The levels of activity measured before clean-out are low and the exposure does not present a health risk for the occupants.

1.5 Nuclear safety and radiation protection in the transport of radioactive substances

With regard to the transport of radioactive substances in Ile-de-France, 12 inspections concerned road transport carriers, 2 concerned air carriers; of 3 inspections focusing on the management of transport by the BNIs of Saclay and Fontenay-aux-Roses, 2 concerned nuclear licensees receiving or dispatching radioactive substances and one concerned a commission agent. ASN participated in 2 unannounced inspections on the public highway in collaboration with the law enforcement authorities. ASN also carried out 2 inspections on the transport of radioactive substances by air and their interim storage in the airport zone.

BNIs excepted, the inspections showed that the players must improve the way they take on board the regulations applicable to the transport of radioactive substances, particularly in the phases preceding carriage (preparation, pre-shipping checks, loading) and following carriage (unloading, acceptance inspections) of the substances. Worker training in transport operations should be improved, and the procedures relating to these operations should be better formalised. This is a general finding, but it is particularly the case with nuclear medicine and brachytherapy departments.

The inspections in BNIs focused primarily on the quality management systems, the operational measures applied, compliance with package approvals and the radiological verifications. Transport operations within BNI sites were also inspected. These inspections showed that the regulations applicable to road transport are correctly applied. The main areas for improvement concern the management of deviations, radiological verification procedures, the auditing of subcontracted activities, the provision and monitoring of training, and operations traceability in compliance with the quality assurance provisions. The significant events had no notable impacts. They primarily concerned labelling and placarding anomalies, package classification errors resulting from insufficient radiological verifications, incomplete shipping documents and noncompliance with organisational provisions.

2. Additional information

2.1 Informing the public

ASN held a press conference in Vincennes division on 18th October 2017 to present the results of its regional action. It took part in the meeting of the monitoring committee of the Curie site in Arcueil and the three meetings of the Fort de Vaujours monitoring committee.

Normandie

The Caen division regulates nuclear safety, radiation protection and the transport of radioactive substances in the 5 *départements* of the Normandie region.

The installations and activities to regulate comprise:

- BNIs:
  - 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;
  - the Ganil (National Large Heavy Ion Accelerator) in Caen;
- small-scale nuclear activities in the medical sector:
  - 8 external-beam radiotherapy departments (21 devices);
  - 1 proton therapy centre currently being set up;
  - 3 brachytherapy departments;
  - 11 nuclear medicine departments;
  - 35 centres performing fluoroscopy-guided interventional procedures;
  - 66 computed tomography scanners;
  - some 2,100 medical and dental radiology devices;
- small-scale nuclear activities in the veterinary, industrial and research sectors:
  - about 450 industrial and research establishments, including 18 companies exercising an industrial radiography activity, 1 cyclotron, 21 laboratories situated mainly in the universities of the region, 10 companies using gamma ray densitometers and 150 users of devices for detecting lead in paint;
  - about 260 veterinary surgeries or clinics practising diagnostic radiology;
- ASN-approved laboratories and organisations, including:
  - 9 head offices of laboratories approved for taking environmental radioactivity measurements;
  - 3 head offices of organisations approved for radiation protection controls.

In 2017, ASN carried out 201 inspections in Normandie, comprising 59 inspections in the Nuclear Power Plants (NPP) of Flamanville, Paluel and Penly, 19 inspections on the construction site of the Flamanville 3 EPR reactor, 66 inspections on fuel cycle facilities, research facilities and facilities undergoing decommissioning, 47 inspections in small-scale nuclear activities and 10 in the transport of radioactive substances.

In addition to this, 48 days of labour inspection were carried out on the NPP sites and the Flamanville 3 worksite.

During 2017, 12 significant events rated level 1 on the INES scale were notified to ASN. In addition, 3 events rated level 1 on the ASN-SFRO scale were notified by the heads of radiotherapy departments in the Normandie region.

1. Assessment by domain

1.1 The nuclear installations

Areva NC La Hague plant

ASN considers that the situation of the plants operated by Areva NC in La Hague is relatively satisfactory with regard to nuclear safety, control of personnel exposure to ionising radiation and compliance with the environmental discharge limits.

ASN noted shortcomings in the operational documentation and in practices during situational exercises carried out in 2017 which aimed to assess the licensee's organisation in degraded situations. Areva NC must enhance the robustness of the operational management of accident situations, particularly by verifying the completeness of its management procedures and the preparedness of the operating teams. In October 2017, ASN authorised the On-site Emergency Plan (PUI) modifications, which more specifically concern the criteria for activating this plan, the local emergency organisation, the reflex response sheets and updating of the accident scenarios.

ASN noted shortcomings in the control and monitoring of handling equipment, which reveal reduced rigour in the application of the instructions. These shortcomings led to 2 significant events for safety involving the dropping of loads.

Checks of the internal authorisation system revealed deficiencies in taking into account the recommendations formulated by the licensee's experts in the safety analyses of the modification authorisation files. ASN also observed weaknesses in the use of the site's organisational and human factors expertise for the analysis, implementation or monitoring of the site's reorganisation projects. ASN performed several targeted inspections in 2017 – some unannounced – to check the conformity of the organisation with the modification authorised on 12th October 2016. Carried out on a sampling basis, these inspections revealed no reduction in the level of safety of the organisation.

The analysis of three significant events for safety which revealed malfunctions in Areva NC's integrated management system, highlighted the need to reinforce the organisations in place with regard to the capacity to analyse the safety issues associated with degraded operating situations, the monitoring of outside contractors and more generally, a questioning attitude with respect to the conditions of performance of the operating and decommissioning operations.

Areva NC's organisation of radiation protection is satisfactory on the whole. The licensee must nevertheless remain particularly attentive to the conditions of access to prohibited areas.

During 2017, Areva NC continued the UP2-400 plant decommissioning operations authorised by the decrees published in November 2013 for BNIs 33, 38 and 47 and in July 2009 for BNI 80. Areva NC has finished retrieving the fissile material from room 107 of the MAPu facility and the waste from dissolver 222-51 in the HADE facility. Areva NC has implemented an action plan to retrieve the residual materials from the compartments of the settling tanks of the STE2 facility (BNI 38) and started the complementary analyses of the ÉLAN IIB facility (BNI 47) civil engineering in order to consolidate the installation decommissioning scenario. Lastly, Areva NC has initiated an action plan to redefine the overall decommissioning scenario of the HAO South facility (BNI 80). ASN notes disparities in the progress of the decommissioning projects for BNIs 33, 38, 47 and 80, with some that could fail to meet the regulatory deadline specified in the decommissioning decrees. Areva NC must improve the safety culture of outside contractors and of the Areva NC personnel responsible for managing the decommissioning operations. It must also improve the methods of monitoring outside contractors and assess its monitoring actions. Alongside this, ASN has continued the examination of the complete decommissioning applications for BNIs 33 and 38 submitted by Areva NC in July 2015, and of the periodic safety reviews of BNIs 33, 38 and 47.

For the retrieval and packaging of legacy waste, which has major safety implications, ASN notes that Areva NC has continued to produce CSD-U packages for packaging the fission products from the UNGG (Naturel Uranium - Graphite-Gas) fuels, but without achieving the production target for 2017. During an inspection in July 2016, ASN found that Areva NC had not actually begun to recover the waste stored in silo 130. In view of the justifications provided by Areva NC concerning the technical difficulties encountered and considering that the operations completion deadline of 31st December 2023 was not called into question, ASN – through ASN resolution 2017-DC-0612 of 26th October 2017 – pushed back the date of start of retrieval to 30th April 2018. ASN notes the progress of the work on the project to retrieve the waste from silo 130, particularly the installation of the process equipment to start retrieval of the solid waste, and the completion of construction of the unit for the retrieval and packaging of the waste from the HAO silo.

Flamanville nuclear power plant

ASN considers that the performance of the Flamanville NPP with regard to nuclear safety, radiation protection and environmental protection is, on the whole, in line with the general assessment of EDF plant performance.

With regard to reactor operation and management, ASN considers that the site's performance is satisfactory on the whole, but it must improve the traceability of the periodic tests analysis, particularly when restarting the reactor after an outage.

With regard to the maintenance outage of reactor 2, the maintenance operations were well managed on the whole. The licensee must nevertheless improve monitoring of the operations, particularly those involving significant radiological risks. The site's organisation for waste management during reactor outages must be improved.

With regard to radiation protection, the organisation of the risk prevention department is satisfactory when the plant unit is in operation, but worksite dosimetric monitoring and worker monitoring during outages need to be improved.

With regard to environmental protection, the site's waste management organisation must be improved, more particularly in the management of waste in the storage areas and the tracking of the monitoring programme for the overall worksite assistance service.

ASN considers that emergency situation management, particularly during the event affecting the reactor 1 alternator on 9th February 2017, is satisfactory. This event enabled the licensee and ASN to learn lessons from this type of emergency situation.

Paluel nuclear power plant

ASN considers that performance of the Paluel NPP with regard to nuclear safety and radiation protection is on the whole in line with the general assessment of EDF, and that its environmental protection performance is even more satisfactory.

ASN notes that error-reduction practices concerning the preparation for, and retrospective verification of, operation and maintenance activities are still insufficiently deployed. ASN more specifically observes a large number of significant events linked to organisational and human factors.

During 2017, the10-yearly outage of reactor 3 was carried out and involved major maintenance operations and system modifications with the particular aim of improving reactor safety. The main primary system of reactor 3 underwent complete requalification. This outage went smoothly. However, a major technical incident affecting one of the reactor coolant pump sets obliged the licensee to unload the reactor core after having reloaded it, in order to carry out the necessary work.

With regard to reactor 2, continuation of the 10-yearly outage consisted essentially in restoring the conformity of the equipment damaged by the fall of the steam generator in 2016 and preparing for resumption of the steam generator replacement operations which were started in this reactor in early 2016. ASN considers that performance of these operations was satisfactory on the whole. It notes that removal of the last old steam generator and introduction of the four replacement steam generators at the end of 2017 involved intensive work in both engineering and dealing with problems on the handling line.

ASN considers that the refuelling outage of reactor 4 was satisfactory. ASN does however note that EDF must take better account of the seismic interaction risk on the worksites in the reactor building.

In the area of radiation protection, ASN notes an improvement compared with 2016. The site's organisation must however be bolstered, particularly in the preparation of activities involving radiological risks and the monitoring of outside contractors.

With regard to environmental protection, the site must reinforce its organisation to guarantee the leak-tightness of the cooling units. In addition, the file submitted by EDF to request modifications to the site's discharge authorisations was made available for public consultation in 2017 and its examination should be concluded in 2018.

Penly nuclear power plant

ASN considers that the performance of the Penly NPP with regard to nuclear safety, radiation protection and environmental protection is, on the whole, in line with the general assessment of EDF plant performance.

ASN did nevertheless detect several low-level events in 2017, particularly during the inspections, indicating that safety management must be stepped up. Operating experience feedback management and internal checks on the site must be improved.

With regard to operation and reactor management, ASN considers that the site's performance is satisfactory on the whole. However, although operating rigour has improved in certain activities, as is the case for the configuring of systems, it must be further improved for the activities relating to the periodic tests. The site must also be particularly attentive to compliance with instructions and the quality and usability of the operating documents.

The maintenance performance of the site remains stable. ASN has nevertheless detected deficiencies in maintenance work preparation and implementation. ASN considers that the site must make further progress in the in-service monitoring of Nuclear Pressure Equipment (NPE). Particular care must be taken to ensure that deviations affecting the installation are characterised and corrected within appropriate time frames.

The maintenance operations carried out during the reactor 1 maintenance outage were well managed on the whole. Technical incidents did however occur, particularly during requalification of the NPEs. The licensee must improve monitoring of the operations, particularly those involving significant radiological risks.

As far as environmental protection is concerned, the site must improve its performance. Knowledge of the regulatory requirements considered as a whole remains insufficient and the organisational setup for the management of waste in the storage areas must be improved.

Labour inspection in the nuclear power plants

ASN conducted oversight actions concerning the conditions of health and safety during maintenance and construction operations and the management of subcontracting in the nuclear power plants.

Following the fall of a steam generator on 31st March 2016 during its handling in reactor building 2 of the Paluel NPP, ASN examined the conditions of removal of this steam generator. ASN also conducted inspections on certain repair operations inside the reactor building, such as the repair work on the pool. Before the steam generator handling operations resumed, ASN required a third-party organisation check the conformity of the modified handling systems. Lastly, ASN monitored resumption of the steam generator lifting operations in reactor building 2, which were completed in December 2017.

Construction of the Flamanville 3 EPR reactor

After issue of Creation Authorisation Decree 2007-534 of 10th April 2007 and the building permit, construction work began on the Flamanville 3 reactor in September 2007.

The mechanical assembly work continued in 2017 with, for example, installation of the main secondary system equipment of the nuclear steam supply system, protection valves on the main primary system, reactor auxiliary systems, mechanical penetrations in the reactor containment, effluent treatment systems and the equipment necessary for the operation of the emergency diesel generator sets. Alongside this, the cable pulling and electrical connection operations have been stepped up. Lastly, the system start-up tests have entered an overall tests phase with the "primary system flushing" operations, part of the "functional tests with reactor vessel open" and starting of the "cold test[1]" of the nuclear steam supply system. 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 put in place by EDF can be improved, particularly in the following areas:

- ensuring that the requirements specific to the break preclusion process are effectively taken into account before assembling the main secondary systems and correcting the significant deviations encountered in these activities,

1. Cold tests: these tests constitute the regulatory hydrostatic test of the main primary system.

- the rigour of the start-up tests documentation and informing ASN of the progress of these tests and the deviations encountered,
- environmental protection.

In addition, the time taken to deal with deviations must be improved and allow all deviations to be corrected before the contingent commissioning of the reactor.

Lastly, the future EPR reactor licensee must speed up its preparation in view of the current EDF schedule.

The electromechanical assembly operations continued in 2017 and led EDF to report 2 significant events for safety concerning the assembly of the main secondary systems. As the first event concerning the detection of several deviations was caused more specifically by a lack of safety culture in the workers responsible for these activities, ASN checked the identification of the root causes and the implementation of appropriate corrective action before the activities resumed. The second event relative to the failure to take into account the specific requirements of the break preclusion process prior to the manufacture and assembly of the equipment is currently being examined by ASN. EDF must also step up its monitoring of deviations detected by outside contractors responsible for mechanical assembly operations and ensure that they are suitably dealt with before the start-up tests and, whatever the case, before the contingent commissioning of the reactor.

In view of the reactor commissioning time frames announced by EDF and further to the deviations in the preservation and commissioning of new heat exchangers in 2016 and 2017, EDF must remain attentive to the preservation of the equipment already installed, taking into account the consequences of filling the systems with water for the hydrostatic pressure tests and the start-up tests.

ASN continued its oversight of the start-up tests with, for example, performance of the first overall tests of the EPR reactor. ASN considers that the organisation put in place for the preparation and implementation of the start-up tests can be improved on the whole. EDF must more specifically increase the rigour with which the test procedures are recorded and ensure that the deviations encountered are suitably documented. EDF must also improve the quality of the information given to ASN on the performance of the start-up tests and the deviations detected during these tests. Lastly, the verifications by EDF's independent safety organisation must be reinforced in this area and lead to effective improvement measures.

ASN inspected EDF's environmental protection organisation on the worksite and considers that it can be improved. EDF must more specifically improve its monitoring of outside contractors in this area. EDF must also ensure appropriate management of the groundwater intake structures and of the buried legacy waste found on the site.

ASN has stepped up its oversight of the organisation put in place by the teams tasked with future operation of the Flamanville 3 reactor for the management of safety, production of the operating and maintenance documentation, control of hazards, occupational radiation protection, transport and preparation for partial commissioning of the reactor. The organisation put in place by EDF to prepare for operation can be improved and, in view of EDF's current schedule, requires a considerable amount of work in a short time frame.

ASN ensures the labour inspection missions on the Flamanville 3 worksite. In 2017, ASN checked that outside contractors working on the site complied with the provisions relative to labour law. Regular checks were made to verify compliance with the applicable safety rules. With regard to these aspects, ASN made sure that the contractors' organisation for work in confined spaces was reinforced and drew EDF's attention to the need to maintain extreme vigilance with regard to the risks of falls from height and the impact of the start-up tests which entail the powering on of systems or the pressurisation of equipment. Lastly, ASN conducted several inspections focusing on the regulatory provisions governing the transnational secondment of workers, exemptions from the Sunday rest rule and the design rules for work premises.

Andra's Manche repository

ASN considers that the condition and the operation of the Manche Repository (CSM) facilities are satisfactory. Andra must nevertheless continue its efforts to reinforce the stability of the cover and to eliminate the residual infiltrations of rainwater into the repository via the edge of the membrane.

The examination or the periodic safety review guidance file led ASN to make requests in late 2017 concerning subjects on which Andra is falling behind schedule (justification of the technical principles of implementation of the permanent cover, the means of preserving the CSM site memory) and themes representing challenges for the next periodic safety review, such as updating of the impact study.

A new version of the on-site emergency plan was authorised by ASN in April 2017, and the examination of the request to modify the BNI perimeter of the facility continued in 2017 and should be completed in 2018.

Andra must continue to assess the effectiveness of the draining trench put in place during 2016 behind drainage chamber No. 11 (CD11) in order to collect part of the stormwater upstream of the chamber, and must continue the investigations to characterise the infiltrations detected in 2016 in CD14.

During 2017, Andra sent ASN two authorisation applications, one concerning the updating of the waste study, the other concerning the revision of the CSM general operating rules. These authorisation applications are intended more specifically to integrate the requirements of ASN resolution 2015-DC-0508 of 21st April 2015 relative to the waste management study and the assessment of the waste produced in the basic nuclear installations.

Ganil (National Large Heavy Ion Accelerator)

After observing in November 2016 the lateness in implementing several requirements of ASN resolution 2015-DC-0516 of 7th July 2015 relative to the monitoring of discharges and the environment, ASN gave the Ganil formal notice to comply by 30th September 2017 through ASN resolution 2017-DC 0586 of 21st March 2017. A follow-up inspection on 12th December 2017 confirmed that the necessary compliance work had been carried out.

ASN continued the examination of the commissioning application for phase 1 of the SPIRAL 2 project submitted in October 2013, and in summer 2017 it requested the last complements in order to finalise its examination. The persistent lateness in meeting the commitments made further to the periodic safety review completed in June 2015 has led ASN to demand that these commitments be met before any further commissioning authorisation is issued. The organisation of project monitoring, which was modified at the end of 2016, has not so far restored a satisfactory situation with regard to project monitoring and meeting commitments made to ASN.

In 2017, ASN noted the completion of the compliance work further to the serving of formal notice on 21st March 2017, the improvement in the procedures for removing very low-level and low-level waste, deemed improvable in 2015, and the satisfactory operational management of the radioactive sources. Nevertheless, the tracking of used cooling fluids must be improved and the training of some of the people involved in emergency management must be perpetuated.

1.2 Radiation protection in the medical field

Radiotherapy and brachytherapy

In 2017, ASN continued the multi-year inspection cycle covering all the radiotherapy departments in Normandie; an annual inspection is maintained for departments with identified points requiring particular attention. The four inspections conducted in 2017 revealed the maintaining of a real process to improve the rigour, organisation and traceability of interventions and the implementation of management systems to ensure treatment quality and safety. Nevertheless, despite 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 in medical physicists and sometimes radiation oncologists. These difficulties constitute a hindrance to the ongoing progress initiative. The inspections conducted in 2017 also showed that the majority of the centres do not analyse detected malfunctions in sufficient depth.

In 2017, ASN authorised the company IBA to complete the installation of an accelerator in Caen which will ultimately enable proton therapy treatments to be performed (Archade facility). This authorisation also enables the entity responsible for the activity to perform the tests required for facility acceptance before it is placed at the disposal of the radiotherapy department of the François-Baclesse centre.

Fluoroscopy-guided interventional practices

ASN maintained its tightened monitoring in 2017 in the departments performing fluoroscopy-guided interventional procedures. The activities in these facilities entail risks for both patients and workers, and these risks must be duly controlled. The inspections revealed contrasting situations and many areas for improvement, such as the training and qualification of personnel using the devices, performing device quality controls, personal protection of the personnel, medical monitoring of private practice workers, or the optimisation of practices in this sector. Greater involvement of the medical physicist would, among other things, enable the equipment to be used more efficiently, with the setting up of protocols tailored to the procedures performed, and the development of dosimetric reference levels. ASN notes that radiation protection is generally better integrated in the rooms dedicated to interventional practices than in the operating theatres.

Nuclear medicine

In 2017, ASN inspected two nuclear medicine departments in Normandie. The inspections revealed a contrasting situation. The situation is satisfactory on the whole, but there are a few areas for improvement in the coordination of the prevention measures for outside contractors and taking account of radiation exposure of workers' extremities (hands). One department nevertheless needs the person in charge of the activity to take corrective action in order more specifically to make the examination process more robust. Given the functional context of this department, an unannounced inspection was carried out jointly with the Regional Health Agency (ARS) of Normandie.

Computed Tomography

In the light of the inspections carried out in 2017, occupational radiation protection is found to be satisfactory on the whole. Patient radiation protection measures are still variable and are often based on the use of the optimisation procedures specified by the device manufacturers. The level of involvement of medical physicists varies significantly from one department to another; increasing their involvement could help to optimise practices.

1.3 Radiation protection in the industrial sector

Industrial radiography

The oversight of industrial radiography remains a priority for ASN, which carried out unannounced night-time inspections on worksites in 2017. These inspections revealed a widely contrasting situation between companies in 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 must still make significant progress while others must remain vigilant to maintain their standard of radiation protection.

At the same time, ASN continued, in collaboration with Direccte (Regional Directorate for Enterprises, Competition, Consumption, Labour and Employment) of 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 Normandie. In 2017, the prospective work carried out with a view to extending the charter to the whole of Normandie and to the nuclear and naval construction sectors was continued. At present, some thirty companies, ordering customers and radiology companies have signed this charter. It has been decided to extend this charter to the whole of Normandie in 2018.

1.4 Radiation protection of the public and the environment

Contaminated sites and soils

In March 2013 work was undertaken jointly by Andra and by the EPF (Public Land-management Corporation) of Normandie to complete the decontamination and to rehabilitate the industrial site of *Établissements Bayard*, situated in Saint-Nicolas d'Aliermont. *Établissements Bayard* was specialised in the production of pendulum clocks and alarm clocks. From 1949 until the workshops closed in 1989, the site produced and used luminescent paint based first on radium-226, then on tritium.

ASN has assisted the Dreal (Regional Directorate for the Environment, Planning and Housing) of Normandie in the monitoring of the rehabilitation of the site. A sampling inspection to verify compliance with the clean-out objectives was carried out in July 2016. The demonstration of compliance with the clean-out objectives and the implementation of institutional controls enabled the site – rehabilitated as a public outdoor area – to be opened to the public in 2017.

1.5 Nuclear safety and radiation protection in the transport of radioactive substances

ASN considers that the regional consignors involved in the transport of radioactive substances maintained a level of safety in 2017 that was on the whole satisfactory.

With regard to shipments of radioactive substances from basic nuclear installations in Normandie, the requirements specific to these operations are met on the whole. ASN more specifically carried out an inspection on the La Hague site in June 2017 during preparation of the shipment of packages containing fresh MOX fuel to Japan. This inspection revealed no significant deviations. ASN also carried out an inspection into the transport of radioactive substances as part of the preparation for operation of the EPR reactor.

In 2017, ASN continued checking the implementation in the BNIs of the new regulatory requirements applicable to on-site transport operations. ASN resolutions concerning the modifications of the general operating rules for transport operations within the La Hague site were issued in 2017.

2. Additional information

2.1 Informing the public

Press conferences

ASN held two press conferences in Rouen and Caen on the 13th and 20th of September 2017 respectively to present the situation of nuclear safety and radiation protection in the Normandie region.

Work with the Local Information Committees (CLIs)

ASN participated in the various general assemblies of the Local Information Committees (CLI) of Normandie and presented more specifically its assessment of the safety of the nuclear facilities concerned, the examination of the ERP reactor pressure vessel domes and the application file for modification of the Paluel site discharge and water intake authorisation. In accordance with the provisions introduced by Act 2015-992 of 17th August 2015 relative to the Energy Transition for Green Growth, the CLIs of the Cotentin area (Areva NC La Hague, Flamanville and the CSM) organised a conference-debate on the perceived level of safety of the BNIs in that area in the light of the Fukushima Daiichi accident, while the Paluel-Penly CLI organised a public meeting on the continuous monitoring of nuclear power plants, the role of the stakeholders in informing the public, and the risk awareness culture.

2.2 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 STÜK *(Säteilyturvakeskus),* the Finnish nuclear regulator. In 2017, staff from the Caen division took part in a technical exchange with their Finnish counterparts in France, then participated in a joint visit of the Flamanville 3 EPR construction site.

Two ASN inspectors went to China in March 2017 to attend "first in series" tests conducted on the EPR reactor 1 of the Taishan site, which aimed at testing the vibrational behaviour of the reactor pressure vessel internal components. As EDF had announced its intention to capitalise on the result of these tests in the start-up of Flamanville 3, it was necessary for ASN inspectors to observe the quality of performance of these operations.

Nouvelle-Aquitaine

The Bordeaux division regulates nuclear safety, radiation protection and the transport of radioactive substances in the 12 *départements* of the Nouvelle-Aquitaine region. The 3 *départements* of the former Limousin region have been under the competence of the Bordeaux division since 1st July 2017, following the regional reform of ASN.

The installations and activities to regulate comprise:

- BNIs:
  - the Blayais NPP (4 reactors of 900 MWe);
  - the Civaux NPP (2 reactors of 1,450 MWe);
- small-scale nuclear activities in the medical sector:
  - 19 external-beam radiotherapy departments;
  - 6 brachytherapy departments;
  - 22 nuclear medicine departments;
  - 93 centres performing fluoroscopy-guided interventional procedures;
  - 89 computed tomography scanners;
  - some 5,700 medical and dental radiology devices;
- small-scale nuclear activities in the veterinary, industrial and research sectors:
  - 592 industrial and research establishments, including 41 companies exercising an industrial radiography activity, 1 Cyclotron particle accelerator, 85 laboratories situated mainly in the universities of the region, 20 companies using gamma ray densitometers and 337 users of devices for detecting lead in paint;
  - about 450 veterinary surgeries or clinics practising diagnostic radiology;
- ASN-approved laboratories and organisations:
  - 4 organisations approved for radiation protection technical controls
  - 1 organisation approved for measuring radon;
  - 4 laboratories approved for taking environmental radioactivity measurements.

In 2017, ASN carried out 134 inspections in the Nouvelle-Aquitaine region, comprising 35 inspections in the area of nuclear safety in the Blayais and Civaux Nuclear Power Plants (NPPs), 5 inspections concerning the transport of radioactive substances and 94 inspections of small-scale nuclear activities.

ASN also carried out 16 days of labour inspection at the Blayais NPP and 9 days at the Civaux NPP.

During 2017, seven significant events rated level 1 on the INES scale were notified by the NPP licensees of Nouvelle-Aquitaine. In small-scale nuclear activities, 3 significant events rated level 1 on the INES scale were notified to ASN. Added to these events are significant events concerning radiotherapy patients, of which 16 were rated level 1 on the ASN-SFRO scale and 2 were rated level 2.

1. Assessment by domain

1.1 The nuclear installations

Blayais nuclear power plant

ASN considers that the performance of the Blayais NPP with regard to nuclear safety, environmental protection and radiation protection is, on the whole, in line with ASN's general assessment of EDF plant performance.

With regard to safety, ASN has noted that the four reactor outages for maintenance and refuelling proceeded smoothly on the whole. ASN nevertheless observes that the site has persistent difficulties in planning, preparing and performing the periodic tests required by the general operating rules to guarantee correct operation of the equipment. The quality of the operational documentation is still a weak point for the smooth running of these tests, and more generally for the operational control and maintenance activities.

With regard to radiation protection, ASN observes that the site continues to make progress in the optimisation of the radiation doses received by workers and in the control of the radiological cleanliness of worksites during reactor outages, thanks in particular to satisfactory integration of the lessons learned from preceding reactor outages. ASN notes positively the measures taken by the site to implement the Everest initiative in 2018, which involves entering controlled areas in normal working overalls.

With regard to environmental protection, ASN considers that the site must improve its management of the containment of liquid radioactive effluents. ASN also considers that the site must improve the operating checks of equipment items that use refrigerants for the thermal regulation of certain premises, even though the emissions of these gases which contribute to the greenhouse effect dropped significantly in 2017.

Civaux nuclear power plant

ASN considers that the nuclear safety and environmental protection performance of the Civaux NPP on the whole matches ASN's general assessment of EDF and that its radiation protection performance stands out positively.

In the area of safety, ASN has noted that during the reactor 1 refuelling and maintenance outage, the licensee had difficulties in preparing and scheduling a large number of maintenance activities and in providing its contractors with the necessary means to accomplish their tasks. These problems led to errors during the maintenance of equipment important to safety, which were subsequently corrected. ASN considers that the site must improve these aspects during the next reactor outages. With regard to operating activities, ASN considers that the measures implemented to improve the rigour of operational management of the reactors must be continued.

At the request of ASN[1] , reactor 1 was shut down in February 2017 to perform analyses on the channel heads of the steam generators displaying high carbon content. In view of the analysis results, and provided that more restrictive operating procedures are applied, ASN has given its consent to restart reactor 1.

ASN observes that occupational radiation protection is integrated satisfactorily in work preparation and performance. ASN nevertheless considers that the site must improve the management of worker access to areas that are subject to temporary access restrictions in order to limit the risk of exposure to ionising radiation.

ASN considers that the site must improve its operation of equipment that contributes to environmental protection by reinforcing its management of liquid effluent containment to ensure stricter compliance with the applicable rules.

Labour inspection in the nuclear power plants

The personnel in charge of labour inspection continued their oversight actions on the work presenting a risk of exposure to asbestos, particularly in the performance of maintenance work during reactor outages. They also conducted inspections on the construction sites of the buildings that are to house the future ultimate backup diesel-generator sets. They also verified compliance with the rules governing the secondment of foreign employees and continued the actions in progress since 2013 on the risks of work at height and the conformity of work equipment. Despite the efforts made, these latter actions can be further improved. The labour inspectors checked implementation of the action plans established by the licensees further to the work equipment conformity verifications decided in 2016. They consider that the time frames proposed by the licensees to definitively bring the fuel loading machines into compliance, from the point of view of worker safety, are not ambitious enough.

Alongside this, the inspections concerning management of the explosion risk have begun. Several failures to meet regulatory obligations were observed in this context.

Lastly, specific investigations were carried out following work accidents and in response to specific requests concerning employees of outside companies.

1.2 Radiation protection in the medical field

Radiotherapy and brachytherapy

ASN performed 11 inspections in radiotherapy departments in the Nouvelle-Aquitaine region in 2017. ASN takes positive note of the renewal of the particle accelerator pool; 3 inspections were carried out to verify the installation conditions of the new devices before treating the first patients.

Three inspections of brachytherapy departments were also carried out, one further to the reporting of a Significant Radiation Protection Event (ESR) by the Bordeaux University Hospital.

In 2017, ASN oversight focused in particular on risk management and on the implementation of new techniques in radiotherapy, including hypofractionated treatments.

ASN considers that the requirements of ASN resolution 2008-DC-0103 setting the quality assurance obligations in radiotherapy are satisfied on the whole. Progress is nevertheless expected in some departments in which internal communication and the quality objectives are not sufficiently promoted by senior management.

ASN considers that sufficient means are devoted to medical physics, but insists on the need to look ahead and assess changes in demand for medical physicists to manage projects to put in place new techniques or new equipment.

Although all the departments carry out prospective analyses of the risks to which patients are exposed, they are not always taken to any depth and are too rarely updated prior to the use of new equipment or a new technique. Consequently, the departments are not always able to identify potential failures or the actions to take to prevent them from occurring.

All the radiotherapy departments have an organisation that enables adverse events to be detected, recorded and dealt with. Further progress must also be made with event analyses, so that they do not stop at the immediate causes but go on to examine the root causes, including the organisational factors. As a general rule, monitoring of the corrective actions applied and the assessment of their effectiveness can be improved.

1. *ASN resolution 2016-DC-0572 of 18th October 2016 prescribing inspections and measurements on the channel head of certain steam generators of the nuclear power reactors operated by* Électricité de France – Société Anonyme *(EDF-SA).*

In 2017, the Bordeaux University Hospital notified ASN of 2 significant radiation protection events in brachytherapy and in contact radiotherapy which were provisionally rated level 2 on the ASN-SFRO scale. In both these cases, the dose administered to the patients was significantly higher than the prescribed dose and could potentially cause moderate alteration of an organ or function, therefore regular medical monitoring is required.

ASN conducted an inspection at the Bordeaux University Hospital dedicated to these events in order to verify effective implementation of the corrective actions announced by the hospital. Tightened monitoring will also be ensured during scheduled inspections in 2018.

With regard to occupational radiation protection, ASN considers that the regulatory requirements are correctly applied in the radiotherapy and brachytherapy departments.

Fluoroscopy-guided interventional practices

ASN inspected 25 centres practising fluoroscopy-guided interventional procedures in the Nouvelle-Aquitaine region in 2017. These inspections were carried out as much in the operating theatre as in facilities dedicated to cardiology, neuroradiology or vascular radiology.

With regard to patient radiation protection, ASN observes that the optimisation of doses delivered to the patients is generally satisfactory in the structures dedicated to the performance of fluoroscopy-guided interventional procedures, but insufficiently applied in the operating theatre, due in particular to the absence of radiographers and medical physicists, and the surgeons' lack of knowledge of the technical possibilities of optimisation offered by the equipment used. In addition, the surgeons are insufficiently trained in patient radiation protection. ASN does nevertheless take positive note that procedures are put in place to monitor patients having undergone long, high-exposure treatments in the dedicated facilities. One significant event concerning patient radiation protection was reported to ASN in 2017.

With regard to occupational radiation protection, ASN observes shortcomings in the designation of radiation protection expert-officers by private practitioners. The regulatory provisions concerning dosimetric monitoring (especially of the extremities), medical monitoring and the training of exposed workers are still poorly applied in the operating theatres. The use of collective protective equipment, which is satisfactory in the dedicated facilities, must be further improved in the operating theatres.

ASN continued to verify implementation of the provisions of ASN resolution 2013-DC-0349 of 4th June 2013 setting the design rules for premises in which X-ray generators are used. It observes that the majority of operating theatres have undertaken compliance procedures (studies and additional work where necessary), but the situation can be further improved.

Nuclear medicine

ASN performed 6 scheduled inspections in nuclear medicine departments in the Nouvelle-Aquitaine region in 2017. Two commissioning inspections were moreover carried out for the opening of a new PET (Positron Emission Tomography) sector in Pau and the transfer of the scintigraphy activity of the Saint-Augustin Clinic in Bordeaux to new premises.

The new facilities provide the opportunity for ASN to verify, from the new premises design stage, that the provisions of ASN resolution 2014-DC-0463 of 23rd October 2014 relative to the design and operation of nuclear medicine facilities have been taken into account. ASN also verifies compliance with these requirements during its inspections. It considers that the requirements are met on the whole. Nevertheless, application of the requirements relative to the ventilation of rooms accommodating patients receiving Internal Targeted Radiotherapy (ITR) treatment must be improved.

ASN considers that patient and worker radiation protection is on the whole ensured correctly in the nuclear medicine departments. ASN takes positive note of the transparency of the nuclear medicine departments in the reporting of ESRs. In effect, 19 ESRs were reported in 2017, compared with 8 in 2016. The majority of these events resulted from organisational or human causes – usually an error in the preparation of the radiopharmaceutical or a patient identity error when giving the injection.

With regard to protection of the general public and the environment, ASN observes that the difficulties in the management of radioactive effluents persist, particularly the effluents produced by patients hospitalised in ITR rooms. One significant event concerning the leak of a pipe carrying contaminated urine was reported to ASN in 2017; the event had no impact outside the centre. Constant vigilance must be exercised in the monitoring and maintenance of the pipes carrying these radioactive effluents to prevent the occurrence of such events.

1.3 Radiation protection in the industrial and research sectors

Industrial radiography

ASN carried out 18 inspections of industrial radiography activities in fixed facilities or on worksites in 2017.

Further to the significant radiation protection event that occurred in 2015 in an X-ray radiography bunker of an agency of *Apave Sud-Europe* in Colomiers (Haute-Garonne *département),* rated level 2 on the INES scale, ASN attaches particular importance to the monitoring of fixed facilities in which X-ray generators are used. 7 inspections on this theme were thus carried out in 2017, including 5 in enterprises which were licensed but had never yet been inspected by ASN.

With regard to industrial radiography in fixed facilities, ASN observed unacceptable shortcomings in certain enterprises in 2017 concerning the administrative situation of their activity; these situations were only brought into compliance further to the ASN inspections. ASN will remain extremely vigilant in this respect in 2018. The enterprises must make further progress in the evaluation of the risks to which workers and the public are exposed, in the analysis of jobs and work environments and the conformity of the facilities with regulatory requirements concerning their design, particularly regarding their signalling. ASN does nevertheless note that the radiation protection technical controls, the general organisation of radiation protection, and the training and dosimetric monitoring of the personnel exposed to ionising radiation are satisfactory on the whole.

With regard to industrial radiography on worksites, ASN notes an overall improvement in radiographers' practices, particularly on gamma radiography work sites, in verifying that the radioactive source has returned to the storage position. ASN nevertheless observes that efforts must continue in the development of work area cordoning off and signalling instructions.

Universities and laboratories or research centres

ASN conducted 2 inspections in universities and research laboratories in the Nouvelle-Aquitaine region in 2017.

ASN considers that the research laboratories on the whole comply with the regulatory requirements of occupational radiation protection, particular concerning the job and work environment analyses, passive dosimetric monitoring and the classification of personnel exposed to ionising radiation. It observes that the radiation doses received by workers remain low.

ASN observes with approval that the research laboratories are increasingly endeavouring to acquire electrical ionising radiation generators that comply with the regulations, despite the presence on the market of numerous devices that are noncompliant and not referenced by ASN. ASN remains vigilant regarding the use of non-referenced devices. It also notes the continuing tendency for establishments to share ionising radiation sources and radiation protection means between several research units.

Lastly, ASN considers that the Universities of Bordeaux and Poitiers have adopted effective procedures for managing the elimination of disused, unused or accidentally discovered radioactive sources. It nevertheless observes that the search for agencies to take back the sources and the costs of removal often slow down the source removal process.

1.4 Radiation protection of the public and the environment

Contaminated sites and soils

During 2017 ASN assisted the public authorities in the management of various sites and soils contaminated by radioactive substances in the Nouvelle-Aquitaine region.

ASN more specifically monitored the measures taken by the city of Bordeaux concerning a site contaminated with radium. In response to a Prefectural Order issued in 2015, the city of Bordeaux drew up a complete and precise map of the radioactive contamination and had various scenarios established for site decontamination. ASN took part in the discussions between the stakeholders concerning these scenarios. In 2018 it will continue to assist the Prefectural authority with the regulatory oversight of the chosen site decontamination solution.

ASN also accompanied the Regional Directorate for the Environment, Planning and Housing (Dreal) in the radiological monitoring and rehabilitation of a site contaminated with natural uranium and thorium as a result of a former monazite crushing activity located in the municipality of Boucau (Pyrénées-Atlantiques).

Former uranium mines

ASN continued to assist the Dreal in the management of mining waste rock and of the former uranium mine in the three *départements* of the former Limousin region in 2017. As a reminder, 250 mining sites were operated in France between 1947 and 2001.

ASN has participated in all the former uranium mining Site Monitoring Commissions (CSS) of the Limousin *départements*. The main role of the CSS's is to inform the public of the risks for human health and the environment resulting from the operation of former uranium mines. They bring together representatives of the State, the local authorities, environmental protection associations and the licensees.

Cleaning out the mining waste rock reuse sites by removing these materials continued in the Limousin, in order to reduce the exposure of persons to ionising radiation in accordance with the objectives set in the Circular of 22nd July 2009.

The work already accomplished has made it possible, for certain sites:
- to make them safe with respect to the public;
- to integrate the sites in a landscaped environment;
- to ensure radiological monitoring;
- to monitor the collected water;
- to manage the reconversion of the former mining sites while preserving the site memory.

The examination of some of the site monitoring files required additional analyses and expert assessments by IRSN and the BRGM (Bureau of Geological and Mining Research). These were systematically presented at the CSS meetings.

ASN also responded to several requests from the Limousin prefectures concerning projects within the perimeter of former uranium mining sites.

1.5 Nuclear safety and radiation protection in the transport of radioactive substances

ASN carried out five inspections concerning the transport of radioactive substances in the Nouvelle-Aquitaine region in 2017: 2 in nuclear power plants, 2 in nuclear medicine centres and one on departure of a consignment from a radiopharmaceutical production site (cyclotron).

ASN underlines the competence of the personnel of the Blayais NPP responsible for preparing the spent fuel shipments. As regards the Civaux NPP, the inspectors consider that the measures taken by EDF for the shipping of radioactive substances are satisfactory on the whole. ASN does nevertheless consider that the licensee must shorten the times taken to integrate the recommendation of its transport safety advisor.

With regard to the reception and shipping of radioactive substance packages by the nuclear medicine centres, the Bordeaux division continued its campaign of multi-year inspections in 2017. Fifteen centres have been inspected on this theme since 2013, including two in 2017. ASN observes that the main regulatory requirements are met, particularly those relative to reception of the packages. The main demands of ASN following the inspections are for the transport operations to be subject to strict quality assurance measures and the nuclear medicine centres to monitor their transport service providers.

In 2017, two significant events – which had no serious impacts – were reported to ASN, namely a road accident involving a radiopharmaceutical transport carrier and the unauthorised shipping of a postal package containing a naturally radioactive collection-piece mineral.

2. Additional information

2.1 Informing the public

Press conference

ASN held a press conference in Bordeaux on 5th October 2017 to present the situation of nuclear safety and radiation protection in the Nouvelle-Aquitaine region.

Work with the Local Information Committees (CLIs)

ASN accompanied the work of the two Local Information Committees of the Nouvelle-Aquitaine region, namely the Blayais CLI and the Civaux CLI, by participating in their general assemblies. The two CLIs decided to make public these general assemblies in response to the provisions introduced by Act 2015-992 of 17th August 2015 relative to the Energy Transition for Green Growth. These meetings were devoted more specifically to ASN's 2016 assessment of the Blayais and Civaux NPPs, the updating of the off-site emergency plans around the NPPs, the state of the Blayais NPP embankments and the reinforcing of the sealing of the concrete of the Civaux NPP containment. The Civaux CLI moreover sent observers who attended several inspections carried out by ASN primarily on the themes of services and the transport of radioactive substances.

Occitanie

The Bordeaux and Marseille divisions jointly regulate nuclear safety, radiation protection and the transport of radioactive substances in the 13 *départements* of the Occitanie region.

The installations and activities to regulate comprise:

- BNIs:
  in Golfech (Tarn-et-Garonne *département*):
  - the Golfech NPP comprising 2 pressurised water reactors of 1,300 MWe;

  In Marcoule (Gard *département*):
  - the Mélox MOX nuclear fuel production facility;
  - the CEA Marcoule research centre, which includes the civil BNIs Atalante and Phénix and the Diadem waste storage facility construction site;
  - the Centraco facility for processing low-activity waste;
  - the Gammatec industrial ioniser;

  in Narbonne (Aude *département*):
  - facility for storing Écrin waste on the Malvési site;
- small-scale nuclear activities in the medical sector:
  - 14 external-beam radiotherapy departments;
  - 6 brachytherapy departments;
  - 19 nuclear medicine departments;
  - 96 centres performing fluoroscopy-guided interventional procedures;
  - 111 computed tomography scanners;
  - some 5,000 medical and dental radiology devices;
- small-scale nuclear activities in the veterinary, industrial and research sectors:
  - about 400 industrial and research establishments, including 26 companies exercising an industrial radiography activity, 4 Cyclotron particle accelerators, 79 laboratories situated mainly in the universities of the region, and about 300 users of devices for detecting lead in paint;
  - about 450 veterinary surgeries or clinics practising diagnostic radiology;
- ASN-approved laboratories and organisations, including:
  - 3 head offices of laboratories approved for taking environmental radioactivity measurements;
  - 6 head offices of organisations approved for radiation protection controls.

In 2017, ASN carried out 116 inspections in the Occitanie region, of which 37 were in BNIs, 71 in small-scale nuclear activities and 8 in the transport of radioactive substances.

ASN also carried out 8 days of labour inspection at the Golfech NPP.

During 2017, one significant event rated level 1 on the INES scale was notified by nuclear installation licensees in Occitanie. In the small-scale nuclear activities, 1 significant event rated level 1 on the INES scale was notified to ASN. Three events involving radiotherapy patients were rated level 1 on the ASN-SFRO scale.

1. Assessment by domain

1.1 The nuclear installations

Golfech nuclear power plant

ASN considers that the performance of the Golfech NPP with regard to nuclear safety, environmental protection and radiation protection is in line with ASN's general assessment of of EDF plant performance.

The scheduled outages of reactors 1 and 2 went well on the whole as far as nuclear safety is concerned. Deficiencies in activity preparation were nevertheless discovered. ASN observes that the Golfech NPP licensee has improved its performance in the recording, analysis and handling of deviations affecting its facilities but considers that further progress is required. ASN takes positive note of the questioning attitude of the personnel responsible for checking the conformity of the anchoring of equipment contributing to the safety of the facilities. Lastly, on several occasions ASN noted a lack of rigour in the application of the baseline operating requirements by the operational management teams.

With regard to environmental protection, the licensee has undertaken work to renovate its liquid effluent environmental discharge monitoring stations. ASN observes that the licensee has nevertheless been unable to meet its set objectives for gaseous radioactive discharges – due in particular to the fuel assembly cladding defects – but without exceeding the regulatory limits. ASN considers moreover that the radioactive waste storage and sorting conditions can be improved.

With regard to occupational radiation protection, ASN notes deficiencies in the preparation and conducting of activities involving serious radiation risks. The site had occasional difficulties in controlling radiological cleanliness during certain phases of the reactor shutdowns and in meeting its set objectives.

Labour inspection in the nuclear power plants

The personnel in charge of labour inspection continued their oversight actions on the work presenting a risk of exposure to asbestos, particularly in the performance of maintenance work during reactor outages. They also verified compliance with the rules governing the secondment of foreign employees and continued the actions in progress since 2013 on the risks of work at height and the conformity of work equipment. Despite the efforts made, these actions can be further improved.

The labour inspectors checked implementation of the action plans established by the licensees further to the work equipment conformity verifications decided in 2016. They consider that the time frames proposed by the licensees to definitively bring the fuel loading machines into compliance, from the point of view of worker safety, are not ambitious enough. In addition, particular attention was focused on compliance with the labour regulations during construction of the buildings to accommodate the future ultimate backup diesel generator sets.

Marcoule platform

In 2017, further to the publication on 1st March 2016 of the resolutions regulating the liquid and gaseous effluent discharges from Mélox, Centraco, Atalante and Gammatec, ASN examined the impact study submitted for the decommissioning of the Phénix NPP and started the updating of the installation's discharge resolutions. These resolutions will be made available in 2018 for consultation by the general public, the Local Information Committee (CLI), the licensee and the CODERST (Departmental Council for the Environment and for Health and Technological Risks). This updating will finalise the work to take into account changes to the installations, with a significant drop in the overall discharge limits and an environmental monitoring plan common to all the civil nuclear installations on the platform.

Mélox plant

ASN conducted 6 inspections in the Mélox plant in 2017 and one follow-up inspection of the organisation approved for radiation protection controls in the facility, and considers that the level of nuclear safety and radiation protection is satisfactory on the whole.

The containment barriers on which a large part of the safety case is based are effective and robust. The radiation protection issues are addressed with rigour and the licensee seems to be lastingly committed to carrying out, year after year, operations that bring non-negligible dosimetric gains in the context of ageing of the facilities, and the necessary optimisation of work stations. ASN does nonetheless note the persistence of low-level events, more specifically concerning the crossing of controlled areas by personnel and waste, causing radiation protection problems.

Taking into account the criticality risk is one of the major challenges in this facility, and it is adequately ensured on the whole. Nevertheless, with regard to the criticality risk, the licensee reported one significant event, rated level 1 on the INES scale, for a significant exceedance of the authorised mass of fissile material in a waste drum. ASN conducted a reactive inspection further to this event. The stakeholders' analysis of the event showed that it was caused by Organisational and Human Factors (OHF).

Further to the 10-yearly safety review of the installation, for which the report was submitted in 2013, the licensee met all its commitments and complied with all the ASN requirements.

With regard to the improvement actions undertaken further to the Fukushima accident, the means of remediating the cooling of the fuel rod storage facility are operational and the construction of the new emergency command post has been authorised.

CEA Marcoule Centre

ASN carried out 12 inspections in the CEA Marcoule centre in 2017, comprising 3 cross-centre inspections, one conducted jointly with ASND – the Defence Nuclear Safety Authority, 4 inspections of the Phénix NPP, 4 inspections of the Atalante facility and 1 inspection of the Diadem storage facility construction site. ASN considers that the level of nuclear safety and radiation protection in the centre is satisfactory on the whole.

The transverse organisation of the centre for fire risk management was found to be relatively satisfactory although some aspects can be improved, such as the deployment of the teams over the vast perimeter of the centre and coordination with the other facilities of the centre. The organisation for the transport of radioactive substances is satisfactory.

The level of safety of the Atalante facility is stable, in a context of significant changes due to the arrival in 2017 of certain activities from the Cadarache LEFCA (Laboratory for research and experimental fabrication of advanced nuclear fuels), and remains satisfactory on the whole. The ASN inspectors nevertheless noted a lack of rigour in the application of the operating rules of the installation, to which ASN remains attentive.

ASN is currently examining the periodic safety review concluding report for Atalante, submitted at the end of 2016, and has requested additional information. It should be presented in 2018 to the Advisory Group for Laboratories and Plants before ASN rules on the continued operation of the facility.

At the Phénix NPP, the licensee has continued to remove the spent fuel but at a slower pace than planned due to unforeseen factors. ASN remains particularly attentive to compliance with the fuel removal deadline stipulated in Decree 2016-739 of 2nd June 2016 relative to the decommissioning of the facility. Alongside this, the licensee is continuing the removal of large components (pumps, heat exchangers) taken from the reactor pressure vessel and various very low-level waste materials. ASN carried out a reactive inspection further to a significant event reported by the licensee concerning the incorrect loading of an on-site transport container. This inspection highlighted the licensee's appropriate management of the event.

With regard to the Diadem facility dedicated to the storage of waste from the decommissioning of the Phénix NPP, the civil engineering operations are practically finished; lining of the vault compartments and installation of the racks are in progress, as is the finishing work. The inspection conducted in 2017 was devoted to reviewing the manufacturing and assembly files of certain equipment items and processing nonconformities. In the light of the observed elements the inspection results were satisfactory.

Centraco plant

ASN conducted 4 inspections on the Centraco facility in 2017 and considers that the level of nuclear safety and radiation protection is satisfactory on the whole. ASN considers that the significant events reported by the licensee are dealt with competently.

Following the same trend as in 2016, the solid and liquid waste incineration unit functioned slightly below the maximum possible rate. Similarly, the fusion unit functioned under suitably safe conditions without yet reaching its maximum processing capacity.

Complementary studies concerning the aircraft crash, lightning and earthquake risk, submitted by the licensee in accordance with ASN's requirements issued further to the facility's periodic safety review of 2011, are currently being examined .

Gammatec ioniser

ASN conducted an inspection on the Gammatec irradiator and considers that the level of nuclear safety and radiation protection remain satisfactory in a situation where the treatment capacity of the facility is increasing and the commissioning authorisation for the experimental laboratory has been issued.

Progress is still required however in the regulatory watch and the monitoring of the safety baseline requirements applicable to the facility.

Écrin facility

ASN has extended by one year the examination time for the facility commissioning application through ASN Chairman's resolution CODEP-DRC-2017-019002 of 30th August 2017, in order to examine the additional elements demanded of the licensee, taking the regulatory term of the examination to 7th September 2018. This commissioning authorisation is a prerequisite for the performance of development work, and more specifically the application of a bituminous cover intended to limit the environmental impact of the facility.

1.2 Radiation protection in the medical field

External radiotherapy and brachytherapy

During 2017, ASN conducted 7 inspections in the Occitanie region, of which 2 were devoted to the commissioning of a new facility. One of these inspections, carried out before treating the first patients, concerned the commissioning of a Gammaknife ICON device at the Toulouse University Hospital. This device, the only one of its type in the Occitanie region, allows very precise treatment of intracranial lesions thanks to high-activity radioactive sources.

Four inspections were also carried out in brachytherapy departments.

In 2017, ASN oversight focused in particular on risk management and the implementation of new techniques in radiotherapy, including hypofractionated treatments.

ASN considers that the treatment quality and safety management systems of the inspected radiotherapy and brachytherapy centres are on the whole appropriate. Improvements are nevertheless expected in some departments in which internal communication and the quality objectives are not sufficiently promoted by senior management. ASN remains attentive to seeing that these departments implement a continuous improvement loop driven by management reviews, audits and patient satisfaction surveys.

ASN observes moreover that the prospective risk analysis procedure, which should lead to the setting up of appropriate barriers to prevent adverse patient radiation protection events, is not carried out in sufficient depth or is not always updated prior to the installation of a new device or technique. The centres must thus ensure that they give a formal structure to the procedure in accordance with the November 2014 opinion of the Advisory Committee for Radiation Protection in Medical and Forensic Applications of Ionising Radiation.

All the radiotherapy departments have an organisation that enables adverse events to be detected, recorded and dealt with. ASN nevertheless notes that some departments have not reported any significant events for several years. Further progress must also be made with event analyses, so that they do not stop at the immediate causes but go on to examine the root causes, including the organisational and human factors. Lastly, the monitoring of corrective actions applied and the assessment of their effectiveness can be improved.

With respect to the compliance notice served on the radiotherapy department of Rodez in 2016, ASN conducted a further follow-up inspection of this department in 2017. ASN has observed that the necessary recruitment and investment measures have been taken and that the corrective actions relative to quality management and the organisation of the medical physics unit are satisfactory.

Fluoroscopy-guided interventional practices

ASN inspected 15 centres practising fluoroscopy-guided interventional procedures in the Occitanie region in 2017. These inspections were carried out as much in the operating theatre as in facilities dedicated to cardiology, neuroradiology or vascular radiology.

With regard to patient radiation protection, ASN observes that the optimisation of doses delivered to the patients is generally satisfactory in the structures dedicated to the performance of fluoroscopy-guided interventional procedures, but insufficiently applied in the operating theatre, due in particular to the absence of radiographers and medical physicists, and the surgeons' lack of knowledge of the technical possibilities of optimisation offered by the equipment used. In addition, the surgeons are insufficiently trained in patient radiation protection. ASN does nevertheless take positive note that procedures are put in place to monitor patients having undergone long, high-exposure treatments in the dedicated facilities.

With regard to occupational radiation protection, ASN observes shortcomings in the designation of radiation protection experts-officers by private practitioners. The regulatory provisions concerning dosimetric monitoring (especially of the extremities), medical monitoring and the training of exposed workers are still poorly applied in the operating theatres. The use of collective protective equipment, which is satisfactory in the dedicated facilities, must be further improved in the operating theatres.

ASN continued to verify implementation of the provisions of ASN resolution 2013-DC-0349 of 4th June 2013, setting the design rules for premises in which X-ray generators are used. It observes that the majority of operating theatres have undertaken compliance procedures (studies and additional work where necessary) but the situation can be further improved.

Nuclear medicine

ASN performed 4 inspections in nuclear medicine departments in the Occitanie region in 2017. Two commissioning inspections were also carried out for the opening of a new PET (Positron Emission Tomography) sector in Albi Hospital Centre and the transfer of this centre's scintigraphy activity to new premises.

The new facilities provide the opportunity for ASN to verify, from the new premises design stage, that the provisions of ASN resolution 2014-DC-0463 of 23rd October 2014 relative to the design and operation of nuclear medicine facilities have been taken into account. ASN also verifies compliance with these requirements during its inspections. It considers that the requirements are satisfied on the whole.

ASN considers that patient and worker radiation protection is on the whole ensured correctly in the nuclear medicine departments. Eighteen significant radiation protection events were reported in 2017. The majority of them were caused by organizational or human failings, usually an error in the preparation of the radiopharmaceutical or a patient identity error when it was injected.

With regard to protection of the general public and the environment, ASN noted no major deviations, but remains attentive in particular to the provisions limiting the discharges from these facilities.

1.3 Radiation protection in the industrial and research sectors

Industrial radiography

ASN carried out 9 inspections of industrial radiography activities in fixed facilities or on worksites in 2017.

ASN observes that the general organisation of radiation protection, training and dosimetric monitoring of the personnel exposed to ionising radiation and the conformity of the facilities with their regulatory design requirements remain satisfactory on the whole. ASN has however identified a need for vigilance in ensuring compliance with the required maintenance frequency for certain gamma ray projector models (GR50 and GMA2500). ASN also had to remind a large number of enterprises of the requirement to provide the personnel representatives with the annual report on the radiation dose received by the exposed personnel, to ensure transparency with respect to all the workers.

In the context of their oversight mission in Occitanie, the ASN inspectors drew up one violation report in 2017 due to the recurrent storage of gamma ray projectors in premises that do not figure in the license delivered by ASN.

Universities and laboratories or research centres

ASN conducted 7 inspections in universities and research laboratories in the Occitanie region in 2017.

ASN considers that the research laboratories on the whole comply with the regulatory requirements in radiation protection, particularly as concerns personnel training and the radiation protection controls. It observes that the radiation doses received by workers remain low. In addition, the tendency for establishments to share ionising radiation sources and radiation protection means between several research units is continuing in a satisfactory manner. ASN nevertheless expects greater diligence in the reporting of significant radiation protection events in some establishments.

ASN observes with approval that the research laboratories are increasingly endeavouring to acquire electrical ionising radiation generators that comply with the regulations, despite the presence on the market of numerous devices that are noncompliant or not referenced by ASN. ASN remains vigilant regarding the use of non-referenced devices.

ASN continued to check the implementation of the action plan of the Paul-Sabatier University in Toulouse for the removal of the expired sources and contaminated waste present in its waste bunker. It observes that the university has not achieved its end-of-2017 target deadline for removing these sources and waste and directing them to appropriate management routes.

Installations Classified for Protection of the Environment (ICPEs)

Regular discussions have been held between ASN and the Regional Directorate for the Environment, Planning and Housing (Dreal) of Occitanie concerning the modification of the nomenclature of Installations Classified for Protection of the Environment (ICPE) introduced by Decree 2014-996 of 2nd September 2014, which changes the division of competences between Dreal and ASN in these installations.

For the Areva Malvési ICPE in Narbonne, licensed by Prefectural Order and under the oversight of the classified installations inspectorate, occupational radiation protection is subject to joint monitoring by Dreal and ASN. One significant radiation protection event was reported to ASN in 2017. ASN takes positive note of this reporting, as it contributes to the licensee's transparency actions, but expects greater rigour in the curative and preventive measures applied to deal with such events. On this account, ASN participated in a widened health, safety and working conditions committee meeting in July 2017 convened on the installation following various adverse events.

1.4 Radiation protection of the public and the environment

Mining sites

In 2017, ASN continued to assist the Dreal in the monitoring of former uranium mining sites in the Hérault *département*.

Further to discussions with the Regional Health Agency (ARS), the Dreal of Occitanie and Areva Mines concerning monitoring of the former mining sites of Lodévois (Hérault *département*), the Dreal referred matters to ASN, firstly concerning the analysis of the conditions defined by Areva for the management of the old mining waste rock used in the public domain, secondly concerning the redevelopment work on the land of the former Bosc mining site which is to accommodate the future Michel-Chevalier regional business park (PRAE). In 2017, ASN gave a specific response about the methods of demolishing the buildings situated on the future regional business park, and plans giving a response to the remaining referred matters during 2018.

1.5 Nuclear safety and radiation protection in the transport of radioactive substances

ASN carried out 8 inspections in the area of radioactive substance transport addressing diverse players in 2017: BNIs, hospital centres and research organisations in Occitanie.

In the BNIs, on completion of the inspection carried out on the Golfech NPP, ASN considers that the site's organisation to ascertain the conformity of the packagings used to ship radioactive substances is on the whole satisfactory. Further to the inspections conducted on the Mélox plant and the Centraco facility, ASN also considers that the measures taken by the licensees of these two BNIs with regard to the shipment and reception of radioactive substances are satisfactory.

In the field of small-scale nuclear research, ASN underlines the good practices observed during the inspection carried out in 2017. The documentary system must nevertheless be improved.

In the medical field and in nuclear medicine departments in particular, the issues, the responsibilities and, more generally, the regulations relating to transport are still insufficiently taken into consideration, particularly in the management system of the centres. In some of the inspected centres ASN has nevertheless noted that inspections are carried out on reception and departure of the packages, which is an improvement in the management of this activity.

2. Additional information

2.1 Informing the public

Press conferences

ASN gave two press conferences on the situation of nuclear safety and radiation protection in the Occitanie region, held in Montpellier and Toulouse on the 3rd and 4th of October 2017 respectively. They addressed the safety of the Golfech NPP, of the Marcoule platform and the Ecrin facility, the transport of radioactive substances in the region and the radiation protection culture deficiencies observed in operating theatres.

Work with the Local Information Committees (CLIs)

ASN accompanied the work of the Golfech CLI by participating in one general assembly and several technical commission meetings. The CLI moreover designated observers who attended several inspections conducted by the ASN Bordeaux division at the Golfech NPP.

ASN was involved in the activities of the Marcoule-Gard CLI, and presented the results of its oversight actions conducted in 2017. ASN underlines the commitment of the members of this CLI regarding questions relating to BNI decommissioning and post-accident management.

In accordance with the provisions introduced by Act 2015-992 of 17th August 2015 relative to the Energy Transition for Green Growth Act, the Marcoule-Gard and Golfech CLIs each organised a public meeting held on 7th and 8th November respectively, in which ASN participated.

The public meeting organised by the Golfech CLI was devoted more specifically to the integration of the lessons learned from the Fukushima Daiichi accident, the updating of the off-site emergency plan around the NPP, and 2 events that occurred in 2017 and were rated level 2 on the INES scale.

The public meeting organised by the Marcoule-Gard CLI was devoted more specifically to application of the defence-in-depth concept to the Marcoule site facilities, during which ASN took positive note of the way the CLI fostered the involvement of the residents, living both near to and further from the site.

Pays de la Loire

The Nantes division regulates nuclear safety, radiation protection and the transport of radioactive substances in the 5 *départements* of the Pays de la Loire region.

The installations and activities to regulate comprise:

- the Ionisos irradiator in Sablé-sur-Sarthe;
- the Ionisos irradiator in Pouzauges;
- the facilities and activities using ionising radiation in the medical, industrial and research sectors:
  - medical services: 6 external-beam radiotherapy departments, 4 brachytherapy units, 11 nuclear medicine departments, 40 centres performing fluoroscopy-guided interventional procedures, 52 computed tomography scanners, about 2,500 medical and dental radiology devices;
  - industrial and research uses: one cyclotron, 34 industrial radiography companies, including 7 gamma radiography contractors, about 400 licences for industrial and research equipment, including 220 users of devices to detect lead in paint;
  - 5 radiation protection technical control agencies, one radon screening agency and one head office of laboratories approved for taking environmental radioactivity measurements.

In 2017, ASN carried out 34 inspections, of which 32 were in small-scale nuclear activities and 2 in the transport of radioactive substances.

Among the notified events, none was rated level 1 or higher on the INES scale and 7 events in radiotherapy were rated level 1 on the ASN-SFRO scale and one was rated level 1+ (cohort of patients).

1. Assessment by domain

1.1 The nuclear installations

Industrial irradiators operated by the company Ionisos

ASN considers that the Ionisos irradiators in the Pays de la Loire region are operated with due attention to nuclear safety and radiation protection.

ASN continued the examination of the periodic safety review of the Sablé-sur-Sarthe irradiator in 2017. ASN asked IRSN for an analysis and expert assessment of 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 is also 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.

In 2017, ASN authorised the extension of the handling hall of the Sablé-sur-Sarthe facility and the renovation of its fire safety and remote alarms transmission system. ASN also authorised the renovation of the Pouzauges facility's fire detection and extinguishing system.

Ionisos submitted the first periodic safety review of the Pouzauges site in 2017. ASN had asked the licensee to integrate the lessons learned from the safety review of the Sablé-sur-Sarthe site. ASN will examine this file in 2018.

1.2 Radiation protection in the medical field

External-beam radiotherapy

Three external-beam radiotherapy accelerator replacements were registered in 2017. The change in equipment is accompanied by the development of new techniques (primarily stereotaxy) which lead to new risks. Two of the six external-beam radiotherapy centres of the Pays de la Loire region were inspected in 2017. Risk management and the implementation of new treatment techniques (stereotaxy, etc.) were verified in depth.

As in 2016, following a phase of consolidation of the quality approach, the inspected centres are now resolutely engaged in a phase of quality management and continuous improvement. Although the "quality" objectives are regularly updated by their respective governing bodies, their monitoring and assessment can still be improved in some cases.

The risks induced by the new techniques are integrated in the prospective risk analysis with the putting in place of new requirements or defence barriers. However, deadlines and the people responsible for their implementation are not always specified.

The organisation for detecting and analysing adverse events is effective on the whole and contributes to the development of the risk analysis. A total of 7 significant radiation protection events concerning patients were reported to ASN in 2017 and rated level 1 on the ASN-SFRO scale. Among these events, 2 concerned medical prescription errors and gave rise to reactive inspections. Several common lessons have been learned from these events, particularly the difficulty in defining and putting in place effective barriers in order to detect this type of error as early as possible. Furthermore, one event concerning a symmetry defect in the treatment beam due to premature wear of the accelerator target will be made known at national level in view of its potentially generic nature. As this event concerned a cohort of patients it was rated level 1+ on the ASN-SFRO scale.

Finally, the efforts made in the last few years to recruit medical physicists, dosimetrists and physical measurement technicians now mean that all the centres can ensure, each day, the presence of at least one medical physicist during the treatment periods while freeing up medical radiation physicist time for the deployment of new treatment techniques. Nevertheless, the assessment of needs in medical physics merits being better finalised in most of the centres.

Fluoroscopy-guided interventional practices

Oversight of interventional practices has figured among the priority objectives of the Nantes division since 2014[1].

Despite the effort made over the last few years in the number of inspections and their prioritisation, the division has not yet inspected each centre at least once, emphasis having been placed on monitoring the sites presenting the most serious radiation protection issues. However, to raise radiation protection awareness within the centres and to reinforce the prioritisation approach, a survey was carried out in 2017 with the centres that had never been inspected and with a few centres with a very low level of activity in this area but whose practices nevertheless were considered to merit monitoring in view of the findings of the first inspection. This initiative moreover allowed the volume of activity of these centres to be updated and the two sites which in the first survey had declared they did not carry out fluoroscopy-guided interventional procedures to be identified. This instrument was also used to refine the targeting of the inspections on the 2018 schedule.

Ten centres were inspected in 2017 out of the 40 centres in the Pays de la Loire region. The results show that the situation with regard to radiation protection remains contrasted. Thus, despite the generally active involvement of the radiation protection expert-officers, their action suffers from a lack of coordination and institutional follow-up, which limits its impact.

Among the inspected centres, the Angers University Hospital, which performs procedures involving significant radiation risks, has made little progress in radiation protection in the operating theatres despite the regular inspections by ASN and the involvement of its radiation protection and medical physics department. The inspection scheduled for this hospital in 2018 will serve to check the effectiveness of the measures to improve radiation protection in the operating theatres defined by the hospital general management in the action plan it presented to ASN in January 2018.

Generally speaking, radiation protection is better taken into account for workers than for patients, even if continued efforts are required in the quantification of doses and protection of the lens of the eyes and the extremities of health professionals.

Regarding the radiation protection of patients, there is significant room for progress in the training of practitioners in the radiation protection of patients and in terms of effective implementation of the optimisation procedures, particularly when using third-party medical physics services. The creation of regional hospital groupings could provide an opportunity for pooling medical physics functions and developing the effective presence of medical physicists in the hospitals.

Nuclear medicine

Five nuclear medicine units were inspected in 2017. These inspections on the whole revealed an improvement in the integration of ASN's demands.

With regard to occupational radiation protection, the involvement of the radiation protection expert-officers and the efforts devoted to the radiation protection training and the medical monitoring of workers are to be underlined. Worker dosimetric monitoring means are also satisfactory, save for nuclear medicine physicians, who do not make sufficient use of dosimeters. Coordination of radiation protection measures for outside companies, such as cleaning contractors, can be improved in the majority of the centres inspected.

As far as patient radiation protection is concerned, the analysis of the dosimetric readings with respect to the diagnostic reference levels in order to optimise the doses administered to the patients can be improved.

1. *62 inspections carred out in the Bretagne – Pays de la Loire regions during the 2014-2017 period, out of a total of 77 centres (82 sites).*

With regard to environmental protection, waste and effluent management is satisfactory but the formalisation of the waste and effluent management plans can be improved to comply with ASN resolution 2008-DC-0095 of 29th January 2008. Furthermore, evidence to substantiate the conformity of the ventilation system of the premises with ASN resolution 2014-DC-0463, approved by the Order of 16th January 2016 is to be provided in 2018.

Lastly, 6 significant radiation protection events were reported in 2017 (10 in 2016).

Computed Tomography

Only one centre was inspected in 2017. This inspection focused more specifically on patient radiation protection, which is found to be properly implemented in this centre. Quality controls and personnel training are carried out at the required frequencies and measures are taken to optimise the doses delivered to patients.

A few adjustments are nevertheless still required to improve worker radiation protection with regard to the signalling of regulated work areas and the revision of the job and work environment studies.

1.3 Radiation protection in the industrial sector

Industrial radiography

ASN carried out 5 inspections of industrial radiography activities in the Pays de la Loire region in 2017, of which one was a worksite inspection.

The findings are relatively similar to those of 2016. ASN notes that the regulatory requirements are on the whole met with regard to the organisation of radiation protection, operator training and monitoring and equipment maintenance. Progress remains to be made however in the assessment of risks, the analysis of doses received by workers, the tidiness of exposure bunkers, the filling out of gamma ray project tracking documents, operator knowledge of their dosimeter alarm thresholds, the existence of prevention plans with all the outside contractors working in controlled work areas and the communication of projected worksite schedules.

1.4 Nuclear safety and radiation protection in the transport of radioactive substances

In 2017, ASN conducted 2 inspections dedicated exclusively to the transport of radioactive substances in the Pays de la Loire region. One of the inspections focused on the duties of the Transport Safety Advisor (TSA) of a company providing TSA services to other radioactive substance transport carriers. This inspection did not lead to any corrective action requests. The second inspection concerned a nuclear medicine department, and more specifically the organisational set-up for the reception of pharmaceutical packages. This inspection, which was the first transport inspection for this nuclear medicine department, concluded that its organisation needed to be substantially improved in the short term. More specifically, serious shortcomings were noted in the checks conducted on reception and shipping of the radionuclides. In addition, the centre had neither a radiological protection plan nor a plan for the management of radioactive substance transport incidents and accidents.

1.5 Radiation protection of the public and the environment

Radon

ASN has participated since 2009 in the campaigns for radon measurement in private homes organised by the city of Nantes. Two public meetings were held during each campaign: the first ending with the issuing of dosimeters to the inhabitants of the districts concerned by the campaign, and the second during which the measurement results are detailed and remediation actions are proposed. Since 2016, other campaigns for radon measurement in private homes have been undertaken by Pays de la Loire municipalities with the support of associations funded by the call for proposals baptised “Act for an environment that fosters health” of the second Regional Health and Environment Plan (“PRSE2”). Consequently, ASN gave public presentations on radon-related risks in 2017 in the towns of Nantes, Bouguenais, Blain and in five municipalities of the Vendéen Bocage Territory.

Distribution of the general public information leaflet on radon-related health risks, which was created in 2016 in collaboration with the Regional Directorate for the Environment, Planning and Housing (Dreal) and the Regional Health Agency (ARS), continued, in particular as part of the communications drive on indoor air quality.

ASN also contributes to the finalisation of the third Regional Health and Environment Plan (PRSE3) of the Pays de la Loire region, coordinated by the Dreal and the ARS. It more specifically leads the working group responsible for conducting radon communication actions with the general public, professionals of the building trade and health sectors, building trade training organisations, owners of buildings open to the public, etc.

Mining sites

ASN keeps a close watch on the progress of Areva’s actions around the sites in the public domain where uranium mining waste rock has been reused.

Two inspections were carried out in 2017 on the sites in the region which have been chosen and authorised to receive the mining waste rock resulting from remediation work conducted in Pays de la Loire: the Écarpière site (Loire Atlantique *département)* and the Commanderie site (Vendée *département)*. These inspections confirmed that Areva complies with the provisions concerning radiation protection, the Prefectural Orders regulating the disposal of these materials, dated 4th August 2016 and 9th January 2017 for the Écarpière and Commanderie sites respectively.

ASN has also focused particular attention on Areva’s work in the region to remove the mining waste rock reused in the public domain and on the complementary studies conducted in the Guérande sector. ASN also backed the Dreal’s request to have IRSN perform an analysis and expert appraisal in this sector in view of the work carried out by Areva.

ASN also took part in the information and consultation meeting organised by the Loire-Atlantique Prefecture in October 2017 concerning the Écarpière site. During this meeting, ASN reiterated its desire to have Areva conduct complementary studies on the sites on which mining waste rock has been reused and which have had no work done on them. These studies will enable ASN and the State services to decide whether or not it is necessary to oblige Areva to perform additional remediation work on these areas.

With regard to mining waste rock reuse sites presenting a radon problem in living areas (residential or corporate buildings), Areva carried out an initial radon screening campaign at the request of the State. Despite a return rate of less than 50%, this campaign led to the identification of eight places with radon concentrations exceeding 2,500 Bq/m^3. For some buildings, the Dreal and ASN asked IRSN to perform a third-party expert assessment to determine whether the radon was of natural or anthropogenic origin. In situations where anthropogenic origin was confirmed, Areva was asked to carry out work in 2016 to reduce the radon concentrations. As the radon exposure reduction work had not yet been started, the Prefect, on proposal from the Dreal and after consulting ASN, issued formal notice to Areva to carry out this remediation work. ASN also asked for dosimeters to again be distributed to the populations concerned.

Lastly, ASN has issued a favourable opinion on the disposal project for the radiologically marked sludge and sediments from the former Breton mining sites. The disposal of these materials was authorised by Prefectural Order dated 21st August 2017.

2. Additional information

2.1 Informing the public

Press conference

ASN held a press conference in Nantes on 19th September 2017 to present the situation of nuclear safety and radiation protection.

Work with the Local Information Committees (CLIs)

ASN took part in the meeting of the Sablé-sur-Sarthe CLI on 5th October 2017 and that of the Pouzauges CLI on 26th October 2017, during which Ionisos presented its annual reports.

2.2 International action

The Nantes division contributed to a training course organised by the International Atomic Energy Agency (IAEA) in Cameroon on the effective and lasting regulatory control of ionising radiation sources with the heads of the African radiation protection Authorities.

Provence-Alpes-Côte D'azur

The Marseille division regulates nuclear safety, radiation protection and the transport of nuclear substances in the 6 *départements* of the Provence-Alpes-Côte-d'Azur (PACA) region.

The installations and activities to regulate comprise:

- BNIs:
  in Cadarache:
  - the CEA Cadarache research Centre which counts 21 BNI's, including the Jules Horowitz Reactor currently under construction;
  - the ITER installation construction site, adjacent to the CEA Cadarache Centre;

  In Marseille:
  - the Gammaster industrial ioniser;
- small-scale nuclear activities in the medical sector:
  - 12 external-beam radiotherapy departments;
  - 4 brachytherapy departments;
  - 19 nuclear medicine departments;
  - 108 centres performing fluoroscopy-guided interventional procedures;
  - 102 computed tomography scanners;
  - some 8,200 medical and dental radiology devices;
- small-scale nuclear activities in the industrial and research sectors:
  - about 400 industrial and research establishments, including 21 companies exercising an industrial radiography activity, 3 Cyclotron particle accelerators, 144 laboratories situated mainly in the universities of the region, and about 300 users of devices for detecting lead in paint;
  - about 260 veterinary surgeries or clinics practising diagnostic radiology;
- ASN-approved laboratories and organisations:
  - 3 head offices of laboratories approved for taking environmental radioactivity measurements;
  - 5 organisations approved for radiation protection controls.

In 2017, ASN carried out 109 inspections in the PACA region, of which 51 were in BNIs, 52 in small-scale nuclear activities and 6 in the transport of radioactive substances.

During 2017, two significant events rated level 1 on the INES scale were reported by nuclear installation licensees. In small-scale nuclear activities, 5 significant events rated level 1 on the INES scale were reported to ASN. Seven events involving radiotherapy patients were rated level 1 on the ASN-SFRO scale.

1. Assessment by domain

1.1 The nuclear installations

CEA Cadarache centre

ASN carried out 47 inspections relating to BNIs in the CEA Cadarache centre in 2017 and considers that the level of nuclear safety remains satisfactory on the whole. It notes that the disparities observed previously between the centre facilities are still present in certain areas. Inspections of the STD and STE facilities nevertheless ascertained that the operating rigour and the compliance with commitments, the subject in 2016 of ASN's formal notice to improve, have returned to a satisfactory level. ASN nevertheless remains attentive to the licensee's commitments regarding these facilities and which have not yet been met. ASN also noted the transfer of operational management of the Plutonium Technology Facility (ATPu) and the Chemical Purification Laboratory (LPC) to the CEA on 31st January 2017, and remains attentive to the continuity of the decommissioning operations that Areva NC began.

ASN points out that the CEA must carry out several concurrent large-scale projects of different types and with varied safety risks on the Cadarache centre. With regard to the decommissioning and legacy radioactive waste retrieval and packaging work, whether it concerns the spent fuel storage pool on the Pégase installation, the Rapsodie experimental reactor (shut down), the enriched uranium processing facilities, the central fissile material warehouse or the radioactive waste storage yard, ASN notes that the milestones for removal of waste and spent fuel are duly followed. With regard to the ATPu and the LCP, the work coordinated by Areva NC to remove the glove boxes and proceed with the radioactive clean-out of the cells is finished. Concerning the continued operation of the old facilities, the licensee submitted ten periodic safety review reports in 2017. These reports, which analyse the regulatory conformity of the facilities and present continuous improvement action plans for nuclear safety and radiation protection, will be examined in the years to come. With regard to the BNI construction or redevelopment work, ASN considers that construction of the Jules Horowitz Reactor (JHR) is proceeding with the required rigour. The qualification tests of the Cabri reactor in its new configuration were satisfactory, although management of the reactor trips associated with these tests could be improved.

The measures taken in the Centre with regard to the management of nuclear safety and radiation protection are on the whole satisfactory, despite the complexity of the CEA's organisation. With regard to the monitoring of outside contractors, ASN notes the entry into application of monitoring plans for work performed on elements important to protection. In addition, the coordination of analyses to learn lessons from significant events that could be of interest to several BNIs at the Centre is now operational.

ASN makes a positive assessment of operation of the BNIs in several areas. Skills and training are well managed. Social, organisational and human factors are generally properly taken into account in the events analyses and in the modifications requests. The management of periodic checks and tests has improved and reached a satisfactory standard. ASN notes the progress in compliance with the operating rules and related documents.

ASN considers that the CEA must continue its efforts to improve protection against the fire risk and waste management. With regard to protection against the fire risk, ASN has asked the CEA to ensure greater operational readiness of its emergency teams. It will notably be attentive so ensure that the "fire" drills are conducted under as realistic conditions as possible. With regard to waste management, an in-depth inspection conducted from 25th to 29th September 2017 concluded that waste management in the centre was relatively satisfactory, with good practices to be consolidated and some areas to be improved, such as compliance with the storage rules. Overall coordination of the Cadarache centre is relatively satisfactory, but must be tightened, particularly in taking into account the challenges of the BNIs concerned by waste management and deviation management. ASN will also be attentive to ensure that ASN resolution 2017-DC-0587 of 23rd March 2017, applicable on 1st July 2018, is taken into account in the centre's planned change in coordination.

With regard to experience feedback from the Fukushima accident, the CEA has met with difficulties in starting the construction of robust premises for emergency situation management provided for in ASN resolution 2015-DC-0479 of 8th January 2015. The licensee has asked that the initial prescribed deadline of 30th September 2018 be pushed back. This request is currently being examined. ASN will take into account the fact that these premises will have to be designed to withstand extreme earthquake and tornado hazards.

The environmental protection measures taken by the centre are satisfactory. The revision of the provisions relative to the discharge authorisations was concluded in July 2017 when ASN signed resolutions relative to the discharge "conditions" and "limits" for the site BNIs. The new arrangement takes better account of the actual operating situation of the centre's BNIs and governs the updating of the impact studies of some of the BNIs. The licensee is currently integrating the new provisions of these resolutions in its operating baseline requirements.

ITER

ASN carried out 3 inspections of ITER in 2017, including one 3-day inspection of the European domestic agency[1] Fusion for Energy (F4E) in Barcelona. This inspection was carried out as a follow-up to ASN's request to the nuclear licensee ITER Organization to reinforce its monitoring of the domestic agency F4E with regard to certain work packages manufactured in Europe.

Despite substantial delays, the construction and manufacturing work and the procurement of equipment for the facility continued under satisfactory conditions. ASN notes the continued efforts in the organisation of this international project. The nuclear licensee asked for a modification of ASN resolution 2013-DC-0379 of 12th November 2013 governing the project design/construction, further to ITER's adoption of a strategy of gradual commissioning of the facility and "critical path" management of the project schedule. ASN resolution 2017-DC-0601 of 24th August 2017 amends the abovementioned resolution.

The ASN inspections have highlighted a significant improvement in the way the licensee ITER embraces the safety requirements and in their dissemination along the subcontracting line. ASN nevertheless expects more attentive monitoring of the activities important to protection of certain work packages, particularly concerning the buildings and utilities.

Gammaster ioniser

ASN carried out one inspection of Gammaster in 2017 and considers that the level of nuclear safety and radiation protection remains satisfactory. Improvements have been observed in deviation management. The licensee must continue its efforts, for example, by taking into account international experience feedback from similar facilities, by improving its environmental sampling methodology and control, and by finalising the regulatory watch measures undertaken.

The licensee moreover submitted the first periodic safety review of the installation to ASN on 30th December 2016, for which an additional information request was made on 24th July 2017.

1. *Each of the seven countries or group of ITER member countries (China, the European Union, India, Japan, South Korea, Russia, the United States) has created a "Domestic Agency" responsible for providing the nuclear operator with the elements of the installation for which it has been entrusted the manufacture.*

1.2 Radiation protection in the medical field

External radiotherapy and brachytherapy

ASN carried out 4 inspections in external-beam radiotherapy and 2 in brachytherapy in the radiotherapy departments of the PACA region in 2017. ASN observed the continued efforts made by the radiotherapy departments to effectively implement a treatment quality and safety management system. Nevertheless, proper implementation of management reviews that take into account experience feedback, internal and external audits, patient satisfaction analyses and continuous improvement loops still requires particular attention.

ASN observes moreover that the prospective risk analysis procedure, which should result in the setting up of appropriate barriers, is still not carried out in sufficient depth. This procedure must be carried out and updated prior to the installation of a new device or a new technique in order to avoid adverse events concerning patient radiation protection. In this respect the departments will have to ensure that their approach is formally structured, in accordance with the opinion of the Advisory Committee for Radiation Protection in Medical and Forensic Applications of Ionising Radiation.

Fluoroscopy-guided interventional practices

ASN carried out 7 inspections of centres performing fluoroscopy-guided interventional procedures in the PACA region in 2017. These inspections, carried out as much in the operating theatre as in facilities dedicated to cardiology, neuroradiology and vascular radiology, revealed disparities between dedicated structures, which on the whole comply with regulatory requirements, and operating theatres, where there is a lack of radiation protection culture in the medical personnel. In this respect, ASN notes that in 2017 it received no significant event notifications relating to patient radiation protection from any of the 108 centres concerned.

The regulatory provisions relative to worker dosimetric monitoring are poorly applied and the use of collective protective equipment, the provision and wearing of dosimeters and the performance of radiation protection technical controls remain weak points.

With regard to patient radiation protection, the observed weaknesses concern aspects such as the generally insufficient number of medical physicists and radiographers, the technical training of practitioners in the use of the machines (and the possibilities of patient dose optimisation that they offer), or the drawing up of dose optimisation protocols for the most common procedures and the indication of dosimetric information in the procedure reports.

Nuclear medicine

ASN carried out four inspections in nuclear medicine in the PACA region in 2017. The generally positive momentum in taking radiation protection into account in the inspected departments and centres is continuing, with the noteworthy gradual involvement of senior management.

The inspected departments have increasingly modern premises and equipment at their disposal further to the relocating of departments and the replacement of old equipment. Patient radiation protection is satisfactory. Worker radiation protection is generally satisfactory, but the coordination of prevention measures must be improved, not only with the private practitioners but also with the outside contractors performing work in the departments concerned. The improvement in the management of radioactive waste and effluents noted in 2016 continued in 2017, with ASN noting in particular a substantial increase in the number of authorisations to discharge non-domestic wastewater into the public sewage networks, as provided for by the Public Health Code. The waste management plans on the other hand, are most often either incomplete or require updating.

Computed Tomography

ASN performed three inspections in computed tomography in 2017 and considers that the radiation protection implications of this activity are on the whole well taken into account given the risks inherent to the activity. ASN notes a relatively stable number of significant radiation protection event notifications in computed tomography, with 10 events reported in 2017 compared with 12 in 2016, which adds to the experience feedback and lessons learned, while remaining low with respect to the 104 computed tomography licenses currently in effect in the PACA region.

As far as worker radiation protection is concerned, ASN takes positive note of the involvement of the radiation protection expert-officers in the centres, the means allocated to them and the recognition of their role by senior management. Progress is however still required in the medical monitoring of exposed workers, particularly private-sector physicians. With regard to patient radiation protection, ASN considers that the robustness of the patient identity verification process needs to be improved. Furthermore, the medical physics organisation plans remain incomplete, particularly with regard to the coordination of several centres belonging to a same given structure.

ASN also remains attentive to the use of the computed tomography scanner in particular conditions. More specifically, the provisions for radiation protection when mobile CT scanners are installed and used in vehicles when centres are undergoing works can usually be improved. Furthermore, ASN can only authorise the use of remote scanners (teleradiology) if particular radiation protection measures can be guaranteed.

1.3 Radiation protection in the industrial and research sectors

Industrial radiography

ASN carried out 11 inspections of industrial radiography activities in bunkers or on worksites in 2017, and the overall radiation protection result is satisfactory. ASN nevertheless observes a contrasted situation regarding the transmission of work schedules, with the improvement that began in 2016 remaining gradual and vulnerable.

Universities and laboratories or research centres

In 2017, ASN carried out one inspection in a university that uses ionising radiation, and in which the management of radioactive sources is relatively satisfactory. The inspection revealed an improvement in the radiation protection controls of the measuring devices, but radiological zoning remains a weak point. The management of radioactive effluents can also be improved.

1.4 Radiation protection of the public and the environment

Contaminated sites and soils

In 2017, ASN continued its initiative to identify – and make safe – sites contaminated by radioactive substances. This initiative resulted more specifically in providing technical support to the PACA Dreal for the development of the soil information sectors provided for by Act 2014-366 of 24th March for access to housing and renovated urban planning and by the Environment Code, which inventory the plots of land for which the knowledge of any soil pollution justifies, particularly in the event of a change in use, the performance of soil studies and taking of pollution management measures.

Technologically enhanced naturally occurring radioactivity

In 2017, ASN provided the PACA Dreal with technical support, notably through the analysis of the draft Prefectural Orders containing a radiological section.

Radon

ASN performed 2 inspections on the radon theme in primary schools of the Hautes-Alpes in 2017. These inspections, conducted jointly by ASN and the ARS, targeted buildings in which radon concentrations exceeding the regulatory action triggering thresholds had been evidenced in 2004. These inspections showed that measures had been taken to ventilate the buildings in question. However, the measurements of the radon concentration in the building after installing the ventilation systems had not been carried out, therefore it is not yet confirmed that the concentration has fallen below the regulatory threshold of 400 Bq/m^3. The setting up of additional actions will be monitored in 2018 and verified by an approved organisation.

1.5 Nuclear safety and radiation protection in the transport of radioactive substances

ASN carried out 4 inspections in the area of radioactive substance transport addressing diverse players: BNIs, hospitals and transport carriers working in small-scale nuclear activities.

In the BNIs, ASN considers that application of the regulations is on the whole satisfactory, given the notified events and the facilities inspected in 2017.

With regard to small-scale nuclear activity carriers, ASN considers that the regulations are on the whole correctly applied in practice (verifications, condition of vehicle, transport documents, etc.). Nevertheless, the carriers' proficiency in the use of the documentary system must be significantly improved.

In the medical field and in nuclear medicine departments in particular, the issues, the responsibilities and, more generally, the regulations relating to transport are still insufficiently taken into consideration, particularly in the management system of the centres. In some of the inspected centres ASN has nevertheless noted that inspections are carried out on reception and departure of the packages, which is an improvement and demonstrates enhanced management of this activity.

2. Additional information

2.1 Informing the public

Press conference

ASN held a press conference in Marseilles on 5th October 2017 on the situation of nuclear safety and radiation protection in the PACA region.

Work with the Local Information Committees (CLIs)

ASN involved itself in the activities of the Cadarache CLI (which also has competence for the ITER and Gammaster facilities), by participating in some ten technical meetings.

In accordance with the provisions introduced by Act 2015-992 of 17th August 2015 relative to the Energy Transition for Green Growth, the Cadarache CLI organised public meetings for the Cadarache CEA on the one hand and ITER on the other. It also organised a meeting between the CLIs of the Rhône valley which took place on 18th and 19th May 2017. This event brought together about ten CLIs and their stakeholders (local authorities, departmental and regional councils, ASN, IRSN, licensees, etc.). Three themes (relations between the public, the licensee and ASN; the performance of independent analyses and expert assessments; waste management) were adopted with a view to sharing experience, and should lead to the creation in 2018 of a national working group on the management of very low level radioactive waste. It also organised a measurement campaign to assess the possible migration of contamination from the interior to the exterior of the site. ASN underlines the dynamism of this CLI and the level of investment of its members on the national scale.

2.2 International action

In 2017, ASN participated for the PACA region in an exchange of good practices with the Belgian nuclear safety authority, AFCN, on the safety of irradiators through cross-inspections in France and Belgium.

2.3 Other notable events

ASN took part in an emergency exercise played out at the CEA Cadarache centre, which on the first day involved activation of the site's off-site emergency plan further to a simulated accident on a defence basic nuclear installation, followed on the second day by the management of a population protection phase and entry into the post-accident phase.

09

Medical uses of ionising radiation

Fore more than a century now, medicine has made use of ionising radiation produced either by electric generators or by radionuclides in sealed or unsealed sources for both diagnostic and therapeutic purposes. 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 treatments using ionising radiation is regulated by specific provisions of the Public Health Code. 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

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 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 examination exposure level and the dose history and the possibilities offered by other non-irradiating investigative techniques. An updated guide intended for medical doctors *(Guide to good medical imaging examination practices)* indicates the most appropriate examinations to request according to the clinical situations (see box).

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 tree (arteriography) or venous tree (venography) 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 required in order to make a diagnosis, 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 technique for three-dimensional imaging of the breast called "tomosynthesis", which reconstructs the breast from

FUNDAMENTALS

Medical imaging: several imaging techniques can be used for a given organ

The physician's diagnostic approach based on the history of the illness and the clinical examination of the patient can be supplemented by specific examinations (medical imaging, biological analyses, etc.).

Four broad medical imaging techniques are available today. 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 (a drug consisting of a vector marked by a radioactive isotope or an isolated radionuclide) administered to a patient. 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 the properties of ultrasounds to echo (reflect) off interfaces, whether these interfaces are the anatomical boundaries of organs or heterogeneous areas within an organ or tissue. The recorded echoes allow the reconstruction of an image of the explored area. By combining this with the Doppler effect 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 produce a slice image.

Radiology and nuclear medicine that use ionising radiation are regulated by ASN, the French nuclear safety Authority. 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*.

a series of slice images, is developing 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 for use in 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, also known as a multi-slice or volumetric CT scanner) has been increased in recent machines, enabling thinner slices to be produced. An examination can comprise several helical image acquisitions of a specific anatomical region (with or without injection of a contrasting agent) or of different anatomical regions.

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 technologies developed 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.[1] The placing of mobile computed tomography systems on the market for intraoperative use is to be underlined, as is the increase in fluoroscopy-guided interventional CT procedures.

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). Technical progress has nevertheless brought a new mode of image reconstruction in the form of iterative reconstruction. Computed tomography can thus provide consistent image quality at reduced doses.

As at 31st December 2017, the French pool of radiological devices included slightly more than 1,100 computed tomography facilities covered by an ASN license.

1. *The term indication means a clinical sign, an illness or a situation affecting a patient which justifies the value of a medical treatment or a medical examination.*

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.

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 images to a radiologist in order to obtain an interpretation. 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 (fluoroscopy-guided interventional practices) group *"all the techniques using ionising radiation to perform invasive medical or surgical procedures for diagnostic, preventive and/or therapeutic purposes, and surgical and medical procedures using ionising radiation for the purpose of guidance or verification"*.

The devices used are either fixed devices installed in rooms dedicated to this activity, chiefly vascular specialities (neuroradiology, cardiology, etc.), or mobile radiology devices used in operating theatres in several surgical specialities, such as gastroenterology, orthopaedics and urology.

The detectors present on the dedicated fixed devices and on the operating theatre radiology devices are image intensifiers or flat panel detectors. These devices employ techniques that use fluoroscopy and dynamic radiography (called "photofluorography", or "cineradiography") intended to produce high-resolution spatial images. After injecting a contrast agent, practitioners can also use the subtraction method to obtain images.

The O-arm®, new CT scanner for the operating theatre.

Surgeons have recently started to use CT scanners, sometimes mobile, in the operating theatre. This type of equipment helps the practitioner perform the procedure by providing multi-plane images allowing virtual navigation. These scanners however are not equipped with the latest dose reduction technologies.

The staff usually work in the immediate vicinity of the patient and are also exposed to higher dose levels than during other imaging 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 and recent 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 because these healthcare activities require an authorisation from the Regional Health Agency (ARS). The regional divisions of ASN moreover use 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 trade-off for this better diagnostic performance is that these devices deliver significantly higher doses than in conventional dental radiology.

Portable X-ray generating devices

ASN and the Dental Radiation Protection Commission (CRD) published an information notice in May 2016[2] reiterating the rules associated with the possession and utilisation of portable X-ray generating devices. They draw attention to the fact that *"the performance of radiological examinations outside a room fitted out for that purpose must remain the exception and be justified by vital medical needs, limited to intraoperative examinations or for patients who cannot be moved. Routine radiology practice in a dental surgery equipped with a compliant facility shall not be carried out using mobile or portable devices"*.

This position is supported by that of HERCA (Heads of the European Radiological protection Competent Authorities), for which the use of such devices should be reserved for incapacitated patients, forensic medicine and military field operations (*HERCA Position Statement on use of handheld portable dental x-ray equipment,* June 2014).

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.

Mobile facilities, but which are often always used in the same room, such as the X-ray generators used in operating theatres, are to be considered fixed facilities.

Radiological facilities must be fitted out in accordance with the provisions of the new ASN technical resolution 2017-DC-0591 of 13th June 2017 (see chapter 3). This decision applies to all medical radiology facilities, including computed tomography and dental radiology. It does not however apply to X-ray generators that are used exclusively for bedside radiography.

2. *www.asn.fr/Informer/Actualites/Appareils-electriques-portables-rappel-de-l-ASN-et-de-la-Commission-Radioprotection-Dentaire*

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.

About 1,460,000 procedures were carried out in 2016[3], including 406,000 Positron Emission Tomography (PET) examinations. Nuclear medicine comprises slightly more than 700 specialist practitioners, along with another 1,000 or so physicians from other specialities working together in nuclear medicine units (interns, cardiologists, endocrinologists, etc.).

At the end of 2016, this sector of activity comprised 232 nuclear medicine units accommodating the associated *in vivo* and *in vitro* facilities. Nearly 160 automated or semi-automated devices for preparing radiopharmaceuticals marked with fluorine-18 and as many injection devices are used.

Some fifty *in vitro* diagnostic laboratories were inventoried in 2017, but this number is tending to drop due to the gradual phasing out of this activity in favour of methods that do not use radionuclides.

For therapeutic purposes, there are 157 Internal Targeted Radiotherapy (ITR) hospital rooms spread over 45 nuclear medicine units[4].

Medical dispensaries are mandatory in public health institutions. The radiopharmaceutical preparation room, called the "radiopharmacy" within the nuclear medicine department, is part of the dispensary. There are 128 nuclear pharmacies among the 232 nuclear medicine departments. The radiopharmacist is primarily responsible for managing the medication circuit (procurement, possession, preparation, dispensing and traceability) and can be assisted by a hospital dispensary preparation technician or by radiographers.

3. *Dashboard of the SFMN (French Society of Nuclear Medicine and Molecular Imaging): www.sfmn.org/drive/SECRETARIAT%20GENERAL/ENQUETE_ANNUELLE/EnqueteNationale2016_publicWeb.pdf*
4. *Source: ASN review of nuclear medicine department inspections (2016).*

TABLE 1: Some of the main radionuclides used in the various *in vivo* nuclear medicine examinations

TYPE OF EXAMINATION	RADIONUCLIDES 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
Renal exploration	Technetium-99m
Oncology - search for metastasis	Technetium-99m, Fluorine-18, Gallium-68
Neurology	Technetium-99m, Fluorine-18

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.). Table 1, for example, 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 (Positron Emission Tomography – PET camera). The principle of operation of PET cameras is the detection of the coincidence of the two 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. In 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).

The installation of semi-conductor cameras (CZT -Cadmium Zinc Telluride), which have very high detection sensitivity, is developing in particular in healthcare centres that perform a large number of examinations of the myocardial function.

2.1.2 *In vitro* diagnosis

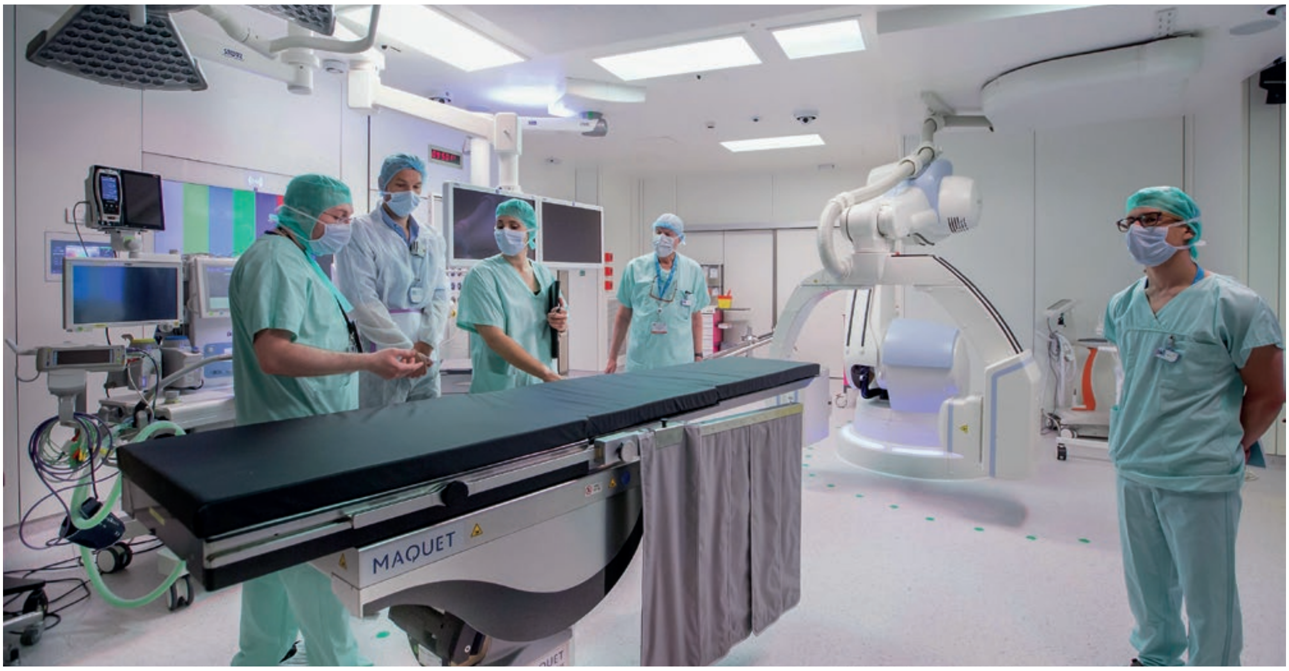
This is a medical biology technique for assaying certain compounds contained in biological fluid samples taken from the patient, such as hormones, tumour markers, etc., and it does not involve administering radionuclides to the patients. The technique uses assay methods based on immunological reactions (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 Internal targeted radiotherapy

Internal Targeted Radiotherapy (ITR) aims to administer a radiopharmaceutical emitting ionising radiation which will deliver a high dose to a target organ for curative or remedial

TABLE 2: Number and type of tomography cameras used in nuclear medicine (2017)

POSITRON EMISSION TOMOGRAPHY CAMERAS COUPLED TO A COMPUTED TOMOGRAPHY SCANNER (PET-CT)	SINGLE PHOTON EMISSION COMPUTED TOMOGRAPHY (SPECT) CAMERAS	HYBRID CAMERAS COMBINING A COMPUTED TOMOGRAPHY SCANNER WITH SPECT-CT	PET CAMERAS COUPLED WITH AN MRI MACHINE
145	200	250	3 and 2 at project stage



ASN inspection of the interventional radiology department at the Strasbourg University Hospital, May 2017.

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 through a catheter placed in a hepatic artery).

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 or 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 Research in nuclear medicine involving humans

Research on humans in nuclear medicine has been particularly dynamic in the last few years: protocols are regularly developed for new radionuclides and vectors. Research is continuing into the use of:
- PET with fluorine-18, gallium-68 and rubidium-82;
- ITR with radium-223, microspheres labelled with yttrium-90, vectors labelled with yttrium-90 or lutetium-177 (particularly for the treatment of neuroendocrine tumours).

The use of new radiopharmaceuticals means that the radiation protection requirements associated with their use 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.

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 to the handling of certain radionuclides (case with fluorine-18, iodine-131 or yttrium-90) when preparing and injecting radiopharmaceuticals, and a risk of internal exposure through accidental intake of radioactive substances. Given these conditions, 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 governing *in vivo* nuclear medicine facilities.

This resolution details in particular the rules for the ventilation of nuclear medicine unit premises and the rooms accommodating patients receiving, for example, treatment for thyroid cancer with iodine-131. Guide No. 32 detailing certain aspects of this resolution was published by ASN in May 2017 (*www.asn.fr*). 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 2017-DC-0591 of 13th June 2017 (see chapter 3).

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 200,000 patients[5] are treated each year, which represents nearly 4 million radiation sessions. 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.

One hundred and seventy-two radiotherapy centres hold an ASN license, half with public status and half in private practice. The pool of external-beam radiotherapy facilities comprises 476 treatment devices, of which 461 are conventional linear accelerators (Radiotherapy observatory, INCa 2016). Seven hundred and fifty radiation oncologists were listed in the directory of the French Society for Radiation Oncology (SFRO) in 2016. Lastly, 63 radiotherapy centres hold an ASN license to perform brachytherapy treatments.

3.2. The various external-beam radiotherapy techniques

The irradiation sessions are always preceded by preparation of a treatment plan which precisely defines the dose to be delivered, the target volume(s) to be treated, the volumes at risk to be protected, 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).

3.2.1 Three-dimensional conformal radiotherapy

This technique uses three-dimensional images of the target volumes and neighbouring organs obtained with a CT scanner, sometimes in conjunction with other imaging examinations (MRI, PET, etc.).

During a three-dimensional conformal radiotherapy treatment, the shape of each beam is fixed and the dose delivered by each beam is uniform within the treatment field delimited by the multi-leaf collimator.

In its guide giving recommendations for the practice of external-beam radiotherapy and brachytherapy (Recorad) published in September 2016, the SFRO considers that this irradiation technique is used as the basic technique by all the French centres for all patients receiving curative treatment.

It has nevertheless been observed in the last few years that the proportion of treatments using this technique is giving way to intensity-modulated conformal radiotherapy.

3.2.2 Intensity-modulated conformal radiotherapy

Intensity-Modulated (conformal) Radiotherapy (IMRT) is a technique that was developed in France in the early 2000's. Unlike 3D conformal radiotherapy, the collimator leaves move during irradiation, enabling the intensity of the beams - and therefore the delivered dose - to be modulated during irradiation to better adapt to complex volumes and better protect the neighbouring organs at risk.

Volumetric modulated arc therapy

Following on from IMRT, volumetric arc therapy is now being used more and more frequently 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.

Helical radiotherapy

Helical radiotherapy, marketed under the name TomoTherapy®, or RadixactTM for the subsequent generation, 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

5. 204,471 persons with cancer were treated by radiotherapy in 2015: 113,384 in the public sector and 91,087 in the private sector. www.e-cancer.fr/Professionnels-de-sante/Les-chiffres-du-cancer-en-France/Activite-hospitaliere#toc-radioth-rapie 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. The system requires the acquisition of images under the treatment conditions of each session for comparison with reference computed tomography images in order to reposition the patient.

Thirty-two systems of this type were installed in France (Radiotherapy observatory INCa 2016).

3.2.3 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 190 cobalt-60 sources towards a single focal spot (five units are currently in service in four centres in France);
  - CyberKnife® which consists of a miniaturised linear accelerator mounted on a robotic arm (robotic stereotactic radiotherapy);
- multi-purpose linear accelerators equipped with additional collimation means (mini-collimators, localisers) that can produce mini-beams.

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 six 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.

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.

Twelve sites in France were equipped with this type of radiotherapy device (Radiotherapy observatory, INCa 2016).

3.2.4 Radiotherapy using a linear accelerator coupled to a magnetic resonance imaging system

The installation of the first linear accelerator coupled to a Magnetic Resonance Imaging (MRI) system should take place in a French centre at the end of the first half of 2018.

The recent combining of these two technologies (linear accelerator and MRI) raises new questions regarding its clinical use, in terms not only of measurement and calculation of the dose delivered to the patient but also the quality control of the complete machine comprising both the accelerator and the imaging device.

Consequently, in July 2017, ASN asked the Institute of Radiation Protection and Nuclear Safety (IRSN) to conduct a study of the installation and the utilisation of this type of accelerator coupled with an MRI device. The results of this study are expected in summer 2018.

MRIdian® Linac system (MRI-guided radiotherapy integrating a Linac system).

3.2.5 Intraoperative radiotherapy

Intraoperative radiotherapy combines surgery and radiotherapy, which are carried out at the same time in an operating theatre. 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 was to carry out a medico-economic assessment 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 French National Authority for Health (HAS) published the results of its assessment[6] in April 2016. According to the HAS, current knowledge is insufficient to demonstrate the benefits of intraoperative radiotherapy in the adjuvant treatment of breast cancer compared with standard external-beam radiotherapy. The HAS concludes that at present, the elements necessary to propose that it be covered by the health insurance scheme are not yet established and considers that the clinical and medico-economic studies must be continued in order to acquire clinical data over the longer term. At the end of this assessment, the HAS does however recommend continuing the assessment of intraoperative radiotherapy for clinical research purposes.

3.2.6 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 certain tumours.

Hadron therapy with protons is currently used in two centres in France:
- the Curie Institute in Orsay (equipment modified in 2016): in March 2017, this centre treated its first patient using the Pencil-Beam Scanning (PBS) technique. This new technology enables the tumour to be scanned with the beam of protons and thus treat tumours of complex volumes;
- and the Antoine Lacassagne Centre in Nice (new equipment installed in 2016).

A third installation is being set up in the hadron therapy research and treatment centre (Archade project) in Caen and treatment of the first patient is planned for summer 2018.

According to its advocates, hadron therapy with carbon nuclei is more suited to the treatment of the most radiation-resistant tumours and could result in several hundred additional cancer cases being cured per year. The claimed biological advantage is

6. *www.has-sante.fr/portail/jcms/c_2562276/fr/evaluation-de-la-radiotherapie-peroperatoire-rtpo-dans-le-cancer-du-sein*

Intra-cranial treatment by proton therapy, in the isocentric gantry room (Proton therapy centre of the Curie Institute).

purportedly due to the very high ionisation of these particles at the end of their path, combined with a lesser effect on the tissues they pass through before reaching the target volume.

In June 2016, the INCa published a report on proton therapy treatment indications and possibilities.

3.2.7 Contact radiotherapy

Contact therapy or contact radiotherapy is an external-beam radiotherapy technique. The treatments involve an X-ray generator delivering low-energy beams varying from 50 to 200 kV. These low-energy beams are suitable for the treatment of skin cancers because the dose they deliver decreases rapidly with depth.

3.3 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, either in contact with or inside the solid tumours to be treated.

The main radionuclides used in brachytherapy are iridium-192 and iodine-125.

Brachytherapy techniques involve three types of applications.

3.3.1 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.

These iodine-125 sources (seeds) are used to treat prostate cancers. The seeds - which are implanted permanently in the patient's prostate gland - have unit activity levels of between 10 and 30 MBq, and as a treatment requires about one hundred seeds, this gives a total activity of 1 to 2 gigabecquerels (GBq).

3.3.2 Pulsed Dose-Rate (PDR) brachytherapy

- delivering dose-rates of between 2 and 12 Gy/h;
- using sources of iridium-192 displaying a maximum activity of 18.5 GBq and applied using a specific 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 are delivered in sequences of 5 to 20 minutes, 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.

3.3.3 High Dose-Rate (HDR) brachytherapy

- delivering dose-rates in excess of 12 Gy/h;
- using sources of iridium-192 displaying a maximum activity of 370 GBq and implemented with a specific afterloader (some afterloaders use a high-activity cobalt-60 source [91 GBq]).

This technique does not require the patient to be hospitalised in a room with radiological protection; it is performed on an out-patient 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 lasting a few minutes, spread over several days.

High dose-rate brachytherapy is used mainly for gynaecological cancers. This technique can also be used to treat prostate cancers, and can be combined with an external beam radiotherapy treatment.

3.4. Technical rules applicable to facilities

3.4.1 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 Radiation Protection Expert-Officer (RPE-O)[7].

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, a set of safety systems informs the operator of the machine operating status (exposure in progress or not) and switches off the beam in an emergency or if the door to the irradiation room is opened.

3.4.2 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.

7. *In France, the Radiation Protection Expert-Officer (RPE-O) [formerly referred to in ASN documents as the PCR (Person Competent in Radiation protection), reflecting the French term and acronym* "Personne compétente en radioprotection (PCR)"*], is appointed by the employer of persons exposed to ionising radiation in the course of their work. Under the responsibility of the employer, the RPE-O participates in preparing the notification or licensing file and assessing the nature and extent of the risks to which the workers are exposed and in organising radiation protection. The RPE-O carries out internal radiation protection controls and keeps track of third-party radiation protection controls carried out by approved organisations. The RPE-O monitors worker radiation protection. Lastly, the RPE-O is involved in defining and implementing worker safety training for aspects concerning radiation protection and participates in the management of cases where worker exposure limit values are exceeded. These duties correspond to those of both Radiation Protection Expert (RPE) and Radiation Protection Officer (RPO), hence the adoption of the umbrella term Radiation Protection Expert-Officer (RPE-O).*

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.

Since 2009, source irradiators have been gradually replaced by X-ray generators, for which notification to ASN has been required since 2015. In 2017, the inventory stood at 29 irradiator devices equipped with X-ray generators.

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.

Irradiators equipped with X-ray generators must be installed in rooms that comply with the provisions of ASN's new technical resolution 2017-DC-0591 of 13th June 2017 (see chapter 3).

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, radiographers, nurses, nursing auxiliaries, etc.) who are required to use or participate in the use of ionising radiation, and also the population, such as members of the public who may 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; these are available at *www.asn.fr*.

The results of the inspections carried out in 2016 in computed tomography, radiotherapy, nuclear medicine and in facilities practising fluoroscopy-guided interventional practices, were published in 2017. These results are used to present the situation of radiation protection in the medical sector; they are supplemented by the review of significant radiation protection events in 2017.

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 above all 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 internal contamination must be taken into consideration in the risk assessment (in nuclear medicine and in the laboratory).

FOCUS

ASN initiatives concerning the training of medical professionals in patient radiation protection

The substantial work undertaken by ASN since 2014 in training in patient radiation protection further progressed in 2017:

- as far as continuous training is concerned, the publication of ASN resolution 2017-DC-585 of 14th March 2017 relative to the training of professionals in the radiation protection of persons exposed to ionising radiation for medical purposes updates the preceding training arrangement. The training guides called for by this resolution shall be submitted to ASN for approval in 2018;
- following its approval by the Ministry of Higher Education on 21st April 2017, the initial training of physicians in patient radiation protection is now included in the university curriculum of medical studies. It is part of the post-graduate cycle training syllabus dispensed to all future physicians without exception. This is a three-level scheme comprising:
  - first, the acquisition of generic knowledge by all medical students, whatever their specialist subject (including general practitioners), chiefly oriented towards the justification of imaging examinations,
  - followed by a complementary course for specialists performing fluoroscopy-guided procedures (interventional cardiologists, rhythmologists, rheumatologists, digestive tract endoscopists and surgeons), oriented towards dose optimisation and the use of X-ray generators,
  - and lastly an expert-level course (which already exists) for specialist areas in which ionising radiation is at the core of the activity (oncology-radiotherapy, nuclear medicine and radiology-medical imaging).

FOCUS

Patient radiation protection actions taken by HERCA

The question of justification in the medical sector is a priority issue for HERCA. Several meetings have been organised since 2016, bringing together the various stakeholders, whether European (European societies of radiology, nuclear medicine, radiographers, representatives of equipment suppliers and manufacturers, the European Commission), international (the International Atomic Energy Agency – IAEA, the World Health Organisation – WHO, the International Society of Radiographers) or French. The conclusions of a seminar organised by HERCA and held at ASN in October 2016 were published in 2017 (*www.herca.org*).

In November 2016 HERCA also organised a week of inspections targeting implementation of the principle of justification in medical radiology.

The conclusions of this joint European initiative were presented at the international conference on radiation protection in medicine organised by the IAEA and held in Vienna in December 2017.

In addition to this, in November 2017 HERCA published the conclusions of several years of work in collaboration with the COCIR (European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry) concerning dose optimisation in computed tomography. This 2107 report (*www.herca.org*) presents the advances in four subjects committed to by the COCIR and the main CT scanner manufacturers: the characterisation of CT scanner performance, the implementation of dose reduction tools, dose management and training.

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. Only the principles of justification and optimisation are applicable (see chapter 3).

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 targeted 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. Controlling doses remains a priority for ASN which, following on from the first plan initiated in 2011, drew up a second plan in 2017 in order to continue promoting a culture of radiation protection with the professionals (see chapter 1).

5.1.3 Exposure of persons providing support and comfort to patients

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. In 2016, ASN asked IRSN (Institute of Radiation Protection and Nuclear Safety) to issue recommendations for setting dose limitations for persons providing support or comfort to patients during their medical diagnosis or treatment. The GPMED (Advisory Committee for Radiation Protection in Medical and Forensic Applications of Ionising Radiation) gave its opinion on these recommendations in 2017; the recommendations were forwarded to the SFMN in order to update the existing good practice recommendations.

5.1.4 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 units.

The available information concerning radiological monitoring of the environment carried out by IRSN, 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, particularly people working in 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).

5.2 Some general indicators

5.2.1 Licenses and declarations

In 2017, ASN issued:
- 5,286 acknowledgements of receipt of declarations of medical and dental diagnostic radiology devices;
- 634 licenses (for entry into service, renewal or cancellation), of which 56% were in computed tomography, 24% in nuclear medicine, 16% in external-beam radiotherapy and 4% in brachytherapy.

5.2.2 Dosimetry of health professionals

According to the data collected in 2016 by IRSN, 227,980 people working in sectors using ionising radiation for medical and veterinary purposes were subject to dosimetric monitoring of their exposure. Medical radiology (50%) and dental care (22%) alone account for nearly 72% of the medical personnel exposed.

More than 99% of the health professionals monitored in 2016 received an annual effective dose below 1 millisievert (mSv). No exceedance of the annual effective dose limit of 20 mSv was observed. Two cases in which the annual equivalent dose at the extremities (500 mSv) was exceeded were registered (in the radiology sector). The average annual individual dose calculated for people having received a dose exceeding the registration threshold is 0.33 mSv/year and is stable compared with the value for 2015.

1,821 persons were monitored (radiotoxicological and whole-body radiation measurement analyses) for a risk of internal exposure in 2016. An effective dose calculation was carried out for eight workers (four working in nuclear medicine and four in a radioimmunology laboratory, and in all eight cases the committed effective dose was less than 1 mSv.

5.2.3 Report on 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. In 2017, ASN published two bulletins on radiotherapy patient safety (No. 10 and 11) and two event analysis sheets (see points 5.3.3). Incident notices are also published on *www.asn.fr*.

Since July 2015, radiotherapy departments can notify significant radiation protection events on line. This portal falls within the framework of the single vigilance portal created by the Ministry of Health. It was extended to cover the entire medical sector in april 2017.

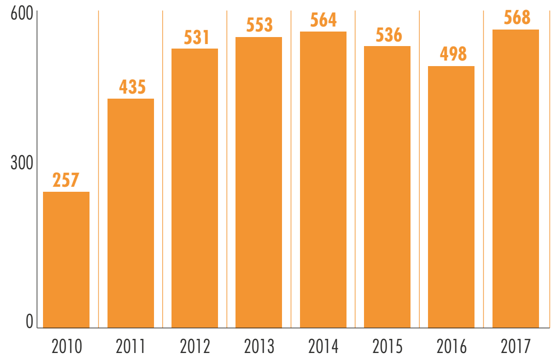
Since 2012, the number of ESR notifications stands at about 500 per year. In 2017, 568 ESRs in the medical sector were notified to ASN. This increase is primarily due to the notification of a larger number of ESRs in radiology (conventional and computed tomography) and, to a lesser extent, in nuclear medicine. It is probable that setting up the on-line service for notifying events to ASN has facilitated this procedure, particularly in the radiology sector.

On the other hand, the number of ESR notifications concerning radiotherapy has dropped steadily since 2015.

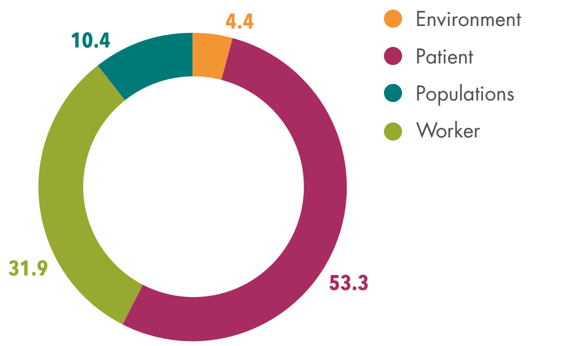
The Graphs below illustrate the breakdown of the number of ESRs in 2017 by sector and how they have evolved since 2007, along with the breakdown of events by notification criterion.

About 80% of the notified events originate from either computed tomography (29%), radiotherapy (25%) or nuclear medicine (26%) departments. For the first time since 2007, when the ESR notification system was put in place, computed tomography is the area with the largest number of ESR notifications per year.

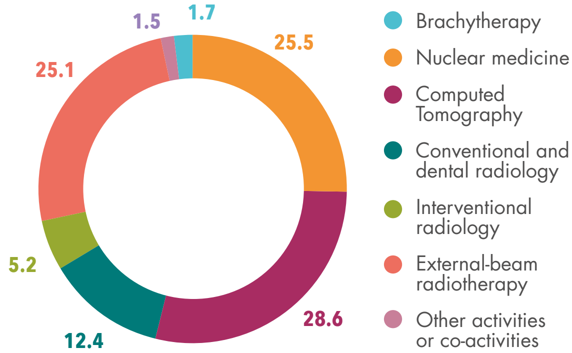
NUMBER OF SIGNIFICANT EVENTS over the years



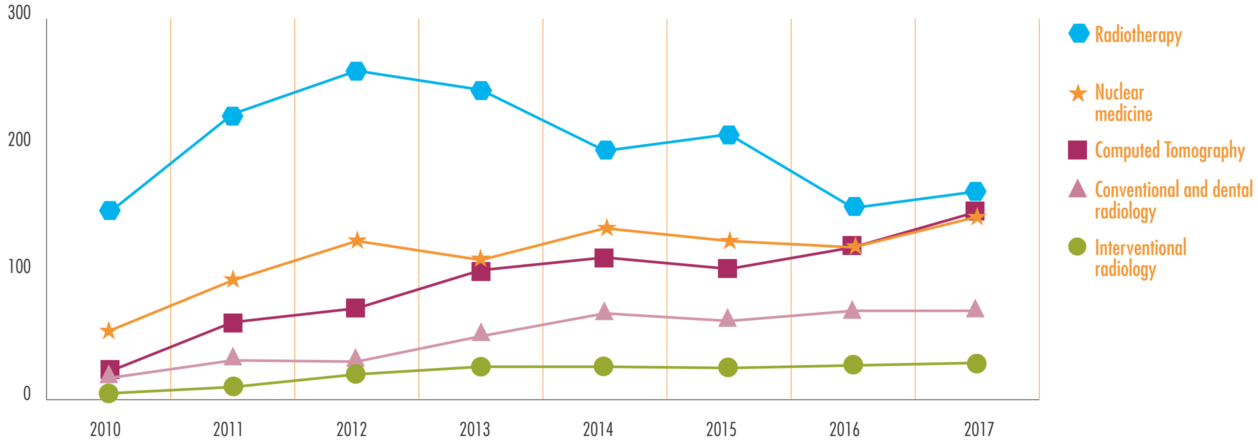
DISTRIBUTION OF SIGNIFICANT EVENTS by category in 2017 (%)



DISTRIBUTION OF SIGNIFICANT EVENTS by activity in 2017 (%)



NUMBER OF SIGNIFICANT EVENTS by type of activity over the years



The notified events in the medical sector chiefly concern the exposure of patients (53%) and foetuses in pregnant women unaware of their pregnancy (30%), a figure which has risen markedly.

In the light of the events notified to ASN in 2017, the most significant consequences from the radiation protection aspect concern:

- for workers: fluoroscopy-guided interventional practices (external exposure of operators, and their hands in particular) with cases where dose limits are exceeded, and nuclear medicine (contamination of workers, external exposure);
- for patients: interventional practices with deterministic effects observed in some patients having undergone long and complex procedures, radiotherapy with excess doses associated in particular with treatment overlaps[8], prescription errors and, lastly, nuclear medicine, with radiopharmaceutical administration errors;
- for the public and the environment: nuclear medicine, with losses of sources, leaks from radioactive effluent pipes and containment structures.

Information detailed by area is provided on the following points.

In late 2016, supported by ASN, HERCA organised a seminar on accidental and unintentional medical exposures. The report and conclusions of this seminar were published in May 2017(*www.herca.org*).

5.3 Radiation protection situation in radiotherapy

The safety of radiotherapy treatments has been a priority area of ASN oversight since 2007. The programme of inspections defined for the 2016-2019 period, the orientations of which were communicated to all the radiotherapy departments in early 2016, was continued in 2017. The inspections focused on the ability of the centre to deploy a risk-management procedure and, depending on the situation found by the inspectors, on the implementation of hypofractionated treatments, skills management, the implementation of new techniques or practices, and control of the equipment.

ASN is continuing its graded approach to oversight:

- by reducing, in the light of the progress made in the control of treatment safety, the average frequency of inspection, which since 2016 has been reduced to once every three years (instead of the previous two-yearly frequency);
- by maintaining a higher inspection frequency for the centres displaying vulnerabilities or risks.

In 2016, ASN carried out 89 inspections in 79 external-beam radiotherapy centres, that is to say 46% of the centres in France. In 2017 it carried out 95 inspections.

5.3.1 Radiation protection of radiotherapy professionals

When the facilities are correctly designed, the radiation protection risks for the professionals in radiotherapy are limited due to the protection provided by the walls of the irradiation room.

5.3.2 Radiation protection of radiotherapy patients

Although the requirements set by ASN technical resolution 2008-DC-0103 of 1st July 2008 for the management of quality and safety in radiotherapy departments are complied with on the whole, there are still disparities between centres.

Experience feedback

The results of the inspections carried out in 2016 showed that the experience feedback process gave overall satisfaction in only 41% of the centres inspected. While the detection of adverse events, their notification (internally or to ASN) and their recording were deemed satisfactory on the whole in about 90% of the centres, the analysis of these adverse events was only satisfactory on the whole in 63% of the inspected centres:

- The analysis of the causes of an event is still too succinct, often not going beyond the immediate causes.
- Similarly, the analyses of recurrent events are still poorly developed even though recurrent events constitute alert signals.

8. *Treatment overlap: irradiation during a second treatment of an anatomical region which has already been irradiated; the area concerned by the overlap receives summed doses resulting from several separate irradiations.*

The improvement in practices through experience feedback and the assessment of the effectiveness of the corrective actions were deemed satisfactory in only 36% of the centres inspected. Although the majority of these procedures brought together representatives of all the professional categories, not all the members of personnel are involved, particularly the physicians, which limits their effectiveness.

In order to achieve effective continuous improvement in treatment quality and safety, progress was required in the monitoring and evaluation of the corrective actions put in place, in the involvement of all the personnel and in the utilisation of the experience feedback to assess and enrich the prospective risk analysis.

The risks analysis

The prospective risk analysis was available in 92% of the centres. For 95% of them this analysis resulted from the work of a multi-professional group which had been set up in 89% of the inspected centres. However, in 44% of the centres it had not been updated, and in 51% of them it had not been assessed. Consequently, the overall situation was satisfactory in only half the inspected centres and these centres had not yet fully embraced the prospective risk management approach.

More generally, on completion of the inspections carried out in 2016, ASN had considered that the management of the risk management procedure was on the whole satisfactory in only half of the inspected centres. These were the centres whose management had defined a policy with shared, assessable and assessed operational objectives, had communicated on the results of this policy and allocated the necessary resources, particularly to the operational quality manager. Furthermore, the involvement of all the professionals, especially the medical professionals, remains an essential prerequisite for the risk management procedures to produce concrete improvements in the safety of practices.

In 2017, ASN inspected more specifically the risk management policies of the Amethyst and U2R groups, each of which manages four radiotherapy centres. The inspections carried out over time in the different centres managed by the same group have effectively led to similar findings revealing the absence of pooling and of a group-level risk management policy. These groups are currently organising themselves to deploy a coordinated risk management policy.

The implementation of new techniques

Seventy percent of the centres inspected in 2016 were implementing a new technique or using a new item of equipment. ASN considered that the new technique or the equipment was adequately mastered in 79% and 86% of these centres respectively. The training needs for the personnel concerned had been defined in 96% of the cases and they had all been trained in the new technique in 98% of the cases. The operating procedures associated with the new technique or the use of the equipment had been established in 96% of the centres. Nevertheless, the analysis of the impact of the new technique - particularly on staff numbers, and the adequacy of the means for the new needs, could be improved in 30% of the centres inspected. Moreover, the risk analysis prior to deployment of the new technique had been carried out in only 77% of the centres.

More generally, ASN observes that the impacts of the technical, organisational or human changes on the activity of the operators are not sufficiently analysed, despite the fact that they can weaken the existing lines of defence. In 2017, in partnership with IRSN, health sector institutions and radiotherapy professionals, ASN launched the IMRTH project (Impact of a modification in radiotherapy), which aims to give centres the means to identify the impact of a change on the work activity and take the necessary measures to protect the activity. The work carried out in 2017 will continue in 2018 with an experiment conducted with two radiotherapy centres which have technical or organisational changes scheduled.

Hypofractionated treatments

The analysis of events notified to ASN in 2016 had underlined the high potential risks of hypofractionated treatments. ASN had inspected 17 centres performing this type of treatment, examining more specifically the robustness of the defence barriers formed by the validation of the prescription, the verification of patient identity and the check of patient positioning. The inspections revealed that although the verifications and checks are written into the quality procedures and subject to a degree of traceability, they should nevertheless be set out in greater detail, indicating the types of verifications/checks performed, the stage in the process at which they are performed, the person performing them and the cross-check methods.

5.3.3 Notified events in external-beam radiotherapy

146 radiotherapy events were notified in 2017, and they almost exclusively concerned patient exposure.

The large majority of ESRs (97%) had no clinical consequences for the patients. Sixty-five percent of the events were rated level 1 on the ASN-SFRO scale in 2016. Nevertheless, three ESRs in radiotherapy rated level 2 were notified in 2017. They involved two cases of excess doses after overlaps between two treatments and one excess dose in contact radiotherapy.

As in preceding years, these events highlight the organisational weaknesses in managing the movements of patients' files, in validation steps that are not sufficiently explicit and in the upkeep of patients' files to ensure an overall view and access to the necessary information at the right time. Variations in practices within the same centre, frequent task interruptions, a heavy and uncontrolled workload with, among other things, an impact on treatment ranges or the deployment of a new technique or practice, constitute situations which can foster errors.

In 2016 and 2017, ASN observed a distinct reduction in ESRs notified by the radiotherapy departments in France as a whole. Indeed, since 2008, some 240 ESRs per year were being notified. While this drop may be partly due to a loss of momentum in the feedback procedures, it seems more likely that it reflects a reluctance of the centres to declare minor events (rated ≤1 on the ASN-SFRO scale), which very often represent no real risk with regard to the safety of practices.

FOCUS

Making the patient a partner in treatment safety

The analysis of events notified to ASN shows that patient vigilance can help to detect errors and mitigate their consequences. Furthermore, having a good understanding of the treatment protocol contributes to the delivery of safer and more effective treatments.

This issue of the patient safety bulletin aims to echo the ongoing reflections on the role of patients as actors in their own treatment safety. Three themes promoting involvement of the patients are developed: building a relationship of confidence, improving the clarity and the observance of instructions and explanations, and encouraging cooperation. These recommendations are the result of a reflection by the working group on experience feedback analysis, with two ergonomics specialists.

FOCUS

Overdose in contact radiotherapy

Among the three level-2 ESRs notified to ASN in 2017, one ESR associated with a large radiation overdose in contact radiotherapy occurred in the Bordeaux university hospital.

In this particular case, for the treatment of cutaneous lesions, the patient was prescribed a total ionising radiation dose of 40 Gy to be delivered by contact radiotherapy in ten sessions of 4 Gy each. The treatment time applied during eight sessions was 2.69 minutes instead of the 0.96 minutes necessary to the deliver the prescribed dose to the patient. The error was detected at the 9th session and the treatment was stopped. IRSN made a retrospective assessment of the dose effectively received by the patient.

The event was caused by an error in the manual entry of the irradiation time into the software controlling the device. This event occurred in a situation where the medical staff were overstretched.

Following this event, improvement measures were put in place, comprising systematic verification of the treatment parameters by a medical physicist prior to the first treatment session in all cases, and setting up of the equipment in the treatment room by the radiotherapist and the radiographer during a "practice run" session with no dose delivery.

In 2017, ASN published *Patient safety* bulletin No. 11, and event analysis sheets No. 3 and No. 4 concerning an error in setting treatment table density parameters and a problem of beam asymmetry linked to premature target degradation.

5.3.4 Synthesis and prospects

In radiotherapy in 2017, although the safety fundamentals are in place (equipment verifications, medical staff training, quality and risk management policy), ASN still observes significant disparities between centres. The quality procedures struggle to achieve continuity over the long term, and sometimes even regress due, for example, to lack of assessment or the departure of the person with operational responsibility for quality. Moreover, the risk analyses remain relatively theoretical and are insufficiently deployed prior to organisational or technical changes. ASN underlines that the long-term involvement of all medical professionals – and radiation oncologists in particular – in the management of treatment quality and risks is necessary in order to improve treatment safety.

ASN also observes that the radiotherapy centres belonging to a given group and inspected over a certain period of time show the same shortcomings and little sharing of experience feedback, highlighting the fact that there is no real policy of quality and risk management in the healthcare groups.

Given the diversity of situations encountered, the centres displaying vulnerabilities or particular risks will continue to be subject to particular scrutiny in 2018.

5.4 Radiation protection situation in brachytherapy

Twenty brachytherapy centres were inspected in 2016 (31% of the centres). In 2017, 23 centres were inspected.

5.4.1 Worker radiation protection

The occupational radiation protection measures deployed in 2016 by the brachytherapy departments were considered satisfactory, but various points can still be improved:

- All the inspected centres had a designated RPE-O dedicated to this activity; their duties were defined but their means were insufficient in three of the centres inspected.
- All the inspected centres had carried out working environment analyses but in six of the centres they did not cover all the jobs.
- The risk assessment was effectively carried out in all the centres but in three of them it was not consistent with the delimitation of regulated areas.
- The majority of the centres inspected had drawn up the technical programme of internal and external radiation protection controls. However, the internal technical controls were either not exhaustive or were not carried out at the required frequency in six centres.

5.4.2 Radiation protection of patients

The treatment quality and safety management system

The results of the inspections carried out in 2016 showed that the majority of the brachytherapy units had deployed a quality approach assisted by the external-beam radiotherapy departments and showed the same shortcomings with regard to the risks incurred by the patients and the management of adverse events.

The following findings were made:
- All the centres inspected had designated an operational quality manager and defined the person's missions, objectives and the means at their disposal.
- All the centres inspected had formalised the mapping of the processes.
- 17 of the centres inspected had defined treatment quality and safety objectives, but 3 centres did not follow them all or did not update them all.
- The study of the risks run by patients in brachytherapy was carried out in the majority of the inspected centres but in six of them it was not updated.
- All the inspected centres made improvement proposals following the adverse events analysis, but six centres did not keep track of their implementation.
- All the inspected centres had put in place a management review and eight of them also carried out internal audits and process reviews.

Maintenance and quality controls

In 2016, the majority of the centres had an inventory of medical devices and a register for recording maintenance operations and quality controls. In the absence of a decision from the ANSM (Health Products Safety Agency) defining the quality controls for brachytherapy devices, the nature of the quality controls always resulted from past practices and was based on recommendations provided by the device manufacturers or the professionals.

Maintenance of the HDR and PDR afterloaders was ensured by the manufacturers. More specifically, the manufacturers performed the afterloader operating verifications when replacing the sources. The brachytherapy units relied on these verifications to guarantee correct operation of the devices. The source activity was verified at each delivery and source removal verifications were also carried out.

5.4.3 Management of sources

Management of the brachytherapy sources was satisfactory. All the centres inspected in 2016 recorded the tracking of source movements, transmitted the source inventory to IRSN and stored the sources waiting to be loaded or collected in a suitable place. Twenty-one percent of the centres inspected in 2016 stored expired sealed sources pending their removal.

5.4.4 Emergency situations

Two events involving the jamming of an iridium-192 source in a PDR or HDR afterloader, which occurred in 2013 and 2016, led to the exposure of a worker and a patient. These events emphasised the importance of training the personnel in emergency measures. This training must focus in particular on the emergency measures to implement in the event of loss of control of a high-activity source (jamming of the source, for example). However, exercises to prepare for and assess intervention methods were still very rare.

There was progress in compliance with requirements concerning increased training in occupational radiation protection for the use of high activity sealed sources, but further efforts were still necessary so that, in each centre, all the personnel concerned could receive this training (14 of the 20 centres inspected had provided this training for all the personnel).

5.4.5 Notified events in brachytherapy

10 ESRs were notified in brachytherapy in 2017. These events concerned patient identity errors, afterloader positioning errors, source management deficiencies (loss of iodine seeds, discovery of orphan source) and dose errors.

Among the dose errors, one event was rated level 2 on the ASN-SFRO scale. A dose of 20 grays in two 10-gray sessions was delivered, whereas the total dose prescribed was 10 grays to be delivered in two 5-gray sessions. This error resulted from incorrect manual entry of the dose per session in the R&V (record and verify) system. Analysis of the event revealed organisational deficiencies in the defining and planning of tasks. The procedures were imprecise with regard to the points to check and the brachytherapy appointment schedule did not take account of the schedules of the physicians and physicists.

With regard to the management of sources, a loss-of-sources ESR was rated level 1 on the INES scale because an incident of this type had occurred previously and the checks carried out failed to prevent it from recurring. In this particular case, three grains of radioactive iodine (iodine-125) used for brachytherapy treatments of the prostate were lost, then detected when they activated a radiation portal monitor at the entrance to a waste disposal site. The checks carried out with a radiation detector in the intervention room and on leaving the centre failed to detect the three grains which had fallen into a bin for potentially infectious clinical waste. This event revealed a lack of rigour in the end-of-intervention checks.

5.4.6 Summary

Despite the encouraging findings of the inspections in the last few years, ASN considers that efforts must still be made to reinforce the radiation protection training of workers when high-activity sources are involved.

5.5 Radiation protection situation in nuclear medicine

Since 2013, the inspection frequency is established each year applying a graded approach to oversight by distinguishing:
- those facilities in which only diagnostic procedures are performed, where an inspection is carried out every five years instead of every three years;
- the departments practising a therapeutic activity, with or without patient hospitalisation in a radiation-shielded room, for which a three-year frequency is maintained.

Sixty-seven nuclear medicine departments were inspected in 2016 (i.e. about 29% of the departments). Among these departments, 44 had a nuclear pharmacy authorised by the ARS and 20 had at least one ITR room (from 1 to 7 rooms) out of a total of 48 rooms. In 2017, 72 departments were inspected.

5.5.1 Radiation protection of nuclear medicine professionals

On completion of the inspections performed in 2016, ASN had observed that virtually all the nuclear medicine departments had defined and implemented means of protection (lead-shielded cases or trolleys) aiming to limit the exposure of workers and the public when radiopharmaceuticals had to be transported for utilisation outside the nuclear medicine department, for example in a neurology department or an interventional radiology room.

ASN had nevertheless considered that weaknesses subsisted:
- This was because the working environment analyses were not carried out for all the jobs and did not always include the internal exposure of the workers.
- Only 69% of the departments carried out all of the internal technical controls at the required frequencies.
- The continuous training of workers in radiation protection remained incomplete for newly hired personnel, nuclear physicians, physicians performing procedures from time to time (cardiologists) and the cleaning services personnel.
- Shortcomings were still observed in the coordination of the general prevention measures which the nuclear medicine departments were to provide when an outside company was required to work in the facility. Only 34% of the departments had formalised the coordination of the prevention measures.
- In 80% of the departments with ITR rooms, protection equipment had been made available to the workers (gloves, masks, sometimes coveralls, overshoes and caps covering hair and, if necessary, lead aprons).

5.5.2 Radiation protection of patients in nuclear medicine

ASN observed that the external quality verifications of the medical devices were now carried out in virtually all the nuclear medicine departments inspected and that the information relative to the dispensing and recording of staff training in patient radiation protection was available in nearly 80% of these departments.

With regard to the utilisation of automated systems for preparing and injecting radiopharmaceuticals, which are becoming common practice for the handling of fluorine-18, particularly for injecting the patient, nearly all personnel had received training in routine use and in the event of a malfunction. The utilisation protocols however were not always subject to strict quality assurance procedures and the points to check were not all formalised.

The other weaknesses observed concerned the following points:
- With regard to optimisation, although the diagnostic reference levels were systematically recorded and forwarded to IRSN, only 10% of the inspected departments analysed the values recorded to assess their practices.
- The utilisation protocols for CT scanners coupled with gamma cameras were only optimised in 62% of the inspected facilities and iterative image reconstruction software was available in less than 50% of the facilities.
- The marking efficiency checks (percentage of the radiopharmaceutical actually marked by a radionuclide), provided for in the commercialisation authorisation for each radiopharmaceutical, were carried out in 75% of the departments inspected.

5.5.3 Protection of the general public and the environment

ASN has observed a steady improvement in the quality of the effluent and waste management plans produced by nuclear medicine departments, which are now implemented in all the departments. There are nevertheless still some shortcomings:
- Only 86% of the inspected departments are in compliance with ASN resolution 2008-DC-0095 of 29th January 2008.
- The accessible pipes which carry contaminated effluents are identified and signalled in 74% of the facilities.
- Periodic checks were carried out at the outflow from the centre at frequencies varying according to the facilities inspected (in 2016, out of 63 departments inspected, 89% perform a check at least once per year and 3% have never performed checks).
- 65% of the departments had been issued an authorisation to discharge contaminated effluents from the manager of the public sewage network (the number of departments with an authorisation has nevertheless been increasing since 2014).

With regard to the implementation of the recommendations issued in ASN's circular letter of 17th April 2012 drawing up the lessons learned from several ESRs involving leaks in pipes carrying liquid effluents contaminated by nuclear medicine radionuclides, the following findings were made:
- In 63% of the facilities, the department's pipeline networks and, where applicable, the ITR rooms, had been mapped.
- In 49% of the departments, the condition of the pipes and tanks was monitored.
- In about 40% of the departments, an intervention protocol and a reflex response sheet in the event of tank leakage had been drawn up.

5.5.4 Nuclear medicine facilities

ASN resolution 2014-DC-0463 of 23rd October 2014 relative to nuclear medicine facilities set requirements for the ITR rooms with entry into effect on 1st July 2018 (dedicated rooms, independent ventilation system and under negative pressure).

Among the 20 departments inspected having at least one ITR room (from 1 to 7 rooms), 5% of the rooms, at present not dedicated exclusively to patients to whom radionuclides have been administered for therapeutic purposes, were to be brought into compliance before 1st July 2018. The same goes for half of the rooms which, on the day of the inspections, were not ventilated with negative pressure.

5.5.5 Notified events in nuclear medicine

One hundred and forty-eight ESR were notified in 2017, representing an increase of 28% over 2016. It is probable that the opening of ASN's on-line notification portal in 2017 contributed to this increase due to the simplification of the procedure. As in the preceding years, most of the notified events concerned patients examined for diagnostic purposes (63%).

Significant events concerning patients (98 ESRs, i.e. 66% of the notified ESRs)

The majority of these ESRs were linked to errors in the administration of radiopharmaceuticals to a patient (interchanging of syringes or patients), errors in prepared doses (adult dose injected into a child, injection of a dose higher or lower than the prescribed dose, etc.) or to errors during the preparation of the medication (interchanging of bottles). Only a few patients were involved in patient identity errors.

Six extravasations[9] were described, of which two occurred during treatment. One occurred after injecting lutetium-177, in a difficult treatment context due to the patient's state of health. The second arose during a treatment of hepatic metastases with microspheres of yttrium-90, in which an arterial reflux occurred. The patients were subject to medical monitoring.

Three patients were affected by an ESR resulting from failure to check radionuclide marking quality before giving the injection.

Significant events concerning workers (14 ESRs, i.e. 10% of the notified ESRs)

Fourteen events concerning workers were notified in 2017. Five involved a radiopharmaceutical coming into contact with the face, eyes or hands. Two resulted from pricks with needles during syringe depressurisation or the use of new injection devices.

Delivery errors (bottles delivered in inappropriate packaging) and errors in the handling of shielded bins caused accidental exposure of workers.

Significant events concerning the public (15 ESRs, i.e. 10% of the notified ESRs)

Twelve of these ESRs resulted from the exposure of the foetus in women unaware of their pregnancy. The doses received had no consequences on the child after its birth (ICRP, 2007).

The exposure of persons not in the category of workers exposed to ionising radiation was observed during work on the drain pipes of toilets used by patients or through the discovery of a bottle of urine from a patient treated with lutétium-177, which was found in an infectious waste disposal route. These events had no consequences on the exposed persons.

Significant radiation protection events concerning radioactive sources, waste and effluents (18 ESRs, i.e. 12% of the notified ESRs)

Most of these ESR were associated with the loss of radioactive sources (old sources or following the retrieval of sources), the dispersion of radionuclides (leaks of radioactive effluents from pipes or tanks) or the channelling of waste towards an inappropriate disposal route.

One of the ESRs was linked to the discharging into the public sewage network of tanks containing iodine-131 with an activity level above the regulatory threshold of 100 Bq/l. The discharging occurred following plumbing work in which a valve had not been properly closed. Deficiencies in management of the "high level" filling alarm prevented detection of the leak.

5.5.6 Summary

The inspections carried out in 2016 had revealed progress in:
- the effective implementation of means of protection aiming to limit exposure of workers and the public when radiopharmaceuticals had to be transported for use outside the nuclear medicine department;
- the performance of external quality controls of the medical devices;
- the dispensing and recording of medical staff training in patient radiation protection;
- the training of personnel in the use of automated systems for preparing and injecting radiopharmaceuticals;
- the quality of the effluent and waste management plans produced by the nuclear medicine departments.

Shortcomings were still found in:
- the coordination of the general prevention measures when outside companies work in the nuclear medicine facilities;
- the securing of the administration of the radiopharmaceutical and the use of automated devices to prepare the administered activities and/or give the injection with, more specifically, the radiopharmaceutical dispensing process being subject to strict quality assurance procedures;
- the optimisation of the protocols for the use of CT scanners coupled with gamma cameras;
- contaminated effluent management, consisting firstly in locating, identifying and monitoring the pipes carrying radioactive effluents, and secondly in formalising a response protocol in the event of leakage.

5.6 Radiation protection situation in conventional radiology and computed tomography

In 2016, ASN renewed the verifications of the radiation protection regulations in the area of computed tomography, given the increase in the contribution of this imaging technique to the average effective dose per capita (chapter 1).

The computed tomography inspections carried out in 2016 concerned 63 facilities dedicated exclusively to medical imaging. 56 centres were inspected in 2017.

5.6.1 Inspection results

The organisation of worker radiation protection in 2016 was generally satisfactory, but a few points remained to be improved:
- The RPE-Os still did not have adequate means to fulfil their duties.
- The assessment of risks and ensuring zoning consistency accordingly, and the work environment analyses were carried out, but often required updating.
- The radiation protection technical controls were carried out at the required frequencies but were not followed up by corrective actions.
- The training of exposed personnel remains a weak point, particularly for private practice physicians working on a contract basis.

9. *The extravasation of a radiopharmaceutical, administered by a peripheral intravenous device, is an abnormal passage of the substance outside the catheterised vessel (passage through tissue). Its consequences in terms of lesions caused on neighbouring tissues depend primarily on the volume and the energy level of the extravasated radiopharmaceutical (diagnostic or therapeutic procedure).*

The main weak points in patient radiation protection highlighted yet again concerned the way the medical staff embrace the principles of exposure justification and optimisation.

Thus, the precision of the justification factors on the examination request, the search for an alternative non-irradiating technique, and the training of medical professionals – particularly substitute physicians – in patient radiation protection, should be stepped up. The same finding was made for the optimisation of examination protocols and reviewing practices after analysing the diagnostic reference levels.

5.6.2 Significant events notified in computed tomography and radiology

The very large majority of ESR notifications in computed tomography (165) in 2017 concerned patients (147). The most common case was the exposure of a pregnant woman who was unaware of her pregnancy (112 cases) or patient identity errors. The information provided to women before the procedure, when they made their appointment for the examination, and through the posters in the waiting rooms and undressing cubicles, was nevertheless satisfactory.

About ten notifications concerned situations of accidental exposure of radiographers, essentially when tending to patients (18).

In 2017, ASN was notified of 70 ESRs concerning the area of conventional radiology. The majority of the events (44 ESRs, i.e. 62%) concerned the exposure of pregnant women and identity monitoring errors. On the whole, ASN observes a decrease in vigilance in the search for potential pregnancies in women of childbearing age (e.g. performance of an abdominal ultrasonography examination after taking X-rays of the abdomen or the lumbar spine when these two examinations are requested).

5.6.3 Summary

Although occupational radiation protection is satisfactory on the whole, in some cases the lack of means available to the RPE-Os still leads to shortcomings with regard to risk assessment, work environment analyses and continuous training.

With regard to patient radiation protection in the area of computed tomography, the main lines for progress lie in the justification of examinations, optimisation of delivered doses and the analysis of the diagnostic reference levels.

5.7 Radiation protection situation in fluoroscopy-guided interventional practices

For several years now, ESRs in the area of fluoroscopy-guided interventional practices have been regularly notified to ASN. Although these events represented just a small proportion (about 5%) of the medical events notified to ASN, they most often had serious implications with the occurrence of tissue damage (radiodermatitis, necrosis) in patients having undergone particularly long and complex interventional procedures. Added to these events which emphasise the major implications of radiation protection for patients, were the events concerning professionals whose exposure sometimes exceeded the regulatory limits, particularly at the extremities (fingers).

On account of the radiation protection implications, ASN has increased the number of inspections it carries out in this sector in the last few years. In 2016, it conducted 155 inspections in 213 different departments which practice fluoroscopy-guided interventional procedures. In 2017, 178 departments were inspected.

5.7.1 Radiation protection of professionals using fluoroscopy-guided interventional procedures

The findings established from the inspections carried out in 2016 confirm the observations made over the last few years. Thus, radiation protection of medical staff was still better applied in fixed interventional radiology facilities (cardiology, neuroradiology, vascular imaging, etc.) than in operating theatres in which mobile C-arm units are used (scanner, image intensifier, flat panel detector).

The inspections on the whole still revealed inadequacies in the analyses of working environments and conditions, particularly with respect to doses to the extremities and to the lens of the eye, and in dosimetric monitoring (active and at the extremities).

The lack of training of medical professionals, especially practitioners working in operating theatres, was a recurrent inspection finding in this sector in which a poor radiation protection culture was predominant. The training of operators using the fixed facilities however has progressed over time.

Although collective radiation protection equipment was available for the dedicated activities, it was still too rarely present in operating theatres. Personal Protective Equipment (PPE) was available and worn by everybody, with the exception of lead glasses. The medical personnel in question showed little concern for their own radiation protection and were not aware of the doses they could and/or did receive, due in particular to the failure to wear the appropriate dosimeters (full body, extremities and lens of eye) even though they were available.

The lack of appropriate dosimetric monitoring, particularly of the extremities in certain fluoroscopy-guided procedures, and the absence of medical monitoring of the practitioners, made it difficult to assess the status of worker radiation protection in this sector. ASN had nevertheless observed improvements in the inspected departments and greater awareness among professionals as a result of information feedback from the notified events.

There were still methodological and organisational difficulties for the RPE-Os who did not always have the means or the necessary authority 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, represented a recurrent difficulty.

5.7.2 Radiation protection of patients

The findings established from the inspections in 2016 with regard to patient radiation protection also confirmed the observations made over the last few years. Shortcomings were observed in the application of the dose optimisation principle, be it in the setting of the machines and the protocols used or in the practices. They resulted firstly from insufficient training and secondly from a lack of optimisation of the available protocols with a view to improving patient radiation protection.

A distinct improvement was however observed in the fixed facilities, particularly in cardiology and neuroradiology, where widespread implementation of dosimetric reviews has fostered dose optimisation. Reference levels for the most common examinations were being developed locally more and more often. This approach also enables, among other things, alert levels to be set to trigger appropriate medical monitoring of the patient according to the dose levels received.

The Dose Archiving and Communication Systems (DACS) currently being deployed facilitate the development of local reference levels and alert levels per machine and per type of procedure. These DACS's are a valuable means of tracking the doses previously received by the patient and of monitoring the patient.

Practitioners in the operating theatre rarely have access to a dose indicator during their intervention. The medical personnel had insufficient knowledge of the reference dose levels for the type of procedure performed. The operating theatre C-arm units, due to their mobility, were more rarely connected to the DACS of the centre than the fixed facilities in the interventional rooms.

Insufficient use of medical physicists in departments practising fluoroscopy-guided interventional procedures was still hindering application of the optimisation principle. Greater involvement of the medical physicist would, among other things, enable the equipment to be better used, with the establishing of appropriate protocols for the procedures performed and the development of dosimetric reference levels. When medical centres called upon outside medical physics service providers, it was observed that the centres rarely adopted the procedures and documentation proposed by these service providers.

5.7.3 Significant events notified in the area of fluoroscopy-guided interventional practices

24 significant events were notified in the area of fluoroscopy-guided interventional practices in 2017. Among these events:

- Five events concerned workers. They reported cases of exceeding the projected doses evaluated during the working environment analysis or exceeding the permissible regulatory dose limits for the whole body and/or the extremities.
- Nine events concerned overexposure of patients, some of which led to deterministic effects such as transient alopecia (hair loss) or erythema.
- Four events concerned pregnant patients exposed during a fluoroscopy-guided interventional examination. In most cases the exposed woman was unaware of her pregnancy.
- Six events concerned the equipment (lead apron, dosimeter, radiology table, theft of equipment).

Three ESRs concerning interventional practitioners who received doses to the extremities (hands) exceeding the regulatory dose limit were notified in late 2017 and rated level 2 on the INES scale. These events highlighted the deficiencies in the organisation of occupational radiation protection. The centres in question will be inspected in early 2018 to get a fuller idea of their practices.

| ASN inspection of the nuclear medicine unit of the Eugène-Marquis regional cancer centre in Rennes, July 2015.

The investigations revealed that overexposure of the patient and/or workers was due to jamming of the fluoroscopy pedals in two cases and to a collimator defect and the lack of additional filtration in two other cases. These figures were comparable with those for 2016, during which four similar events were notified. These events indiscriminately concerned mobile equipment used in the operating theatre and fixed equipment in rooms dedicated to fluoroscopy-guided interventional procedures.

In the other cases, overexposure of the patient and/or practitioner was due to long and complex procedures on account of the patient's illness and/or body size.

ASN observes that although knowledge of the ESR notification system has improved, under-notification is still an issue in this area. The on-line notification of ESRs (*teleservices.asn.fr*), which has been available since 1st April 2017, facilitates the notification of events and transmission of analysis reports within two months.

5.7.4 Summary

ASN considers that the urgent measures it has been recommending for several years to improve the radiation protection of patients and professionals during interventional practices in the operating theatres have still not been taken. The inspections frequently reveal deviations from the regulations, concerning the radiation protection of patients as much as the radiation protection of medical staff, and ASN is regularly notified of events concerning interventional surgeons who have exceeded the dose limits for the extremities.

Due to the implications for radiation protection of the medical staff and patients, and a lack of radiation protection culture among the staff, as observed during inspections and illustrated by the under-notification of ESRs, ASN has asked the GPMED to establish recommendations to improve radiation protection in the operating theatres. Its recommendations are to be submitted at the end of 2018.

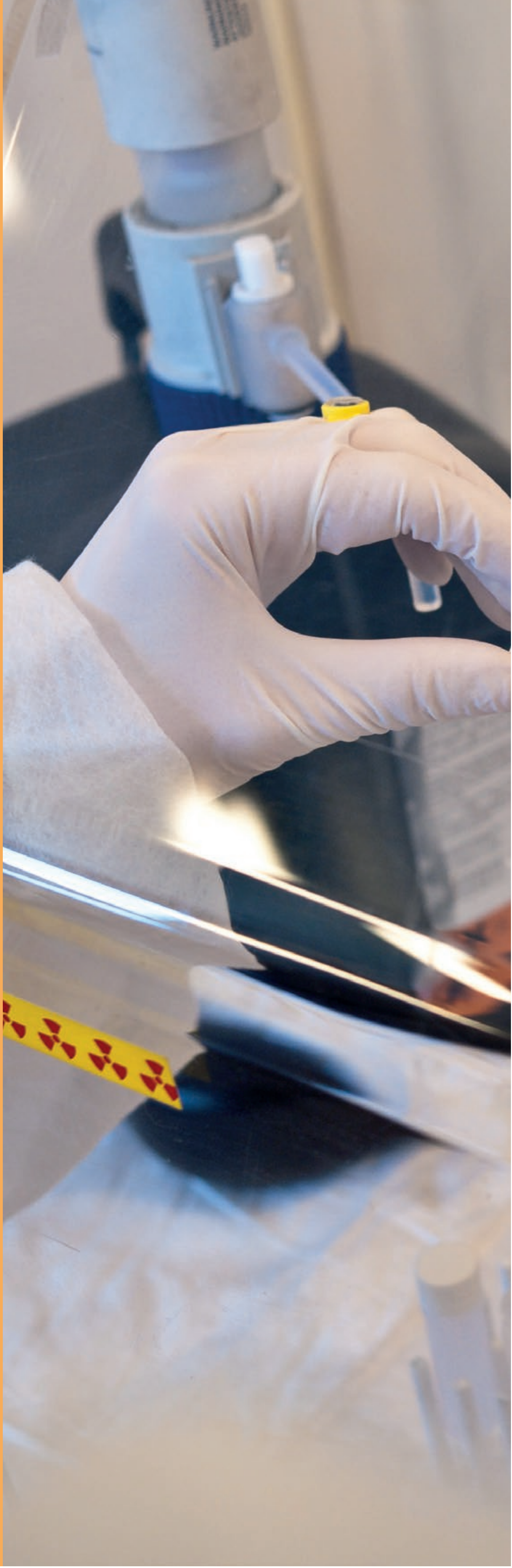
6. Outlook

In radiotherapy, although the safety fundamentals are in place (equipment verifications, medical staff training, quality and risk management policy), ASN still observes significant disparities between centres. The quality initiatives are struggling to achieve long-term continuity, or are even regressing. Furthermore, the experience feedback procedures are losing momentum and the risk analyses remain relatively theoretical and are insufficiently deployed prior to organisational or technical changes. ASN observes a lack of involvement in quality and risk management on the part of the medical staff as a whole, and radiation oncologists in particular, which is nevertheless vital for improving safety.

The opinion of the GPMED concerning the conditions of implementation of high-precision irradiation techniques in radiotherapy and the associated practices has led ASN to assist the learned societies in defining baseline requirements for clinical audits by peers. ASN will remain particularly attentive to the question of the means necessary for the deployment of these audits. ASN has also started to set up a new committee to ensure a coordinated watch over the new techniques and new practices using ionising radiation in the medical field, comprising institutions, learned societies and professional associations involved in radiotherapy. Lastly, the work to better anticipate and manage the organisational and technical changes will be continued in 2018, with volunteer radiotherapy centres and the assistance of the professionals, hospital federations and healthcare institutions.

Verification of the control of doses in medical imaging remains a priority for ASN, particularly when associated with fluoroscopy-guided interventional practices. The recent and rapid development of new imaging techniques, including the arrival of CT scanners in the operating theatre 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. ASN has tasked the GPMED with issuing recommendations to improve the radiation protection of medical staff and patients in the operating theatre.

In early 2018, ASN will publish a new action plan to improve the control of doses in medical imaging, which follows on from the plan developed in 2011, in order to continue promoting a radiation protection culture with medical professionals. The publication of this new plan in the ASN *Official Bulletin* will be accompanied by an ASN opinion intended to update deliberations 2011-DL-0018 and 0019 of 14th June 2011 relative to the improvement of radiation protection in interventional radiology and the increase in doses delivered to patients during computed tomography and conventional radiography examinations.



Sources of ionising radiation and their industrial, veterinary and research applications

10

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 ongoing updating of the regulatory framework for nuclear activities established by the Public Health Code and the Labour Code (see chapter 3) is leading to a tightening of the principle of justification, consideration of natural radionuclides, the implementation of a more graded approach in the administrative systems and measures to protect the sources against malicious acts. These changes will bring substantial modifications in the oversight of industrial, research and veterinary activities which will be introduced progressively as from 2018.

The radiation sources used are either radionuclides - essentially artificial - in sealed or unsealed sources, or electrical devices generating ionising radiation. The practices/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 regulated under the Basic Nuclear Installations (BNI) 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 surrounding 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 can also be used to modify the properties of materials, such as for hardening polymers.

These consumer product irradiation techniques can be authorised because, after being treated, the 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 non-destructive inspection method used for detecting homogeneity defects in materials such as weld beads. It involves obtaining a radiographic image on silver-based or digital media using the gamma rays emitted by a radioactive source and passing through the object to inspect.

It is widely used in fabrication and maintenance operations in diverse industrial sectors such as boilermaking, petrochemicals, nuclear power plants, public works, aeronautics and armament.

Gamma radiography devices contain high activity sealed sources, mainly iridium-192, cobalt-60 or 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:

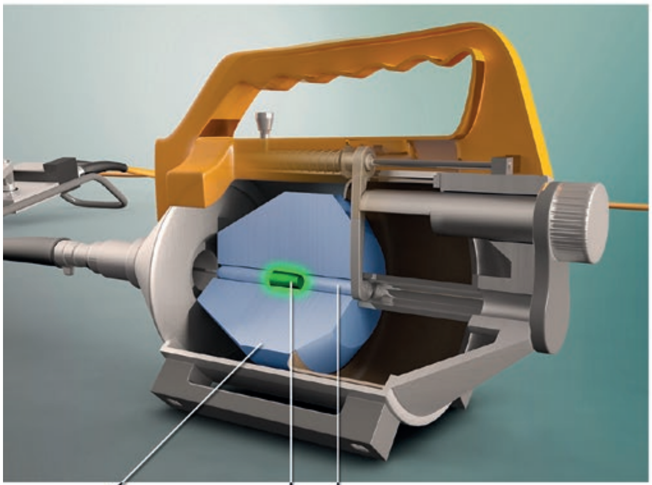
- a source projector which acts as a storage container and ensures radiological protection when the source is not in use;
- a guide tube which guides the movement of the source up to the object to be examined;
- and a remote control cable allowing remote manipulation by the operator.

When the source is ejected out of the projector, the dose rates can reach several grays per hour one metre from the device, depending on the radionuclide and its activity level.

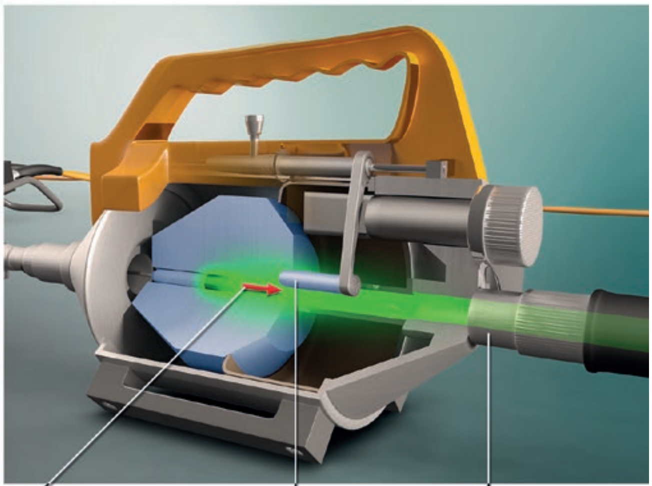
On account of the activity of the sources and the movement of the sources outside the storage container when the device is being used, gamma radiography can entail significant risks for the operators in the event of incorrect use, failure to comply with radiation protection rules, or operating incidents. Furthermore, these gamma radiography activities are often carried out on work sites under difficult conditions (working at night, or in places that are exposed to the elements, or in cramped spaces). This is therefore an activity with serious radiation protection implications that figures among ASN's inspection priorities.

OPERATING SCHEMATIC of a gamma ray projector

Safe position



Open position



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 desired information.

The radionuclides most frequently used are carbon-14, krypton-85, caesium-137, americium-241, cobalt-60 and promethium-147. The source activity levels range from a few kilobecquerels (kBq) to a few gigabecquerels (GBq).

These sources are used for the following purposes:
- Atmospheric dust measurement: the air is permanently filtered through a tape placed between the source and detector running at a controlled speed. 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 megagecquerels – MBq) or promethium-147 (activity level: 9 MBq). These measurements are 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. Generally speaking, americium-241 (activity level: 1.7 GBq), caesium-137 - barium-137m (activity level: 37 MBq) are used, as appropriate.

FUNDAMENTALS

Selenium-75 gamma radiography

The use of selenium-75 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 reason for this is that equivalent dose rates are about 55 millisieverts (mSv) per hour and per TBq one metre from the source, as opposed to 130 mSv/h/TBq for iridium-192. In France, about 17% of the devices are equipped with selenium-75 sources. Although the use of selenium has been increasing constantly since 2014, ASN considers that it is still insufficiently used by the industry professionals. Yet it can be used in place of iridium-192 in numerous industrial fields, especially the petrochemical or boilermaking industry, and it enables the safety perimeters to be significantly reduced and facilitates intervention in the event of an incident (see point 5).

- 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), particularly 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 containing a source of cobalt-60, caesium-137, americium-241 or californium-252. Some sources used are high-activity sealed sources.

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 allows 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 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 in case of sale, a new rental contract, or work significantly affecting the coatings in the common parts of the building.

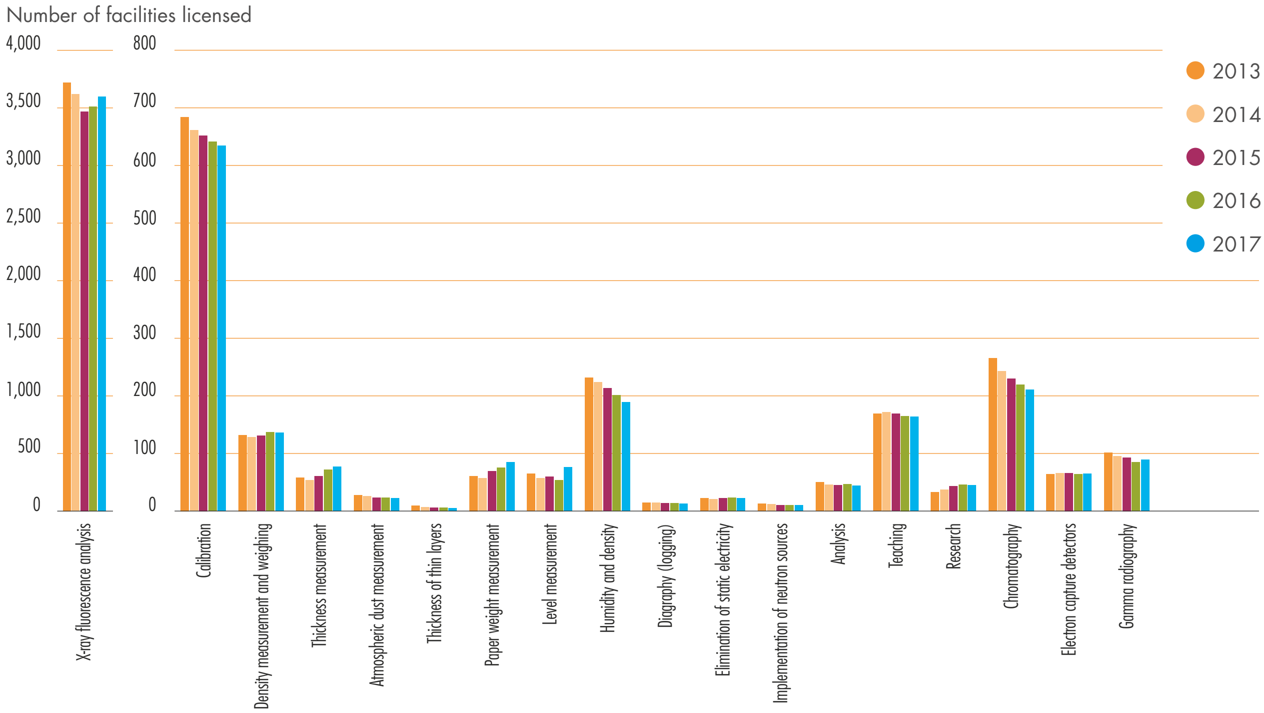
Graph 1 specifies the number of facilities authorized to use sealed radioactive sources for the applications identified. It illustrates the diversity of these applications and their development over the last five years.

It should be noted that a given facility may carry out several of these activities, and if it does, it appears in Graph 1 and the following diagrams for each activity.

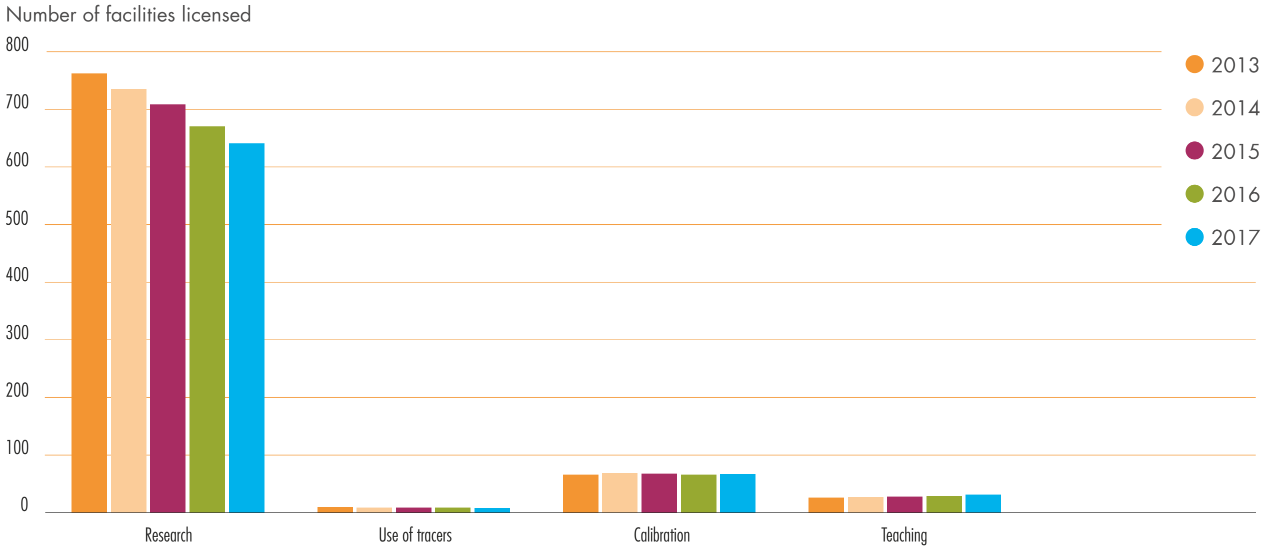
1.2 Unsealed radioactive sources

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 used in particular in research and in the pharmaceutical sector. 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

GRAPH 1: Use of sealed radioactive sources



GRAPH 2: Use of unsealed radioactive sources



measuring wear, looking for leaks or friction spots, building hydrodynamic models and in hydrology.

As at 31st December 2017, the number of facilities authorised to use unsealed sources stood at 747.

Graph 2 specifies the number of facilities authorised to use unsealed radioactive sources in the applications inventoried in the last five years.

2. The use of electrical devices emitting ionising radiation in the industrial, research and veterinary sectors

In industry, electrical devices emitting ionising radiation are used mainly in Non-Destructive Testing (NDT), where they replace devices containing radioactive sources. They are also used in veterinary diagnostic applications. Graphs 3 and 4 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. This evolution is closely related to the regulatory changes which have gradually created a new licensing or notification system concerning the 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).

These devices, which function using the principle of X-ray attenuation, are used 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 to 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.

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 application is mentioned 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). Some experiments have been carried out in France using non-ionising imaging technologies (millimetre waves).

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.

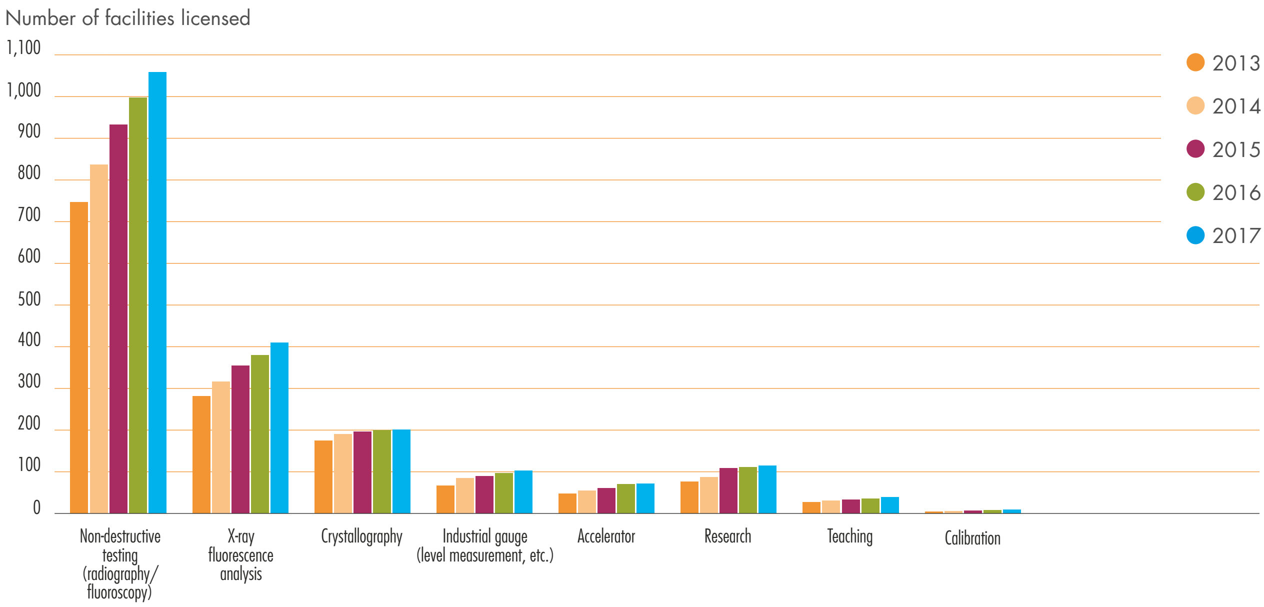
2.2 Veterinary diagnostic radiology

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 indoors - whether in dedicated premises or not - or outside in the open air. This activity has significant radiation protection implications for veterinary surgeons and grooms.

In order to better ensure compliance with regulatory requirements, ASN introduced a notification system in 2009 for what were termed «canine» activities involving less serious radiation risks (see paragraph 4.2.2). This simplification has led to regularisation of the administrative situation of a growing number of veterinary structures (see Graph 4) with about 85% of the structures being notified or licensed

GRAPH 3: Use of electrical devices generating ionising radiation (outside the veterinary sector)

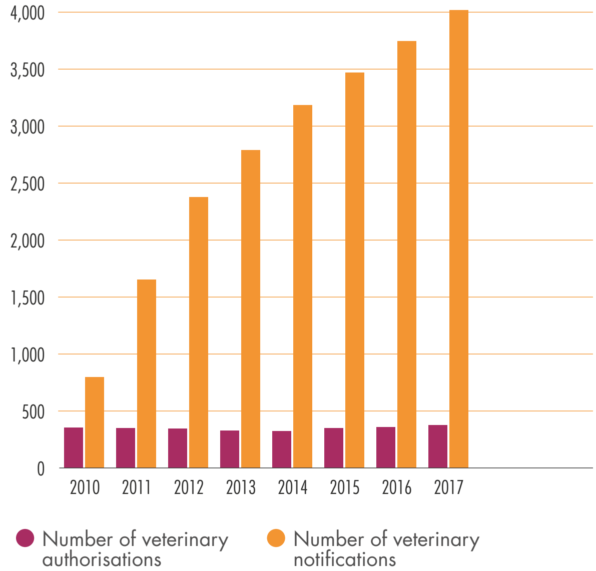


The devices used in the veterinary sector are sometimes derived from the medical sector. However, the profession is increasingly adopting new devices specially developed to meet its own specific needs.

2.3 Particle accelerators

A particle accelerator is defined 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).

GRAPH 4: Use of electrical devices generating ionising radiation for veterinary activities



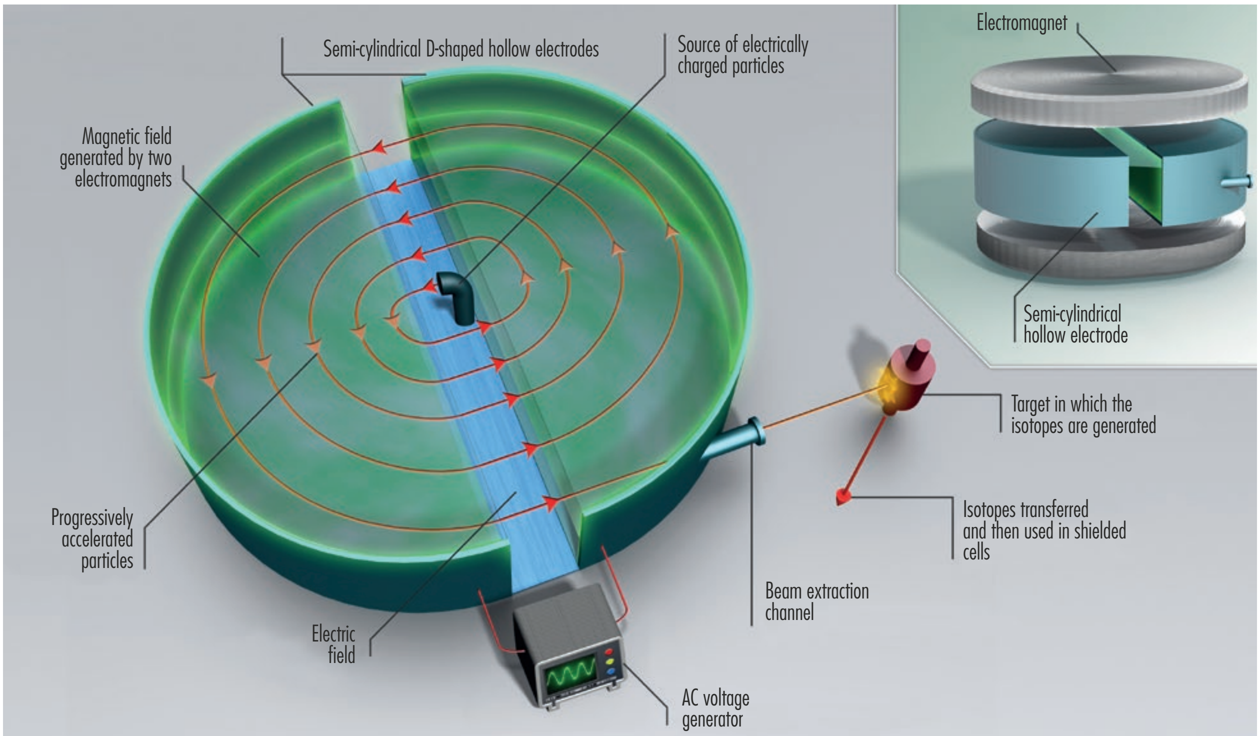
When they meet the characteristics specified in Article 3 of Decree 2007-830 of 11th May 2007 concerning the BNI nomenclature, these facilities are listed as BNIs.

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.

Particle accelerators have been used for a few years now in France to fight fraud and large-scale international trafficking. This technology, which the operators consider effective, must

SIMPLIFIED DIAGRAM of the operation of a cyclotron



FUNDAMENTALS

Synchrotrons

The synchrotron is a member of the same family of circular particle accelerators as the cyclotron (see point 3), but is far larger, enabling energies of several gigaelectronvolts 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.

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 excludes 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.
- 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. Thus, the use of ionising technologies to seek out illegal immigrants in transport vehicles is prohibited in France. 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 concerned by the license and notification exemption criteria set out in Article R. 1333-18 of the Public Health Code.

This category includes, for example, devices generating ionising radiation but not used for this property, such as ion implanters, electron-beam welding equipment, klystrons, certain lasers and certain electrical devices such as high-voltage fuse tests.

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 technical examination of the devices and sources with respect to operating safety and radiation protection conditions during future utilisation and maintenance. It also allows the tracking of source transfers 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, 33 low and medium-energy cyclotrons are currently licensed under the Public Health Code in France. As at 31st December 2017, 31 cyclotrons were in operation. Among these, 18 are used exclusively for the daily production of radiopharmaceuticals, 6 are used for research purposes and 7 are used exclusively for joint production and research purposes.

FUNDAMENTALS

Cyclotrons

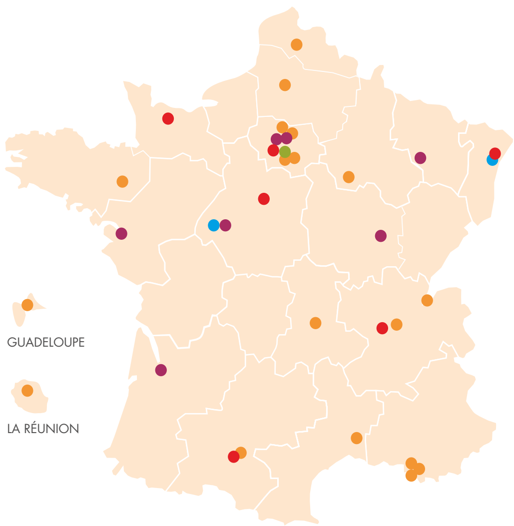
A cyclotron is a device 1.5 to 4 metres in diameter, belonging to the circular particle accelerator family. The accelerated particles are mainly protons, with energy levels of up to 70 MeV. A cyclotron consists of two circular electromagnets producing a magnetic field and between which there is an electric 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 (^{11}C). 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 are oxygen-15 and nitrogen-13. 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.

LOCATION of cyclotrons in France



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. The decree currently under preparation will change the provisions of the Public Health Code. These provisions will change in 2018, particularly with the introduction of the protection of sources against malicious acts and the creation of a new simplified administrative licensing system called registration.

4.1 The Authorities regulating the sources of ionising radiation

ASN is the Authority that grants the licenses, that will issue the registration decisions (see chapter 3) 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 obligation of notification to ASN or licensing by ASN 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 for Protection of the Environment (ICPE) which come under Articles L. 511-1 to L. 517-2 of the Environment Code, and have a licensing system. The Prefect is responsible for including, in the licenses it delivers, radiation protection requirements for the nuclear activities carried out on the site.
- The installations and activities relating to national defence for which 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 under this system. Holding and using other sources within the bounds 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 complying with the requirements of the Public Health Code, and in particular 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 requirements applicable to these installations are therefore now those of the Public Health Code. However, Article 4 of the abovementioned Decree provides that the license or notification issued 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. Before any change relating to the license is made, it shall either be notified to ASN or form the subject of a new license application, depending on the case.

Only establishments holding unsealed radioactive substances or managing radioactive waste in quantities exceeding 10 m^3 for either of these activities are subject to the ICPE System (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 for nuclear materials intended for defence needs, and by the Minister in charge of Energy for 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. 1333-2), namely justification, optimisation of exposure and dose limitation (see chapter 2 and 3).

FUNDAMENTALS

International think tank on alternative technologies

Radioactive sources present safety and security risks for their users, the general public and the environment, which must be taken into consideration in the reflection phase preceding the deployment of a nuclear activity. Consequently, in France, when technologies presenting lower risks than a nuclear activity are available under technically and economically acceptable conditions, they must be implemented instead of the nuclear activity initially envisaged: this is the principle of justification.

On this basis, as of 2014 and subsequently at the Washington Summit on nuclear safety in April 2016, France was the initiator of an international commitment made by 29 States and by Interpol. The aim is to support research into and the development of technologies that do not use high-activity sealed radioactive sources and to promote their use.

In this context, since April 2015 ASN has, along with the National Nuclear Security Administration (United States), initiated a think tank involving several States working on the theme of replacing high-activity radioactive sources by alternative technologies. The think tank's aim is to share the experience feedback of each State in this area in a way that does not constrain its members, who are volunteers. In application of the principle of justification, ASN has presented in particular the work conducted by the French blood bank to replace its irradiators that use radioactive sources by electric irradiators that emit X-rays. ASN also enabled the French Confederation for Non-Destructive Tests to present the progress of its work in replacing gamma radiography by other non-destructive testing technologies. In December 2016, during the international conference on nuclear safety organised by the International Atomic Energy Agency (IAEA), ASN presented the work of the working groups at a round table dedicated to this subject.

The think tank continued its meetings in 2017. Other foreign licensees were able to put forward their experience. These meetings can highlight difficulties in developing or implementing alternative technologies for which further work is needed.

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 applications, 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. As indicated in chapter 3 which describes the applicable regulations, the transposition of European Directive 2013/59/Euratom of 5th December 2013 into French law will more specifically allow a third administrative system situated between the notification and licensing systems to be put in place: this is a simplified authorisation system called "Registration System". ASN is preparing a classification nomenclature for the various categories of nuclear activities between these three systems, which will be progressively implemented as of 2018.

This change will enable ASN to continue 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.

The licensing system

As part of this simplification process (see above), ASN has produced licensing application forms adapted to each activity which are available on *www.asn.fr.*

These documents are designed such that the licensing applications can be made by the representative of a legal person or entity as permitted by the Public Health Code. They do however provide the possibility, subject to justification, of a physical person or entity applying for a license. The forms 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 inspection. It is moreover possible that ASN will request further information during its examination of the license application.

Small-scale nuclear activities stand out through their extreme heterogeneity and the very large number of licensees concerned. ASN must therefore adapt its efforts to their radiation protection implications to ensure effective oversight of these activities. The abovementioned revision of the administrative systems means that these forms will gradually be revised.

The notification system

In 2009, to better adapt the regulatory requirements to the radiation risks, ASN introduced a notification system in the industrial, research and veterinary sectors. This led to the publication of several approved ASN resolutions (see chapter 3), defining on the one hand the scope 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);
- 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 radiation shielding.

The notification system also applies to the activities relating to the installation, maintenance or removal of Ionisation Chamber Smoke Detectors (ICSD) (see point 4.3).

The notification forms drawn up by ASN have been designed to simplify their use and processing. No document is to be enclosed with the notification form. ASN is considering widening the field of activities subject to notification while at the same time continuing to open up its on-line notification portal which further simplifies the procedures. This system is already up and running for transport activity (see chapter 11) and medical activity notifications.

4.2.3 Statistics for 2017

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 2017, 62 source distribution license applications or license renewal applications were examined by ASN, and 41 inspections were carried out.

FOCUS

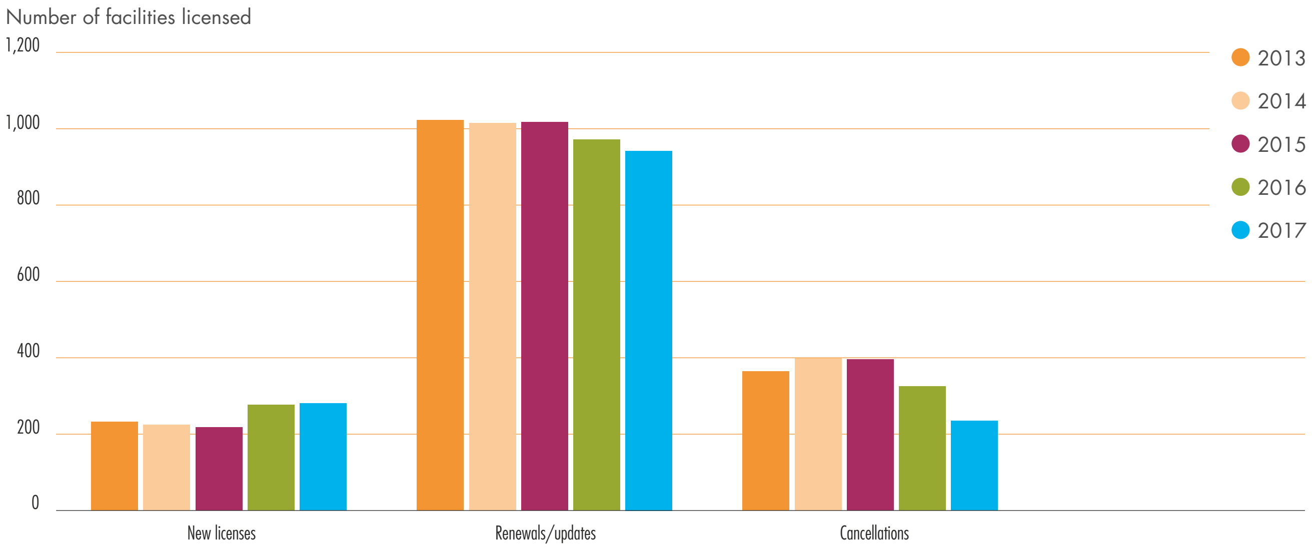
Tracking radioactive sources

Articles R. 1333-47 to 49 of the Public Health Code provide for prior recording by IRSN of transfers of radioactive sources and Article R. 1333-50 for tracking these sources.

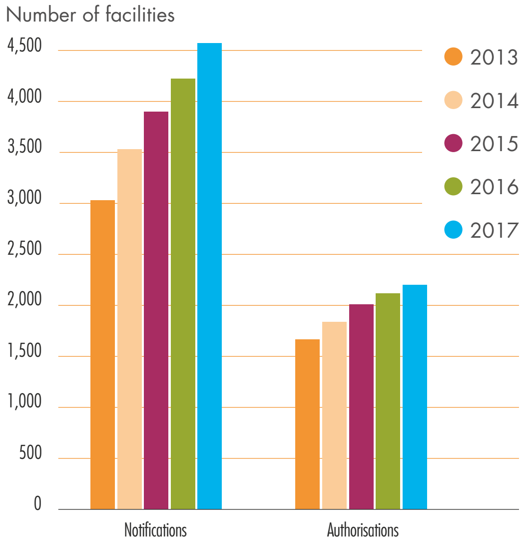
ASN resolution 2015-DC-0521 of 8th September 2015 relative to the tracking and methods of registering radionuclides in the form of radioactive sources and products or devices containing them details the methods of registering transfers and the rules for tracking radionuclides in the form of radioactive sources.

This resolution, applicable as of 1st January 2016, takes into account the existing practice and supplements it as follows by:
- grading source monitoring according to how dangerous the sources are;
- confirming the non-registration of sources whose activity is below the exemption thresholds;
- imposing deadlines between the registering of source transfer and the actual transfer;
- 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.

GRAPH 5: Radioactive source "user" licenses delivered each year



GRAPH 6: Total number of "user" license and notifications for devices generating ionising radiation



Users

Case of radioactive sources

In 2017, ASN reviewed and notified 280 new licenses, 942 license renewals or updates and 235 license cancellations. Graph 5 presents the licenses issued or cancelled in 2017 and trends in this area for the last five years.

Once the license is obtained, the licensee can procure radioactive 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 transfer is then recorded by IRSN, which notifies the interested parties that delivery can take place. If there is any difficulty, the transfer is not validated and IRSN refers the case to ASN (see box).

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 brought into compliance. In 2017, it granted 146 licenses and 319 license renewals for the use of X-ray generators. ASN also issued 346 notification acknowledgements for electrical devices emitting ionising radiation in 2017.

A total of 2,199 licenses and 4,570 notification acknowledgements 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.

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 any addition of radionuclides […] to consumer goods and construction products is prohibited"* (Articles R. 1333-2 and 3). Article R. 1333-4 of this same Code states that waivers to these prohibitions can, if justified by the advantages they bring, 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) (see chapter 3).

Thus, the trading of accessories containing sources of tritium such as watches, key-rings, hunting equipment (sighting devices), navigation equipment (bearing compasses) or river fishing equipment (strike detectors) is specifically prohibited.

ASN considers that this mechanism of granting waivers to the regulations must remain the exception. 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 denied (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).

In 2017, the waiver for the use of a neutron analysis device was renewed for ten years for three cement works, the fourth cement work mentioned in the initial Order of 2011 having closed (Order of 19April 2017 of the Ministers responsible for Health and Construction, ASN opinion 2017-AV-0292 of 7th March 2017).

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, radium-226). The activity of the most recent sources used does not exceed 37 kBq, and the structure of the detector, in normal use, prevents any release 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 Ionisation Chamber Smoke Detectors (ICSDs) 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.

Six years after the implementation of the new regulatory system for ICSD removal and maintenance activities, as at 31st December 2017 ASN had delivered 320 notification acknowledgements and 7 national licenses (delivered to industrial groups with a total of 104 agencies) for ICSD removal and fire safety system maintenance activities. Furthermore, five companies are authorised to perform ICSD decommissioning operations, thereby guaranteeing a disposal route for all the existing detectors.

A smoke detector.

With regard to tracking of the pool of ICSDs, 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. The transmitted information is nevertheless not exhaustive enough to allow a conclusive assessment.

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[1]. ASN participates with the association in communication campaigns targeting the holders of ICSDs and professionals (Expoprotection trade fair, Mayor's 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, storing 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 granting of a license governing the removal of all surge suppressors containing radionuclides present on the Orange network in France and their storage on designated 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 is being 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 at present to remove the radioactive lightning conductors installed in France, except 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).

1. *www.lne.fr/certification/certification-label-qualdion*

A lightning conductor.

ASN nevertheless expects all existing radioactive lightning conductors to be removed and placed in the care of Andra, given the risks they can represent, depending in particular 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 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 conducts field oversight operations targeting the companies involved in recovering these objects, combined with unannounced inspections on the removal sites.

Andra estimates that some 40,000 radioactive lightning conductors were installed in France. Nearly 10,000 have already been removed and transfered to 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

ASN resolution 2017-DC-0591 of 13th June 2017 setting the minimum technical design rules which facilities using X-rays must comply with came into effect on 1st October 2017 (see chapter 3). This resolution replaces ASN resolution 2013-DC-0349 of 4th June 2013 without creating additional requirements for already compliant facilities. It concerns facilities in the industrial and scientific (research) sectors, such as industrial X-ray radiography in bunkers and veterinary radiology. It takes account of experience feedback and sets the radiation protection goals by adopting a graded approach to the risks.

With regard to the design of devices, ASN intends 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.

On the basis of the work done by the LCIE (Electrical Certification and Testing Entity for Bureau Véritas), CEA and IRSN, 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) was conducted in 2015. The various contributions are currently being analysed with the assistance of IRSN and the reference players (CEA and LCIE). The conclusions of this work will be taken into account when defining the new systems mentioned in paragraph 4.2.2 in order to create a new regulatory framework for the distribution of electrical devices generating ionising radiation.

4.5 Implementation of oversight 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 the IAEA which published a Code of Conduct for the Safety and Security of Radioactive Sources (approved by the IAEA 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 the 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 of Conduct 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.

4.5.1 The organisation adopted for overseeing the security of sources

Regulatory oversight of sources for radiation protection and safety purposes and oversight to combat malicious acts have many aspects in common and mutually consistent objectives. This is why ASN's counterparts abroad are usually responsible for oversight in 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 the ASN regional divisions.

For nuclear materials, France can also rely on a system of protection against malicious acts that is implemented by the services of the Defence and Security High Official (HFDS) of the Ministry responsible for Energy.

The Government has therefore decided to set up an organisation for overseeing the protection of ionising radiation sources against malicious acts (hereinafter called oversight of the security of sources) which takes into account the existing oversight systems by entrusting:
- to the services of the HFDS of the Ministry responsible for Energy, oversight of the security of sources in installations whose security is already under their control;
- to ASN oversight of the security of sources held by the other persons/entities responsible for nuclear activities.

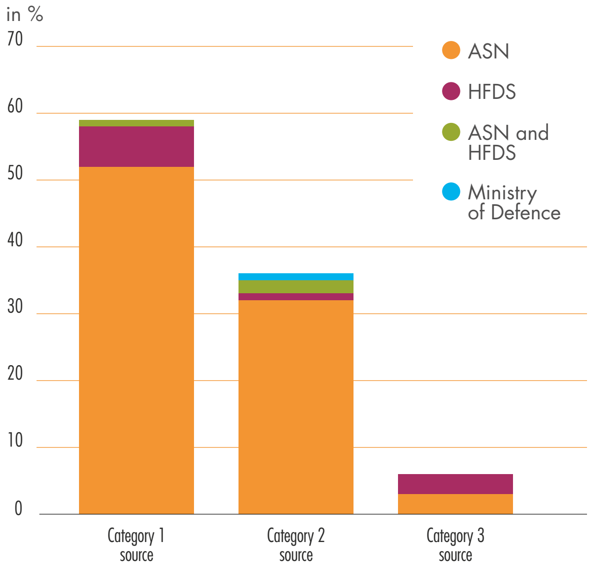
The legislative process necessary for this oversight to be put in place, initiated in 2008 by the Government with the assistance of ASN, resulted in Ordinance 2016-128 of 10th February 2016, which allocates oversight competence in the various installations, and places protection against malicious acts among the concerns to be addressed by the persons/entities responsible for nuclear activities and the services examining license applications.

4.5.2 The sources and installations concerned

Oversight of source security will concern all sources of ionising radiation. Additional regulatory prescriptions will nevertheless be issued to increase the security of the sources presenting the greatest risks. This concerns more particularly sealed radioactive sources in categories 1, 2 and 3 as defined in the IAEA categorisation scheme.

In the civil sector there are about 4,000 sources presenting such risks held in some 250 installations in France. These sources are used essentially for the purpose of industrial irradiation, telegammatherapy, industrial radiography and brachytherapy.

GRAPH 7: Breakdown of the regulatory oversight of protection of sources against malicious acts



Due to their frequent use on worksites, industrial radiography sources present particular security risks during transport.

As explained in section 4.6.1, security oversight of these sources will be ensured essentially by ASN.

Sources that are not in categories, 1, 2 or 3 but which present identical security risks, due to being grouped with other sources when in storage, for example, may also be subject to tightened security provisions.

4.5.3 An initial review of the security of high-activity sealed sources

ASN has continued its actions to determine the situation regarding the security of high-activity sealed sources or presenting equivalent safety risks, currently held in the existing facilities. This resulted in ASN making some 350 visits. At present, virtually all the licensees holding high-activity sealed sources who will be regulated by ASN for the protection of sources against malicious acts have been visited.

ASN has produced a synthesis of the information gathered during these visits, which has among other things fuelled the work to produce the future legally-binding requirements coordinated by the HFDS of the Ministry responsible for Energy and enabled the impact of these requirements to be assessed (see next paragraph).

FUNDAMENTALS

Categorisation of radioactive sources

Radioactive sources are classified by the IAEA, on the basis of predetermined exposure scenarios, in five categories from 1 to 5, according to their ability to create early harmful effects on human health if they are not managed safely and securely. Category 1 sources are considered extremely dangerous while those in category 5 are considered very unlikely to be dangerous. Sources in categories 1 to 3 are considered dangerous for humans to varying degrees.

This categorisation is based solely on the capacity of the sources to produce deterministic effects in certain exposure scenarios and cannot therefore, under any circumstance, be understood as indicating that there is no danger in exposure to a category 4 or 5 source, as such exposure could cause stochastic effects in the longer term. The principles of justification and optimisation must therefore be respected in all cases.

4.5.4 Regulatory work

In 2017, the working group coordinated by the Defence and Security High Official of the Ministry responsible for the Environment continued its work to produce draft regulations concerning the security of sources, and more specifically:
- by incorporating the provisions necessary for the implementation of oversight of the protection of sources against malicious acts in the decree currently under preparation and amending the Public Health Code (see chapter 3), taken in application of Ordinance 2016-128 of 10th February 2016. More specifically, as soon

it becomes applicable, some persons/entities responsible for nuclear activities will have to categorise their sources according to the security risks they present and draw up a list of persons who shall be authorised to have access to the most dangerous sources, to transport them, and to have access to information concerning their protection against malicious acts;
- by preparing a draft ministerial order aiming at setting technical and organisational requirements that persons/entities responsible for nuclear activities will have to apply to protect their sources against malicious acts. This order, whose publication is planned for 2018, should enter into effect progressively. The prescriptions aim, on the basis of a graded approach to the security risks, to limit access to the sources to duly authorised persons, to place one or more physical protective barriers between the sources and persons not authorised access to them, and to make intrusion detection devices mandatory or to ensure the tracking of these sources. Manufacturers and stakeholders have been invited to take part in some of this work in order to give their opinions and comments on the proposed principles.

As indicated earlier, ASN, building on its knowledge of the sources and facilities, actively participated in the drafting of this regulation. In 2018, ASN will be consulted on the draft ministerial order concerning the security of sources.

5. The main incidents in 2017

The inspections conducted on radiation sources and a complete round-up of radiation protection events in the small-scale nuclear activities sector reported to ASN are presented in chapter 4 of this report.

Industrial radiography

Each year ASN is notified of several incidents involving industrial radiography activities. As in 2016 and unlike previous years, no incident was rated level 2 on the INES scale in 2017.

Graph 8 illustrates the trends in the number of incidents notified in the last few years. Graph 9 indicates the main factors implicated in these incidents.

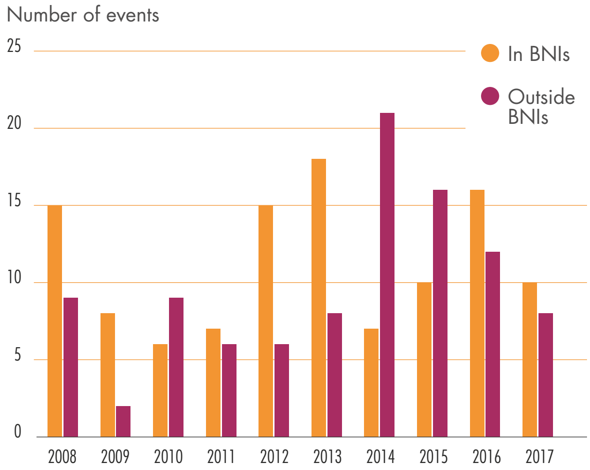
Analysis of the events confirms that cordoning-off the work zone is one of the key steps in the preparation and management of gamma radiograpy worksites.

Experience feedback also shows that properly verifying that the source is in the safe position is essential for avoiding unintended and potentially significant radiation exposure. To do this the operators have various complementary means which constitute the safety barriers (indicators on the device, measurement with a radiation meter, etc.).

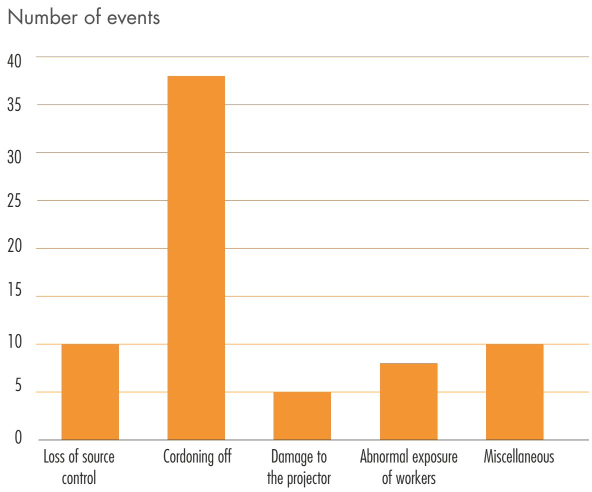
The most noteworthy incident in 2017 concerns the abnormal exposure of two operators who entered the cordoned-off work zone to replace films, not realising that the source had not been returned to the safe position. The operators' passive dosimeters registered effective doses of 9 and 3 mSv, which for one of the operators represents receiving well over a quarter of the regulatory maximum annual individual dose (20 mSv) in a single operation.

The analysis conducted by the licensee and ASN identified numerous deficiencies in the organisation of radiation protection, including in particular the absence of a lighted indicator signalling the actual emission of ionising radiation, the failure to wear an active dosimeter and the absence of an operator holding the Certificate of competence to operate industrial radiography devices.

GRAPH 8: Trend in the number of industrial radiography events notified reported to ASN



GRAPH 9: Main causes of industrial radiography events notified to ASN over the 2015-2017 period



- Loss of source control: situation where the source cannot return normally to the safe position inside the projector.
- Cordoning off: work zone insufficiently or incorrectly cordoned off; intrusion – whether intentional or not – inside the cordoned off work zone.
- Damage to the projector: situation where the gamma ray projector is damaged (for example: fall of the projector).
- Abnormal exposure of workers: situations in which the worker exposure is not consistent with the job analysis (for example: exposure of a radiographer when the source is not in the safe position).

FUNDAMENTALS

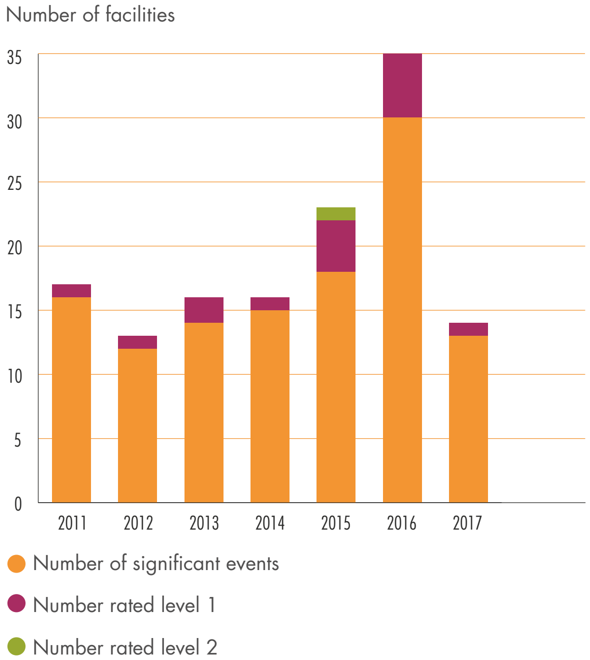
Gamma radiography
Serious accidents abroad

The number and consequences of gamma radiography accidents in France have remained limited 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 keeps a watchful eye for accidents occurring abroad which have had major deterministic effects.

Recent examples brought to ASN's attention include:

- In 2016, in Turkey, the operators had apparently not verified that the source had returned to the safe position after using a gamma ray projector. A 16-year old adolescent found the source the day after the inspection and took it home where several persons said they handled it. 20 people in all were reportedly exposed, with most severely exposed person reportedly receiving a dose of 1 gray (Gy). This event was rated level 2 on the INES scale.
- In 2015, in Iran, two operators were exposed to effective doses of 1.6 and 3.4 gray (Gy) respectively. The gamma ray projector source (iridium-192 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 (iridium-192, 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.

GRAPH 10: Trends in the number of events notified to ASN in the research sector



A series of incidents recorded in 2014 caused by rupture of the plug on GAM 80/120 devices had led ASN to require the supplier to implement preventive measures during annual maintenance of the devices. Only one event of this type has been notified to ASN since 2015, and that was in 2016.

Other source jamming incidents have been 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 still required in worksite preparation and incident management.

Research activities

ASN notes that the follow-up and reporting of events in this area are rarely carried out systematically. Nearly half the inspected licensees do not have procedures relating to the management of significant events. In 2017, ASN registered 15 significant radiation protection events concerning research activities, that is to say half as many as in 2016, which corresponds to the reporting trends observed for the years 2011 to 2014.

FUNDAMENTALS

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 area. It can lead to significant exposure of the workers situated nearby, or even of the public when working 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 moved.

In France, gamma radiography projectors comply 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. Inappropriate operator actions are also observed following source jamming incidents.

ASN notes in particular that the procedures and steps to be taken by radiographers when confronted with these situations are not well enough known and applied.

The reported significant events are of three main types:
- theft or loss of radioactive sources (29%);
- discovery of sources (43%);
- detection of contamination that can sometimes lead to contamination of workers (44%).

The predominance of these themes matches the findings already noted for the period 2014-2016. The source losses and discoveries can be explained in particular by poor overall traceability: lack of measures to ensure their disposal when laboratories ceased their activities in the past; irregular and non-exhaustive inventories.

The detection of contamination, which caused several significant events, is due to the type of sources used in this sector, these being mainly unsealed sources for which contamination cannot be completely excluded, plus bad handling practices. The individual doses involved in these events in 2017 however did not exceed 150 µSv.

6. Assessment of radiation protection in the industrial, research and veterinary sectors, and outlook

In the regulation of practices involving ionising radiation in the industrial, research and veterinary sectors, ASN is working to ensure that the operators take full account of the risks involved in the use of ionising radiation.

Industrial radiography

Industrial radiography activities involve serious radiation risks 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 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. On the whole, the regulations relating to worker training, to the periodic third party inspection of sources and devices and to worker dosimetry are complied with. The preparation of radiography operations however, particularly on worksites, with the cordoning off of the work zone and the estimation of predicted doses, remains insufficient despite the progress made. To remedy these problems, the various actors involved, namely the ordering customers and service providers, must improve their coordination to implement effective preventive measures. ASN considers the deficiencies in work zone delimitation and marking to be worrying, as cordoning off constitutes the main safety barrier in the worksite configuration, in particular to prevent incidental exposure.

The work conditions on the site (poor accessibility, night work, etc.), equipment maintenance (projectors, guide tubes, etc.) are major factors affecting worker safety. The incidents often result from sources getting jammed outside the safe position. ASN notes that the radiographer's workload and condition of the equipment are not unrelated to the probability of an incident. It moreover underlines that if any 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 (see paragraph relative to incidents). Furthermore, if a source becomes jammed, no improvised attempt should be made to free it. The blocking of a source should lead to the deployment of on-site emergency plans, which are required by the regulations but rarely drawn up by the companies.

With regard to justification and optimisation, the work undertaken by the non-destructive inspection professionals have resulted in guidelines which aim to promote the use of alternative methods to industrial radiography. The work is continuing within the professional bodies, in particular with the updating of the construction and maintenance codes for industrial equipment, in order to promote the use of non-ionising inspection methods.

ASN considers that the ordering customers have a key role to play in ensuring progress in radiation protection in industrial radiography. Enhancing the awareness of all the players is therefore a priority. The regional initiatives to establish charters of good practices in industrial radiography implemented for several years now at the instigation of ASN and the labour inspectorate, particularly in areas corresponding to the former regions of Provence-Alpes-Côte d'Azur, Haute-Normandie, Rhône-Alpes, Nord-Pas-de-Calais, Bretagne and Pays de la Loire, allow regular exchanges between the various participants. The ASN regional divisions and other relevant regional administrations also organise regional awareness-raising and discussion symposia which are attracting growing interest from the actors of this professional branch.

Since the noteworthy incidents that occurred in the early 2010's concerning blocked industrial gamma radiography sources, the stakeholders and IRSN have looked into defining, on the basis of experience feedback, typical loss of source control scenarios, developing the technical retrieval solutions and defining good practices in the event of a loss of control incident. Generic technical solutions to facilitate the retrieval of gamma radiography sources following loss of control (see box) have been identified. Several specific tools have been designed and implemented by the supplier for this purpose.

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, devices with iridium-192 sources are the most commonly used, representing two-thirds of the worksites. X-ray generators are mainly used on the other worksites. Very few non-destructive 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 some parts could probably have been transported to a secure bunker for NDT.

The work that ASN and the General Directorate for Labour (DGT) began in 2016 to overhaul the existing regulatory texts, with tightening of the requirements in the area of justification, will be continued in 2018 after publication of the decrees amending the Labour Code and the Public Health Code and transposing the BSS Directive (see chapter 3).

Research establishments

In the research sector, ASN has delivered about 680 licenses under the Public Health Code. The majority of the licensed institutions and laboratories use unsealed sources of radiation for medical and biomedical research, molecular biology, the agri-food industry and the sciences of matter and materials, etc. They also use sealed sources for performing gas-phase chromatography, liquid scintillation counting or in irradiators. Electric generators emitting X-rays are also used for X-ray fluorescence or X-ray diffraction spectrum analyses. Particle accelerators are used in research into matter or for the manufacture of radionuclides.

Each year, ASN carries out 60 inspections on average. Generally speaking, the steps taken in the last few years have brought improvements in the way radiation protection is taken into account in research laboratories and an overall rise in awareness of radiation protection issues. The most remarkable improvements concern the Radiation Protection Expert-Officer (RPE-O) and the conditions of storage of waste and effluents.

ASN does however note that nearly one structure in two does not have procedures governing the reporting and management of 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 for 2012-2015 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 the source to the original supplier.

FUNDAMENTALS

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 used in research into matter or for the manufacture of radionuclides.

The number of licenses issued by ASN in the research sector remains stable at around 800. Each year, ASN carries out 50 to 60 inspections on average in this sector.

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. An annual meeting is held to assess the functioning of this collaboration.

Veterinary surgeons

With regard to veterinary facilities, the administrative situation has been continuously improving for a number of years now. At the end of 2017, ASN counted 4,391 notified or licensed facilities out of approximately 5,000 veterinary structures using ionising radiation in France.

Among 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 most significant radiation risks, more specifically for persons external to the veterinary practice taking part in these procedures. The inspections carried out by ASN on these veterinary clinics have revealed areas for improvement regarding which ASN remains vigilant when reviewing licensing applications and performing inspections:
- worker monitoring by active dosimetry and in-house radiation protection controls;
- setting up supervised or controlled areas;
- the necessity to reinforce the radiation protection of persons external to the veterinary practice who participate in the diagnostic procedures.

The result of the efforts made by the veterinary professional 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 RPE-Os in the majority of structures;
- the virtually systematic use of personal protective equipment;
- efforts to optimise the conditions of diagnosis in nearly all the structures.

The extensive nationwide commitment of this profession to harmonising practices, raising awareness, training student veterinary surgeons and drafting framework documents and guides is viewed in a very positive light by ASN, which each 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 (baptised «canine activities» in France) involve lower radiation risks 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 risks, ASN conducted an experimental control campaign in 2015 and 2016 which called upon new dematerialised control methods. The campaign was carried out in seven *départements* (Aisne, Allier, Aube, Cantal, Haute-Loire, Pas-de-Calais and Puy-de-Dôme). Conducted in close collaboration with the Higher Council of the Order of Veterinarians, this experiment is viewed positively by ASN, which will consider whether it would be worthwhile applying this type of control in other domains or other regions in the coming years.

Suppliers of ionising radiation sources

ASN considers that the regulatory oversight of suppliers of electrical ionising radiation generators is still insufficient, when the design and marketing of such devices contributes significantly to optimising the future radiation protection of the users of these devices (see point 4.4). The work carried out by ASN in this area led to the publication of ASN resolution 2013-DC-0349 of 4th June 2013, which was then revised in 2017 with publication of the resolution of 13th June 2017. Regulatory supervision of the devices distributed in France based on the model for devices containing radioactive sources is also envisaged.

Cyclotrons

ASN has been exercising its oversight duty in this field since early 2010; each new facility or major modification of an existing facility undergoes a complete examination by ASN. The main radiation protection issues on these facilities must be addressed at 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", ensures safe use of the equipment and a significant reduction in risks.

The facilities that have 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.

Systems for filtering and trapping the gaseous effluents are installed in the production enclosures and in the facilities' ventilation systems in order to minimise the activity discharged at the stack outlet. 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 – as close as possible to the shielded enclosures – systems for recovering the gases to let them decay before being discharged, bringing a substantial reduction in the activities discharged into the environment.

ASN performs about ten inspections at facilities of this type each year. Matters relating to radiation protection and safe and 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 – monitoring and maintenance of the production equipment, 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 on the requirements

ASN inspection of the Cyclopharma facility in Saint-Beauzire (Puy-de-Dôme *département*).

necessary for the control of the radiological risks applicable to facilities using a cyclotron. A draft regulatory text on the minimum technical design, operating and maintenance rules for this type of facility was prepared by ASN in 2016 and made available for consultation by the stakeholders. A second version has been drawn up taking account of the comments received and thereby clarifying the content of certain articles. The work has been suspended pending completion of rewriting of the provisions of the Labour Code and the Public Health Code in the regulations (see chapter 3). The work carried out is nevertheless already used in the review of the license application and to set the specific licencing conditions for the facility.

In the same area, ASN has undertaken an in-depth study of the discharges into the environment by these facilities. In 2016, all licensees using a cyclotron to produce radionuclides were sent an initial questionnaire drawn up by ASN and IRSN. IRSN was tasked with analysing the responses and the results of these studies were submitted to ASN in 2017. Complementary discussions with IRSN and the licensees will be continued in 2018 in order to establish a doctrine regarding gaseous effluent discharges for this type of facility.

Implementation of new administrative systems governing nuclear activities

As from 2018, ASN will prepare the entry into effect of new administrative systems applicable to nuclear activities by establishing more specifically, as early as possible, a classification nomenclature for the various categories of nuclear activities. It will use this as a basis for issuing the necessary ASN resolutions so that the nuclear activities can be classified in the notification or registration systems and will define the requirements to be satisfied when exercising the activities. It will also modify the resolutions relating to the content of notifications and of the license application files by incorporating the elements necessary for overseeing the security of sources, among other things.

Overseeing the protection of radioactive sources against malicious acts

In 2017, ASN and its institutional partners continued preparing the texts required for effective monitoring of the protection of radioactive sources against malicious acts. As soon as they are published, initial provisions shall be applicable and the persons/entities in charge of nuclear activities shall more specifically be required to individually authorise access to the most dangerous sources, their transportation and access to sensitive information. They shall be gradually required to take all necessary measures to protect their ionising radiation sources against malicious acts, in accordance with a schedule set by the future texts, which will enable them to look ahead to and plan the measures to implement. ASN has been designated the oversight authority with regard to these provisions for the majority of radioactive sources.

ASN has lastly continued the actions it had undertaken to keep ahead with its staff training and the development of appropriate tools to ensure prompt and efficient embracing of this new mission. Several training sessions have already been organised in 2017. ASN will continue this action in 2018 and will adapt the tools it is already using to control radiation protection (decisions relative to the constitution of license applications, associated forms, publication of guides for the professionals and the inspectors, etc.). It will also ensure that targeted communication actions are directed towards those in charge of the activities concerned.

Transport of radioactive substances

11

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 international regulations.

1. Radioactive substances traffic

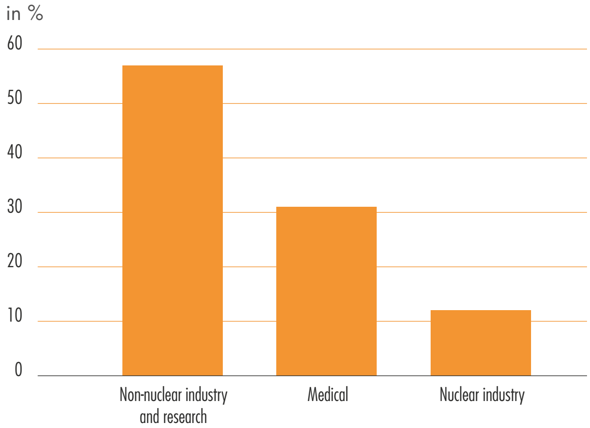
The regulations divide the dangerous goods liable to be transported into nine "classes" according to the nature of the corresponding risk (for example: explosive, toxic, flammable, etc. materials). Class 7 covers radioactive substances.

The transport of radioactive substances stands out through its considerable diversity. Packages of radioactive substances can weigh from a few hundred grams up to about a hundred tons and the radiological activity of their content can range from a few thousand becquerels to billions of billions of becquerels for the packages of spent nuclear fuel. The safety issues are also extremely varied. The vast majority of packages have limited individual safety implications, but for a small percentage of them, the potential safety consequences are high.

About 770,000 consignments 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 vast majority of shipments are made by road, but some also take place by rail, by sea and by air (see Table 1). These shipments concern three activity sectors: non-nuclear industry, medical sector and nuclear industry (see Graph 1).

Most of the packages transported are intended for the non-nuclear industry, or for non-nuclear research: this mainly involves devices containing radioactive sources which are not used in a single location and which therefore need to be transported with considerable frequency. For example, these could be devices for detecting lead in paint, used for real estate sale diagnostics, or gamma radiography devices used to detect defects in materials. Travel to and from the various worksites explains the very large number of transport operations for the non-nuclear industry. The safety issues vary considerably: the radioactive source contained in lead detectors has very low radiological activity, while that contained in gamma radiography devices has a far higher activity.

GRAPH 1: Proportion of packages transported per field of activity



About one third of the packages transported are used in the medical sector: this involves providing health care centres with radioactive sources, for example sealed sources used in radiotherapy, or radiopharmaceutical products, and removing the corresponding radioactive waste. The activity of radiopharmaceutical products decays rapidly (for example, the radioactive half-life of fluorine-18 is close to two hours). Consequently, these products have to be regularly shipped to the nuclear medicine units, creating a large number of transport operations, which have to be carried out correctly to ensure the continuity of the health care given. Most of these products have limited activity levels, although a small proportion of them, such as the sources used in radiotherapy or the irradiated sources used to produce technetium (used in medical imaging) have significant safety implications.

Finally, 12% of the packages shipped in France are for the nuclear industry. This represents about 19,000 shipments annually, involving 114,000 packages. These transport operations are necessary for the working of the fuel cycle, owing to the distribution of the various facilities and NPPs around the country (see map below). Depending on the step in the cycle, the physicochemical form and radiological activity of the substances varies widely. The transport operations with very high safety implications are shipments of uranium hexafluoride (UF_6) whether or not enriched (dangerous more specifically owing to the toxic and corrosive properties of the hydrogen fluoride formed by UF_6 in contact with water), the spent fuel shipments to the La Hague reprocessing plant and the transport of certain nuclear wastes. The annual transports linked to the nuclear industry can be broken down approximately as follows:

- 200 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;
- 400 shipments of new uranium-based fuel and some 50 shipments of new uranium and plutonium-based "MOX" fuel;
- 2,000 shipments from or to foreign countries or transiting via France, representing about 58,000 packages shipped (industrial and type A and B packages).

TRANSPORT OPERATIONS relating to the fuel cycle in France

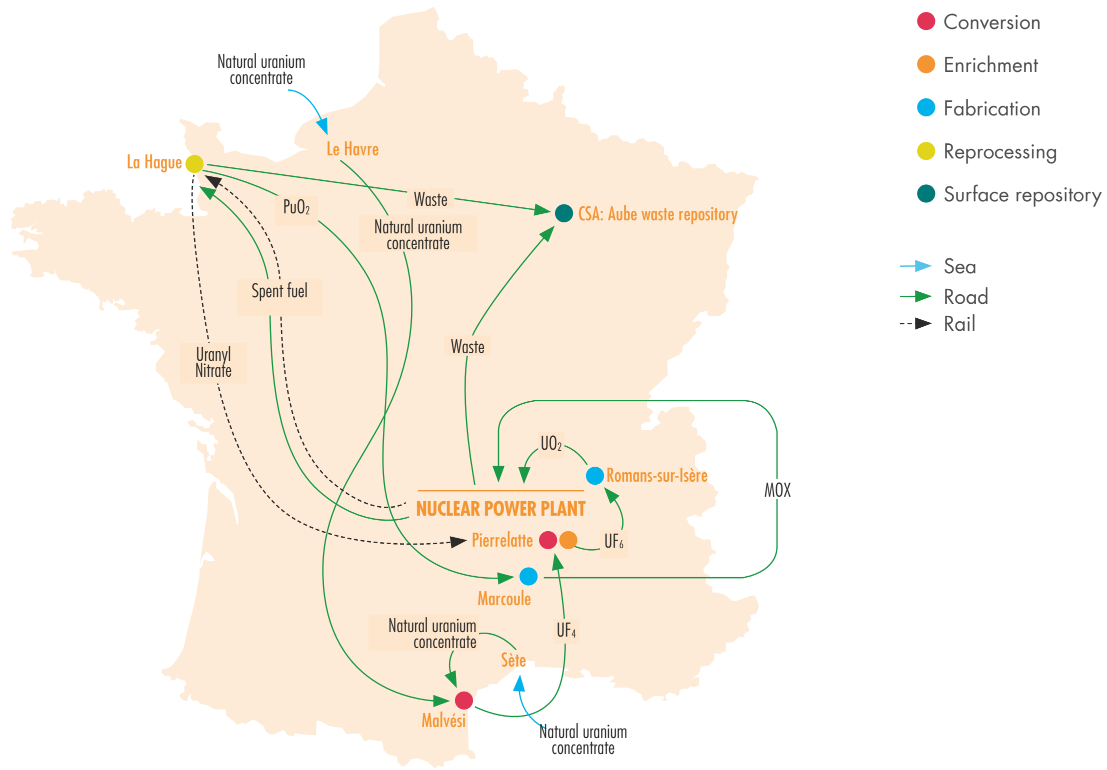


TABLE 1: Breakdown per mode of transport (rounded figures)

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	18,000	1,300	460	1,900	0	0
	Number of shipments	12,500	1,250	380	390	0	0
Packages not requiring approval by ASN	Number of packages	870,000	47,000	2,900	6,800	34,500	5,300
	Number of shipments	740,000	21,000	530	910	80	5,300

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 dangerous goods 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 (ASN survey on radioactive substances traffic)*

2. Regulations governing the transport of radioactive substances

2.1 Risks associated with the transport of radioactive substances

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 "radiological protection" of the packages, a material that reduces the radiation received through contact with the packages of radioactive substances;
- the risk of inhalation or ingestion of radioactive particles in the event of release of radioactive substances out of the packaging;

- contamination of the environment in the event of a release of radioactive substances;
- the onset of an uncontrolled nuclear chain reaction (criticality risk) that can cause serious irradiation of persons. This risk only concerns fissile substances.

Radioactive substances can also present a chemical risk. This, for example, is the case with shipments of natural uranium with low radioactivity, for which the major risk for humans is related to the chemical nature of the compound, more particularly 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 toxic agent.

By their very nature, transport operations take place across the entire country and are subject to numerous contingencies that are hard to control or anticipate, such as the behaviour of other vehicles using the same routes. A transport accident at a given point in the country cannot therefore be ruled out, possibly in the immediate vicinity of the population. Unlike events occurring within Basic Nuclear Installations (BNI), the personnel of the companies concerned are generally unable to intervene immediately, or even give the alert (if the driver is killed in the accident) and the first responding emergency services are not in principle specialists in dealing with a radioactive hazard.

To deal with these risks, specific regulations have been set up to handle radioactive substance transport operations.

2.2 Principle of defence in depth

In the same way as the safety of facilities, the safety of transport is based on the concept of defence in depth, which consists in implementing several technical or organisational levels of protection, in order to guarantee the safety of the public, workers and the environment, in routine conditions, in the event of an incident and in the event of a severe accident. In the case of transport, defence in depth is built around three complementary levels of protection:
- The robustness of the package is designed to ensure that the safety functions are maintained, including in the event of a severe accident and if the implications so warrant. To guarantee this robustness, the regulations stipulate reference tests which the packages must be able to withstand.
- The reliability of the transport operations minimises the occurrence of anomalies, incidents and accidents. This reliability is guaranteed by compliance with the regulatory requirements, such as training of the various persons involved, the use of a quality assurance system for all operations, compliance with the package utilisation conditions, effective stowage of packages, etc.
- Emergency situation management enables the consequences of incidents and accidents to be mitigated. For example, this third level entails the preparation and distribution of instructions to be followed by the various parties in the event of an emergency, the implementation of emergency plans and the performance of emergency exercises.

A transport accident can in theory occur anywhere and could be remote from specialised emergency response services. Consequently, the robustness of the packages is particularly important: the package must, as a last resort, offer sufficient protection to mitigate the consequences of an incident or accident (depending on the level of hazard represented by the content).

2.3 The requirements guaranteeing the robustness of the various types of package

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 which represents the degree of concentration of the material, and its physicochemical form.

The regulations define tests, which simulate incidents or severe accidents, following which the safety functions must still be guaranteed. The severity of the regulation tests is appropriate to the potential danger of the substance transported. Furthermore, additional requirements apply to packages carrying uranium hexafluoride or fissile materials, owing to the specific risks these substances entail.

2.3.1 Excepted packages

Excepted packages are used to transport small quantities of radioactive substances, such as very low activity radiopharmaceuticals. Due to the very limited safety issues, these packages are not subject to any qualification tests. They must nevertheless comply with a certain number of general specifications, notably with regard to radiation protection, to guarantee that the radiation around the excepted packages remains very low.

2.3.2 Type A packages and industrial packages containing non-fissile substances

Type A packages can, for example, be used to transport radioisotopes for medical purposes commonly used in nuclear medicine departments, such as technetium generators. The total activity which can be contained in a type A package is limited by the regulations.

Type A packages must be designed to withstand incidents which could be encountered during transportation or during handling or storage operations (small impacts, package stacking, falling of a sharp object onto the packages, exposure to rain). These situations are simulated by 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 1m.

Additional tests are required if the content of the package is in liquid or gaseous form.

Industrial packages allow the transportation of material with a low specific activity, or objects with limited surface contamination. Uranium-bearing materials extracted from foreign uranium mines are, for example, carried in France in industrial drums with a capacity of 200 litres loaded into

| Areva TN81 transport packaging.

industrial packages. Three sub-categories of industrial packages exist according to the risk presented by the content. Depending on their sub-category, the industrial packages are subjected to the same tests as type A packages, some of the tests or only the general provisions applicable to excepted packages.

As a result of the restrictions on the authorised contents, the consequences of destruction of a type A package or an industrial package would remain manageable, provided that appropriate emergency management measures are taken. The regulations do not therefore require that this type of package be able to withstand a severe accident.

Due to the limited safety issues, type A and industrial packages are not subject to ASN approval: the design of the packages and the performance of the tests are the responsibility of the manufacturer. These packages and their safety demonstration files are subject to spot checks during the ASN inspections.

2.3.3 Type B packages and packages containing fissile substances

Type B packages are those used to transport the most radioactive substances, such as spent fuel or vitrified high-level nuclear waste. The packages containing fissile substances are industrial, type A or B packages, which are also designed to carry materials containing uranium-235 or plutonium and which can thus lead to the start of an uncontrolled nuclear chain reaction. These packages are essentially for the nuclear industry. Gamma radiography devices also fall into the type B package category.

Given the high level of risk presented by these packages, the regulations require that they must be designed so that, including in the case of a severe transport accident, they maintain their ability to confine the radioactive material and ensure radiological protection (for type B packages) as well as sub-criticality[2] (for packages containing fissile materials). The accident conditions are simulated by the following tests:

- A 9m drop test onto an unyielding target. The fact that the target is unyielding means that all the energy from the fall is absorbed by the package, which is highly penalising. If a heavy package actually falls onto real ground, the ground will deform and thus absorb a part of the energy. A 9m drop onto an unyielding target can thus correspond to a fall from a far greater height onto real ground. This test can also be used to simulate the case of the vehicle striking an obstacle. During the 9m free-fall test, the package reaches the target at about 50 km/h. However, this corresponds to a real impact at far greater speed, because in reality, the vehicle and obstacle would both absorb a part of the energy.
- A penetration test: the package is released from a height of 1m onto a metal spike. The aim is to simulate the package being damaged by perforating objects (for example debris torn off a vehicle in the event of an accident).
- A fire test at 800°C for 30 minutes. This test simulates the fact that the vehicle can catch fire after an accident.
- An immersion test under 15m of water for 8 hours. This test is used to verify the pressure-resistance if the package were to fall into water (river by the side of the road or port during offloading from a ship). Certain type B packages must also undergo a more severe immersion test, which involves immersion under 200m of water for one hour.

2. *www.asn.fr/Informer/Actualites/Enquete-de-l-ASN-sur-les-flux-de-transport-de-substances-radioactives (ASN survey on radioactive substances traffic)*

The first three tests (drop, penetration and fire test) must be performed in turn on the same package specimen. They must be performed in the most penalising configuration (package orientation, outside temperature, position of content, etc.).

The type B package models and those containing fissile substances must be approved by ASN or, in certain cases, by a competent foreign Authority, before they can be allowed to travel. To obtain this approval, the designer of the package model must demonstrate the ability to withstand the above-mentioned tests in the safety file. This demonstration is usually provided by means of tests on a reduced-scale mock-up representing the package and by numerical calculations (to simulate the mechanical and thermal behaviour, or to evaluate the criticality risk).

2.3.4 Packages containing uranium hexafluoride

Uranium hexafluoride (UF_6) is used in the fuel cycle. This is the form in which the uranium is enriched. UF_6 can thus be natural (i.e. formed from natural uranium), enriched (i.e. with an isotopic composition enriched in uranium-235), and depleted.

Apart from the dangers arising from its radioactivity, or even its fissile nature, UF_6 also presents a significant chemical risk. The regulations thus set out particular prescriptions for packages of UF_6. They must meet the requirements of standard ISO 7195, which governs the design, manufacture and utilisation of packages. These packages are also subject to three tests:

- a free-drop test of between 0.3 and 1.2 metres (depending on the mass of the package) onto an unyielding target;
- a thermal test, with an 800°C fire for 30 minutes;
- a hydrostatic resistance test at 27.6 bar.

Packages containing enriched, and therefore fissile UF_6, are also subject to the prescriptions previously presented (see point 2.3.3).

The UF_6 is transported in type 48Y or 30B metal cylinders. In the case of enriched UF_6, this cylinder is transported with a protective shell, which provides the necessary protection for withstanding the tests applicable to packages containing fissile materials. The package models containing UF_6 must also be approved by ASN or a competent foreign Authority, before they can be allowed to travel.

2.3.5 Type C packages

Type C package models are designed for the transport of highly radioactive substances by air. In France there is no approval for type C packages for civil uses.

2.4 The requirements guaranteeing the reliability of the transport operations

2.4.1 Radiation protection of workers and the public

The radiation protection of workers and the public around shipments of radioactive substances must be a constant concern.

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).

TABLE 2: Breakdown of transported packages by type

	TYPE OF PACKAGE	APPROXIMATE SHARE OF PACKAGES TRANSPORTED ANNUALLY
Packages approved by ASN	Type B packages, packages containing fissile materials and packages containing UF_6	2%
Packages not requiring approval by ASN	Type A packages not containing fissile radioactive substances	32%
	Industrial packages not containing fissile radioactive substances	8%
	Excepted packages	58%

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 may be raised to 10 mSv/h in “exclusive use”[3] conditions, because the consignor or consignee can then issue instructions to restrict activities in the vicinity of the package. In any case, 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 metres from the vehicle. Assuming that radiation at the surface of a transport vehicle reaches the limit of 0.1 mSv/h at 2 metres, a person would have to spend 10 consecutive hours at a distance of 2m 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 companies working in transport operations are required to implement a radiological protection programme, comprising the steps taken to protect the workers and the public from the risks linked to exposure to ionising radiation. This programme is more specifically based on a forecast evaluation of the doses to which the workers and the public are exposed. According to the results of this evaluation, optimisation measures must be taken to ensure that these doses are As Low as Reasonably Achievable (ALARA principle): for example, lead-lined trolleys could be made available to handling staff to reduce their exposure. This evaluation also makes it possible to decide on whether to implement dosimetry to measure the dose received by the workers, if it is anticipated that this risk could exceed 1 mSv/year. Finally, all the transport stakeholders must be trained in the risks linked to radiation, so that they are conscious of the nature of the risks, as well as how to protect themselves and how to protect others.

The workers involved in the transport of radioactive substances are also subject to the provisions of the Labour Code concerning protection against ionising radiation.

3. *Exclusive use corresponds to cases in which the vehicle is used by a single consignor. This consignor may then give specific instructions for all the transport operations.*

FOCUS

Steps by ASN to improve how radiation protection regulatory requirements are taken into account

The inspections carried out by ASN in recent years show that certain transport stakeholders do not take adequate account of the risk of exposure of workers and the public to ionising radiation. However, transport activities can have considerable radiation protection implications, in particular for workers. The individual monitoring of exposure to ionising radiation shows that drivers carrying radiopharmaceutical products are more exposed than the average worker in other activity sectors, with annual doses that can reach 14 millisieverts (mSv). This represents a significant fraction of the regulatory limit set at 20 mSv/year.

The regulatory provisions designed to protect the public, workers and the environment stem from a variety of sources: the specific regulations governing the transport of radioactive substances, the Labour Code and the Public Health Code. Reconciling these various texts may lead to difficulties with interpretation. In order to promote coherent oversight of radiation protection, ASN and the General Directorate for Labour issued a joint document in 2017 intended for radiation protection and labour inspectors, specifying how the various texts are interconnected.

On the basis of this document, ASN prepared a draft guide in 2017 intended for transport professionals which aims to recall the various regulatory requirements, specifying how they are interconnected when this can lead to difficulties, and which presents ASN's recommendations for their correct implementation. This draft guide was submitted for public consultation in November 2017; it will be published on the ASN website in 2018.

2.4.2 Package and vehicle signage

So that the workers can be informed of the level of risk involved in each package and so that they can protect themselves effectively, the regulations require that the packages be labelled. There are three types of labels, corresponding to different dose levels in contact and at 1m from the package. The personnel working in proximity to the packages are thus visually informed of those which lead to the highest dose rates and can thus limit the time they spend close to them and can put them as far away as possible (for example by loading them towards the rear of the vehicle).

The packages containing fissile materials must also carry a special label. This is to ensure that these packages are kept apart to prevent the triggering of a nuclear chain reaction. The special label enables compliance with this prescription to be easily verified.

Finally, the markings on packages must comprise their type, the address of the consignor or consignee and an identification number. This enables delivery errors to be avoided and allows packages to be identified if lost.

The vehicles carrying packages of radioactive substances must also have specific markings. Like all vehicles carrying dangerous goods, they carry an orange-coloured plate at the front and back. They must also have a placard with the radiation trefoil and the word "RADIOACTIVE". The purpose of these vehicle placards is to provide the emergency services with the necessary information in the event of an accident.

2.4.3 Responsibilities of the different transport players

The regulations define the responsibilities of the various parties involved during the lifetime of a package, from its design up to the actual shipment. These responsibilities entail special requirements. Therefore:

- The package model designer shall have designed and sized the packaging in accordance with the intended conditions of use and the regulations. It must obtain an ASN certificate (or in certain cases a certificate from a foreign authority) for type B or fissile packages containing UF_6).
- The manufacturer must produce packaging in accordance with the description given by the package designer.
- The consignor is responsible for providing the carrier with a package complying with the requirements of the regulations. It must in particular ensure that the material is authorised for transport, verify that the package is appropriate for its content, use a package that is approved (if necessary) and in good condition, carry out dose rate and contamination measurements and label the package.
- The loader is responsible for loading the package onto the vehicle and for stowing it in accordance with the consignor's specific instructions and the rules of professional good practice.
- The carrier is responsible for carriage of the shipment to its destination. It must notably check the good condition of the vehicle, the presence of the on-board equipment (extinguishers, driver's personal protection equipment, etc.), compliance with the dose rate limits around the vehicle and the positioning of the orange plates and placards.
- The transport may be organised by the forwarding agent. They are responsible, on behalf of the consignor or the consignee, for obtaining all the necessary authorisations and for sending the various notifications. The forwarding agent also selects the means of transport, the carrier and the itinerary, in compliance with the regulatory requirements.
- The consignee is under the obligation not to postpone acceptance of the goods, without imperative reason and, after unloading, to verify that the prescriptions concerning it have been satisfied. It must more specifically take dose rate measurements on the package after receipt in order to detect any problems that may have occurred during shipment.
- The package owner must set up a maintenance system in conformity with that described in the safety file and the approval certificate in order to guarantee that the elements important for safety are maintained in good condition

All the transport stakeholders must set up a quality assurance system, which consists of a range of provisions for guaranteeing compliance with the regulatory requirements and providing proof thereof. This for example consists in performing double independent checks on the most important operations, in adopting a system of checklists to ensure that the operators forget nothing, in keeping a trace of all the operations and all the checks performed, etc. The quality assurance system is a key element in ensuring the reliability of transport operations.

The regulations also require that all operators involved in transport receive training appropriate to their functions and responsibilities. This training must in particular cover the steps to be taken in the event of an accident.

Contractors who carry, load, unload or handle (after loading and before unloading) packages of radioactive substances on French soil shall declare themselves to ASN.

Seven days before departure, the transport of some radioactive substances (notably fissile materials) is subject to prior notification of 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 consigner, the carrier and the consignee. It is a means of ensuring that the public authorities have rapid access to useful information in the event of an accident. In 2017, 1,659 notifications were sent to ASN.

2.5 Preparedness for emergency management

Emergency management is the final level in the defence in depth system. In the event of an accident involving transport, it should be able to minimise the consequences for persons and the environment.

As a transport accident can happen anywhere in the country, it is probable that the emergency services arriving on the scene would have no specific training in radiological risks and that the population in the vicinity would be unaware of this particular risk. It is therefore particularly important that the national emergency response organisation be robust enough to take account of these points.

In this respect, the regulations set obligations on the various stakeholders in the field of transport. All those involved must therefore immediately alert the emergency services in the event of an accident. This is more particularly true for the carrier, who would in principle be the first party to be informed. It must also transmit the alert to the consignor. Furthermore, the vehicle crew must have written instructions available in the cab, stipulating the first steps to be taken in the event of an accident (for example, trip the circuit-breaker, if the vehicle is so equipped, to prevent any outbreak of fire). Once the alert has been given, the parties involved must place themselves at the disposal of the public authorities to assist with the response operations, more specifically by providing all pertinent information in their possession. This in particular concerns the carrier and the consignor who have information about the package and its contents that is of great value for determining the appropriate measures to be taken. To meet these regulatory obligations, ASN recommends that the parties involved implement emergency response plans allowing the organisation and tools to be defined in advance, enabling them to react efficiently in the event of a real emergency.

The driver may be unable to give the alert, if injured or killed in the accident. In this case, detection of the radioactive nature of the consignment would be the entire responsibility of the emergency response services. The orange-coloured plates and the trefoil symbols on the vehicles thus indicate the presence of dangerous goods: the emergency services are then ordered to automatically evacuate an area with a radius of 100 m around the vehicle and notify the radioactive nature of the load to the office of the Prefect, which will then alert ASN.

Management of the accident is coordinated by the Prefect, who oversees the response operations. Until such time as the national experts are in a position to provide him or her with advice, the Prefect relies on the emergency plan adopted to deal with these situations (see box). Once its national emergency centre has been activated, ASN is able to offer the Prefect assistance by providing technical advice on the more specific measures to be taken. In these situations, IRSN assists ASN by assessing the condition of the damaged

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ASN recommendations in the event of a transport accident

The response by the public authorities in the event of a transport accident comprises three phases:

1. The emergency services reach the site and initiate "reflex" measures to limit the consequences of the accident and protect the population. The radioactive nature of the substances involved is discovered during this phase.
2. The entity coordinating the emergency response confirms that the substances are indeed radioactive, alerts ASN and IRSN and gives more specific instructions to the responders, pending the activation of the national emergency centres.
3. Once the ASN and IRSN emergency centres have been activated, a more detailed analysis of the situation is made in order to advise the person in charge of the emergency operations.

During the first two phases, the emergency services must manage the situation without the support of the national experts. In 2017, with the assistance of IRSN and the national Nuclear Risk Management Aid commission (MARN), ASN drafted a document to help direct the actions of the emergency services. It contains general information about radioactivity, general recommendations for the emergency services so that their response can take account of the specific nature of radioactive substance transports, plus sheets organised per type of substance, providing more detailed information and advice for the emergency response coordinator during phase 2.

This enabled old sheets to be updated by incorporating changes in accident management procedures and lessons learned from emergency exercises.

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Stress tests in the field of transport

As radioactive substances are transported on the public highway, the possibility of an accident exceeding the regulation package design criteria (see point 2.3) cannot theoretically be ruled out. For packages transporting the most dangerous contents, the consequences for public health and safety and the environment could be significant. ASN thus expressed the desire to see the stress tests approach extended to the transport field, in the same way as was done in the BNIs.

The Advisory Committee for Transport (GPT) met on 12th June 2017 to examine a methodology for applying the stress tests approach to transports. In the light of its opinion, ASN in November 2017 asked the six consignors of the packages with the most significant public health and safety or environmental protection implications:

- to determine the "extreme" hazards, in other words of an intensity exceeding those of the regulation tests, to which these potentially high-risk packages could be subjected, given the actual or envisaged transport conditions encountered;
- on the basis of a qualitative assessment, to identify the packages liable to lead to significant consequences in the event of an extreme hazard;
- to plan measures to mitigate these consequences, the means necessary for implementing them and the corresponding response times;
- to include these measures, means and times in their emergency plan and take steps to ensure that they remain valid for the future.

package and anticipating how the situation could develop. Furthermore, the ASN regional division dispatches a staff member to the Prefect to facilitate liaison with the national emergency centre.

At the same time, human and material resources would be sent out to the scene of the accident as rapidly as possible (radioactivity measuring instruments, medical means, package recovery means, etc.). The fire service teams specialising in the radioactive risk (the Mobile Radiological Intervention Units – CMIR) would be called on, along with IRSN's mobile units, or the mobile units of certain nuclear licensees (such as CEA or EDF), which could be requisitioned by the Prefect if necessary, even if the shipment in question does not concern these licensees.

As with other types of emergency, communication is an important issue in the event of a transport accident so that the population can be informed of the situation and given instructions on what to do.

In order to prepare the public authorities for the eventuality of an accident involving a shipment of radioactive substances, exercises are held to test the entire response organisation that would be put into place. In 2017, ASN thus took part in a national emergency exercise simulating a rail accident involving a package of high-level waste. The office of the Prefect, the emergency services, ASN, IRSN and a carrier were involved in this exercise.

2.6 Regulation governing the 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 Order of 7th February 2012 setting out the general rules applicable to BNIs (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 2017, ASN published guide N° 34 providing the licensees with recommendations for implementing the regulatory requirements concerning on-site transport operations. In 2017, ASN also authorised on-site transport operations for dangerous goods taking place in the EDF NPPs and within the perimeter of the Areva plant at La Hague.

3. Roles and responsibilities in regulating the transport of radioactive substances

3.1 Regulation of nuclear safety and radiation protection

In France, ASN has been responsible for regulating the safety and the radiation protection of transports of radioactive substance for civil uses since 1997, while ASND (the Defence Nuclear Safety Authority) fulfils this role for transports relating to national defence. Within its field of competence, ASN is responsible, in terms of safety and radiation protection, for the regulation and oversight of all steps in the life of a package: design, manufacture, maintenance, shipment, actual carriage, receipt, etc.

3.2 Protection against malicious acts

The prevention of malicious acts consists in preventing sabotage, losses, disappearance, theft and misappropriation of nuclear materials that could be used to manufacture weapons. The Defence and Security High Official (HFDS), under the Minister responsible for Energy, is the Regulatory Authority responsible for preventing malicious acts targeting nuclear materials.

3.3 Regulation of the transport of dangerous goods

Regulation of the transport of dangerous goods is the responsibility of the dangerous materials transport commission of the Ministry for Ecological and Solidarity-based Transition. 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. Inspections in the field are carried out by land transport inspectors attached to the Dreals (Regional Directorates for the Environnment, Planning and housing).

For the regulation of dangerous goods to be as consistent as possible, ASN collaborates regularly with the administrations concerned. For example, in 2017 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 3.

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 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 with all the regulatory requirements. Before deciding whether or not to issue approval, ASN examines this file, drawing on the expertise of IRSN, in order to ensure that the safety cases are pertinent and conclusive. If necessary, the approval is issued with requests in order to improve the safety cases.

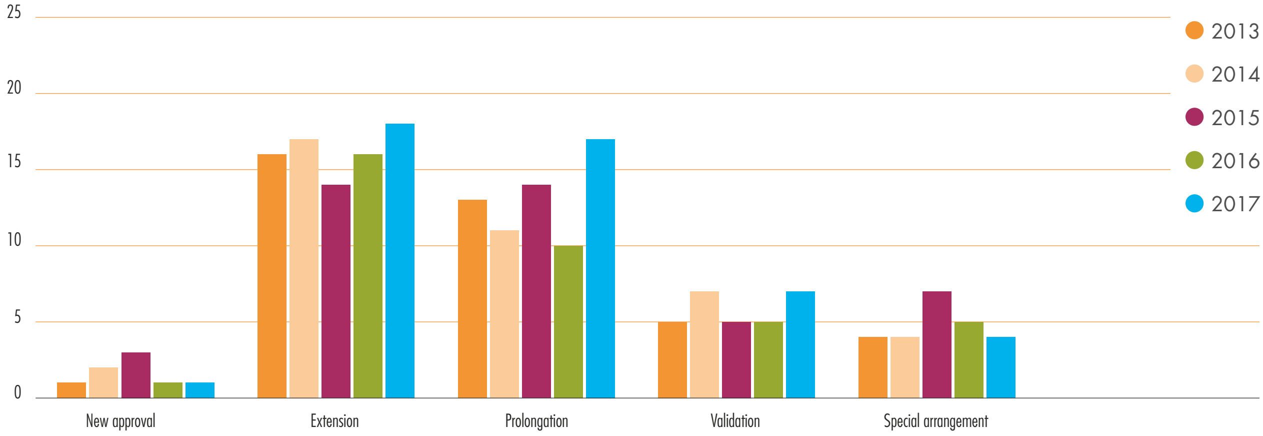
In some cases, IRSN's appraisal is supplemented by a meeting of the Advisory Committee for Transport (GPT). The opinions of the Advisory Committees are always published on *www.asn.fr.* The GPT for example met in 2017 to examine the TN G3 package model developed by the Areva TN company to transport spent fuel from the EDF NPPs.

The approval certificate specifies the conditions for the manufacture, utilisation and maintenance of the transport package. It is issued for a package model independently of the

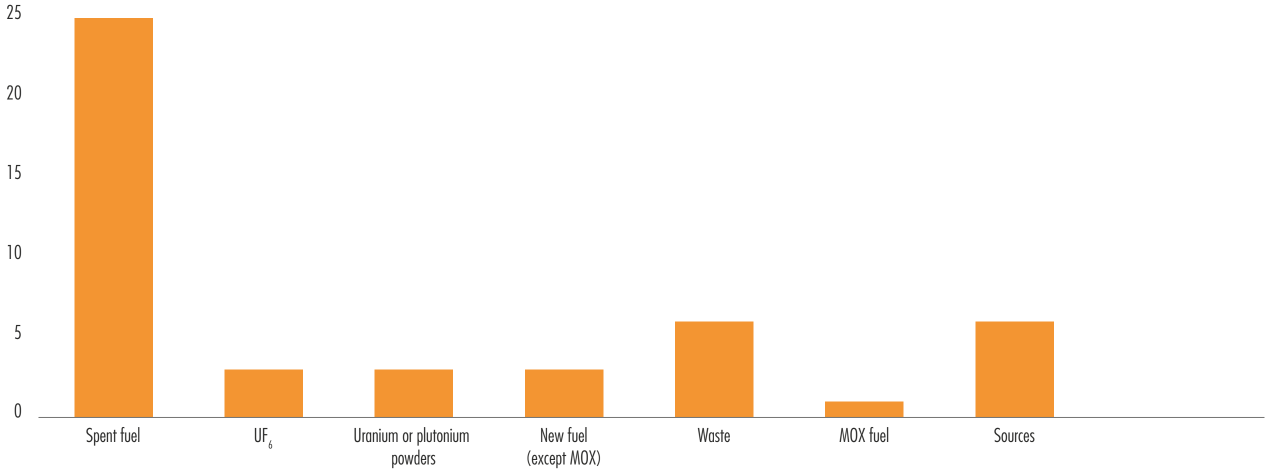
TABLE 3: Administrations responsible for regulating the mode of transport and the package

MODE OF TRANSPORT	REGULATION OF MODE OF TRANSPORT	PACKAGE REGULATION
Sea	General Directorate for Infrastructures, Transports and the Sea (DGITM) at the Ministry for Ecological and Solidarity-based Transition. In particular, the DGITM is responsible for regulating compliance with the prescriptions applicable to ships and 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).	The DGITM has competence for regulation of dangerous goods packages in general and is in close collaboration with ASN for radioactive substances packages.
Road, rail, inland waterways	General Directorate for Energy and Climate (DGEC) of the Ministry for Ecological and Solidarity-based Transition (MTES).	The General Directorate for the Prevention of Risks (DGPR) is responsible for regulation of packages of dangerous goods in general and, in close collaboration with ASN, of packages of radioactive substances.
Air	General Directorate of Civil Aviation (DGAC) of the MTES.	The DGAC has competence for regulation of dangerous goods packages in general and, in close collaboration with ASN, of radioactive substances packages.

GRAPH 2: Breakdown of the number of approvals according to type



GRAPH 3: Breakdown of the number of approvals in 2017 according to the transported content



actual transport operation itself, for which no prior ASN opinion is generally required. This operation may however be subject to security checks (physical protection of the materials against malicious acts under the supervision of the HFDS at the Ministry for Ecological and Solidarity-based Transition).

These approval certificates are usually issued for a period of five years.

If a package is unable to meet all the regulatory requirements, 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 requirements been met. For example, if it cannot be completely demonstrated that a package is able to withstand the 9-metre drop, a compensatory measure may be to reduce the speed of the vehicle and have it escorted. The probability of a serious 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, stipulating the compensatory measures to be applied.

Castor HAW28 packaging being loaded.

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. In 2017, 65 approval applications were submitted to ASN by the manufacturers.

ASN delivered 47 approval certificates or shipment approvals, for which the breakdown by type is shown in Graph 1. The nature of the transport operations and packages concerned by these certificates is shown in Graph 2.

4.2 Monitoring all the stages in the life of a package

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 2017, ASN carried out 105 inspections in the field of radioactive substances transport (all sectors considered). The follow-up letters to these inspections are available on *www.asn.fr.*

4.2.1 Regulation of package manufacturing

The manufacture of transport packaging is subject to the regulations applicable to the transport of radioactive substances. The manufacturer is responsible for producing packagings in accordance with the specifications of the safety analysis file, demonstrating regulatory compliance of the corresponding package model. To do this, it implements a quality assurance system covering all the operations from procurement of parts and materials up to final inspections. Furthermore, the manufacturer must be able to prove to ASN that it complies with the regulatory provisions and, in particular, that the packagings manufactured are compliant with the specifications of the safety analysis file.

Preparation of the Robatel R76 packaging for shipment, November 2017.

The inspections carried out by ASN in this field aim to ensure that the manufacturer satisfactorily fulfils its responsibilities.

In 2017, ASN carried out five inspections on the manufacturing operations for various packagings certified by ASN, at various steps in the process: welding, final assembly, manufacturing completion checks, assembly of internals (for immobilising the contents), etc. For example, on 23rd March, ASN inspected the manufacture of examples 3 and 4 of the TN 112 package model used to transport spent MOX fuel from the EDF NPPs to La Hague. The inspectors examined how Areva TN, the client, monitored its subcontractor and they attended the installation of lead shielding around the shell of a packaging. Some packagings are used for international shipments. Three inspections on the manufacturing operations were thus carried out jointly with a safety regulator from another country: Belgium, Switzerland and Spain.

During these inspections, ASN checks the quality assurance procedures implemented for the production of a package on the basis of the design data and verifies their effective implementation. ASN ensures that the inspections and any manufacturing deviations are traceable. It also visits the manufacturing shops to check the package components storage conditions, the calibration of the inspection instruments and compliance with the technical procedures at the various manufacturing steps (welding, assembly, etc.).

ASN checks the monitoring of package manufacturing by the lead contractor and may intervene directly on the sites of any subcontractors, who may sometimes be located abroad.

ASN may also inspect the manufacture of the specimens used for the regulation 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. There were no inspections of this type in 2017, because, as far as ASN was aware, no test specimens were being 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 analysis 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, welds, seals, etc.);
- the periodic inspections of the securing and handling components;
- definition of the frequency of replacement of the package components which must take account of any reduction in performance due to wear, corrosion, ageing, etc.

In 2017, ASN carried out six inspections on the conformity of the maintenance operations, for example on the MX 8 (package model used to transport new MOX fuel from the Mélox plant to the EDF NPPs), UX 30 (package model used to transport a

ASN inspection of a package shipment, November 2017.

cylinder of enriched UF_6) or GMA 2500 (gamma ray projector model requiring transport approval because it is shipped once loaded with its radioactive source).

4.2.3 Inspections of packages not requiring approval

For the packages that do not require ASN approval, the consignor must, at the request of ASN, be able to provide the documents proving that the package model complies with the applicable regulations. More specifically, for each package, a file demonstrating that the model meets the regulation requirements and that it can in particular withstand the specified tests, along with a certificate delivered by the manufacturer attesting full compliance with the model specifications, must be held at the disposal of ASN.

The various inspections carried out in recent years confirm the progress made concerning the documents presented to ASN and the integration of the ASN recommendations made in its guide concerning packages which are not subject to approval (Guide No.7, volume 3).

In 2016, ASN published the updated version of this guide. 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 requirements, along with the minimum content of a declaration 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. The representativeness of the tests performed and the associated safety case remain the focal points during the ASN inspections, in particular for type A packages.

Furthermore, ASN still finds that some of the entities (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 focus in particular on the following:
- the description of the authorised contents per type of package;
- the demonstration that there has been no loss or dispersion of the radioactive content under normal transport conditions;
- compliance with the regulatory requirements regarding radiation protection, more specifically the demonstration as of the design stage that it would be impossible to exceed the dose limits with the maximum authorised content.

In 2017, ASN carried out seven inspections on the design, manufacture and maintenance of packages not requiring approval. It more particularly carried out a joint inspection with the Belgian Authority at a Belgian designer of a package model used to transport fluorine-18 (used in the medical field) in France. This inspection was conducted as a result of several events involving these packages. It showed that the quality management system set up by the package manufacturer needed to be improved. The safety analysis files and compliance certificates issued by the manufacturer were incomplete. Subcontractor monitoring also needed to be reinforced.

4.2.4 Monitoring the shipment and transportation of packages

ASN devotes more than half of its transport inspections to checking consignors and carriers.

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 radiological protection programme, satisfactory stowage of packages, dose rate and contamination measurements, documentary conformity, implementation of a quality insurance programme, etc.

Among the observations or findings formulated further to the inspections, the most frequent discrepancies concern quality assurance, compliance with implemented procedures and worker radiation protection.

ASN inspection of the transport of nuclear waste to Australia, port of Cherbourg, October 2015.

Knowledge of the regulations applicable to the transport of radioactive substances seems to be substandard in the medical sector in particular, where the procedures adopted by some hospitals or nuclear medicine units for package shipment and reception need to be tightened.

In the BNI sector, ASN considers that the consignors must improve how they demonstrate that the content actually loaded into the packaging complies with the specifications of the approval certificates and the corresponding safety analysis files. This demonstration is sometimes carried out by a third-party company. The consignor's responsibilities require that at the least it verify that this demonstration exists and is sufficient and that it monitor the third-party company in accordance with the usual methods of a quality assurance system.

ASN has moreover observed that an increasing number of BNI licensees are using outside contractors to prepare and ship packages of radioactive substances. ASN is particularly attentive to the organisation set up for the monitoring of these contractors.

4.2.5 Oversight of preparedness for emergency management

In order to reinforce the preparedness of the transport operators (mainly consignors and carriers) for emergency management, ASN published Guide No. 17 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 three inspections in 2017 on the topic of preparedness for emergency situations. The inspectors looked in particular at the organisation in place, the material and human resources available, personnel training and the emergency exercises held.

4.2.6 Analysis of transport events

The safety of the transport of radioactive substances is based notably on the existence of a reliable system for detecting and processing anomalies, deviations or, more generally, any abnormal events that could occur. Therefore, once detected, these events must be analysed in order to:
- prevent identical or similar events from happening again by taking appropriate corrective and preventive measures;
- prevent a more serious situation from occurring by analysing the potential consequences of events which could be precursors of more serious events;
- identify the best practices to be promoted in order to improve transport safety.

The regulations also require that ASN must be notified of the most important events so that it can ensure the correct working of the detection system, the analysis approach and the integration of operating experience feedback. This also provides ASN with an overview of events so that the sharing of operating experience feedback can be encouraged between the various stakeholders – including internationally – and so that

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Inspection of a MOX fuel shipment to Japan

In July 2017, two TN 12/2 packages loaded with new MOX fuel assemblies, were shipped to Japan from the La Hague site. The MOX fuel was produced by Areva's Mélox plant and had previously been transported to La Hague, where the assemblies were loaded into the TN 12/2 packages.

The ASN inspectors went to the La Hague plant a few days prior to departure and checked the documents confirming correct loading of the assemblies and closure of the packages. They ran spot checks to ensure compliance with the requirements of the package model safety analysis file. They examined the workshops in which the operations had been carried out, checked the tools used and examined the condition of the two packages on their storage site.

The inspectors also had IRSN staff carry out dose equivalent rate and contamination measurements on the two TN 12/2 packages and on an irradiated fuel package which had arrived from the Paluel NPP. The results obtained showed that the three packages were in compliance with the applicable regulation limits. More particularly the maximum dose rate values measured in contact with the packages were 0.069 mSv/h for the packages loaded with MOX fuel and 0.610 mSv/h for the package loaded with irradiated fuel. The regulation limit is 2 mSv/h.

In the light of this examination, the inspectors considered that Areva La Hague had satisfactorily met its regulation obligations as consignor of packages loaded with MOX Fuel.

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Revision of the ASN guide on the notification of transport-related events

In 2005, ASN published a guide devoted to the notification of events occurring in BNIs and during transport operations. In 2017, ASN split this guide into two parts, one devoted to transports on the public highway and the other to BNIs. The regulatory bases for the notification of events in the two fields are different. As on-site transport is regulated by the same order as all the BNI operations, the corresponding events are subject to the part of the guide devoted to BNIs.

For events related to BNIs, the 2005 guide continues to apply. In 2017, ASN published Guide N°31, which replaces the part of the 2005 guide applying to transports on the public highway, by air or by sea.

This was an opportunity for a complete overhaul of the contents of the guide to take account of changes to regulations and the experience feedback from application of the previous guide. The revision more particularly aims to simplify and rationalise the criteria for the notification of events and clarify the responsibilities of the various transport stakeholders with regard to notification and the drafting of the report. The new guide also specifies the regulatory requirements applicable, notably the obligation of notifying significant events within four working days and of sending ASN a detailed event report two months after notification.

Notification of an event as stipulated in the guide does not take the place of the obligation of immediately alerting ASN to any emergency situation.

it can consider potential changes to the provisions governing the transport of radioactive substances.

Any significant event concerning the transport of radioactive substances, whether the consequences are real or potential, must be the subject of ASN notification within four working days, as stipulated in its event notification guide and as required by Article 7 of the Order of 29th May 2009, amended, on the transport of dangerous goods by road, known as the “TMD Order”. The ASN guide was entirely revised in 2017 (see box) and is available for consultation on *www.asn.fr*. After notification, a detailed event report must be sent to ASN within two months.

Events notified in 2017

In 2017, concerning the transport of radioactive substances, ASN was notified of 64 level 0 events and 2 level 1 events. Graph 4 shows the trend in the number of significant events notified since 2000.

In addition, ASN was notified of 36 events of lesser importance (Events of Interest for the safety of Transport – EIT). Given that they have no actual or potential consequences, these events are not rated on the INES scale (International Nuclear and Radiological Event Scale). There is thus no obligation to notify ASN of them, although ASN nonetheless wishes to be kept periodically informed in order to have an overview of the various events of lesser importance and detect any accumulation or any trends which could be indicative of a problem.

Areas of activity concerned by these events

More than half of the significant events notified concern the nuclear industry. About one third 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 medical activity professionals failing to submit notifications, which can be explained by unfamiliarity with the events notification process and its purpose. ASN does however observe an improvement in the notification rate in the medical sector by comparison with previous years.

The contents concerned by the event notifications are extremely varied: radionuclides for medical uses, contaminated material, fuel, empty packaging, etc.

Graph 5 shows the breakdown of significant events notified according to content and mode of transport.

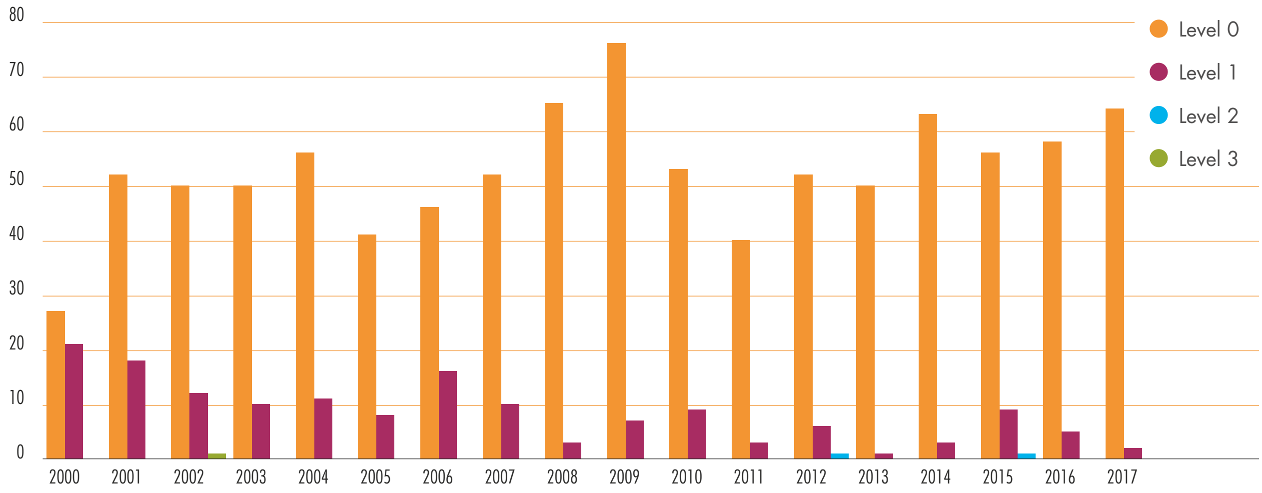
ASN observes that about 80% of EIT are notified by nuclear industry stakeholders. This demonstrates an almost total absence of notification by stakeholders from the medical sector and from non-nuclear industry. ASN does however point out that notification of EITs is not a regulatory obligation.

Causes of events

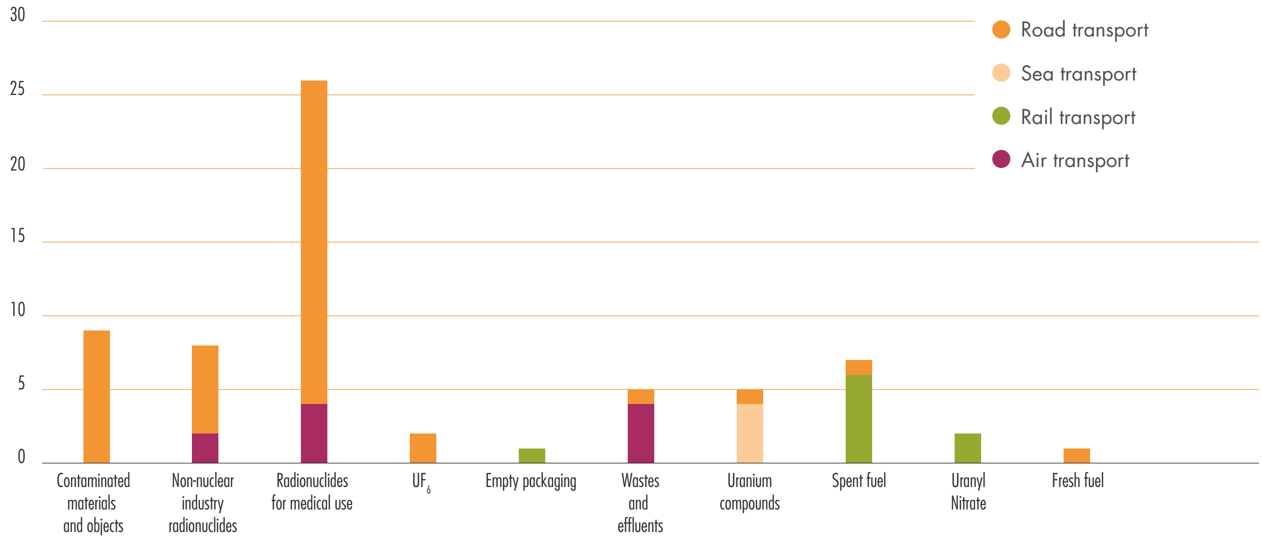
The most frequent causes of the significant events notified include the following:

- material non-conformities affecting a package: use of inappropriate containment seals, loosening of screws during transport, periodic maintenance date exceeded, non-performance of a pre-departure tightness test, etc. These events had no actual consequences for safety or radiation protection. However, in the event of an accident, a non-conformity can impair the strength of the package;
- the shipment of packages containing radioactive substances, without this being notified, as well as delivery errors or packages being temporarily mislaid;
- non-compliance with internal procedures, leading to the shipment of non-conforming packages (for example, container door not properly locked) or with inappropriate labelling;
- the presence of contamination spots exceeding the regulation limits. In this respect, it should be noted that the situation has improved appreciably for packages approved by ASN, more particularly spent fuel packages. However, these situations persist with packages of uranium ore from the mines. The impact of these events on radiation protection is low, because the contamination spots are present on the drums containing the ore, which are themselves carried inside closed metal containers.

GRAPH 4: Trend in the number of significant events affecting the transport of radioactive substances notified between 2000 and 2017



GRAPH 5: Breakdown of notified transport events by content and mode of transport in 2017



ASN also noted a clear drop in events notified owing to poor package stowage or a handling accident leading to package damage. In 2016, ASN published a guide of recommendations for package stowage (Guide N° 27), in order to improve carrier practices in this field.

The EIT of which ASN was notified are primarily deviations relating to incorrect labelling of packages and the absence of transport documents, as well as delivery errors.

4.3 Participation in drawing up the regulations applicable to the transport of radioactive substances

4.3.1 Participation in the work of the IAEA

ASN represents France on the Transport Safety Standards Committee (TRANSSC) which, under the supervision of the International Atomic Energy Agency (IAEA), brings together experts from all the 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 number SSR-6.

At the November 2015 meeting of the TRANSSC, the committee voted in favour of a revision of the SSR-6 and a new revision cycle for the SSR-6 was initiated. ASN thus submitted SSR-6 modification proposals to the TRANSSC, after consulting the GPT. The work by the TRANSSC committee will continue until 2018, before producing a new version of the document, more particularly so that all the countries concerned can be consulted and any points of disagreement cleared up.

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 Order of 29th May 2009 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 for Ecological and Solidarity-based Transition when a modification of the three Orders mentioned above can have an impact on the transports of radioactive substances. In 2017, ASN issued an opinion on two draft orders modifying the Order of 23rd November 1987.

The regulatory framework for the protection of radioactive substances against malicious acts, excluding nuclear materials which are dealt with separately, will be totally revised in 2018. ASN will ensure that appropriate attention is given to transport operations, during which the substances are particularly vulnerable.

4.4 Contributing to public information

Ordinance 2012-6 of 5th January 2012, modifying Books I and V of the Environment Code, extends the public information obligations to the 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. 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.

For several years now, ASN has developed 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 published an analysis of radioactive substances traffic volumes in France on its website. An information sheet on the transport of radioactive substances, intended for the general public, was drawn up in 2014 and is 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 to an emergency by the public authorities or the routes followed for these transport operations.

In 2017, ASN entirely revised the educational file dealing with the transport of radioactive substances. This file can be consulted on *www.asn.fr*.

4.5 Participation in international relations in the transport sector

International regulations are drafted and 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.

4.5.1 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.

4.5.2 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 Germany, Belgium, the United Kingdom and Switzerland.

Germany

In 2016, the French and German Authorities decided to meet regularly to discuss a range of technical subjects. ASN also participates in two Franco-German technical committees concerning the programme for returning German spent nuclear fuel reprocessing waste. A new package is currently being designed in Germany for the transport of compacted waste. The German safety regulator thus informs ASN of the progress being made in the technical review of the approval application. Once issued, the approval certificate will have to be validated by ASN so that the package model can be used in France.

Belgium

For its production of electricity from nuclear power, Belgium more particularly 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 work more closely on reviewing the safety files for the approved French package models validated in Belgium and to discuss inspection practices in each country. In 2017, the Belgian and French Authorities carried out two joint inspections, one on a package model not requiring Belgian approval and used in France and the other on the manufacture of packagings intended for transports between France and Belgium.

United Kingdom

ASN and the British regulator (Office for Nuclear Regulation – ONR) share many subjects of interest, notably with regard to validation of English approvals by ASN and *vice-versa*. Bilateral contacts are held regularly to ensure a good level of communication between the two Authorities.

Switzerland

ASN began bilateral exchanges with the Swiss Federal Nuclear Safety Inspectorate (IFSN) in 2012. ASN and IFSN have decided to meet annually in order to discuss the packaging model safety files and the checks on the requirements associated with the correct utilization of these transport packages. A joint ASN-IFSN inspection was carried out in 2017 to check the conformity of the manufacturing operations of a package model approved by ASN and used in Switzerland.

5. ASN assessment and outlook on the safety of transport of radioactive substances

Radiation protection of the carriers of radioactive substances

ASN considers that the radiation protection situation of the carriers could be improved, in particular for the carriers of radiopharmaceuticals, who are significantly more exposed than the average worker. Thanks to the entry into force of the obligation of notification by carrier companies, ASN now has a clearer picture of the characteristics of the companies, enabling it to tailor its oversight resources more closely to the issues. In 2018, ASN will continue to carry out checks and educational measures with the professionals in order to improve the situation. In 2018, ASN will also publish a guide to remind professionals of the applicable regulatory requirements in terms of radiation protection, specifying how the various regulatory sources are interlinked (regulations specific to radioactive substances transport operations, Labour Code and Public Health Code) and to provide them with its recommendations for the correct application of these provisions.

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.

The regulatory conformity of the packages not requiring approval has improved in recent years, although some deviations persist. In 2018, ASN will therefore continue its efforts regarding the monitoring of package models not requiring approval.

Continuation of inspections in the manufacture and maintenance of transport packages subject to ASN approval

The design of transport package models requiring ASN approval is examined in depth prior to the issuance of any approval. Once it has been ascertained that the package model complies with the regulatory requirements, its manufacture and subsequent routine maintenance in accordance with the requirements of its safety file must be verified. In this respect, the irregularities detected at the Creusot Forge plant, which more particularly affected certain transport packagings, demonstrated the importance of checking the packaging manufacture and maintenance operations. In 2018, ASN intends to maintain a large number of inspections on these topics. It will in particular ensure that the conclusions of the in-house working group tasked with learning the lessons from the Creusot Forge irregularities are transposed to the field of transport.

Improved emergency situation preparedness

The management of emergency situations is the final level of defence in depth in order to mitigate the consequences of an accident. The transport stakeholders are key players in this management, more specifically to give the alert and provide the necessary information to the emergency services. ASN considers that in order to meet these obligations the stakeholders must be well prepared for emergency situations. In 2018, it will therefore continue its inspections to ensure that the recommendations of its guide on emergency plans are satisfactorily taken on board. The stress tests approach will also be implemented for packages entailing potentially high levels of risk.

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 promoting the performance of local emergency exercises and issuing recommendations on the steps to be taken in the event of an accident.

Examination of the approval application for the DN30 package model

In 2017, the Daher NT Company submitted an approval application for the DN 30 package model designed for the transport of a cylinder containing enriched UF_6. ASN referred the matter to the GPT to obtain its opinion on the level of safety of this package model with respect to the regulatory requirements. The GPT will issue its opinion in 2018.

Examination of the approval application for the TNG3 package model

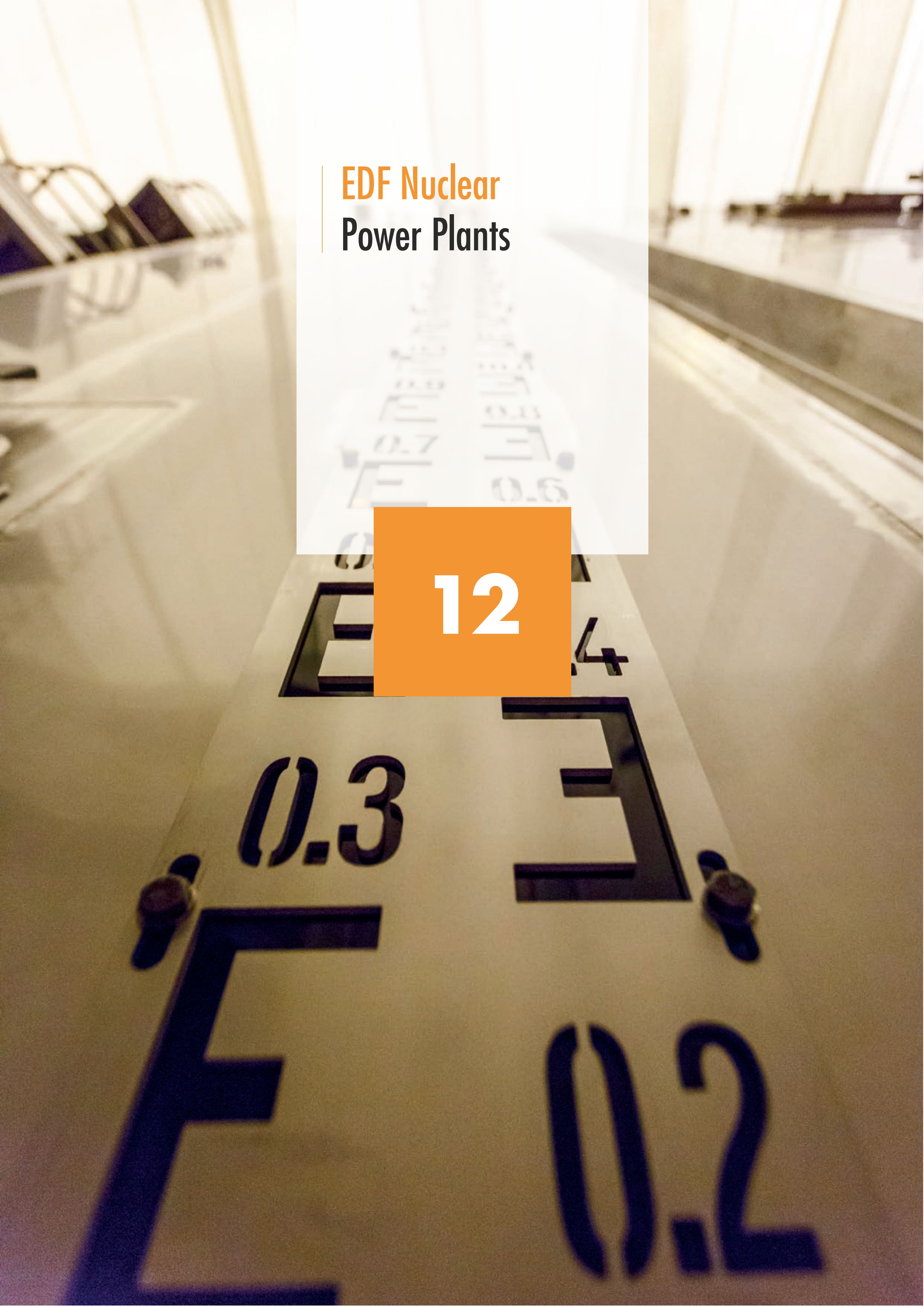
Spent fuel assemblies are currently taken from the NPPs in TN 12/2 and TN 13/2 packages, which are approved under the old version of the IAEA regulations. A few years ago, Areva TN thus began work on the design of a new package model, the TN G3, to replace them. In 2018, ASN will give its decision on the approval application submitted by Areva TN for this new package model.

On-site transport of dangerous goods

Given that certain BNI licensees have not yet incorporated on-site transport operations into their general operating rules, ASN will continue its actions with regard to these licensees.

EDF Nuclear Power Plants

12



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 their operation, it does entail an increased risk in the event of a generic design, manufacturing, or maintenance fault being 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. 2017, marked by several major generic events, once again illustrated the implications and the risks entailed by this standardisation.

ASN demands a high level of stringency in the monitoring of the NPPs and continuously adapts it, in particular in the light of experience feedback from the design, manufacturing, operation and maintenance of NPP reactor components. 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), the Nuclear Pressure Equipment Department (DEP) and the regional divisions. It also calls on the services of some 200 experts from the Institute for Radiation Protection and Nuclear Safety (IRSN).

ASN is developing an integrated approach to facilities monitoring. ASN intervenes at all stages in the life of the NPP reactors, from design up to decommissioning and delicensing. Through its expanded scope of intervention it examines the fields of nuclear safety, organisational and human factors, environmental protection, radiation protection, occupational safety and the application of labour laws, at all stages in the life of the NPP reactors. For each of these fields, it monitors all aspects, whether technical, organisational, or human. This approach requires that it take account of the interaction between these fields and that it adjust its actions accordingly. The resulting integrated view allows ASN to develop a finer appreciation and decide on its position each year with regard to the 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 thermal 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 in the reactor 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. The condensed water is reused in the steam production cycle.

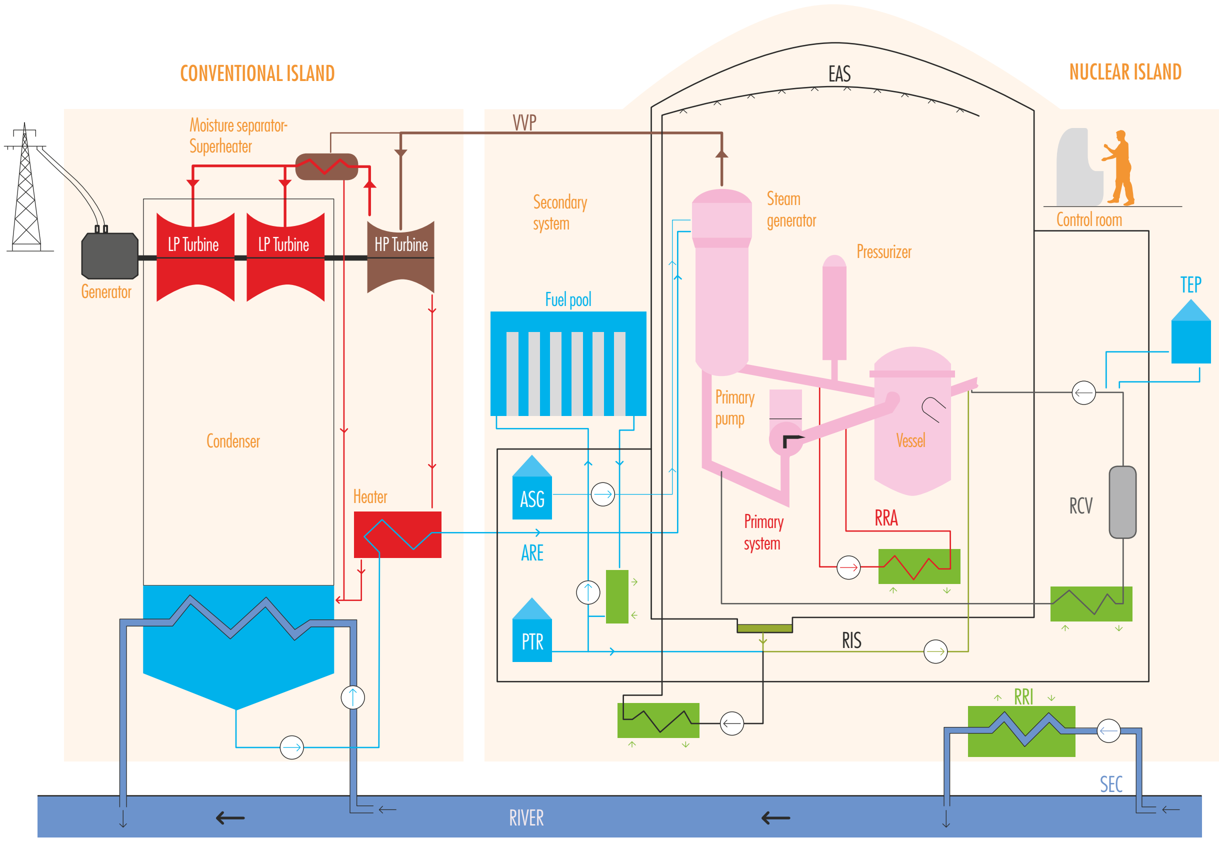
Each reactor comprises a nuclear island, a conventional island, water intake and discharge infrastructures and possibly a cooling tower.

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, boric acid 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 (VVP)) as well as the building housing the Fuel Storage pool (BK). This building, adjacent to the reactor building, is used for storage of new and spent fuel assemblies. 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 shield.

The conventional island equipment includes the turbine, the AC generator and the condenser. Some components of this equipment contribute to reactor safety. The secondary systems belong partly to the nuclear island and partly to the conventional island.

THE PRINCIPLE of pressurised water reactor operation



LP or HP Turbine: low pressure or high pressure
VVP: Main Steam System
ASG: Auxiliary Feedwater System
ARE: Feedwater Flow Control System
PTR: Reactor Cavity and Spent Fuel Pit Cooling and Treatment System
EAS: Containment Spray System

RRA: Residual Heat Removal System
RIS: Safety Injection System
TEP: Boron Recycle System
RCV: Chemical and Volume Control System
RRI: Component Cooling System
SEC: Essential Service Water System (ESWS)

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 are consumed. 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. This enables the reactor's reactivity to be controlled and its power adjusted to the required production of electricity. Dropping the control rod assemblies under the effects of gravity enables the reactor to be shut down in an emergency;
- adjusting the boron concentration (which absorbs neutrons) in the primary system water during the cycle as the fissile material in the fuel gradually becomes depleted;
- the presence of neutron-absorbing elements in the fuel rods which, at the beginning of the cycle, compensates the excess core reactivity after partial renewal of the fuel.

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 (PWR):

- 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 by 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 maximum authorised plutonium content is currently limited to 9.08% (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.

EDF has standardised how the fuel is used in its reactors, referred to as "fuel management"'. Fuel management, which concerns similar reactors, is more particularly 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 tonne of material (expressed in gigawatt days per tonne - 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 coolant or reactor coolant. 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 water in the primary system transfers its heat to the water in the secondary systems in the steam generators. The steam generators are heat exchangers that contain 3,500 to 5,600 tubes, depending on the model, through which the reactor coolant circulates. These tubes are immersed in the water of the secondary system and boil it, without ever coming into contact with the primary water.

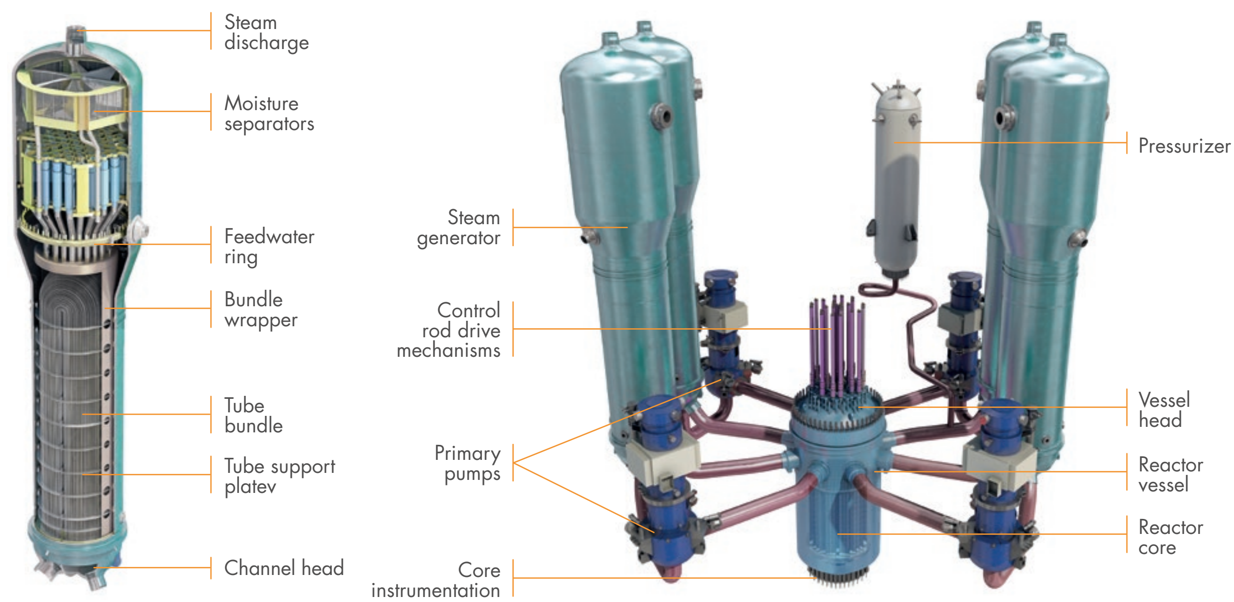
Each secondary system principally consists of a closed loop through which water runs in liquid form in one part and as steam in the other part. The steam produced in the steam generators is partly expanded in a high-pressure turbine and then passes through moisture separators before final expansion in 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

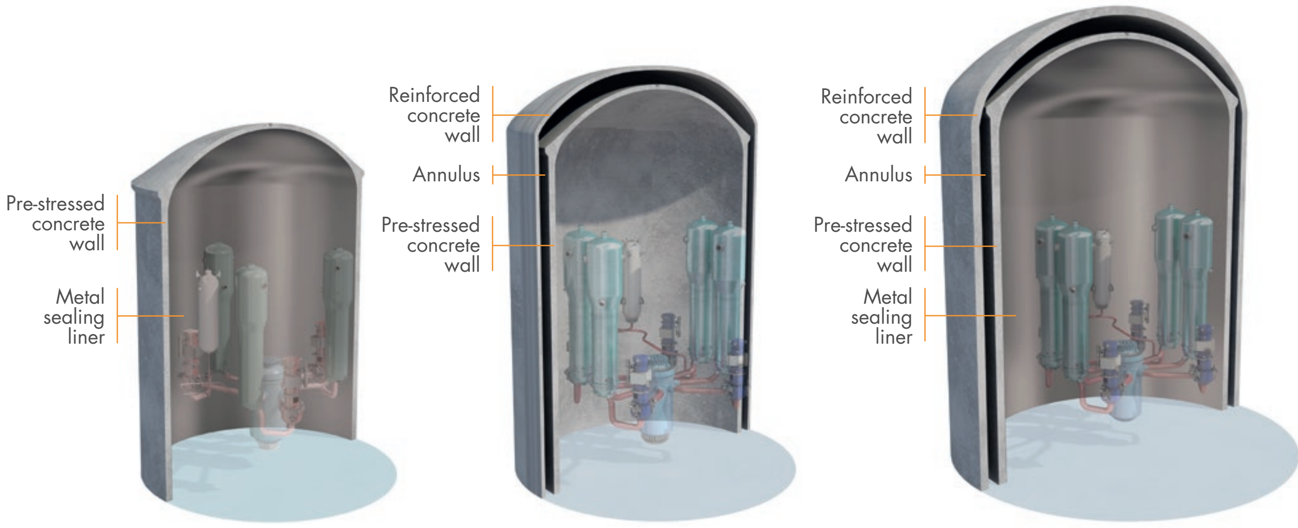
The function of the secondary system cooling system is to condense the steam exiting the turbine. This is achieved by a condenser comprising a heat exchanger containing thousands of tubes through which cold water from outside (sea or river) circulates. When the steam comes into contact with the tubes 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 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 (TAR) (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.

A STEAM GENERATOR and a main primary system of a 1,300 MWe reactor



REACTOR containments



900 MWe reactor containments

1,300 MWe/ 1,450 MWe reactor containments

1,650 MWe reactor containments

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.

There are three containment model designs:

- Those of the 900 MWe reactors comprise a single pre-stressed concrete wall (concrete comprising tensioned steel tendons to compress the structure in order to increase its tensile strength). This wall provides mechanical pressure resistance and ensures the integrity of the structure in the event of an external hazard. Tightness is provided by a metal liner covering the entire internal face of the concrete wall.
- The 1,300 MWe and 1,450 MWe reactor containments consist 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 all and the ventilation system (EDE) which, in the annulus between the two walls, collects and filters residual leaks from the inner wall before discharge. Resistance to external hazards is primarily provided by the outer wall.
- The Flamanville EPR reactor containment consists of two concrete walls and a metal liner covering the entire internal face of the inner 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 in outage states, as well as providing 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:

- 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 major leak from the primary system;
- 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. This system is also used in normal operation during reactor outage or restart phases.

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 certain number of nuclear equipment items. This system functions in a closed loop between the auxiliary and safeguard systems on the one hand and the systems carrying water from the river or sea (heatsink) on the other;
- the Essential Service Water System (SEC) which cools the RRI system with water from the river or sea (heatsink). This is a backup system comprising two redundant lines. In certain situations, each of its lines is capable of removing heat from the reactor to the heatsink;
- 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, which processes the information received from all the sensors in the NPP. It uses transmission networks and sends orders to the actuators from the control room, through the programmable logic controllers or operator actions. Its main role with regard to reactor safety is to monitor reactivity, control the removal of residual heat to the heatsink and take part in the containment of radioactive substances;
- the electrical systems, which comprise sources and electricity distribution. The French nuclear power reactors have two external electrical sources: the step-down transformer and the auxiliary transformer. These two external sources are supplemented by two internal electrical sources: the backup diesel generators. Finally, in the event of total loss of these external and internal sources, each reactor has another electricity generating set comprising a turbine generator and each NPP has an ultimate backup source, the nature of which varies according to the plant in question.

2. Monitoring of nuclear safety

2.1 Fuel

2.1.1 Changes to fuel and fuel management in the reactor

In order to enhance the availability and performance of the reactors in operation, EDF, together with the nuclear fuel manufacturers, is developing improvements to fuels and their use in the reactor.

ASN ensures that each change in fuel management is the subject of a specific safety case. Any change in the fuel or its management must first be examined by ASN and may not be implemented without its consent. When these changes are significant, their implementation requires an ASN resolution.

Fuel behaviour is an essential element in core safety in normal operation or accident conditions, and its reliability is therefore 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. In normal operation, leaktightness is monitored by EDF through permanent measurement of the activity of the radionuclides contained in the primary system. Any increase in this activity beyond predetermined thresholds indicates a loss of leaktightness in the fuel assemblies. 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 General Operating Rules require reactor shutdown before the end of its normal cycle.

ASN ensures that EDF looks for and analyses the causes of the observed leaktightness losses, 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 spot-checks. ASN also carries out inspections to check the nature of EDF's monitoring of its fuel suppliers. Finally, ASN asks EDF to learn the lessons from fuel operating experience feedback.

Fuel assembly.

2.1.2 Evaluation of the condition of the fuel and its management in the reactor

ASN considers that in 2017 the condition of the first containment barrier, which is the fuel cladding, is on the whole satisfactory. On all the NPP sites, management of this point is considered to be satisfactory or could be improved with regard to a small number of aspects. However, ASN still observes the presence of foreign material in the primary system. The organisation implemented to avoid fuel damage through the ingress of foreign material into the primary system could be improved despite the progress made since 2016. In 2017, the number of significant events linked to fuel handling remains small and ASN observes a good level of involvement by the departments concerned.

However, for 2017, ASN notes the following events:

- recurring malfunctions in the "flux" In-core Instrumentation System (RIC) on Civaux NPP reactor 2, which are the subject of particular attention on the part of ASN;
- the recurrence of leaking assemblies in the two Civaux reactors, as well as the detection of leaking fuel rods in certain reactors at Gravelines, Cattenom and Nogent-sur-Seine;
- position defects by certain absorber rod clusters (Le Blayais and Golfech reactors).

Finally, in 2017, ASN observed recurring cases of absorber rod clusters blocking when actuated (Saint-Alban/Saint-Maurice and Belleville-sur-Loire reactors). These blockages led ASN to impose operating restrictions or prohibit the restart of these reactors. Investigations are in progress to define the origin of these blockages.

2.2 Nuclear pressure equipment

2.2.1 Monitoring of the design and manufacturing conformity of Nuclear Pressure Equipment (NPE)

ASN assesses the compliance with regulatory requirements of the NPE the most important in terms of safety, said to be "level N1", which are the reactor pressure vessel, the steam generators, the pressuriser, the reactor coolant pumps, the piping and the control valves and relief valves.

These regulatory requirements are a guarantee of their safety. They are defined by a European Directive on Pressure Equipment and supplemented by requirements specific to NPE.

This conformity assessment concerns the equipment intended for the new nuclear facilities (more than 200 items are concerned on the Flamanville EPR) 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. They are also responsible for assessing conformity with the regulatory requirements applicable to NPE 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 Exploitation, Vinçotte International and the EDF users inspection entity.

FOCUS

Analysis of the irregularities detected in the manufacturing files at the Creusot Forge plant for components installed in reactors in service

Following the detection of irregularities in certain manufacturing files at the Areva NP Creusot Forge plant in 2016, ASN resolution 2017-DC-0604 of 15th September 2017 ordered EDF to send ASN the review report of the manufacturing files for the components forged by the Creusot Forge plant for each reactor in service and no later than two months prior to restart following its next refuelling outage.

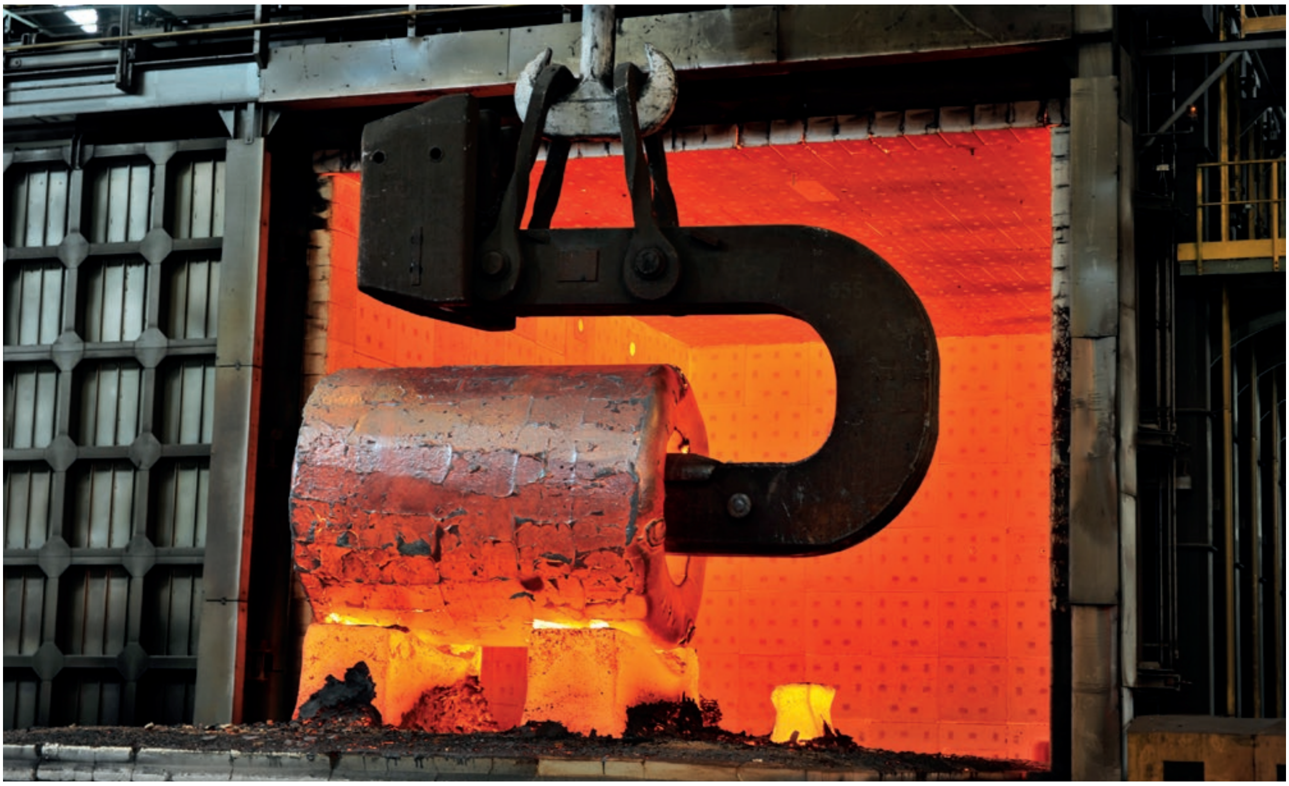
EDF is required to complete its review no later than 31st December 2018.

To date, the ASN examination of deviations on 12 reactors has led to requests for additional justifications and has not brought to light any deviation requiring immediate repair or replacement prior to restart. Subsequent requests could be made for representative checks or tests to clarify the justifications provided.

This examination will continue in 2018 for the other reactors. For each reactor, it concerns an average of more than 50 deviations.

In conjunction with this review, ASN is continuing to investigate the irregularity detected on the lower shell of a steam generator on Fessenheim reactor 2. Following the discovery of this anomaly, ASN suspended the steam generator test certificate on 18th July 2016, the effect of which was to keep this reactor shut down. In July 2017, Areva NP transmitted a file demonstrating the mechanical strength of the component concerned.

In conjunction with its technical support organisation, IRSN, ASN is examining this information which was presented on 27th February 2018 to the Advisory Committee for Nuclear Pressure Equipment (GPESPN). ASN intends to issue a position statement in the first half of 2018.



Manufacture of a shell.

In 2017, ASN and the approved organisations carried out:
- 12,925 inspections, including 3,136 document inspections concerning design, to check the manufacture of the NPE intended for the Flamanville EPR, which represented 17,398 man/days in the plants of the manufacturers, as well as of their suppliers and subcontractors;
- 3,881 inspections, including 999 document inspections concerning design, to check the manufacture of the equipment spares intended for the NPP reactors in service, which represented 4,404 man/days in the plants of the manufacturers, as well as of their suppliers and subcontractors.

Most of these inspections were performed by the approved organisations, under the supervision of ASN.

2.2.2 Evaluation of the design and manufacture of NPE

Irregularities in the manufacturing plants

2017 was marked by the analysis of the consequences of the detection of irregularities in 2016, of varying scope and severity, in several NPE manufacturing plants. This was in particular the case in the Areva NP Creusot Forge plant, where these practices had continued for several decades.

Considering that these irregularities reveal unacceptable practices and that the industry needs to take fundamental measures to restore a high level of quality in the supply chain, ASN asked Areva NP to conduct a review of the files of the components manufactured by Creusot Forge, to analyse the reasons the irregularities were not detected and to develop a quality and safety culture to guarantee the expected irreproachable level of quality. At the same time, ASN asked EDF to analyse the causes of the breakdown in Areva NP monitoring and to assess the steps taken by Areva NP.

These requests were extended to all the Areva NP plants. Satisfactory compliance with these requests is an essential precondition for the resumption of manufacturing in the Creusot Forge plant.

In conjunction with this step and together with the organisations, ASN is examining the handling of the deviations detected during the files review when evaluating the conformity of new equipment. A similar action is also carried out for the components incorporated into equipment in service (see the box concerning the Creusot Forge plant on the previous page).

Reinforcing justification of the design of NPE

ASN has regularly observed that the justifications and demonstrations provided by the manufacturers with regard to NPE regulations, more particularly concerning the correct design of this equipment, are still unsatisfactory. The industrial firms, EDF and Areva NP in particular, therefore took fundamental measures as of the first half of 2015 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 and in 2016 and 2017 recognised the appropriate nature of certain publications from AFCEN. It will be attentive to ensuring the completion of this approach, scheduled for the end of 2018.

FOCUS

Technical anomalies linked to carbon segregations in certain Steam Generator (SG) channel heads

Following the detection of the Flamanville EPR reactor pressure vessel anomaly (see point 2.11.2), EDF informed ASN that the channel heads of SGs fitted to 18 reactors, manufactured by the Creusot Forge plant and by Japan Casting and Forging Corporation (JCFC), were also concerned by the carbon segregation problem.

All of the checks carried out by EDF, in particular those specified by ASN on 18th October 2016, required the shutdown of five reactors and were completed at the beginning of 2017. They enabled EDF to demonstrate that there was no risk of fracture of the channel heads of the 46 SGs concerned. The conservative hypotheses adopted by EDF in its fracture strength calculations, led it to modify the operating conditions of the 18 reactors concerned. These modifications are implemented pending confirmation of the design hypotheses which should be provided by a vast test programme currently being carried out on the channel heads representative of the components in service on the French reactors.

2.2.3 Monitoring the operation of pressure equipment

The reactor Main Primary and Secondary Systems (CPP and CS) operate at high temperature and high pressure and contribute to the containment of the 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 the 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, comprising 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.

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 Gravelines reactor 1 and in 2016 on a vessel bottom penetration in Cattenom reactor 3.

These cracks require that the licensee repair the zones concerned or isolate the part of the system concerned.

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 ensures that the performance and frequency of the checks carried out by EDF are satisfactory and able to detect the deteriorations in question.

The strength of reactor pressure vessels

The reactor pressure vessel is an essential component of a pressurised water reactor and contains the reactor core and its instrumentation. For the 900 MWe reactors, the vessel is 14 m high, 4 m in diameter, 20 cm thick and weighs 330 tonnes. For the EPR, currently under construction, the vessel is 15 m high, 4.90 m in diameter, 25 cm thick and weighs 510 tonnes.

In normal operating conditions, the vessel is entirely filled with water, at a pressure of 155 bar and a temperature of 300°C. It is made of ferritic steel, with a stainless steel inner liner.

Regular monitoring of the state of the reactor pressure vessel is essential for two reasons:
- The vessel is a component for which replacement is not envisaged, owing to both technical feasibility and cost.
- Monitoring also contributes to the break preclusion approach adopted for this equipment. This approach is based on particularly stringent design, manufacturing and in-service inspection provisions in order to guarantee its strength throughout the life of the reactor, including in the event of an accident.

In 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 technological defects are present, which is the case for some of the reactor vessels that have manufacturing defects under their stainless steel liner.

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The principles of demonstrating the resistance of reactor vessels

The regulations in force require in particular that the licensee:
- identify the operating situations with an impact on the equipment;
- take measures to understand the effect of ageing on the properties of the materials;
- take steps enabling it 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.

ASN regularly examines the evidence to substantiate the in-service resistance of the vessels transmitted by EDF, to ensure that it is sufficiently conservative.

In mid-2016, EDF more specifically sent ASN a file substantiating the in-service resistance of the 900 MWe reactor vessels after 40 years of operation and this is currently being reviewed by ASN. This file will be submitted to the GPESPN for its opinion during the course of 2018.

Maintenance and replacement of steam generators

The SGs 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, more specifically the tubes making up the tube bundle, is monitored. This is because any damage to the tube bundle (corrosion, wear, cracking, etc.) can lead to a leak from the primary system to the secondary system. A steam generator tube rupture would lead to bypassing of the reactor containment, which is the third containment barrier. Steam generators are therefore 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.

Clogging of the tubes and internals of the secondary part of the steam generators

Over time, the SGs tend to become clogged with corrosion products from the secondary system exchangers. This leads to a build-up of soft or hard sludge at the bottom of the SGs, fouling of the tube walls and clogging of the tube bundle 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 tube support plates, the deposits prevent the free circulation of the water-steam mixture (clogging), which creates a risk of damage to the tubes and the internal

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Fall by a steam generator of the Paluel NPP reactor 2

During the Paluel NPP reactor 2 outage (since May 2015) for its third ten-yearly outage inspection, a steam generator fell while being handled on 31st March 2016. The reactor vessel was completely emptied of its fuel at the time of the event.

Nine persons were present inside the building at the time of the fall and one person suffered a chest injury.

The assessments carried out by EDF on the condition of the installation revealed a certain amount of damage to the metal liner of the reactor building cavity, electrical and mechanical equipment and the civil engineering structures.

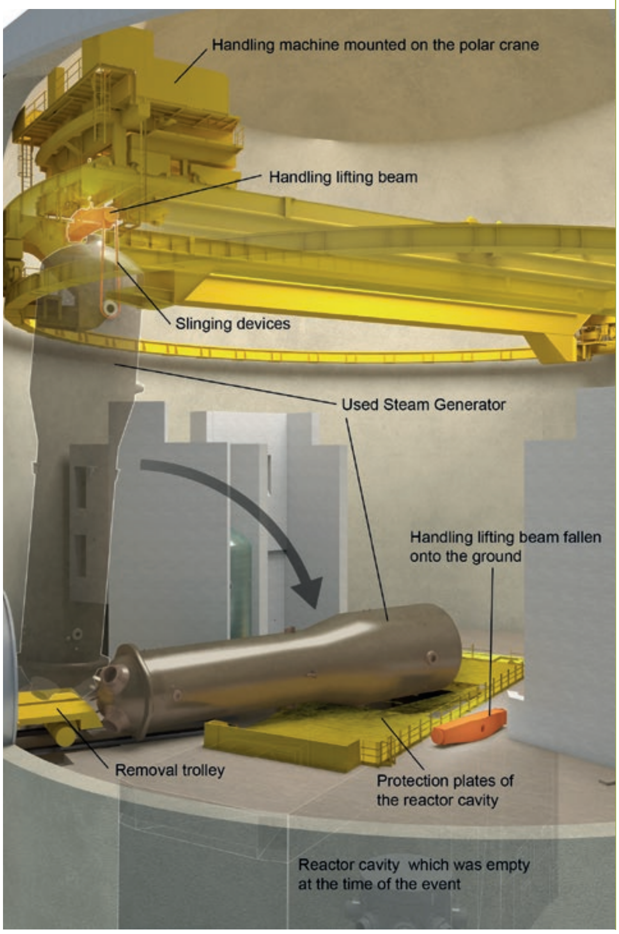
However, as concerns either the concrete or the metal liner, only the cavity required extensive repairs which should be completed at the beginning of 2018. The general assessment methodology and the cavity repairs were examined by ASN, with the support of IRSN.

A new lifting beam was designed and manufactured, enabling replacement SGs to be brought into and installed in the reactor building at the end of 2017.

EDF notified a significant safety event on 1st April 2016. The use of a lifting beam added to the polar crane for the 1,300 MWe reactors, which is different from that of the 900 MWe reactors and which comprises a design flaw, is among the main causes identified by EDF. This event also reveals flaws in the monitoring and decision-making process on the part of EDF, with regard to the contractor in charge of replacing the SGs.

Since the SG fell, ASN has carried out about fifteen inspections on the follow-up to this event in order to check the various operations carried out. It is continuing its monitoring of the operations in preparation for restart of the installation scheduled for 2018, notably with regard to the hydrotesting of the main primary system.

Finally, by an Order of 26th January 2017 and further to the opinion of ASN, the Minister responsible for Nuclear Safety prolonged the period beyond which shutdown is considered to be final.



structures and which can degrade the overall operation of the steam generator.

To prevent or mitigate the fouling effects described above, various solutions can be 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, modification of the chemical products used for conditioning of the systems and an increase in the pH of the secondary system. Some of these operations require licensing for the discharge of the conditioning products.

Some chemical cleaning processes are still being tested to demonstrate that the chemical products utilised are harmless. In particular, the identification of a corrosion risk on reactors which had undergone such cleaning in 2016 led ASN to request the implementation of specific maintenance measures.

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. 2017 saw the replacement of SGs on Cruas-Meysse reactor 1. Replacement of the SGs for Paluel reactor 2 (see box opposite) was resumed at the end of 2017 and will continue in 2018.

Monitoring methods applied to main primary and secondary system pressure equipment

Article 8 of the Order of 10th November 1999 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 power reactors must be qualified before they are used for the first time. This qualification is granted by a body comprising experts from both inside and outside EDF whose expertise and independence are verified by the French accreditation committee.

Qualification is a means of guaranteeing that the non-destructive testing process actually achieves the anticipated level of performance as described in specifications drawn up beforehand.

Owing to the radiological risks associated with radiographic inspection, ultrasound inspections are preferred, provided that they offer equivalent inspection performance.

To date, more than 90 non-destructive test processes have been qualified for the in-service inspection programmes. New processes are currently being developed and qualified in order to meet new needs.

With regard to the Flamanville EPR, virtually all of the test processes for in-service monitoring of the pressure equipment of the main primary and secondary systems was qualified ahead of the Pre-Service Inspection (VCI) of the main primary system and the main secondary systems, corresponding to more than 30 qualified processes specific to the EPR.

2.2.4 Assessment of pressure equipment in operation

ASN considers that the situation of the second containment barrier represented by the main primary system remains a subject of concern in 2017, with the year being marked by the processing of irregularities detected during the review of the manufacturing files for the components produced by the Areva NP Creusot Forge plant (see box p. 337).

Again in 2017, very high levels of fouling were found in certain steam generators in several reactors, which could be liable to impair their operating safety. This situation is the result of maintenance that was insufficient to guarantee satisfactory cleanness.

In addition to this assessment, which is similar to that made in 2016, showing a deterioration by comparison with 2015, ASN observes that the last SG replacement operations for the 900 MWe reactors were postponed notably owing to the numerous deviations in the manufacture of this equipment. These postponements led to operations to make cracked tubes on certain steam generators safe, by plugging or sleeving, until such time as they are replaced.

ASN considers that the in-service monitoring of the other equipment on the main primary system, pursuant to the Order of 10th November 1999, is carried out appropriately. The detection of a new crack on vessel bottom head penetration No. 58 on Cattenom NPP reactor 3 illustrates the risk of further deterioration owing to the ageing of the facilities and confirms the need to adapt the level of in-service monitoring accordingly and to bring forward the development of repair processes. The principles for repair of this vessel bottom head penetration will be presented to ASN in 2018.

2.3 The containments

2.3.1 Monitoring 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 Order of 7th February 2012 which sets out the general rules for basic nuclear installations.

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Leaktightness measurements for the Bugey NPP reactor 5 containment

During the third ten-yearly outage inspection of the Bugey NPP reactor 5 carried out in 2011, an abnormal trend in the containment leaktightness measurement results was observed by comparison with those made in 2001. In order to control this change and ensure compliance with the safety requirements, ASN required the performance of an additional test, which was carried out in 2015. Its results revealed a deterioration in the leaktightness of the containment and situated the leaks in the lower part of the reactor building.

The reactor remained shut down for the time it took EDF to define and implement a repair method, which ASN authorised on 28th March 2017.

Following the repair, further checks and tests enabled EDF to demonstrate compliance with the safety requirements for the coming cycles. ASN gave its consent for restart of the Bugey NPP reactor 5 on 18th July 2017.

2.3.2 Assessment of the condition of the containments

Overall management of the containment function

The organisation adopted by EDF 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 (see box). For the other 900 MWe reactors, the results of the ten-year tests of the reactor containments during the third ten yearly-outage inspections have hitherto shown leak rates in compliance with the regulatory criteria. To date, this test has been performed on 30 reactors and should be carried out for all the 34 900 MWe reactors in 2020.

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 1,450 MWe reactors. The tests performed since this work, during the second and the third ten-yearly outages of the 1,300 MWe reactors and the first ten-yearly outages of the 1,450 MWe reactors, showed that they all complied with the regulation leak rate criteria. In order to ensure that compliance with these criteria will be maintained on a lasting basis, EDF decided to supplement these inner surface sealants with a sealant of the same type on the outer surface of the inner containments of the reactor buildings.

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 effectiveness of the containment function of the double-wall reactors was thus examined by the Advisory Committee for Nuclear Reactors (GPR) on 26th June 2013, in preparation for the third ten-yearly inspections of the 1,300 MWe reactors. ASN issued a ruling on this subject in June 2014 and remains 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.

2.4 Risk prevention and management

2.4.1 Monitoring the drafting and application of the general operating rules

The General Operating Rules (RGE) cover the operation of nuclear power reactors. These are drafted by the licensee and are the operational implementation of the hypotheses and conclusions of the safety assessments constituting the nuclear safety case. They set the limits and conditions for operation of the installation.

Normal and degraded operation

Operating Technical Specifications

The Operating Technical Specifications (STE), which constitute Chapter III of the general operating rules, define the normal operating conditions based on the design and sizing hypotheses and require the systems necessary for maintaining the safety functions, in particular the integrity of the radioactive substances containment barriers and the operability of the control procedures in the event of an incident or accident. They also stipulate what is to be done if a required system fails or if a limit is exceeded, situations which constitute degraded operation.

The STE evolve to take account of the lessons learned from their application and the modifications made to the reactors. Furthermore, on an occasional basis, the licensee can also modify them temporarily, for example to carry out an intervention in conditions that are different from those initially considered in the nuclear safety case. It must then demonstrate the pertinence of this temporary modification and define adequate compensatory measures.

Depending on their nature, STE modifications likely to affect protected interests require either an authorisation application sent to ASN, or notification to ASN before they are implemented. More particularly, the modifications which significantly compromise the safety case are systematically the subject of an authorisation application.

Until 31st December 2017, temporary STE modifications considered to be minor were eligible for the internal inspection arrangement implemented by EDF and thus complied with the requirements of Article 27 of Decree 2007-1557 of 2nd November 2007, as amended, concerning BNIs and the monitoring of the nuclear safety of the transport of radioactive substances. The internal authorisation systems were repealed on 1st January 2018.

In 2017, the working of this internal inspection system was verified by spot-checks and inspections by ASN in the NPPs and in the EDF head office departments. Every year, ASN carries out an in-depth examination of the temporary modifications made to the STE, on the basis of an assessment prepared by EDF. This examination notably enables recurrent temporary modifications to be identified, which would require a lasting change to the STE.

During inspections in NPPs, 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 modifications made to the facilities and the normal operating documents, such as instructions, alarm sheets, the STE and the training of the persons responsible for implementing them.

Periodic tests

Elements Important for the Protection (EIP) of persons and the environment are equipment items identified by the licensee. They undergo qualification to guarantee their ability to perform their assigned functions in the situations in which they are needed. The periodic tests help verify that this qualification is maintained and regularly ensure that these elements are available when required. The associated rules constitute Chapter IX of the general operating rules for EDF reactors. These rules set the nature of the technical checks to be performed, their frequency and the criteria for determining the satisfactory nature of these checks, in other words the compliance of the equipment concerned with the qualification requirements.

ASN ensures that the periodic technical checks on the EIP are relevant and are continuously improved. It carries out this verification when examining the application for authorisation to start-up the reactor and then the applications for authorisation to modify the RGE. In addition, during inspections, it verifies that these periodic technical checks are carried out in accordance with the test programmes stipulated in the RGE.

Core physics tests

The core physics tests contribute to the first two levels of defence in depth. Their purpose is, on the one hand to confirm that the core in operation is compliant with the design baseline requirements and the safety case and, on the other, to calibrate the automatic control and protection systems.

These tests, prescribed in the RGE chapter concerning EDF reactor core physics tests, are performed periodically.

The physics tests at restart are comparable to requalification tests following reloading of the core. The physics tests in progress and for the cycle extension guarantee the availability and representativeness of the instrumentation as well as the performance of the core in operation.

The modifications to Chapter X of the RGE concerning core physics tests are made using a process similar to that for STE modifications and generally require ASN authorisation.

During the on-site inspections, ASN checks the conformity of the tests performed (compliance with procedures and criteria to be verified) and EDF's organisation during these particular operating phases.

Operating rules in the event of an incident or accident

Incident or accident operations

In an incident or accident situation, the reactor operating strategies and rules are defined in the general operating rules. These evolve more particularly to take account of experience feedback from incidents and accidents, to correct the anomalies detected during their application or to take account of modifications made to the facilities, in particular those resulting from the periodic safety reviews. Implementation of the changes made is submitted to ASN for approval.

ASN regularly checks the processes to draft and validate the incident or accident operating rules, their pertinence and how they are implemented.

To do this, ASN can place the facility's control teams in a simulated situation to check how they apply the above-mentioned rules and manage the specific equipment used in accident operating situations. It in particular ensures correct application of the emergency teams' organisation principles described in the EDF baseline requirements validated by ASN in November 2014. This organisation more particularly requires that each emergency team member take part in an exercise every year.

Operation in a severe accident situation

Following an incident or accident, if the safety functions (control of reactivity, cooling and containment) are not guaranteed owing to a series of failures, the situation is liable to develop into a severe accident following severe fuel damage. When faced with such unlikely situations, the installation control strategies place emphasis on preserving the containment in order to minimise the consequences of the accident (see chapter 5, point 1.3.1). The implementation of these strategies requires the participation of the local and national emergency teams. These teams use the On-site Emergency Plan (PUI) plus the severe accident operation guide and the emergency team action guides in particular.

ASN periodically examines the strategies presented by EDF in these documents, in particular for the reactor periodic safety reviews.

2.4.2 Assessment of reactor operations

Normal and degraded operation

The technical anomalies with serious potential consequences observed in 2017 and described in this chapter, as well as the difficulties experienced by EDF in managing activities during reactor outages, lead ASN to consider that the quality of operation of the NPPs is less satisfactory than in 2016.

Certain recurring operations, such as the performance of periodic tests and of hardware modifications, were the cause of deviations during their preparation, which could not be prevented by EDF's error-reduction practices.

As in 2016, non-compliance with the operating technical specifications is the cause of a considerable number of significant events. This is frequently owing to the incompatibility between the available resources and the workload, or the inappropriate nature of some of the resources made available to the personnel.

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The Independent Safety Organisation (FIS)

EDF's in-house Independent Safety Organisation (FIS) verifies the actions and decisions taken by the departments in charge of operating the installations, from the viewpoint of safety. On each NPP, the FIS comprises safety engineers and auditors, who conduct a daily check on the safety of the reactors. The working of each FIS is checked and evaluated at a national level by the FIS at EDF's Nuclear Production Division. Finally, the EDF nuclear inspectorate, in particular the general inspector reporting to the Chairman of the EDF group, assisted by a team of inspectors, represents the highest level of independent verification of nuclear safety within the EDF group.

ASN also observes breaches of basic safety culture, that is a rigorous and prudent approach with a questioning attitude, in particular when designing and applying periodic test rules and technical operating specifications.

In the light of these observations, ASN reinforced its checks on the application of the user-centred design approach when examining changes to the general operating rules.

ASN observes that in 2017 the degree of compliance with the opinions of the Independent Safety Organisation (FIS), deployed within each EDF entity, is down in some NPPs. This trend demands an in-depth analysis. At this stage, ASN considers this to be a warning sign with regard to the working of the EDF decision-making process in situations in which the required actions must give priority to the protection of interests over expected economic or industrial advantages.

This warning sign leads ASN to reinforce its oversight of the FIS actions and how its opinions are taken on-board.

ASN considers that the periodic test performance methods to ensure correct operation of the equipment could be improved. Errors in drafting and implementing periodic test rules are observed and lead to a relatively high number of significant safety events. These errors reveal specific organisational failures at EDF which ultimately weaken the level of safety in the facilities.

ASN also observed that the organisation implemented by EDF in its NPPs did not allow correct assimilation of the defined requirements associated with the In-core Instrumentation System (RIC) during operation. The sharing of responsibilities between the mechanical and electrical departments, along with the use of outside contractors for maintenance of this system, led to management errors by the licensee, leading to the numerous malfunctions observed in 2017.

Operating rules in the event of an incident or accident

Conduct in an incident, accident or emergency situation

In 2017, ASN carried out twenty-one inspections on EDF's organisational and technical provisions in the event of an incident, accident, severe accident and emergency situation. Two reactive inspections, further to events, were carried out following activation of the PUI on the Bugey NPP.

The inspections on the organisation and emergency resources revealed that the organisation, preparedness and management principles for emergency situations covered by a PUI have been correctly assimilated. The teams in charge of implementing this organisation would appear to be correctly sized with respect to the requirements specified in the licensee's baseline requirements.

Although operating experience feedback from exercises and actual situations is correctly identified by EDF, it does not fully assimilate it, given that certain points requiring improvement are identified time and time again. However, this operating experience feedback shows that the relations between each NPP and the third-parties involved in the management of an emergency situation (hospitals, emergency services) are satisfactory and enhance the interest of such exercises.

2017 was marked on the one hand by the activation of the PUI on two occasions by the same NPP – Bugey – and, on the other, by demonstrators breaking into two other NPPs, Cattenom and Cruas-Meysse. These events led to activation of the national emergency organisation by the public authorities and by EDF, as stipulated by the procedures.

In 2017, ASN also checked the procedures for updating, assimilating and improving the documents necessary for controlling a degraded situation. This oversight is extended to the procedures for managing and implementing the mobile resources required in an accident or severe accident situation.

The inspections carried out in 2017 led ASN to ask EDF to reinforce:
- the clarity and usability of the documents concerning the use of the mobile equipment in a degraded situation or an emergency situation;
- its processes for verification and validation of the documents used in an incident or accident situation;
- the integration of operating experience feedback into the processes for modification of the documents used in an incident or accident situation.

In 2018, ASN will check the application of the provisions of its resolution 2017-DC-0592 of 13th June 2017 concerning the obligations incumbent up on BNI licensees in terms of preparedness for and management of emergency situations and the content of the PUI. Most of these provisions have been applicable since 1st January 2018 for nuclear power reactors.

2.4.3 Monitoring maintenance of the facilities

Preventive maintenance is an essential line of defence in maintaining the conformity of a facility with its baseline safety requirements. This is an important topic, checked by ASN during its inspections in the NPPs.

In order to improve the reliability of the equipment contributing to safety but also to industrial performance, EDF is optimising its maintenance activities, drawing on other practices in use in conventional industry and by the licensees of NPPs in other countries.

Since 2010, EDF has thus initiated the deployment of a new maintenance methodology, called AP-913, developed by the American nuclear licensees. The main interest of this method is to make the equipment more reliable through in-service monitoring, in order to improve preventive maintenance.

Deployment of the AP-913 maintenance methodology 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.

After a review of the deployment of AP-913 in mid-2016, EDF aims to change its practices in order to limit the volume of maintenance work generated and focus performance monitoring on the highest risk equipment and systems.

2.4.4 Evaluation of maintenance

ASN considers that the quality of maintenance work could still be improved, given that the number of maintenance work quality defects found remains high.

Delays in the performance of checks or in the integration of new maintenance programmes into the documentation and preventive maintenance measures that are inappropriate to the safety functions performed by the equipment concerned, are still leading to the belated detection of deviations or equipment deterioration. Several significant events related to insufficient maintenance were notified in 2017 (see point 2.4.7).

Even if the numbers are dropping, ASN still observes activity management problems owing to difficulty with the procurement of spares, in particular because spares are unavailable or non-conforming.

The workers still have to deal with constraints linked to work organisation, such as insufficient preparation for certain activities, unplanned scheduling changes and problems with worksite coordination, leading to activity delays or postponements. These difficulties are more particularly encountered with regard to unscheduled activities such as dealing with unexpected events.

ASN also regularly observes a lack of rigour in technical oversight of interventions and in monitoring of contractors, along with deficiencies in the traceability of the interventions.

The management of maintaining equipment qualification for accident conditions is improving. However, post-maintenance qualification of equipment is not always able to detect any work that has been incorrectly performed.

ASN considers that the AP-913 maintenance method will give the licensee a clearer picture of the condition of its facilities and ensure more regular maintenance. However, it considers that proactive measures must be taken by EDF in its NPPs to allow correct implementation and ensure that it is effective. EDF must in particular ensure stricter management and allocate the necessary workforce. EDF must ensure that all participants follow the recommended methods for filling out the equipment monitoring indicators, for the preparation, performance and write-up of field inspections and for the traceability of maintenance decisions.

With a view to extending the service life of the NPPs in operation and in the light of the "major overhaul" programme and the lessons learned from the Fukushima Daiichi accident, ASN considers that it is important for EDF to continue the efforts started to resolve the difficulties encountered and improve the effectiveness of its maintenance work (see point 2.6).

ASN asked EDF to carry out design reviews. It is also conducting inspections to assess the adequacy of the maintenance operations for the potential and actual degradation modes identified. On this subject, it notes that when carrying out its inspections, access to documentation, notably with regard to system and equipment reviews, is sometimes difficult.

2.4.5 Preventing the effects of internal and external hazards

Fire risks

In the same way as the other BNIs, NPPs are subject to ASN resolution 2014-DC-0417 of 28th January 2014 on the control of fire risks.

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.

Design rules must prevent a fire from spreading and mitigate its consequences; they are based primarily on "fire zoning". This involves dividing the facility into sectors and containment areas designed to keep the fire within a given perimeter bounded by items (doors, walls and fire dampers) offering a specific 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, a "fire permit" must be issued and protective measures must be taken for all work liable to cause a fire.

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 zoning 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.

ASN examines the methods for substantiating the sizing of the fire zones in the light of the fire risks determined by EDF during the periodic safety reviews of the 900 MWe reactors.

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.

Internal flooding risks

An internal flood, in other words which comes from within the facility, may lead to failure of equipment necessary for reactor shutdown, fuel cooling and containment of radioactive products. Steps are therefore taken to prevent internal flooding (maintenance of piping carrying water, etc.), or mitigate its consequences (presence of floor drains and water extraction pumps, installation of sills or leaktight doors to prevent the flood from spreading, etc.). These measures are regularly inspected by ASN.

ASN remains vigilant with regard to the risks of internal flooding as a result of an earthquake, as well as with regard to the integration of operating experience feedback, in particular the processing of deviations affecting certain internal flooding protection measures.

External flooding risks

The partial flooding of the Le Blayais NPP in December 1999 led the licensees, under the supervision of ASN, to reassess the safety of their facilities 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 requirements, EDF completed the required work on all its nuclear power reactors in 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.
- for the 1,300 MWe reactors, ASN asked EDF to do this as a priority during the third periodic safety review;
- for the other reactors in service, EDF will do this as a priority during the next periodic safety reviews (fourth reviews for the 900 MWe reactors and second reviews for the 1,450 MWe reactors).

The first studies drawn up in accordance with Guide N° 13 are currently being examined by ASN.

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 2.9).

Seismic risks

Although seismic activity in France is moderate or slight, EDF's inclusion of this risk in the safety case for its nuclear power reactors is the subject of constant attention on the part of ASN, given the potential consequences for the safety of the facilities. 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.

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 ASN guide 2/01 of May 2006, which defines acceptable calculation methods for study of the seismic behaviour of nuclear 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. EDF's NPPs are thus designed for seismic levels with incorporation of the local geological features specific to each one.

As part of the periodic safety reviews, the seismic reassessment consists in 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 are also analysed and integrated into this framework.

Changing knowledge leads EDF to reassess the seismic hazard during the periodic safety reviews, more specifically:
- third periodic safety reviews of the 1,300 MWe reactors;
- fourth periodic safety reviews of the 900 MWe reactors;
- second periodic safety reviews of the 1,450 MWe reactors.

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 the levels 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.

ASN considers that the assessments of the seismic hazards determined by EDF are acceptable, with the exception of those concerning the sites of Saint-Alban/Saint-Maurice, Fessenheim, Chinon and Chooz which are insufficient in the light of current knowledge. ASN therefore asked EDF:
- to reassess the seismic spectra for the SaintAlban/Saint-Maurice, Fessenheim, Chinon and Chooz sites in order to take account of the uncertainties;
- to define a working programme to verify the strength of the equipment and civil engineering structures and make any seismic reinforcements for the periodic safety reviews.

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Seismic resistance fault in the Donzère-Mondragon canal embankment which protects the Tricastin NPP

On 18th August 2017, EDF sent ASN notification of a significant safety event concerning a risk of failure of a part of the Donzère-Mondragon canal embankment for the largest earthquakes studied in the nuclear safety case. This significant safety event was rated level 2 on the INES scale.

The resulting flooding would be such as to cause a nuclear fuel melt accident in the four reactors of the Tricastin NPP and would have made deployment of the on-site and off-site emergency management resources particularly difficult.

After hearing EDF, ASN considered that the information presented by the licensee could not rule out the risk in the short term. It therefore required that EDF temporarily shut down the four reactors on the Tricastin NPP in a resolution dated 27th September 2017.

EDF strengthened the portion of the embankment concerned, after carrying out additional geotechnical surveys. ASN carried out inspections during the works. The assessment carried out by IRSN on the embankment thus strengthened at the request of ASN confirms that there would be no breach in the event of a safe shutdown earthquake. ASN considered that, further to the investigations and the repairs carried out by EDF, the condition of the embankment allowed the restart of the EDF reactors. It thus gave its consent accordingly on 4th December 2017.

ASN has begun to draft requirements, which will be the subject of a public consultation, in order to oversee the actions to be taken by EDF, in particular reinforced surveillance of the embankment, maintaining pre-positioned equipment in place and final reinforcement of the embankment, as rapidly as possible, so that it can withstand the extreme earthquake considered subsequent to the Fukushima Daiichi accident.

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 facilities 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.

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 the effects of a heat wave situation. The capacity of certain cooling systems for equipment required for the nuclear safety case will in particular be improved.

EDF has also initiated a climatic monitoring programme in order to anticipate climate changes, which could compromise the temperature hypotheses adopted in its baseline safety standards.

With regard to the 900 MWe reactors, ASN gave its consent in 2012 to the implementation of the baseline safety requirements and integration 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 other types of reactors.

In 2016, ASN asked EDF to take account of the lessons learned from the heat wave events of 2015 and 2016, along with their effects on the facilities, in the studies planned for the fourth periodic safety reviews of the 900 MWe reactors. The conclusions of these studies could, as applicable, be taken into account in the revision of the studies concerning other types of reactors.

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. These thermal discharges are regulated by ASN resolutions.

Since 2006, provisions have been incorporated into these resolutions in order to define in advance the operating modes of NPPs in exceptional climatic conditions that would lead to significant warming of the watercourse. These special provisions are however only applicable if the security of the electricity grid is at stake.

Lightning risks

The measures taken to address the lightning risk for the NPPs is currently primarily based on the steps specified by the regulations applicable to installations classified for protection of the environment. These regulations require the performance of a lightning risk assessment to identify whether or not it is necessary to protect the various buildings, along with a technical study to determine the nature of the protection systems to be installed (mainly lightning arresters and lightning conductors), where they are installed and how they are checked and maintained.

During the fourth periodic review of the 900 MWe reactors, ASN indicated that it considered that the application of this order would not enable a sufficient level of safety to be attained on the NPPs and asked EDF to transmit a new methodology more particularly taking account of plausible combinations with other hazards and the secondary effects of lightning (fires, loss of off-site electrical power supplies). This methodology is currently being reviewed by ASN.

Other hazards

The safety case for the EDF NPPs also takes account of other hazards such as high winds, tornados, cold air temperature, man-made hazards (transport of dangerous goods, industrial facilities, airplane crashes, etc.), and hazards affecting the heatsink.

2.4.6 Evaluation of the risk prevention measures relating to hazards

The Fukushima Daiichi accident led EDF to reinforce its organisation for the management of risks relating to hazards. Networks of coordinators were in particular appointed on all the NPP sites to oversee the organisation related to these risks. Annual reviews are also held to improve this organisation.

On the basis of its inspections, with regard to the fire risk, ASN observes that the integration of operating experience feedback is on the whole satisfactory and that the refurbishment of the fire detection system is continuing on the nuclear reactors. However, the number of outbreaks of fire recorded for 2017 is slightly higher than that for 2016. An outbreak of fire on 19th June 2017 in the Bugey NPP led to activation of the PUI.

Moreover, the findings made in previous years are still valid with regard to some of the sites inspected:
- management of zoning anomalies in the premises could be improved in order to prevent the spread of fire;
- 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.

ASN notes the efforts made by certain sites to reduce these deviations through the deployment of tools and action plans, but considers that if they are to be effective, the personnel must receive more comprehensive assistance with their implementation. In addition the time taken to remedy certain deviations or to take corrective actions as a result of experience feedback could be reduced.

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.

Despite the steps taken by EDF, management of the explosion risks is not yet satisfactory on all the nuclear reactors. Certain maintenance work and inspections required by EDF's internal doctrine (nitrogen tightness tests of the double wall of certain pipes carrying hydrogenated fluids, etc.) are not always carried out. Furthermore, the updating of certain documents (periodic test procedures and document concerning protection against explosions), the integration of lessons learned, the handling of certain deviations and the deployment of certain modifications can be postponed, something that cannot always be justified with regard to the potential safety consequences.

ASN notes the efforts made by EDF to reduce these deviations through the implementation of reinforced monitoring and deployment of the action plan. However, ASN considers that EDF must continue to pay particular attention to this point and to the application of the regulations concerning the ATEX risk, and ensure that the explosion risks prevention approach is implemented with all necessary rigour on all the sites.

The provisions for the prevention and management of the internal flooding risk are also regularly checked by ASN. These inspections show that the steps taken to manage this type of hazard are not up to the level expected for all the sites. ASN more specifically observes that on some sites, the network of coordinators is still being set up and is not fully operational.

EDF has initiated walkdowns to identify the piping which could cause internal flooding in the electrical buildings, which are particularly vulnerable to this risk, in order to assess the need to reinforce their maintenance. In accordance with ASN's requests, EDF will extend these surveys to the other buildings. ASN sees as positive the fact that EDF has initiated the refurbishment of the circuits of certain cooling systems that are particularly susceptible to corrosion.

In 2016 and 2017 EDF sent ASN notification of several significant safety events concerning the flow of water caused by leaks from piping in poor condition or valve lock-out errors during maintenance operations.

Considerable efforts are required on most sites to improve the management of the flooding risk, in particular with respect to:
- maintenance of the necessary equipment (piping, floor drains, etc.);
- risk assessments during maintenance operations and in the event of detection of a malfunction of a necessary equipment item;
- compliance with the action deadlines identified by the annual reviews;
- the training of the coordinators and awareness-raising among the EDF and contractor personnel.

The operating and maintenance conditions of the seismic detection equipment are considered to be satisfactory. The annual reviews allow the identification of areas for progress and these are on the whole implemented. EDF is however required to continue with its efforts, notably with regard to the training of staff and awareness-raising among contractors. ASN notes that the operating instructions in the event of an earthquake are not always sufficiently operational and that more regular simulations would improve their applicability.

In 2017, EDF notified several significant events of level 2 on the INES scale (International Nuclear and Radiological Event Scale, which comprises eight levels from 0 to 7) concerning seismic resistance defects of equipment necessary for managing the safe shutdown of the reactors, cooling of the fuel and containment of radioactive products. The handling of these deviations was frequently checked by ASN (see point 2.4.7). These deviations reveal that EDF must reinforce its management of the conformity of its facilities with the provisions for dealing with an earthquake.

The inspections concerning the hazards associated with extreme temperatures show that EDF's organisation could be improved on the majority of sites. On several sites, ASN more particularly found a lack of forward planning in preparing the facility for the summer or winter configuration.

During its inspections ASN repeatedly notes that EDF does not systematically initiate the required measures if certain temperature thresholds are exceeded. These findings led ASN to issue requests for corrective action. The risk assessments associated with the deployment of countermeasures should also be improved. Finally, ASN requires efforts from EDF with regard to the training of its staff and awareness-raising

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Leaktightness flaw in the penetrations necessary for managing an internal flood

The integration of the operating experience feedback from the internal flooding that occurred on the Le Blayais (2012) and Fessenheim (2014) reactors led EDF to initiate an inspection campaign on the penetrations (openings in the walls for running cables or piping between two areas) on all its reactors. EDF found numerous leaktightness flaws in the penetrations of the electrical buildings. These deviations stem primarily from poor incorporation of the baseline requirements concerning internal flooding and fire into the databases used to draw up the maintenance programmes. These deviations were the subject of a generic significant safety event notification in 2015 and led to the drafting of a programme to monitor and restore the conformity of the databases and penetrations in all the reactor buildings in operation. In 2016, ASN submitted several requests more particularly concerning the extension and forward planning of these checks. Following the inspections carried out in 2017, ASN considers that the methods for processing this deviation in the electrical buildings of the 900 MWe reactors are appropriate. ASN will remain vigilant in the coming years with regard to the complete handling of this deviation.

among contractors. These points were the subject of requests in the follow-up letters to the inspections performed by ASN.

The inspections relating to lightning reveal the need on all sites to set up an organisation and reinforced oversight to improve the integration of the regulatory requirements concerning the management of this hazard.

The lightning risk assessments can be based on information which does not actually reflect the real situation on the facilities. ASN also observes a significant delay in the performance of the work identified in the technical studies. The deadlines for performance of the periodic checks on the lightning protection systems by the competent inspection organisations are on the whole not adhered to. These points were the subject of requests for corrective action.

2.4.7 Monitoring facilities compliance with the requirements

Maintaining the compliance of the facilities with their design, construction and operating requirements is a major issue insofar as this compliance is essential in demonstrating the protection of interests. The processes employed by the licensee, notably during reactor outages, contribute to maintaining the compliance of the facilities with the requirements resulting from this demonstration.

Reactor outages

Nuclear power reactors need to be periodically shut down in order to renew the fuel, which gradually becomes depleted during the electricity production cycle. One third or one quarter of the fuel is thus renewed at each outage.

These outages mean that it is temporarily possible to access parts of the installation that would not normally be accessible during production. They are therefore an opportunity to verify the condition of the equipment by running checks and tests and performing maintenance work, as well as to carry out work on the facility.

These refuelling outages can be of several types:
- 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 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, enables the licensee to carry out major operations such as a complete inspection and hydrotesting on the primary system, a containment test or incorporation of design changes as a result 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 ensure the safety of the facility, protection of the environment and radiation protection of the workers during the outage, as well as the safety of the reactor for the next production cycle.

The monitoring performed by ASN, in the light of the provisions of its resolution 2014-DC-0444 of 15th July 2014 concerning shutdowns and restarts of pressurised water reactors, primarily concerns:
- during the outage preparation phase, the content of the outage programme drawn up by the licensee. As necessary, ASN may ask 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.

The identification and handling of deviations

The checks initiated by EDF for its operating baseline requirements and the additional verifications requested by ASN on the basis more particularly of operating experience feedback, can lead to the detection of deviations from the defined requirements, which must then be processed. These deviations can have a variety of origins: design problems, construction errors, insufficient management of maintenance work, deterioration through ageing, etc.

The measures for detecting and correcting deviations, prescribed by the Order of 7th February 2012, play an essential role in maintaining the level of safety of the facilities.

FUNDAMENTALS

The defined requirements

The Order of 7th February 2012 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.

"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 detecting 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 production. These operations are mainly used to remedy anomalies already identified, but also lead to the detection of new ones. 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 production cycle.

FUNDAMENTALS

Deviation handling

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 related to the handling of deviations are activities important for the protection of interests. They are thus subject to oversight and monitoring requirements, the implementation of which is regularly checked by ASN.

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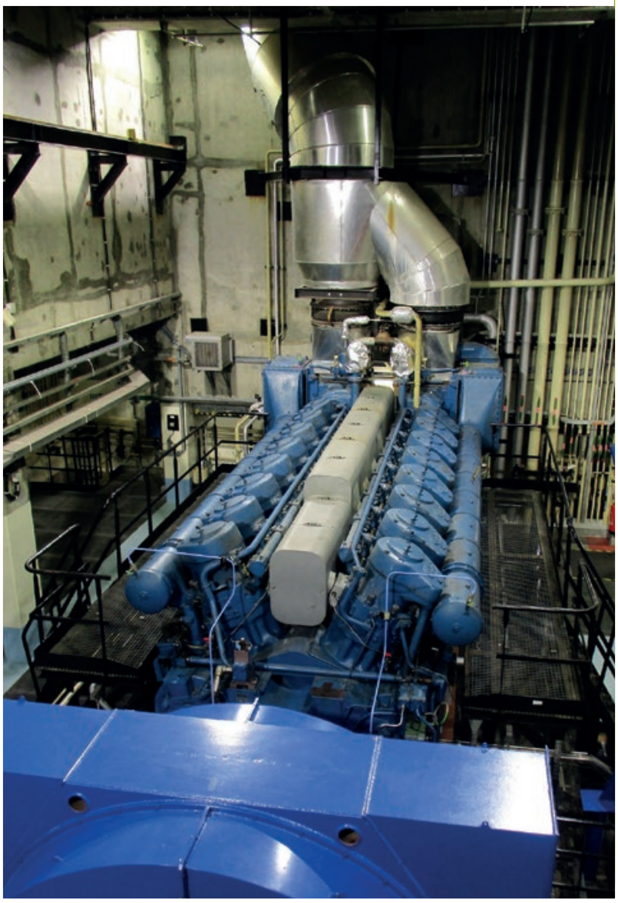
Significant safety event rated level 2 on the INES scale concerning a seismic resistance flaw on the auxiliary systems of the backup diesel generating sets

On 20th June 2017, ASN gave a level 2 rating on the INES scale to a significant safety event concerning the seismic resistance of the auxiliary systems of the backup diesel generating sets for reactors 2 and 5 of the Bugey NPP, reactors 1 and 2 of the Fessenheim NPP and all the 1,300 MWe reactors (Belleville-sur-Loire, Cattenom, Flamanville, Golfech, Nogent-sur-Seine, Paluel, Penly and Saint-Alban/Saint-Maurice NPPs).

Each of the 900 MWe and 1,300 MWe reactors of the French NPPs has two backup diesel generators. This equipment provides a redundant electrical power supply to certain safety systems in the event of the loss of off-site electrical power, more particularly in the wake of an earthquake. The emergency diesel generator sets comprise a generator, a diesel engine and auxiliary systems (cooling, pre-lubrication, etc.).

The significant event concerns the inability to demonstrate the capacity of the civil engineering anchors of the auxiliary systems of the diesel generator sets to withstand an earthquake. In the event of a total loss of off-site electrical power as a result of an earthquake, the operation of the backup diesel electricity generating sets would not have been guaranteed. In the light of the other deviations notified to ASN by EDF, this situation could have led to a main primary system leak from the reactor coolant pumps and loss of cooling of the spent fuel pool.

Following the ASN requirements of 22nd June 2017 and 26th October 2017, EDF carried out the necessary work to reinforce the anchors of the auxiliary systems of the backup diesel generator sets for all the 900 MWe and 1,300 MWe reactors concerned.



Backup Diesel electricity generator set on the Penly site, June 2017.

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 2.10.2). 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.

The additional verifications in response to ASN requests

In addition to the steps taken by EDF with regard to its operating baseline requirements, additional checks are carried out at the request of ASN, whether with regard to operating experience feedback about events which have occurred on other facilities, after inspections, or after examination of the provisions proposed by the licensee within the context of the periodic safety reviews.

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 and 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.

Significant events

EDF is required to notify ASN of and then analyse any significant events occurring in its NPPs (see chapter 4, point 3.3). Each significant event is, whenever appropriate, rated by ASN on the INES scale. This processing of notification and analysis of significant events contributes to operating experience feedback and to the continuous improvement approach for the protection of the interests mentioned in Article L. 593-1 of the Environment Code.

At the local and national levels, ASN examines all significant events notified (a summary of their analysis for 2017 is given in point 2.4.8). The significant events considered to be noteworthy owing to their severity or their recurring or generic nature, are the subject of an in-depth analysis by ASN.

During inspections in the NPPs and the EDF head office departments, ASN checks the licensee's organisation and the steps taken to learn the technical and organisational lessons from operating experience feedback. Finally, at the request of ASN, the GPR in 2017 examined the experience feedback from PWR operations from the viewpoint of control of facility compliance with design, construction and operating requirements.

2.4.8 Evaluation of facilities compliance with the requirements

The periodic tests, equipment maintenance and replacement programmes, the reactor periodic safety review approach and the correction of deviations should make it possible to check and ensure the lasting ability of the equipment 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.

The detection, characterisation and handling of deviations are covered by regulatory provisions of the Order of 7th February 2012. These provisions are important because they contribute to controlling the conformity of the facilities with the requirements for protection of the interests stipulated by the law, a pre-condition for their operation. Moreover, control of conformity should enable the improvements that result from the periodic

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Significant safety event concerning a lack of seismic resistance of the surge tanks of the emergency diesel generators cooling systems

On 17th January 2018, ASN rated as level 2 on the INES scale a significant safety event concerning a lack of seismic resistance on the part of the surge tanks of the emergency diesel generators cooling systems for reactors 1 and 2 of the Paluel NPP. This flaw is linked to a corrosion phenomenon: it is notably the result of insufficient maintenance of this equipment. This flaw was detected by EDF in the Penly NPP and was the subject of a generic significant event notification by EDF on 9th November 2017, with respect to several 1,300 MWe reactors. Work (repair or replacement) was carried out between August and October 2017 on the corroded surge tanks for the nuclear power reactors concerned.

The ASN rating was:

- level 2 on the INES scale for the flaw concerning the two backup diesel generators for reactors 1 and 2 of the Paluel NPP, as the two redundant electricity generating sets were affected;
- level 1 on the INES scale for the flaw concerning only one of the two backup diesel generators for Nogent-sur-Seine 1, Penly 1, Belleville-sur-Loire 2, Cattenom 2 and Paluel 3 reactors, as only one of the two electricity generating sets was affected.

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Significant safety even rated level 2 on the INES scale concerning a risk of total or partial loss of the heatsink for 29 reactors

On 16th October 2017, ASN rated as level 2 on the INES scale a significant safety event concerning a risk of total or partial loss of the heatsink for 29 reactors.

Following an ASN request, EDF carried out checks on the piping of the fire-fighting water production system (also called the JPP system) in the Belleville-sur-Loire NPP in the spring of 2017. On two sections of the JPP system, these checks revealed that the piping was degraded, with a thickness unable to meet the minimum requirements such as to guarantee earthquake resistance. This degradation is the result of corrosion which developed given the lack of appropriate preventive maintenance.

The EDF analyses led it to extend its investigations to the piping of the raw water filtration system (called the SFI system or CFI system depending on the configuration of the nuclear site) and to all the reactors in service.

The piping concerned (JPP and SFI or CFI) is located in the pumping station of the essential service water system (SEC system), which functions permanently and which, using the heatsink available near the installation (sea or watercourse), contributes to cooling of the safety systems. In the event of an earthquake, rupture of the JPP, SFI or CFI piping could lead to flooding of the SEC system pumps and thus loss of this cooling capacity essential to the NPP.

EDF implemented solutions to repair the defective piping sections and compensatory measures to rapidly secure the two redundant channels of the SEC system and aims to complete the final repairs by the end of 2018.

ASN checked that EDF was taking all necessary steps to deal with this event as rapidly as possible. It will ensure that EDF learns all relevant lessons from this event, notably with regard to improving preventive maintenance provisions.

reviews to be based on a known and robust actual status of the facilities.

In 2016 and in 2017, ASN identified the management of deviations affecting NPPs as one of its priority inspection topics. The results of the inspections carried out in 2017 again highlight the difficulties encountered by the NPPs with identification, characterisation and handling of deviations.

The inspections carried out or requested by ASN in 2017 during the scheduled reactor outages and during reactor production periods, revealed a number of deviations which called into question the actual availability of certain systems important for the safety of the installations, such as the electrical systems or the heatsink. Some of the defects identified are linked to equipment design. This is for example the case of the significant event, rated level 2 on the INES scale, concerning the inability to demonstrate the capacity of the civil engineering anchors of the auxiliary systems of the diesel generator sets on the Fessenheim and Bugey 1,300 MWe reactors to withstand an earthquake. Other defects are linked to the poor condition or to non-compliance with the equipment drawings: for example, insufficient seismic resistance owing to corrosion which developed because of a lack of appropriate preventive maintenance of certain pipes, which could lead to the total loss of the heatsink for certain 900 MWe reactors, or non-conformity in the supports of piping on the essential service water system of some reactors in the Gravelines NPP.

ASN considers that these numerous deviations, some of which were rated level 2 on the INES scale in 2017, are indicative of a deterioration in the real condition of the facilities and that EDF must significantly improve its management of the conformity of its facilities. ASN required the repair of the most significant deviations without delay and carried out inspections to check the satisfactory completion of these repairs. ASN will be particularly attentive as to how the situation develops in 2018 and will in this respect continue its inspections of the condition of equipment and systems.

Control of the conformity of the facilities in operation will be a major focal point for ASN oversight in 2018 and it will notably be examined with a view to preparing for the fourth periodic safety review of the 900 MWe reactors, for which the first of wich is scheduled as of 2019.

Analysis of significant events statistics

In accordance with the rules concerning the notification of significant events (see point 3.3 of chapter 4), EDF in 2017 notified ASN of 688 significant safety events, 130 radiation protection events and 98 environmental protection events.

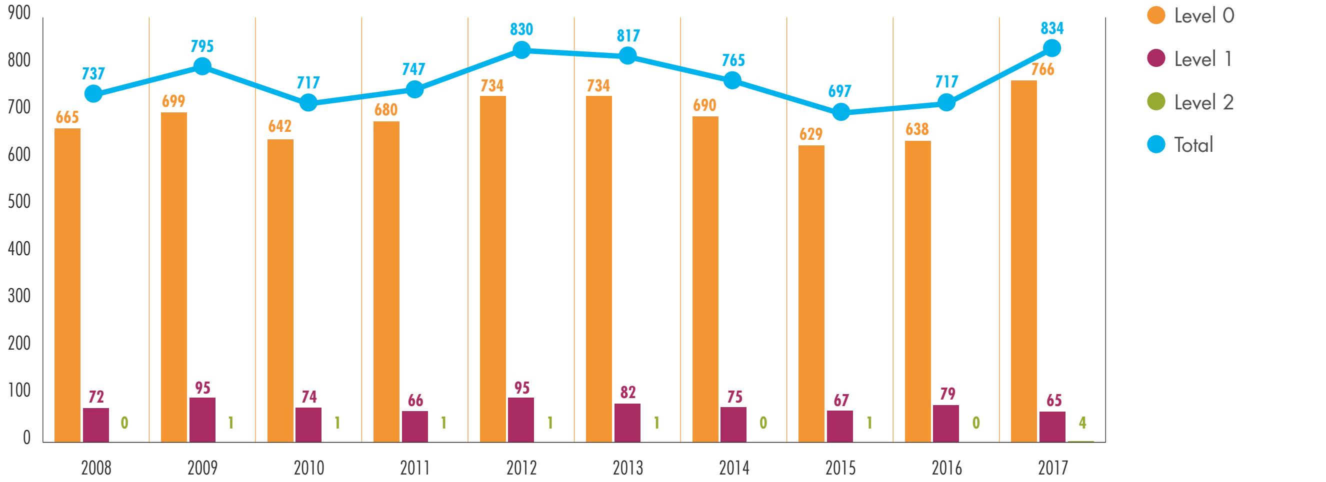
Graph 1 shows how the number of significant events notified by EDF and classified on the INES scale has evolved since 2008.

Graph 2 shows the trend since 2008 in the number of significant events according to the notification field: Significant Safety Events (ESS), Significant Radiation Protection Events (ESR) and Significant Environmental Events (ESE).

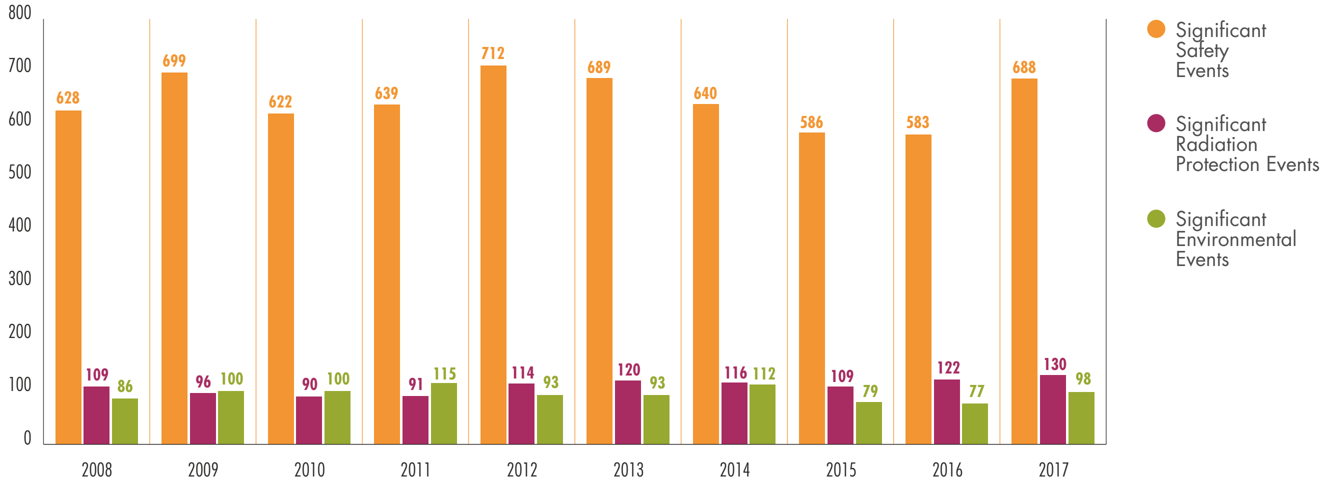
Several events which are similar or the result of common causes affect several NPPs. They are grouped under the term Generic Significant Events (ESG). Seventeen were notified in 2017 in the field of safety, one in the field of radiation protection and one in the environmental field.

The number of significant events increased by about 17% in 2017 by comparison with the previous year. The details of the significant events for each site are presented in chapter 8.

GRAPH 1: Trend in the number of significant events rated on the INES scale in EDF nuclear power plants from 2008 to 2017



GRAPH 2: Trend in the number of significant events per domain in EDF nuclear power plants from 2008 to 2017



Events off the INES scale are also taken into account.

2.5 Prevention and management of environmental and health impacts

2.5.1 Monitoring of discharges and of waste management

Monitoring the management of water intake and environmental discharges

The Environment Code empowers ASN to define binding requirements concerning BNI water intake and discharges (see point 4.1 of chapter 4). The laws and regulations concerning environmental protection which apply to French NPPs comprise generic regulations, primarily the Environment Code, the Order of 7th February 2012 and ASN resolutions 2013-DC-0360 of 16th July 2013 concerning the management of detrimental effects and the health and environmental impact of BNIs, and 2017-DC-0588 of 6th April 2017 concerning procedures for water intake and consumption, effluents discharge and environmental monitoring for PWRs, as well as regulations specific to each of the NPPs:

- decisions setting the procedures for water intake and consumption and environmental discharges of liquid and gaseous effluents (chemical and radioactive);
- decisions setting the environmental discharge limits for liquid and gaseous effluents (chemical and radioactive); These decisions are approved by the Minister responsible for Nuclear Safety;
- the Orders of the Prefect authorising water intake and discharges of liquid and gaseous effluents: pre-dating November 2006, they contain binding requirements concerning the procedures and discharge limits specific to a nuclear site. In order to apply the new regulatory architecture to all the French NPP reactors, revision of the orders has led to them being repealed, with the adoption of ASN resolutions.

For each site, ASN sets the limit values for emissions, water intake and discharge of effluents on the basis of the best

Environmental protection deployment exercise, Bugey NPP, 2017.

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 concerning the management of detrimental effects and the impact on health and the environment of the pressurised water reactor NPPs. These binding requirements are notably applicable to the management and monitoring of water intake and effluent discharge, to environmental monitoring and to information of the public and the authorities (see point 4.1 of chapter 4).

In order to set these requirements, ASN bases its work on operating experience feedback from all the reactors, while taking account of operational changes (change in conditioning of systems, anti-scaling treatment, biocidal treatment, etc.) and changes to the general regulations.

Finally, every year, the NPP licensees send ASN an annual environmental report which notably contains a summary of the intakes from and discharges into the environment, any impacts they may have, the significant events which have occurred and the future outlook.

Oversight of waste management

The management of the conventional and radioactive waste produced by the NPPs falls within the general framework of management of BNI waste. The legal framework for the management of waste applicable to French NPPs comprises

FOCUS

Approval of ASN resolution 2017-DC-0588 of 6th April 2017 relative to the conditions for water intake and consumption, discharge of effluents and monitoring of the environment around PWR reactors

Each ASN licensing decision setting the procedures for water intake and effluent discharge contains about a hundred generic requirements applicable to all French NPPs. These requirements concern procedures for intakes, gaseous, liquid and thermal discharges and environmental monitoring.

ASN resolution 2017-DC-0588 of 6th April 2017, approved by the Order of 14th June 2017, enables these generic requirements to be grouped in a single text, improving the consistency of the requirements applicable to the French NPPs. It proposes no major change to the content of the requirements currently applicable. The content of certain requirements currently appearing in the licensing decisions may have changed, however, in particular in order to clarify what ASN requires or to add new provisions.

This resolution, which has been applicable since 1st January 2018, constitutes a minimum regulatory platform that ASN will build on in each licensing decision, if additional requirements concerning management of intakes and discharges prove to be necessary in the light of the specific features of the site and its environment.

legislative and regulatory texts of general scope, notably the Environment Code, the Order of 7th February 2012 and ASN resolution 2015-DC-0508 of 21st April 2015 concerning the study of waste management and the inventory of waste produced in BNIs.

In compliance with the Environment Code, EDF carries out waste sorting at source, differentiating in particular between waste from nuclear zones and other waste. For all the waste, ASN examines the study produced by the licensee regarding waste management. This document is specific to each facility, as required by the regulations and as described in chapter 3, point 3.4. This document more specifically presents a description of the operations which are the cause of production of the waste, the characteristics of the waste produced or to be produced, an estimation of the waste traffic volumes and a waste zoning plan.

Every year, each site also sends ASN an inventory of its production of waste and the corresponding disposal routes, a comparison with the results of previous years, a summary of deviations observed and of the organisation of the site, the list of significant events which have occurred and the outlook for the future.

These elements taken from the annual reports transmitted by the licensee to ASN, the waste management studies and the inspections carried out by the ASN inspectors, constitute the basis of ASN's monitoring of the management of waste produced by EDF's NPPs and compliance with the regulations.

2.5.2 The prevention of health impacts and soil pollution

Prevention of pollution resulting from accidental spillage of dangerous substances

As on numerous industrial sites, the operation of an NPP involves the handling and storage of "dangerous" chemical substances. The management of these substances and the prevention of pollution, which are the responsibility of the licensee, are regulated by ASN resolution 2013-DC-0360 of 16th July 2013 and the Order of 7th February 2012 and must also comply with the requirements of the European texts. The licensee has obligations regarding the operational management of these substances and the identification of the corresponding potential hazards. It must also be able to take the necessary steps in the event of any unforeseen circumstances leading to pollution.

The licensee must thus for instance precisely identify the location of each dangerous substance on its site, along with the relevant quantities. Drums and tanks must be labelled in compliance with the European CLP (Classification, Labelling, Packaging) regulation and there must be retention areas designed to collect any spills. The NPPs must also adopt an organisation and resources to prevent pollution of the natural environment (groundwater, river, soil).

For several years and at the request of ASN, EDF has been carrying out measures to improve its management of the pollution risk by working to improve the containment of dangerous liquid substances on its sites (see box below).

Through its field inspections, ASN is closely monitoring the organisational and material provisions adopted by EDF to manage the dangerous substances present in its facilities and to deal with any pollution.

FUNDAMENTALS

Improved confinement of liquid dangerous substances in NPPs

Further to an ASN request in 2013, EDF initiated a review of its ability to ensure reliable and lasting prevention of accidental flows into the environment of dangerous substances and effluents liable to result from fire-fighting. If not collected upstream, these flows are liable to spill into the site's wastewater and rainwater drainage network and ultimately into the environment.

This review led to the implementation of a national programme, some parts of which are still being deployed.

A first part consists in developing technical solutions to collect any pollution not retained upstream of the wastewater network. The preferred solution is to build retention tanks to collect the polluted waters and avoid their spilling into the environment. When this solution cannot be envisaged on a site, for example owing to a lack of space, other systems are used. This involves plugs or valves which confine the pollution directly in the wastewater system and prevent it from being drained away.

Work was also carried out on the operation and maintenance of the equipment used in the collection of spills, notably retention areas. After examining operating experience feedback, EDF defines a set of operational management rules for its sites designed to prevent pollution.

Finally, EDF is improving its personnel training to make them aware of the pollution risk and the corresponding prevention measures.

More particularly during the course of inspections, ASN carries out spot-checks on the effective implementation of this national improvement programme.

Prevention of the health impacts caused by the growth of legionella and amoeba in certain cooling systems of the NPP secondary systems

Some cooling systems in NPPs are environments that are favourable to the development of legionella and other amoebas (see point 1.4).

ASN resolution 2016-DC-0578 of 6th December 2016 on the prevention of risks resulting from the dispersal of pathogenic micro-organisms (legionella and amoeba) by PWR secondary system cooling facilities sets requirements concerning:
- the design, upkeep and monitoring of the facility;
- the maximum legionella concentrations in the water in the facility and downstream of it with regard to amoeba;
- the steps to be taken in the event of proliferation of micro-organisms in the systems or identified infection in the vicinity of the facility;
- information of the public and the administrations in the event of proliferation of micro-organisms.

Through its investigations and its field checks, ASN closely monitors 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.

2.5.3 Evaluation of control of detrimental effects and impact on the environment

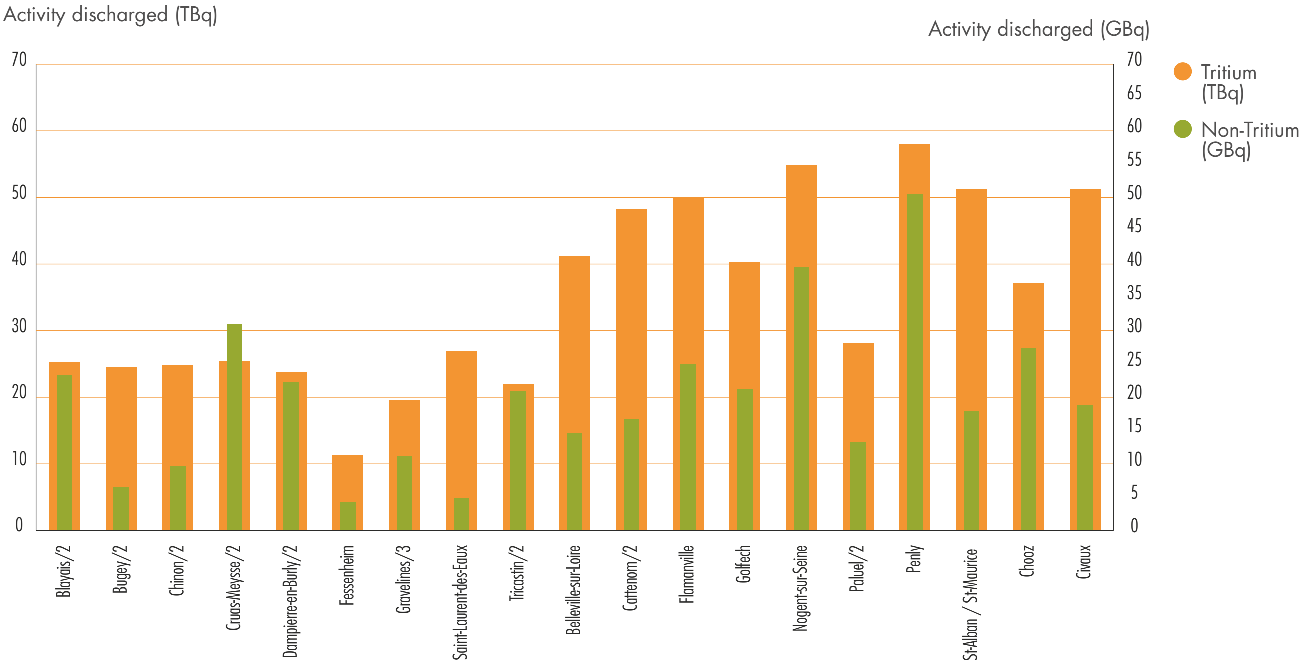
Evaluation of prevention of detrimental effects, control of environmental discharges and waste management

In 2017, ASN carried out 46 inspections on the control of detrimental effects and the impact of the NPPs on the environment, representing a total of about fifty days. These inspections primarily concerned the prevention of detrimental effects, the control of environmental discharges and waste management. The Bugey, Saint-Alban/Saint-Maurice and Tricastin NPPs underwent a reinforced inspection.

ASN considers that EDF's organisation for the detrimental effects and impact control of NPPs on the environment is satisfactory on most sites. As the first provisions of ASN resolution 2016-DC-0578 of 6th December 2016 had entered into force in April 2017, ASN has already inspected the Golfech and Cruas-Meysse NPPs and will continue its inspections in 2018. On the basis of these inspections, ASN observes that the steps taken by the sites to prevent the risks of the dispersal of pathogenic micro-organisms by the cooling installations of the PWR secondary system must be reinforced.

Operational management of radioactive and conventional waste in the NPPs could on the whole be improved, in particular during reactor maintenance outage periods. However, ASN is pleased to see the steps taken by EDF to determine new waste processing methods or new disposal routes.

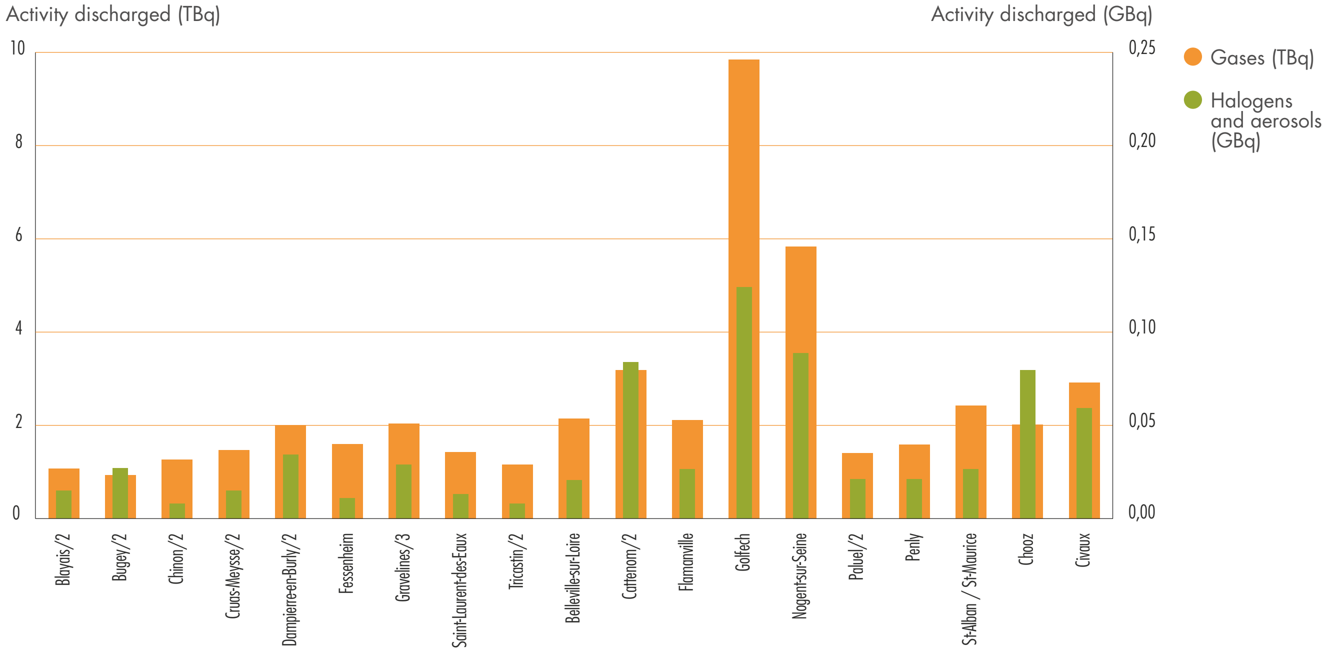
GRAPH 3: Liquid radioactive discharges for the NPPs in 2017 (per pair of reactors)



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).*

In addition, the discharge data transmitted by EDF to ASN for each site are not representative of the operating time of the installations or of the activities performed on the sites.

GRAPH 4: Gaseous radioactive discharges for the NPPs in 2017 (per pair of reactors)



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).*

In addition, the discharge data transmitted by EDF to ASN for each site are not representative of the operating time of the installations or of the activities performed on the sites.

In 2018, ASN will more specifically carry out inspections on:
- the detection and handling of deviations concerning the conformity of the facilities;
- monitoring of activities performed by contractors;
- the prevention and management of spills of dangerous substances ;
- the quality of the documentation on conventional risks and on the operation of the installations, in particular with regard to the display of certain instructions inside the installations and the labelling of hazardous substances.
- EDF's approach to integrating the items and activities concerning the control of detrimental effects and environmental impacts, from among the equipment and activities important for protection defined by the Order of 7th February 2012;
- deviations from the operating baseline requirements concerning waste management, in particular with regard to compliance with the maximum storage capacities for radioactive waste in the specific buildings and areas.

2.6 Prevention and control of organisational risks

The contribution of people and organisations to the safety of NPPs is a decisive factor in all steps of the lifecycle of the facilities (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. It 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.

2.6.1 Monitoring how organisations work

The integrated management system

The Order of 7th February 2012 stipulates that the licensee must in particular have the technical skills needed to manage the activities. Of these, the processing of significant events requires an in-depth analysis of the organisational and human causes in addition to the technical causes.

Furthermore, the above-mentioned Order requires the licensee to define and implement an Integrated Management System (IMS) to ensure that the requirements concerning the protection of interests are systematically considered in any decision concerning the facility. The IMS must specify the steps taken with regard to organisation and to resources of all types, in particular those adopted to manage the activities important for the protection of interests.

ASN monitoring of the working of EDF's organisations focuses on how the IMS is implemented. ASN more particularly ensures that the design or modification approach adopted by the engineering centres when a new facility is designed or an existing facility is modified takes account of the users' needs and does not compromise compliance with the defined requirements.

More broadly, ASN checks the organisation put into place by EDF to manage the skills and staffing needed to perform these activities. Pursuant to the stress tests, ASN issued a first position statement in 2017 regarding the method for defining staffing levels adopted by EDF for management of extreme situations.

Management of subcontracted activities

Maintenance and modification activities on French reactors are to a large extent subcontracted by EDF to outside contractors. 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.

EDF'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 the protection of interests 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 the workers involved.

EDF has taken steps to control the risks associated with subcontracted activities and has reinforced the preparation of outages, more particularly to guarantee the availability of human and material resources.

ASN monitors the conditions in which the work is performed (accessibility of premises, noise, heat and light environment, etc.). It also checks that the workers involved have the means necessary (tools, documentation, etc.) for the performance of the tasks, in particular when these means are made available by EDF.

2.6.2 Evaluation of the working of the organisations and control of activities

Organisation of work and working conditions

In 2017, ASN is still noting numerous shortcomings with regard to the planning and individual and collective preparation of activities, which are key phases in error reduction in terms of safety, whether or not the work is subcontracted. These shortcomings, notably during reactor outages, lead to scheduling changes which are the cause of degraded working conditions owing to the increased number of contractors working in the same place and difficulties with coordinating them.

The checks run on the implementation of work error-reduction practices in the NPPs show that there is still room for improvement. In 2017, ASN on several occasions observed on the one hand that the equipment to be made available to the workers was inappropriate or even missing and, on the other, that certain activities were performed in cramped spaces with difficult access and in unfavourable working environments (light, heat, noise), with signage errors and logistical problems. Problems with communication between departments or between trades during the performance of a task further aggravate the risk of shortcomings in the control of the activities.

ASN still observes that the documents made available to outside contractors are inappropriate, which regularly leads to the occurrence of significant events.

The checks initiated by ASN in 2016 resulted in EDF identifying new situations and new events of the same type in 2017. These checks will be maintained in 2018.

Provisions concerning staff and organisations in operational reactor modification activities

ASN considers that EDF's SOH[1] approach is pertinent and necessary for managing the facilities, their modifications and the conditions in which these are carried out. The effects of this approach, the deployment of which must be continued, are as yet insufficient. ASN still observes modifications that cannot be carried out in the conditions initially envisaged.

In 2017, ASN carried out several inspections at the EDF head office departments to check that the processes implemented by the licensee in fact comply with the user-centred design principles.

Skills management, training and qualifications

The organisation in place on the sites for managing skills, qualifications and training is on the whole satisfactory.

In 2017, on several sites, ASN however observed shortcomings in personnel training, which can be partly ascribed to large-scale retirements. Some advanced or critical skills now lie with just a single individual. In 2017, ASN still considers that the processes used by EDF to manage and maintain the skills necessary for management of the activities, including reactor control activities, must be given particularly close attention by EDF.

Given the retirements to come and the scale of the work needed to allow the continued operation of the reactors, ASN will check that the action plans implemented by EDF to correct the shortcomings observed actually produce the expected effects.

The operating experience feedback process

Operating experience feedback, as an organised and systematic process of collecting and analysing the signals emanating from a system, is one of the key tools in managing safety and radiation protection. Even if the significant event analyses carried out by certain sites are able to go further than the apparent causes and highlight organisational problems, this is not the case for all the sites, which reflects differing levels of involvement by the personnel with competence for organisational and human factors. ASN also observes that the corrective measures taken by EDF are not always able to address the organisational malfunctions highlighted by these analyses.

Generally speaking, there is inadequate sharing and effective utilisation of the lessons learned, whether between sites, between departments on a given site, or between the sites and the EDF head office departments. In 2018, ASN will check that the action plans initiated by EDF to improve how operating experience feedback is shared, including with outside contractors, and the corresponding lessons to be learned, produce the desired effects.

1. *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.*

2.7 Personnel radiation protection

2.7.1 Monitoring of personnel radiation protection

Exposure to ionising radiation in a nuclear power reactor comes from activation of primary system corrosion products (mainly) 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 received come from external exposure to β and 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 when necessary.

Periodic meetings are held with EDF as part of the technical dialogue with the licensee. These enable ASN to check the progress of technical or organisational projects.

Significant contamination events

Three significant contamination events were notified in 2017 in the NPPs operated by EDF. These events, which led to exposure greater than one quarter the regulation limit per square centimetre of skin, were rated level 1 on the INES scale. They concern:
- contamination of the face of a contractor staff member assigned to maintenance worksite tear-down operations in the Le Blayais NPP;
- contamination of the skin of the groin of a contractor staff member assigned to maintenance work on a press compacting radioactive waste in the Fessenheim NPP;
- contamination of the skin behind the ear of a contractor staff member assigned to maintenance work on the fuel loading machine in the Cattenom NPP.

Reinforced radiation protection inspections

In 2017, ASN carried out in-depth inspections on radiation protection in the Cattenom, Chooz and Nogent-sur-Seine NPPs. Each of these inspections required six to eight ASN inspectors and two to three IRSN experts. They more particularly examined the organisation and management of radiation protection, the integration of operating experience feedback, the management of worksites, the application of the optimisation approach, the management of radiological cleanness and of radioactive sources. The main strong points identified by the inspectors are the initiatives taken to improve personnel working conditions. ASN considers that improvements must be made to the process to optimise occupational dosimetry, the characterisation and analysis of radiation protection deviations and the care and treatment of contaminated personnel.

2.7.2 Evaluation of personnel radiation protection

In 2017, ASN carried out 27 radiation protection inspections.

The collective dose on all the reactors fell in 2017 by comparison with 2016 (Graph 6), as did the average dose received by workers for one hour of work in a controlled zone. The doses received by the workers are broken down as shown below in Graphs 5 and 6.

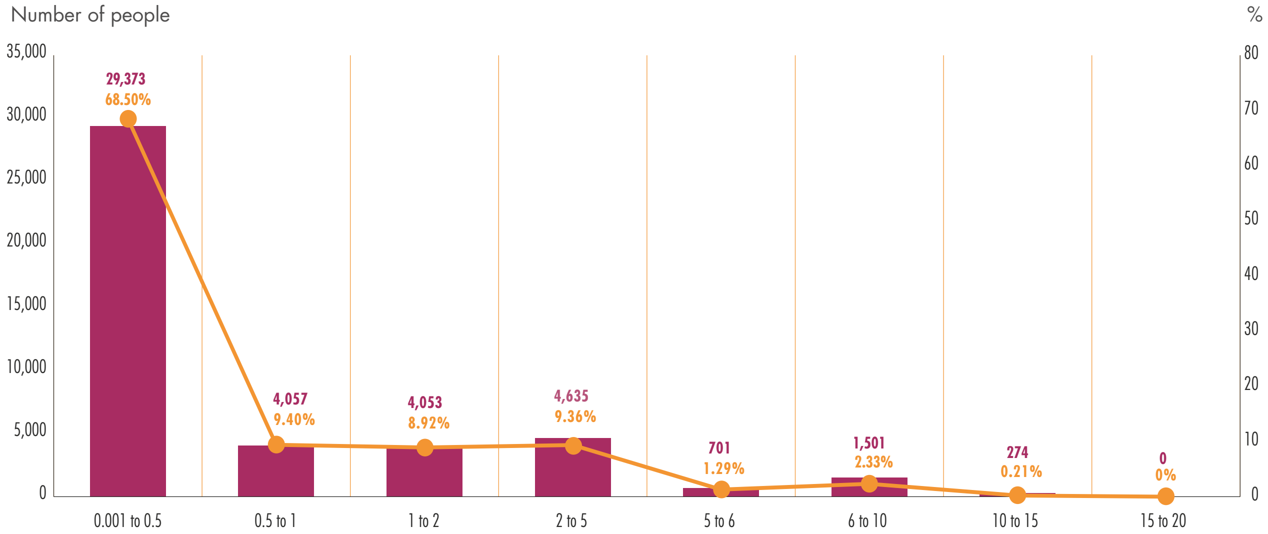
Graph 5 shows the breakdown of the workers in terms of whole body external dosimetry. It can be seen that the dosimetry for 78% of the exposed workers is less than 1 mSv for the year 2017, which corresponds to the annual regulation limit for the public. The annual regulation limit for whole body external dosimetry (20 mSv) was exceeded on no occasion in 2017.

Graph 6 shows the trend in the collective dose received by NPP workers over the past ten years. This graph shows a reduction in the average collective dose per reactor, reflecting contrasting results between the sites, and the continued optimisation efforts at a time of rising volumes of maintenance work in controlled areas in recent years.

Graph 7 shows the trend in whole body average individual dosimetry according to the worker categories in NPPs. The most exposed worker categories in 2017 are personnel in charge of thermal insulation, monitoring, inspection and welding.

ASN considers that the radiation protection situation of the NPPs in 2017 could be improved more particularly on the following points:
- The organisation of control of the dispersal of contamination inside the reactor building must be improved, notably with regard to the confinement of worksites.
- On several sites, the ASN inspectors found a lack of radiation protection culture on the part of certain workers.
- Weaknesses remain in the control of industrial radiography sites: ASN more specifically identified several events involving overstepping of operation areas demarcation lines or the presence of workers inside the exclusion zone demarcation lines. Progress is required in the preparation of the worksites, more specifically multiple contractor activities and the quality of the installation walkdowns carried out when preparing these worksites.
- The radiation protection optimisation approach falls short of that in previous years. ASN more particularly identifies relatively unambitious reactor outage predicted dose targets. Progress is also expected in the drafting of the risk assessments for the work and the integration of contingencies.
- Control of radiological zoning and the associated provisions remains vulnerable. More specifically the risk assessments for the work do not always identify the risk of entering a specially regulated area.
- Shortcomings in the operational dosimetry alarms analysis process and in the assessment of the significant nature of these events were brought to light during ASN inspections in 2016 and 2017, which led EDF to notify a generic significant radiation protection event.

GRAPH 5: Number and percentage of workers per dose range (in mSv) for 2017



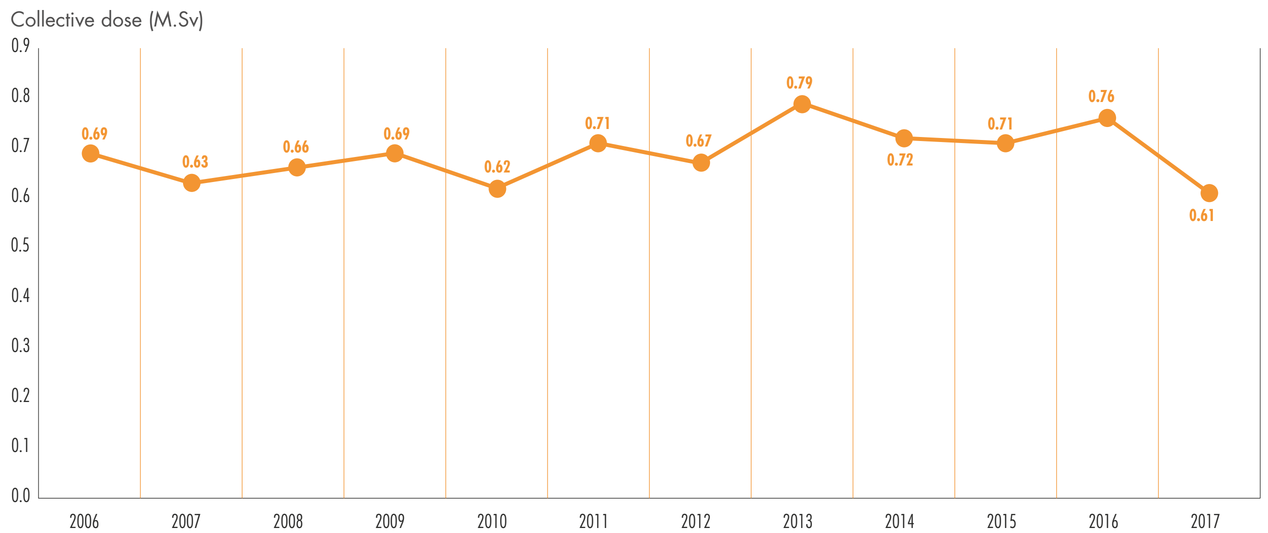
Source: EDF

Shortcomings in the process to care for and treat contaminated personnel were identified in several NPPs. This can lead to delays in treatment, difficulties with dose evaluation and is conducive to inappropriate behaviour on exiting zones with a contamination risk.

The conditions for caring for and treating contaminated personnel are monitored by ASN, notably through simulation exercises. The shortcomings observed are the subject of requests for corrective action.

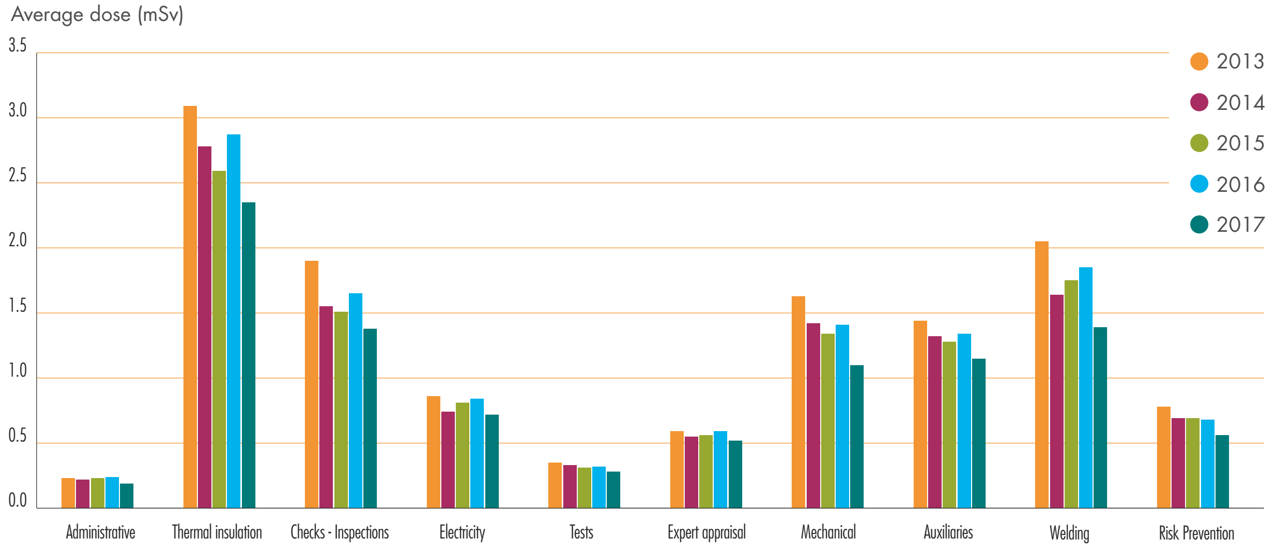
In several NPPs, ASN observes the positive impact of allocating "zone managers" for radiation protection of workers during reactor outages.

GRAPH 6: Average collective dose per reactor



Source: EDF

GRAPH 7: Evolution of mean individual dose according to categories of workers in NPPs



Source: EDF

2.8 Labour Law in the nuclear power plants

2.8.1 Monitoring Labour Law in the nuclear power plants

ASN carries out labour inspectorate duties for the 58 reactors in operation (spread over the 19 NPPs), the eight reactors undergoing decommissioning and the EPR under construction at Flamanville. The number of people working in an NPP varies between 800 and 2,000 employees. The total number of staff assigned to all the nuclear sites is about 24,000 for the employees of EDF, and 23,000 for the employees of the subcontractors, which more specifically take part in maintenance during reactor outages.

ASN labour inspection at the Gravelines NPP, August 2017.

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.

The labour inspectorate takes part in the integrated vision of regulation and oversight sought by ASN and it sees its monitoring work as being linked to all other activities to monitor and oversee the safety of facilities and radiation protection.

In 2017, ASN implemented an action plan to reinforce the labour inspectorate resources and organisation. As at 31st December 2017, the ASN resources for its labour inspectorate duties are therefore:
- 18 labour inspectors, one of whom is being trained, assigned to the regional divisions, 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.

Oversight of occupational health and safety

With regard to occupational health and safety, the ASN labour inspections more specifically covered the following topics in 2017:
- the conformity of the working equipment and more specifically the lifting gear. Collective action was taken by the entire network of labour inspectors: the labour inspectors issued requests to verify the regulatory compliance of the loading machines on all the sites. Following these requests, which revealed a number of nonconformities, EDF initiated a compliance action plan;
- the use of electrical installations. Several inspections were carried out on this topic on several sites, which led EDF to initiate a compliance programme;

- the worksites with asbestos risks. The labour inspectors are particularly vigilant with regard to preventing the risk of inhalation of these fibres during their inspections and had to remind personnel of the regulations on several occasions;
- the use of carcinogenic, mutagenic or reprotoxic chemical products.

Occupational accident inquiries are systematically held in the event of serious accidents or near-accidents. Unfortunately, four fatal accidents occurred in 2017: three caused by a heart attack and one by electrocution.

International subcontracting and provision of services

Steps were taken in 2017 with regard to inspections carried out on notifications and the conditions for secondment of staff from foreign contractors.

Criminal proceedings

With regard to illegal work, ASN closely monitors the criminal proceedings instigated in previous years, more specifically through regular contacts with the Public Prosecutor's offices.

Concerning health and safety, the actions of the ASN labour inspectorate led in 2017 to the opening of eight criminal proceedings against EDF or its contractors in the following areas: asbestos risk, electrical risk, ventilation of premises, risk of falling from height, compliance of lifting gear, worker secondment, non-notification of occupational accidents.

As for working hours (non-compliance with maximum daily and weekly working hours and non-compliance with minimum daily and weekly rest periods), the 11 criminal proceedings instigated in recent years by the labour inspectors have led to guilty pleas before the Public Prosecutor's office of Paris.

The proposed penalty was approved by the judge on 21st April 2017. EDF was sentenced to a fine of €1,500 per employee (or a total of €195,000 € for the 130 staff) and to €5,000 for the misdemeanour of obstructing the labour inspectors.

This sentence is the result of considerable work done by the ASN labour inspectorate and illustrates the benefits of collective, coordinated monitoring.

2.8.2 Health and safety assessment, professional relations and quality of employment in the NPPs

Certain occupational risk situations are still worrying and absolutely must be improved: the risks linked to work equipment, lifting gear in particular, the explosion risk and electrical risks. The labour inspectorate still observes situations in which the risk linked to the presence of asbestos is not systematically considered prior to the work, in order to avoid accidental exposure.

Progress is still required in the management of multiple contractors working simultaneously (quality of prevention plans in particular) and the use of subcontracting and the secondment of foreign employees.

With regard to working hours, the daily and weekly rest periods are on the whole better observed, but continued vigilance is required regarding the maximum daily and weekly working hours.

2.9 Lessons learned 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.

ASN issued a position statement on the results of these stress tests on 3rd January 2012, which was itself reviewed under the European stress tests, in April 2012.

On the basis of the opinions of the Advisory Committee and the conclusions of the European stress tests, ASN issued a series of resolutions dated 26th June 2012 requiring that EDF 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.

In addition to its requests, ASN issued a range of resolutions dated 21st January 2014 aiming to clarify certain design provisions for the "hardened safety core", in particular the definition and justification of the extreme external natural hazard levels to be considered for the "hardened safety core".

Generally speaking, ASN's requests are part of a continuing process to improve safety with regard to the targets set for the 3rd generation reactors and aim in addition to be able to cope with situations far beyond those normally considered for this type of installation.

These requests are issued in application of the defence-in-depth approach and as such concern measures to prevent and mitigate the consequences of an accident, based on both additional fixed means and external mobile means planned for all the installations on a site beyond their initial design basis.

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 lead times 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 nuclear power plants.

To take account of the engineering constraints involved in these major works but also the need to introduce the necessary post-Fukushima improvements as soon as possible, their implementation is planned by EDF in three phases:

Phase 1 (2012-2015)

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. In particular, the FARN, which is one of the main emergency management measures, was deployed. Since 31st December 2015, the FARN teams have the capacity for simultaneous intervention on all the reactors of a site in less than 24 hours (up to six reactors in the case of the Gravelines site).

Phase 2 (2015-2021)

Deployment of certain final design and organisational means that are robust to extreme hazards, in order to deal with the main situations of total loss of the heat sink or of 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).

On the various sites, EDF has begun to implement a large part of the final measures recalled above, more particularly the construction of buildings intended to house the high-capacity ultimate back-up diesel generator sets. ASN is inspecting the performance of the work.

Phase 3 (as of 2019)

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 heat 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.

The implementation of this "hardened safety core" and the provisions of phases 2 and 3 in particular, require validation of the design hypotheses for the material provisions and verification that the solutions proposed by the licensee can meet the safety objectives set and that they are technologically achievable.

On the basis of the files transmitted by EDF and the studies carried out, ASN asked its Advisory Committee for Reactors (GPR) to submit its opinion on the more important points of these files. To date, three meetings of the GPR have been held:
- the GPR was consulted on 28th January and 10th February 2016 concerning the definition and justification of the natural hazard levels adopted by EDF for the "hardened safety core". This review allowed the definition of the hazard levels to be considered for the design of the "hardened safety core" and, on certain points, led ASN to ask EDF for clarification;
- the session of 7th July 2016 concerned the new provisions proposed by EDF to mitigate the short and long term consequences of a core melt accident. This review enabled ASN to validate the principle of the new measures proposed by EDF in order to mitigate the consequences of a core-melt accident. On certain points, ASN asked EDF for clarifications and additional studies;
- the session of 2nd February 2017 focused primarily on the strategies for management of accidents that can occur on the reactor and pool and on the functional adequacy of the (new or existing) equipment for these accidents.

2.10 NPP operating life extension

2.10.1 The age of NPPs

The NPPs currently in service in France were built over a relatively short period of time: 45 nuclear power reactors representing nearly 50,000 MWe, or three-quarters of the power output by all French nuclear power reactors, were commissioned between 1980 and 1990, and seven reactors, representing 10,000 MWe, between 1991 and 2000. In December 2017, the average ages of the reactors, calculated from the date of initial reactor criticality, were as follows:
- 36 years for the thirty-four 900 MWe reactors.
- 30 years for the twenty 1,300 MWe reactors.
- 20 years for the four 1,450 MWe reactors.

2.10.2 The periodic safety review

The principle of the periodic safety review

The periodic safety reviews of nuclear power reactors comprise the following two parts:
- A check on the condition and conformity of the facility: this step aims to evaluate 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 concerned by maintenance programmes, or tests conducted every ten years such as the containment pressure tests. Any

CHRONOLOGY of first criticality of the French nuclear power reactors at the end of 2017

Date of 1st criticality									Total 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

deviations detected during these investigations are then restored to conformity within a time-frame commensurate with their potential consequences. Ageing management is also incorporated into this part of the review.

- 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 nuclear power reactors

In order to benefit from the standardisation of the NPP 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 or 1,450 MWe reactors). The results of this programme are then implemented on each of the nuclear power reactors 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

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Performance of the third periodic safety review of the 1,300 MWe reactors

The first ten-yearly outage inspection associated with the third periodic safety review of the 1,300 MWe reactors began in 2015. The checks carried out by ASN revealed that EDF decided to adapt or de-schedule the performance of certain modifications to the installations planned during these ten-yearly inspections and authorised by ASN. ASN asked the licensee for further information in order to verify that the 1,300 MWe reactors were restarted in a known and authorised documentary and equipment reference state. It asked EDF to redefine the generic standard state for a 1,300 MWe reactor corresponding to the target state of the third periodic safety review. It will check that the reactors to be restarted in 2018 following their third ten-yearly outage inspection will comply with this new state.

ASN asked EDF to learn the lessons from the deployment of the modifications during the third periodic safety reviews on the 1,300 MWe reactors with a view to the fourth periodic safety reviews of the 900 MWe reactors.

modifications made to remedy deviations observed or to improve the safety of the facility. The review report contains elements stipulated in Article 24 of Decree of 2nd November 2007.

The ASN analysis

The guidelines of the generic programmes proposed by EDF 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 the modifications to be made.

Following consultation of the Advisory Committees 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 nuclear power reactor, mentioned in Article L. 593-19 of the Environment Code and can issue new binding requirements regarding its continued operation.

The Energy Transition for Green Growth Act 2015-992 of 17th August 2015 supplemented the framework applicable to the periodic safety reviews on nuclear power reactors. It more specifically requires ASN authorisation, following a public inquiry, of the provisions proposed by the licensee during the periodic safety reviews beyond the thirty-fifth year of operation of a nuclear power reactor. Five years after submitting the periodic safety review report, the licensee also submits an interim report on the condition of these equipment items, in the light of which ASN may supplement its requirements.

The main challenges in managing ageing

Like all industrial facilities, nuclear power plants 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 in the installations for their operating lifetime.

To understand and manage the ageing of an NPP, apart from simply the time elapsed since its start-up, a certain number of factors must be taken into account, in particular the existence of physical phenomena that can degrade 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.

The lifetime of non-replaceable items

Non-replaceable items such as the reactor vessel (see point 2.2) and the containment (see point 2.3) are closely monitored in order to ensure that they are ageing as anticipated and that their mechanical properties remain within limits allowing their satisfactory behaviour.

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 changes in the industrial network of suppliers, with the cessation of manufacture of certain components or the closure of the manufacturing company, potentially leading 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 length of this procedure, the licensee must anticipate these needs well in advance.

The nuclear power reactors ageing management process

The approach adopted by EDF to manage the ageing of its facilities is based on three key points:
- Anticipate ageing in the design: in the design and during 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 2.4.3, 2.4.4, 2.4.7, 2.4.8 and 2.6.1) 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 NPP reactor outages, EDF must seek to anticipate them, 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.

At the request of ASN, EDF established a methodology for managing the ageing of its nuclear power reactors after 30 years of operation, the aim of which 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 the light of the understanding of and ability to manage the mechanisms and kinetics of the damage modes linked to ageing and, on the other, according to the condition of the facilities during their Third Ten-yearly Outage inspections (VD3).

This methodology comprises a first generic phase, which aims to determine the extent to which account has been taken of ageing for an identical reactor series. Subsequently, on the occasion of the VD3 on each nuclear power reactor, a summary file specific to the reactor is produced in order to demonstrate management of the ageing of the equipment and the reactor's ability to continue to operate for the ten-year period following its VD3.

With a view towards the possible continued operation of the nuclear power reactors beyond their Fourth Ten-yearly Outage inspections (VD4), EDF intends to continue with such an approach, which will be extended to all systems, structures and components important for managing not only radiological risks, but also conventional ones.

2.10.3 Management of the review process by EDF

900 MWe reactors

The third periodic safety review

In July 2009, ASN adopted a position statement on the generic aspects of the continued operation of the 900 MWe reactors beyond 30 years. ASN did not identify any generic elements compromising EDF's ability to ensure the safety of the 900 MWe reactors up 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 nuclear power reactors.

As this generic assessment does not take account of any specific individual features, ASN gives an opinion on the ability of each NPP 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 2017, Gravelines reactor 5 incorporated the improvements resulting from the periodic safety review as part of its VD3, raising the number of 900 MWe reactors that had carried out their VD3 to 30 out of a total of 34.

In 2017, ASN also sent the Minister responsible for Nuclear Safety its analysis of the review conclusions reports for the Gravelines 3 reactor. On the basis of this analysis, ASN has not identified any element that would compromise EDF's ability to satisfactorily control the safety of this 900 MWe reactor until the next periodic safety review. Pursuant to Article L.593-19 of the Environment Code, ASN took this opportunity to issue additional requirements designed to reinforce the safety of this reactors.

The fourth periodic safety review

The continued operation of the nuclear power reactors beyond their fourth periodic safety review 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.
- The modifications associated with this periodic safety review allow the completion of the integration on the 900 MWe reactors of the modifications prescribed following the stress tests carried out in the wake of the Fukushima Daiichi NPP accident. This concerns the phase 3 work (see point 2.9).
- Finally, the wish expressed by EDF in 2010 to significantly extend the operating life of the NPP reactors beyond 40 years was examined by ASN. By this time frame, the 900 MWe reactors will be operating alongside EPR or equivalent type reactors which are designed to meet significantly tighter 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 nuclear power reactors beyond 40 years, EDF drafted and, in October 2013, transmitted its Orientation File (DOR) for the fourth periodic safety review for the 900 MWe reactors. Further to ASN's requests for additional data in March 2014, EDF updated its file.

In April 2015, ASN asked the GPR for its opinion on the orientations of the generic studies being envisaged by EDF on the various topics contained in the orientation 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 April 2016, ASN issued a position statement on the orientation of the generic studies programme to be carried out in preparation for the fourth periodic safety reviews on the nuclear power reactors, after consulting the public on the draft requests for additional information to be sent to EDF concerning the studies and verifications to be carried out.

ASN is currently examining the generic studies linked to this review. This is in particular the case of the methods for verifying installation compliance and the management of ageing and obsolescence and studies on the safety of the spent fuel pools, mitigation of the consequences of accidents, improved management of accidents with core melt, the ability of the installations to withstand internal and external hazards and the mechanical strength of reactor pressure vessels. The main files will be submitted for the opinion of the GPR or the GPESPN in 2018 and 2019. ASN intends to issue a position statement on the generic studies linked to this review at the end of 2020 after obtaining the GPR's opinion on the results of the review in 2020.

ASN is also taking part in the work initiated by the High Committee for Transparency and Information on Nuclear Security (HCTISN) to propose methods to involve the public in this fourth periodic safety review for the 900 MWe reactors. The first phase of consultation with the public will take place in the second half of 2018.

In 2019, Tricastin reactor 1 will be the first 900 MWe reactor to undergo its fourth ten yearly outage inspection. The fourth ten-yearly outage inspections for the 900 MWe reactors will continue until 2030.

Ageing management

In preparation for the fourth periodic safety review of the 900 MWe nuclear power reactors, EDF intends to continue the ageing management approach applied since the third periodic safety review of these reactors, while reinforcing its equipment refurbishment and replacement projects with the prospect of continued operation up to 60 years. Ageing management, in particular for irreplaceable items whose integrity is vital for safety (such as the reactor pressure vessel – see point 2.2 – and its containment – see point 2.3), and obsolescence management, are essential for maintaining a satisfactory level of safety.

In 2013 and then in 2016, ASN considered that the implementation of an organisation able to identify the various equipment degradation modes, the corresponding countermeasures and integration of operating experience feedback comply with the majority of its requirements. Nonetheless, this needs to be supplemented, in particular to:
- evaluate the need for exceptional maintenance operations;
- identify the possible vulnerabilities in the industrial processes for replacement of components, including in the case of an unforeseen operational events on the nuclear power 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.
- take account of environmental effects on the mechanical fatigue phenomenon.

This ageing and obsolescence management approach, currently being reviewed with the assistance of IRSN, will again be examined at the beginning of 2018 by the GPR and GPESPN.

In addition, the issue of ageing management was the subject of the first Topical Peer Review stipulated by Council Directive 2014/87/EURATOM of 8th July 2014 amending Directive 2009/71/Euratom establishing a Community framework for the nuclear safety of nuclear installations. This Directive requires a peer review, every six years, of a technical aspect relating to the nuclear safety of their nuclear facilities. The procedures of this review are defined by ENSREG (European Nuclear Safety Regulators Group) (see chapter 7, point 1.1) reporting to the European Commission.

1,300 MWe reactors

The second periodic safety review

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 in 2014 sent its position statement on the continued operation of the two Saint-Alban reactors, Cattenom reactors 2 and 3, the two Nogent-sur-Seine reactors and Penly reactor 1 and took this opportunity to issue additional requirements designed to reinforce the safety of these nuclear power reactors. It is currently preparing its position regarding the continued operation of the other 1,300 MWe reactors.

The third periodic safety review

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 fourth periodic safety review 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 1 was the first 1,300 MWe reactor to carry out its third ten-yearly outage inspection, in 2016. The Paluel 3, Cattenom 1 and Saint-Alban/Saint-Maurice 1 reactors carried out their third ten-yearly outage inspection in 2016 and 2017. The third ten-yearly outage inspection for the Paluel 2 reactor is in progress. These third ten-yearly outage inspections for the 1,300 MWe reactors will continue until 2024.

1,450 MWe reactors

The first periodic safety review

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 carried out, 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 2018.

The second periodic safety review

In 2011, EDF transmitted its orientation proposals for the generic studies programme for the periodic safety review 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 second periodic safety review of the 1,450 MWe reactors. ASN more specifically considers that the safety objectives to be considered for the second periodic safety review of the 1,450 MWe reactors must be defined in the light of the objectives applicable to the new nuclear power 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 1,450 MWe reactors.

The second ten-yearly outage inspections for the 1,450 MWe reactors are scheduled to start in 2019 with the Chooz B2 reactor and will run until 2022.

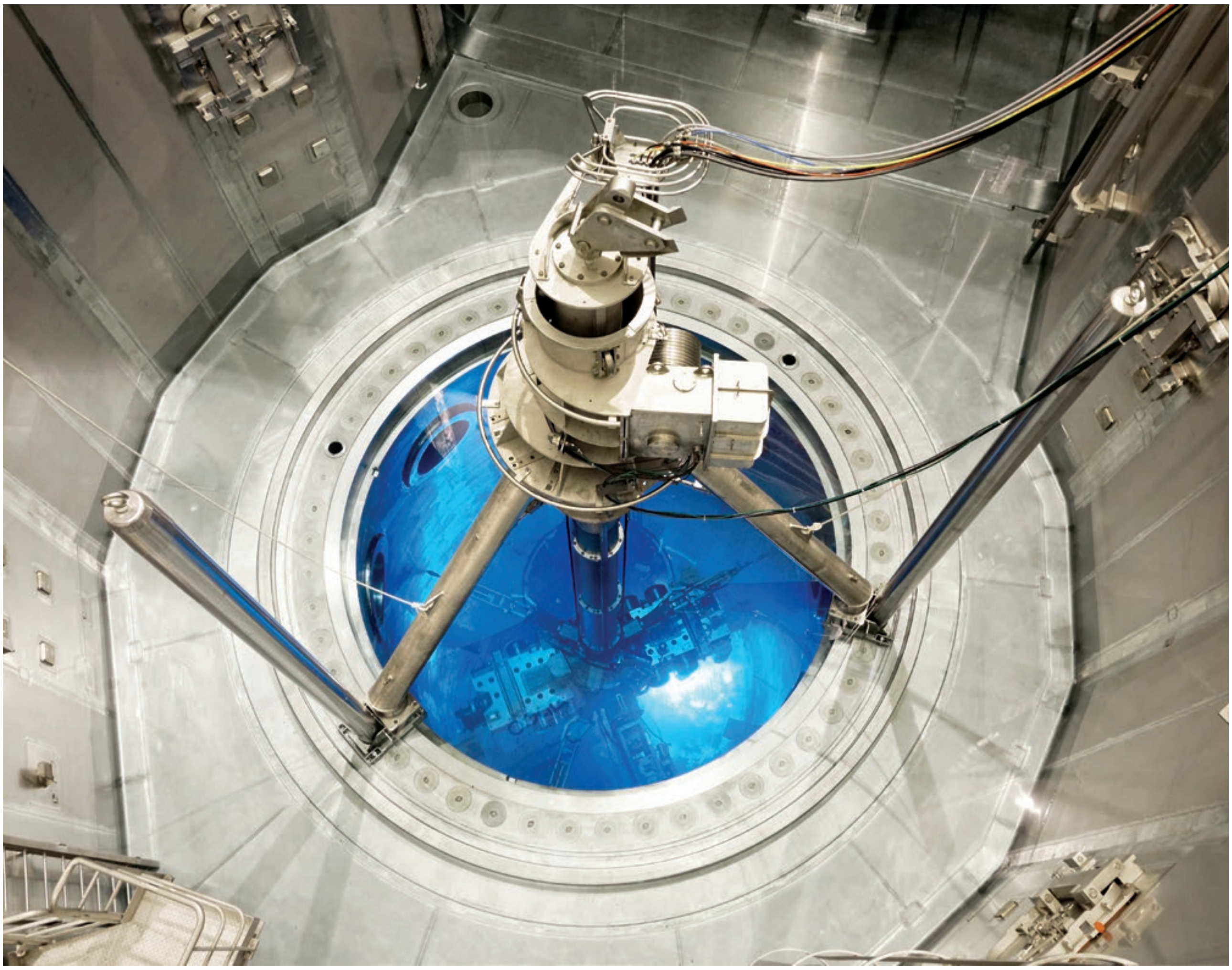
2.11 Flamanville EPR

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 on the Flamanville site, already equipped with 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 its examination of the application. This Decree was modified in 2017 to extend the time allowed for commissioning of the reactor.

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.



Checks on the EPR vessel by the in-service inspection machine, September 2017.

EDF plans to load fuel and start-up the reactor at the end of 2018. ASN however observes delays in the transmission of certain documents for the ongoing investigations, notably with regard to the NPE.

2.11.1 The steps up to commissioning of the Flamanville EPR

Pursuant to the Decree of 2nd November 2007 as amended (see chapter 3, point 3.1.3), the introduction of nuclear fuel within the perimeter of the installation and the performance of particular operating tests on the installation involving the introduction of radioactive substances into it, require partial commissioning authorisation by ASN. The introduction of nuclear fuel into the reactor vessel requires a commissioning authorisation from ASN.

In addition, prior to commissioning, all the NPE shall have obtained an individual certificate of compliance and EDF shall have completed the Pre-service Inspection (VCI) on the main primary and secondary systems in order more particularly to ensure the feasibility of the planned in-service maintenance, before fuel is loaded.

2.11.2 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 the Flamanville EPR. They concern:
- checking the quality of equipment manufacturing and installation construction and testing 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;
- ensuring that the various stakeholders learn the lessons from the construction phase, including the upstream phases (selection and monitoring of contractors, construction, procurement, etc.) which will enable the as-built installation to comply with the safety case for the duration of the project;
- ensuring that the start-up tests programme is satisfactory, correctly performed and that the expected results are obtained;
- ensuring that the licensee take the necessary steps so that the teams in charge of operating the installation after commissioning are well-prepared.

To do this, ASN has set binding requirements regarding the design, construction and start-up tests for the Flamanville 3 reactor and for operation of the two Flamanville 1 and 2 reactors close to the construction site. As this is a nuclear power reactor, ASN is also responsible for labour inspectorate duties on the construction site. Finally, ASN oversees the manufacture of the NPE that will form part of the primary and secondary systems of the nuclear steam supply system. The main steps taken by ASN in 2017 are described below.

Examination of the commissioning authorisation application and the partial commissioning authorisation application for the Flamanville 3 reactor

In March 2015, EDF sent ASN its commissioning authorisation application and its partial commissioning application, including the safety analysis report, the general operating

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Anomaly in the composition of the steel for the Flamanville EPR reactor pressure vessel closure head and bottom head

In 2014, measurements taken by Areva NP showed the presence of a significant carbon concentration in the steel at the centre of the Flamanville EPR reactor pressure vessel closure head and bottom head.

At the end of 2015, the approach proposed by Areva NP to demonstrate the sufficiency of the mechanical properties of the material used in the manufacture of the Flamanville EPR reactor pressure vessel closure head and bottom head was presented to the GPESPN. Subject to its observations and demands being taken into account, ASN considered that the approach proposed by Areva NP is acceptable in principle as it is based on a vast programme of mechanical and chemical tests.

The test programme was run during the course of 2016.

Areva NP transmitted a technical file more particularly presenting the results of the test programme in December 2016 and the demonstration of the serviceability of the reactor pressure vessel.

ASN and its technical support organisation, IRSN, analysed this file and obtained the opinion of the GPESPN, which met on 26th and 27th June 2017. ASN was thus able to present its draft opinion on the Flamanville EPR reactor pressure vessel anomaly on 28th June 2017.

After consulting the public and the High Council for the prevention of technological risks, ASN submitted its opinion on the anomaly in the steel used in the Flamanville EPR reactor pressure vessel bottom head and closure head on 10th October 2017.

The results of the test programme show that the mechanical properties of the material are sufficient to prevent the risk of fast fracture, given the loads applied and taking account of the most unfavourable flaw. ASN thus considers that this anomaly is not such as to compromise the commissioning of the reactor pressure vessel, provided that specific checks are carried out during operation of the installation, to ensure that no flaws appear. As the feasibility of these checks cannot at present be confirmed for the closure head, ASN considers that the current closure head cannot be used beyond 2024.

The commissioning of the Flamanville EPR reactor pressure vessel also remains dependent on an authorisation issued on the basis of demonstration of the serviceability of all its components. Hydrotesting of the entire main primary system, of which the reactor pressure vessel is a part, took place on 5th January 2018.

Framatome (ex-Areva NP) intends to send ASN a file substantiating the reactor pressure vessel commissioning authorisation application during the second quarter of 2018. The examination of this file could lead to ASN issuing a position statement on the commissioning of the vessel before the third quarter of 2018.

rules, a study of waste management in the facility, the on-site emergency plan, the decommissioning plan and an update of the facility's impact assessment. Following a preliminary examination, ASN confirmed that all the documents required by the regulations were indeed present, but it considered that additional demonstrations were needed to enable ASN to rule on a possible commissioning authorisation. ASN however initiated technical examination of the subjects for which most of the information was available, although it did submit some requests on certain points.

In June 2017, ASN received updated versions of the commissioning authorisation and partial commissioning authorisation files for Flamanville reactor 3. Some elements still need to be provided before ASN is able to issue a position statement. A letter of acceptability was issued in response to the partial commissioning authorisation, listing these elements.

In parallel with its examination of the partial commissioning authorisation application file, ASN will in 2018 be updating its 2010 resolutions defining the limits and procedures for environmental discharge of liquid and gaseous effluents for the nuclear reactors on the Flamanville site.

Finally, examination of the general operating rules continued in 2017.

Opinions of the Advisory Committees of Experts

In May and July 2017, ASN issued a position statement on the review of the accident studies for the Flamanville EPR and on the safety of fuel storage and handling in the fuel building.

A GPR meeting is scheduled in 2018. It will be devoted to the latest investigations with a view to commissioning of the Flamanville EPR, more specifically the follow-up to the previous GPR sessions devoted to this reactor. On the occasion of this session, the GPR will give ASN its opinion on the Flamanville EPR safety case so that ASN can issue a position statement on the commissioning authorisation application for this reactor.

A meeting of the GPESPN was devoted to the analysis of the consequences of the anomaly in the domes of the Flamanville EPR reactor pressure vessel on their serviceability (see box opposite). In addition, a GPESPN meeting will be held in the second half of the year on the deviations detected in the production of certain welds on the main steam letdown lines.

Oversight of the Flamanville 3 reactor construction activities

In 2017, ASN carried out twenty inspections on the Flamanville 3 construction site to monitor construction, the performance of the 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:
- mechanical assembly activities, notably concerning the secondary systems of the NSSS, the main primary system protection valves, the nuclear auxiliary systems, the containment mechanical penetrations, the effluent treatment systems and the equipment necessary for operation of the backup electricity generating sets;
- the electrical systems installation activities, including cable connections in the buildings;
- continued start-up tests and the corresponding organisation, in particular during the first tests of the installation as a whole;
- the environmental impact of the construction site;
- the radiation protection of workers during radiographic inspection of welds;
- the organisation of the future operating team for the Flamanville 3 reactor regarding safety management, drafting of operating and maintenance documentation, management of hazards, radiation protection of workers, transports and the preparation for partial commissioning of the reactor.

Oversight of the Flamanville EPR engineering activities

Most of the documents in support of the Flamanville 3 reactor commissioning examination having been transmitted and ASN reduced the number of inspections carried out in the engineering departments for this reactor. In 2017, ASN carried out one inspection in the EDF engineering departments in charge of the detailed design studies for the Flamanville 3 reactor, on the topic of equipment qualification for accident conditions.

Labour inspectorate duties on the Flamanville 3 reactor construction site

The actions carried out by the ASN labour inspectors in 2017 consisted in:
- performing checks on the contractors working on the site;
- answering direct queries from the employees;
- carrying out inquiries following occupational accidents;
- investigating or jointly investigating requests for exemptions to provisions under the labour regulations.

Application of the safety rules was regularly checked.

In 2017, the ASN labour inspectors also initiated and carried out a number of checks on the regulatory provisions governing transnational secondment of workers.

Oversight of NPE design for the Flamanville 3 reactor

During the course of 2017, ASN continued to assess the conformity of manufacture of the NPE for the main primary and secondary systems.

Having observed inadequate justification and incomplete design files for this equipment, more specifically with regard to the risk assessments, choice of materials and in-service inspectability of the equipment, ASN held numerous technical meetings with Areva NP in 2013 and 2014 to define the additional data to be provided. Areva NP began a revision of all technical design documentation for this equipment in 2015, which it continued in 2016 and 2017. It plans to complete this revision in the first half of 2018.

The organisations approved for assessment of NPE conformity are authorised by ASN to assist it with the examination of this design documentation.

Oversight of NPE manufacturing for the Flamanville 3 reactor

During the course of 2017, ASN continued to assess the conformity of manufacture of the Nuclear Pressure Equipment (NPE) for the main primary and secondary systems. Manufacture of the largest equipment items has been completed and is continuing for certain control, stop and check valves.

ASN and the approved organisations review the technical documentation and the monitoring of the assembly of NPE carried out on the site.

The conformity of the equipment intended for the Flamanville EPR is also evaluated in the light of operating experience feedback from the assembly and testing performed on other EPR type reactors such as those of Taishan (China) or Olkiluoto (Finland). ASN asks Areva NP to identify and implement the necessary corrective measures based on this operating experience feedback. This is notably the case with the cracks detected on the seating surfaces of certain valves.

With the support of the organisations it has duly mandated, ASN is also examining the handling of deviations identified by the review of the manufacturing files for the components forged at the Creusot Forge plant and installed on the Flamanville 3 reactor. In 2017, ASN carried out two inspections of Areva NP concerning the assembly of the NSSS and the preparation of the hydrotests and two inspections of approved inspection organisations or entities mandated by ASN to monitor these activities. In addition, these inspection organisations or entities themselves carried out several thousand inspections in 2017 (see point 2.2.2).

Finally, ASN was informed by EDF in 2017 of deviations during welding of main secondary system piping. Some requirements specific to the break preclusion approach for these pipes were not specified to the subcontractors and were therefore not taken into account at manufacturing or installation of the pipes concerned. These deviations are being examined by ASN and this will continue in 2018.

Certification of compliance for Flamanville 3 reactor nuclear pressure equipment

At the end of the design and manufacturing checks and if they prove to be satisfactory in the light of the regulatory requirements, ASN issues certification of NPE compliance. During the course of 2017, ASN issued the first certificates, concerning four control valves for the Atmospheric Steam Dump Valves (VDA). The compliance evaluation of each of the 200 other NPE or level N1 nuclear assemblies will continue in 2018.

2.11.3 Evaluation of construction, start-up tests and preparation for operation of the Flamanville 3 reactor

In its construction site oversight activities, ASN devoted particular attention to the following subjects in 2017:

- the continued mechanical assembly of the installation led EDF to notify two significant safety events relating to the assembly of the main secondary systems. In 2017, ASN paid close attention to identifying the root causes of these events, evaluating their impact on the safety case and the performance of appropriate remedial, corrective and preventive measures. The investigation of one of these events will continue in 2018. ASN also maintains its oversight of EDF monitoring of the outside contractors and in particular ensures that there is adequate management of deviations detected during these operations;
- the preparation for and performance of the start-up tests for the various systems of the installation and the satisfactory EDF organisation for management of the overall tests. ASN more particularly reinforces its monitoring of these tests, which require appropriate documentation. 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 EPR by the EDF entity which will be responsible for it after start-up. 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 reactor construction and 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 that the future operating staff take advantage of operating experience and best practices employed in EDF's NPPs and that they correctly assimilate the working of the equipment during reactor construction and systems start-up tests. ASN also ensures that these preparations for operation are completed before actual commissioning of the reactor;
- maintaining a strategy to conserve the equipment and structures present on the construction site until the commissioning of the Flamanville 3 reactor. Owing to the reactor commissioning postponements announced by EDF and following the deviations encountered during the conservation of new heat exchangers, ASN ensures that EDF continues to focus particular attention on defining and complying with the requirements associated with the conservation of equipment already installed and the structures built, notably taking account of the impact of filling the systems with water for hydro-testing and start-up tests;
- appropriate management of environmental protection by EDF, notably the management of the buried waste discovered on the site and the underground water intake structures, plus monitoring by EDF of outside contractors on this topic;
- radiation protection of workers, given the large number of radiographic inspections performed on the construction site.

Generally speaking, these inspections showed that there was room for improvement in the organisation put into place for performance of these activities. In 2018, ASN will pursue its inspections on these topics, in particular preparation for operation.

2.11.4 Cooperation with foreign nuclear safety regulators

To be able to share experience feedback, 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. Since 2004, reinforced cooperation has existed with the Finnish nuclear safety regulator (STUK, *Säteilyturvakeskus*) around the construction of the Olkiluoto (Finland) and Flamanville (France) reactors. In 2017, a technical progress meeting concerning the two projects was held in France and a visit to the Flamanville reactor 3 construction site was organised. The discussions more specifically concerned the start-up tests for these reactors.

Multinational cooperation

Some international structures such as the Nuclear Energy Agency (NEA) and the Western European Nuclear Regulators Association (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). The plenary group devoted to EPR type reactors met twice in 2017. With the support of IRSN, ASN took part in the work concerning severe accidents, I&C, probabilistic safety assessments and the modelling of accidents and transients and the inspection of suppliers and in the work by the new technical group, set up in 2016 to deal with preparations for the commissioning of new reactors. ASN thus took part in a visit to Taishan reactor 1 to attend certain start-up tests on this reactor, as well as a visit to Olkiluoto reactor 3.

For ASN, these international exchanges are one of the driving forces behind the harmonisation of safety requirements and inspection practices.

2.12 Studies on reactors of the future

EPR new model

In April 2016, EDF asked ASN for its opinion on the safety options for a new reactor called the EPR new model (EPR NM).

This PWR project currently being developed by a team combining EDF and Areva NP, aims to address the general safety objectives of the third generation of reactors.

With this reactor, the EPR NM project aims to integrate the lessons learned from the design, construction and commissioning of the EPR reactors at Flamanville 3, Olkiluoto 3, Taishan 1 and 2 and Hinkley-Point C, along with operating experience feedback from existing reactors.

Moreover, the design of this reactor aims to incorporate all the lessons learned from the Fukushima Daiichi accident. This more specifically entails reinforcing the design against natural hazards and consolidating the independence of the installation and the site in an accident situation (with or without core melt) until such time as the off-site emergency services can intervene.

The technical examination of the Safety Options File (DOS) by ASN with the support of IRSN, took place during 2017 and takes account of the recommendations of ASN Guide No. 22 concerning PWR design. ASN will issue a position statement on the safety options for the EPR NM project in 2018.

FOCUS

ASN Guide No. 22 on the design of pressurised water reactors

Produced jointly with IRSN, ASN Guide No. 22 contains nuclear safety recommendations for the design of pressurised water reactors.

This guide takes into consideration:

- experience feedback from the technical examinations already conducted on new reactor projects;
- lessons learned from the Fukushima Daiichi accident and the subsequent stress tests;
- international publications, particularly those produced by the Western European Nuclear Regulators' Association (WENRA) and the International Atomic Energy Agency (IAEA).

The common technical positions set out in this guide are the culmination of several years of work by ASN and IRSN during which technical discussions were held with the industry players. The guide was examined by the GPR, in conjunction with members of the GPESPN. It also took into consideration the comments stemming from the public consultation conducted via the ASN website in September 2016.

The guide focuses essentially on the prevention of radiological incidents and accidents and the mitigation of their consequences. It details the general design objectives and principles and makes recommendations to help meet regulatory requirements. After giving recommendations of a general nature primarily concerning defence in depth or the nuclear safety case, the guide focuses on the barriers that must be placed between radioactive substances and people and the environment, and on the safety functions. Lastly, it provides recommendations concerning specific subjects such as the storage of fuel assemblies.

ASN Guide No. 22 thus constitutes a reference in France for the design of new reactors and a tool for presenting French nuclear safety practices on the international stage. The recommendations provided in this guide can also be used when seeking to make improvements to the reactors currently in service, particularly during their periodic safety reviews.

Generation IV reactors

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). For their promoters, the main challenge for fourth generation reactors is to allow sustainable development of nuclear energy while optimising the use of natural resources, reducing the production of radioactive waste, improving nuclear safety (reducing the risk of core melt and improved protection of the population) while offering a greater ability to counter 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.

3. Outlook

In 2018, ASN actions in the field of the oversight of NPPs will more specifically concern the following topics.

The conformity of the facilities

Operating experience feedback from regulation and oversight of NPP reactors reveals that there are still inadequacies in the processes employed by EDF to obtain compliance of the facilities with their design and operating baseline requirements and then maintain this compliance over the long term. These difficulties notably indicate shortcomings in the maintenance programmes for certain equipment items. They also highlight the need to continue with the design reviews initiated at the request of ASN. These reviews are bearing fruit by revealing anomalies, some of which have been present since the reactors were built. ASN considers that EDF must reinforce its actions and its decision-making processes when dealing with the deviations, once they are detected.

In 2018, ASN will ensure that the processes used by the licensee are actually able to detect and then deal with all deviations from the design and operating baseline requirements, in good time. In this respect, ASN will enhance its field inspections, notably during reactor refuelling outages.

The periodic safety reviews

In 2018, examination of the generic studies will continue for the fourth periodic safety review of the 900 MWe reactors. ASN intends to issue a position statement on the generic studies linked to this review at the end of 2020 after obtaining the GPR's opinion on the results of the review in 2020.

ASN will also issue a position statement on the subjects for which EDF was asked to provide additional information following the generic examination of the third periodic safety reviews of the 1,300 MWe reactors. On the basis of the checks carried out in 2017 when implementing the material and documentary modifications resulting from this third periodic safety review, ASN will reinforce its checks in the installations concerned and will ensure that the installations are modified in accordance with the licenses it has issued.

As part of the actions initiated by the HCTISN in 2017, ASN will also take part in public consultation measures planned for 2018 concerning the steps proposed by EDF to meet the objectives set for the fourth periodic safety review of the 900 MWe reactors.

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 2018, ASN will continue to review the design, construction and operating provisions adopted by EDF to address the prescriptions concerning the "hardened safety core". ASN will also continue to oversee the work to deploy the "hardened safety core" on the sites (ultimate back-up diesels, ultimate water source, local emergency centre). It will also examine the authorisation application files for the deployment of other "hardened safety core" modifications or equipment.

NPE monitoring

Monitoring of nuclear pressure equipment was marked by two major events in recent years: the detection of uncontrolled carbon segregations in certain forged components and the discovery of irregularities that could be construed as falsifications within the Creusot Forge plant.

In 2018, ASN will continue to check the performance of the reviews of all the components manufactured in the past by this plant. It will ensure that this review process is seen through to completion, in order to assess all the irregularities which could have affected past production and learn all the possible lessons regarding the safety of the facilities.

Finally, in 2018, ASN will continue to draft the regulatory texts necessary for NPE monitoring and will complete the important in-depth work started in 2015 with the manufacturers, licensees and approved organisations, with regard to the application of the regulations concerning NPE.

Oversight of the EPR reactor

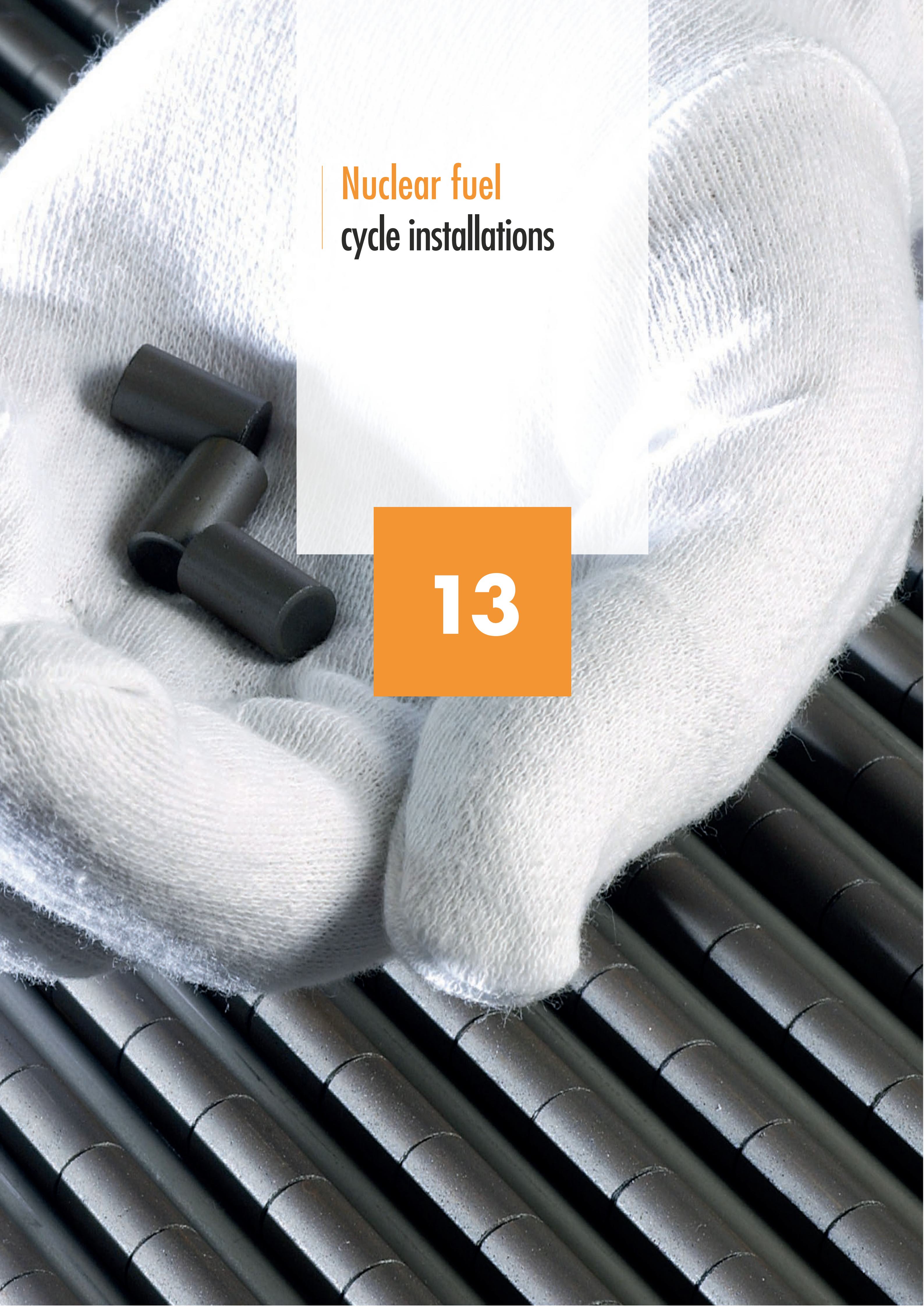
ASN will continue to monitor the installation of equipment, the performance of the start-up tests and the preparation of the various operating support documents. The nuclear safety inspectors will continue with inspections at a sustained rate.

It will also continue with the conformity assessments of the NPE most important for safety.

ASN will issue a position statement in 2018 on the two partial commissioning authorisation applications. These authorisations are necessary to allow performance of the tests requiring the use of radioactive substances and to allow nuclear fuel onto the site.

Nuclear fuel cycle installations

13



The nuclear 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.

The licensees of the nuclear fuel cycle plants are part either of the Areva group, or of EDF (Framatome formerly Areva NP)*: Areva NC operates Mélox in Marcoule, the plants at La Hague, certain plants in Tricastin (Comurhex, TU5, W, Atlas, uranium storage areas in Tricastin, P35), as well as Malvési (which is an Installation Classified for Protection of the Environment – ICPE), the Tricastin enrichment company operates the Georges Besse II plant (GB II), Framatome operates Romans-sur-Isère (former FBFC and former Cerca).

ASN monitors the safety of these industrial facilities, which handle radioactive substances such as uranium or plutonium and constitute specific safety risks, notably radiological risks associated with toxic risks.

ASN monitors the overall consistency of the industrial choices made with regard to fuel management and which could have an impact on safety. ASN therefore periodically asks that together with the fuel cycle companies EDF provide elements to demonstrate long-term compatibility between changes in fuel characteristics and fuel management and developments in fuel cycle installations and the corresponding transports. EDF transmits a "Cycle impact" file in response to this request.

*See point 3.3 of this chapter covering the reorganisation

1. The fuel cycle

The uranium ore is extracted, then purified and concentrated into "yellow cake" on the mining sites. The solid concentrate is then transformed into uranium hexafluoride (UF_6) through a series of conversion operations. These operations are performed by the Comurhex facilities in Malvési and Tricastin belonging to Areva NC. The facilities in question – most of which are regulated under the legislation for Installations Classified for Protection of the Environment (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 6% with the U-235 isotope. In France, uranium hexafluoride (UF_6) enrichment is carried out using an ultra-centrifuge process in the GB II plant at Tricastin.

This enriched UF_6 is then transformed into uranium oxide powder in the Framatome plant in Romans-sur-Isère. The fuel pellets manufactured with this oxide are introduced into cladding to make fuel rods, which are then combined to form fuel assemblies. These assemblies are then placed in the reactor core where they release energy, notably through the fission of uranium-235 nuclei.

After a period of use of about three to four 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.

In this plant, the uranium and plutonium from the spent fuels are separated from the fission products and other transuranic elements[1]. The uranium and plutonium are packaged and then stored for subsequent re-use. However, at present, the uranium obtained from this 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 pending a final disposal solution[2].

The plutonium resulting from the reprocessing of 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 used in certain 900 MWe nuclear power reactors in France.

The MOX nuclear fuels are not reprocessed after being used in the reactors. They would only be reprocessed if future fast neutron reactors were to be commissioned. Since the shutdown of the Superphénix reactor in 1996, no company has as yet initiated the official process to build such a reactor (see chapter 12). CEA is studying a fast neutron reactor 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 for the fuel cycle are presented in Table 1.

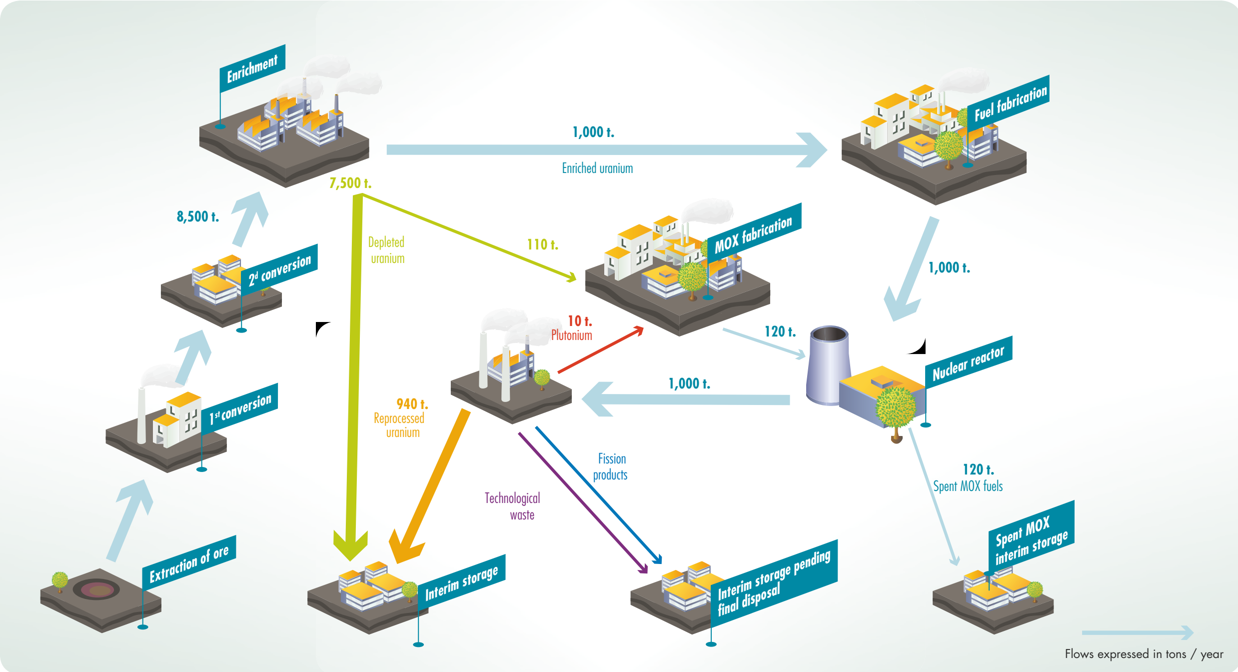
1. *Transuranic elements are chemical elements heavier than uranium.*
2. *Storage is temporary, while disposal is final.*

TABLE 1: Fuel cycle industry movements in 2017

	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 Tricastin	SBNI Marcoule	Uranyl Nitrate	0	U_3O_8	0	DBNI Tricastin	0
	ICPE Malvési	UF_4	8,674	UF_6	10,198	Areva NC Tricastin	10,198
Areva NC Tricastin TU5 facility	Areva NC La Hague	Uranyl Nitrate	1,146	U_3O_8	1,363	Areva NC Tricastin	1,363
Areva NC Tricastin W Plant	Urenco	UF_6 depleted	1,351	U_3O_8	1,095	Areva NC Tricastin	1,095
	SET		9,178		7,325		7,325
	Areva NC		723		571		571
Areva NP Romans-sur-Isère	Germany	UO_2 rods based on natural and depleted uranium	2.6	Assemblies based on natural uranium		EDF	3.3
				UO_2 rods based on depleted uranium		Areva SEPA	6
	CEA Cadarache	UO_2 rods based on natural and depleted uranium	1.1	Depleted uranium powder		Japan	0.1
	United Kingdom	UF_6 (based on enriched natural uranium)	0.9	Assemblies based on enriched natural uranium	603	China	131.6
	Urenco		237.1			EDF	612.1
						Koeberg	26
	Eurodif		411.5			Tihange	29.5
	Russia		8.3			Lingen	0.3
	Germany	UO_2 rods based on enriched natural uranium	10.3	UF_6 (based on enriched natural uranium)		Urenco	1.5
						Eurodif	0.3
				Enriched natural uranium powder	3	CEA Cadarache	3
Areva NC Marcoule Mélox	Germany Areva NC La Hague	UO_2 depleted PuO_2	102.1 tML[3] 9.6 tML	MOX Fuel elements	103.4 tML	EDF	103.7 tML
						Kansai	7.1 tML
Areva NC La Hague	Fuels reprocessed in the La Hague plant						
	EDF, Trino, Borssele	UOX, MOX	983 tML	Uranyl Nitrate	996.853 tML	Areva NC Tricastin	1,035.3 tML
	Osiris, Celestin, BR2 MOL	RTR	0.1 tML	PuO_2	12.753 t	Mélox Marcoule	9.6 tML
	Fuels stored in the La Hague plant pools						
	EDF, Borssele, ILL, BR2 MOL, Osiris	Spent fuel elements	1,183.5 tML	-	-	-	-
GB II SET Tricastin	Converters	UF_6	10,801 t	UF_6 depleted	9,099 t	Defluoration	9,099 t
				UF_6 enriched	1,501 t	Fuel manufacturers	1,501 t

(1) The products obtained may be shipped or stored in the facility concerned
(2) The shipped products may have been obtained during previous years
(3) tHM: tonne equivalent heavy metal (mainly uranium, plutonium)

THE FUEL cycle



Other facilities are needed for the operation of the Basic Nuclear Installations (BNI) mentioned above, more particularly Socatri, which is responsible for the maintenance and decommissioning of nuclear equipment, as well as the treatment of nuclear and industrial effluents from the companies of the Areva group at Tricastin.

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

With a view to simplifying the legal organisation of the Areva Group, a process to merge the subsidiaries of Areva present on the Tricastin site had been initiated in 2012, so that Areva NC could become the licensee of all the BNIs there. This process was completed for the Comurhex BNI in 2013. The process to change the licensee at Socatri, initiated in 2013, was suspended at the request of Areva NC in 2014. It resumed in 2016 and could be completed in 2018. In December 2017, Areva NC also asked to take charge of operating the Eurodif and Georges Besse II BNIs.

Moreover, the BNI licensees on the Tricastin platform asked ASN on 18th April 2016 for authorisation to modify their organisations, with the creation of joint management systems. This change is part of the Areva Group's competitiveness plan and follows on from the "Tricastin 2012" project to pool the site resources. The application aims to achieve an integrated organisation by creating management structures common to all the BNIs on the site for the production, maintenance and decommissioning activities of the facilities on the platform. This modification would also lead to a reorganisation of the management in charge of safety and the environment. During the course of the ongoing investigation, made particularly complex by the governance of the platform, ASN will ensure that the technical capabilities of the platform licensees are on a par with their safety responsibilities.

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 perimeter of the BNI) for converting depleted UF_6 into U_3O_8;
- the Comurhex facility (BNI 105) for converting uranium tetrafluoride (UF_4) and UF_6;
- a defence BNI (DBNI) which more particularly operates the nuclear materials storage areas, virtually all of which are for civil uses.

Areva NC TU5 facility and W plant - BNI 155

U_3O_8 is a stable solid compound making storage of uranium safer than in liquid or gaseous form. BNI 155, called TU5, can handle up to 2,000 tonnes of uranium per year, which allows all the $UO_2(NO_3)_2$ from the Areva plant at La Hague to be processed. Once converted, the uranium from reprocessing is placed in storage on the Areva NC Tricastin site.

The periodic safety review report for BNI 155 was submitted to ASN on 28th November 2014. The conclusions of the review of this file will be issued during the course of 2018.

ASN considers that the operation of the facilities located within the perimeter of this Areva NC BNI includes satisfactory management of the risks and detrimental effects.

The commissioning of the new "emission zone" (EM3), intended to replace the existing emission facility, where the depleted UF_6 will be heated so that it can be injected into the W plant process, is envisaged for 2018. ASN considers that the steps taken by the licensee to manage the operational risks of the EM3 facility are on the whole acceptable. ASN considers that the sizing of the facility and its equipment with respect to external hazards and extreme natural hazards, as presented in the stress tests, is satisfactory.

ASN considers that the TU5 and W facilities continue to be operated with a relatively satisfactory level of safety. Relations with the licensee are sustained and constructive

The Areva NC uranium conversion plants – BNI 105

BNI 105, which notably transformed reprocessed uranyl nitrate into UF_4 or U_3O_8, is being decommissioned (see chapter 15).

ICPEs not necessary for operation of the BNI are included within its perimeter with respect to the risks that they create for the safety of the BNI itself. These ICPEs carry out fluorination of UF_4 into 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. Their status is that of an ICPE subject to licensing with institutional controls ("Seveso" installations) and they are subject to the system of financial guarantees for ensuring the safety of the installations and, finally, to Directive 2010/75/UE of the European Parliament and Council of 24th November 2010, known as the "IED Directive" on industrial emissions (integrated pollution prevention and reduction).

The new fluorination unit, called "Comurhex 2", scheduled for commissioning at the beginning of 2019, will be replacing the fluorination unit of the Comurhex 1 plant which was shut down at the end of 2017 as it no longer complied with current safety standards. ASN had authorised its continued operation until this deadline and required the performance of work to reinforce this plant, in particular 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), extension of the gas knock-down system and improvement of the safety system to make it independent of the control system. Reinforcement work was carried out in 2017 after the discovery of a seismic resistance fault on the "gravel" embankment of the Donzère-Mondragon canal site, so that the mitigation means can carry out their functions in the event of an earthquake (see box below).

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Fault in the seismic resistance of the Donzère-Mondragon canal embankment

On 22nd August 2017, Areva notified a significant event concerning the inability to demonstrate the resistance to a Safe Shutdown Earthquake (SSE) of a portion of the Donzère-Mondragon embankment. The Tricastin site could thus be flooded in the wake of an earthquake.

The main risks concerned the Comhurex 1 and W former chemical facilities, in which the toxic gas knock-down spray systems could become unavailable in such a situation. In its resolution CODEP-CLG-2017-039439 of 28th September 2017 ASN asked Areva to reinforce these provisions before 31st October 2017.

For Comurhex, the improvements made consisted in installing water pumping equipment on a floating barge moored to concrete blocks to prevent it drifting when the water rises, in positioning spray-guns producing a water curtain on weighted raised blocks to maintain them above the flood level and in prepositioning these guns according to the wind direction such that the water curtain is correctly oriented to protect the populations and so that the operators do not have to intervene in the field under any releases.

For the W plant, ASN asked Areva NC to guarantee the operability of the means used to mitigate the consequences of a release of hydrofluoric (HF) acid gas in the plant's "emission zone" in the event of a flood following a breach in this portion of the embankment after a SSE. Areva NC therefore built a protection wall around the equipment designed to produce a curtain of water to knock-down any toxic cloud.

EDF also undertook reinforcement work on the embankment to ensure its seismic resistance (see chapter 12, point 2.4.5).

Reinforcement of Comurhex spray systems following the event notified on 22nd August 2017.

The Eurodif gaseous diffusion enrichment plant – BNI 93

This finally shut down facility is the subject of a decommissioning application and is dealt with in chapter 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. 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 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 former Eurodif enrichment plant: it consumes far less electrical energy (75 MWe as against 3,000 MWe) 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 utilised in gas form at below atmospheric pressure.

The plant comprises two enrichment units (South and North units) and a support unit, the REC II, for which ASN authorised commissioning in 2014.

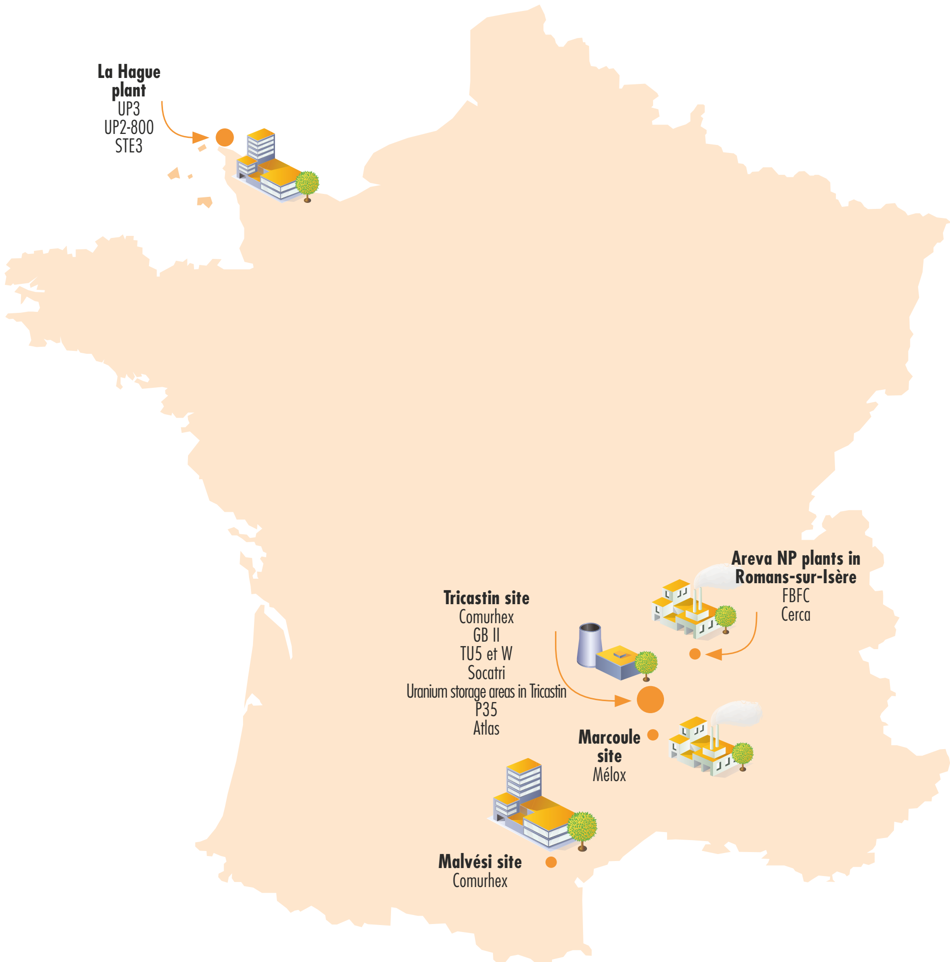
At the beginning of 2009, ASN authorised commissioning of the South unit, comprising eight modules, followed in 2013 by the North unit, comprising six modules, the first two of which are designed to enrich the uranium from spent fuel reprocessing. Enrichment of the uranium resulting from reprocessing in the facility, requiring prior authorisation from ASN, has never been implemented.

In 2017, the level of safety of the GB II plant was satisfactory. The technologies utilised in the facility enable high standards of safety, radiation protection and environmental protection to be maintained.

The gradual entry into production of the enrichment cascades[3] is now complete. The plant's output should therefore rise in 2018.

3. *Referring here to a group of interconnected centrifuges enabling a certain level of enrichment to be achieved.*

THE INSTALLATIONS of the fuel cycle in operation or undergoing decommissioning



The Atlas facility – BNI 176

The creation of the Atlas BNI (Areva Tricastin Analysis Laboratories) by Areva NC was authorised on 30th September 2015.

The purpose of the Atlas facility is:
- to carry out industrial physico-chemical and radio-chemical analyses;
- to monitor liquid and atmospheric discharges and monitor the environment of the Tricastin facilities.

This new laboratory will ensure compliance with the most recent safety requirements. The building chosen for the siting of Atlas is more robust to external hazards than the buildings containing the laboratories it is replacing.

ASN authorised the commissioning of Atlas on 7th March 2017. On 24th April 2017, it then gave its preliminary approval for the receipt of samples for the first analysis work in the "process" laboratory. The entire laboratory, with its sections dedicated to "environment" and "process" checks has been in operation since May 2017, with the exception of certain IR and UF_6 sub-sampling benches, which are scheduled to be relocated at the end of 2017.

In 2017, ASN carried out two inspections prior to issuing the commissioning authorisation and preliminary approval. These inspections verified the organisation implemented to ensure the compliance of the facility's equipment and layout with the provisions of the commissioning authorisation application, in particular those of the safety analysis report.

In 2018, ASN will ensure that operation of the facility and commissioning of the final analysis benches takes place in satisfactory conditions of safety and in accordance with the safety requirements is has set for the facility.

The Tricastin uranium storage facility – BNI 178

Following the delicensing of part of the Pierrelatte defence BNI by decision of the Prime Minister, the Tricastin storage facility BNI was created. This installation groups the uranium storage facilities and the new emergency management premises. ASN registered this facility in December 2016.

Since the BNI was created in 2016, two inspections have been carried out. The results of these inspections are satisfactory. In the last quarter of 2017, Areva NC submitted an application to the Minister for Ecological and Solidarity-based Transition to group within this BNI the storage areas currently present in BNI 93 and which are scheduled to continue in service.

The P35 facility – BNI 179

Following on from the delicensing process for the Pierrelatte DBNI, BNI P35 was created by decision of the Prime Minister. This facility comprises ten uranium storage buildings. ASN registered this facility in January 2018. Together with the Defence Nuclear Safety Authority (ASND), ASN ensured the continuity of nuclear safety oversight for this facility (see point 3.2). Joint actions are carried out: a facility inspection and walk-downs also took place, enabling ASN to verify the facility's baseline requirements, which must be brought into line with the BNI regulations.

Furthermore, as part of the project to group the storage areas of the Tricastin site within the same BNI, Areva submitted a request to the Minister in charge of Nuclear Safety in the fourth quarter of 2017, to merge BNIs 178 and 179.

New uranium storage facility project on the Tricastin site

In February 2015, Areva informed ASN that it wanted to create a new BNI intended for storage on the Tricastin site of uranium-bearing materials resulting from fuel reprocessing. After carrying out work to optimise the existing storage facilities on the site, so that the storage saturation date can be pushed back from 2019 to 2021, Areva sent ASN a safety options file in April 2015 concerning the creation of new storage buildings. ASN issued a negative response to this file, which failed to take account of all the regulations applicable to BNIs and which was based on an inappropriate assessment of the natural hazards. Areva consequently submitted a new safety options file and a creation authorisation application for a new BNI in November 2017. ASN will decide on the acceptability of this application in 2018.

1.1.2 Nuclear fuel fabrication plants in Romans-sur-Isère

The fabrication of fuel for electricity generating reactors involves the transformation of UF_6 into uranium oxide powder. The pellets fabricated from this powder in the "FBFC" plant in Romans-sur-Isère (BNI 98) are placed in zirconium metal tubes to constitute the fuel rods, which are then grouped together to form fuel assemblies. The fuels used in experimental reactors are more varied and some of them for example use highly-enriched uranium in metal form. These fuels are fabricated in the plant at Romans-sur-Isère called Cerca (BNI 63).

In the context of the restructuring of the Areva group (see point 3.3), the responsibility for operation of these BNIs was transferred from Areva NP to New NP (which has since become Framatome, a subsidiary of EDF). On 5th December 2017, ASN observed that the conditions for this transfer had been met, thus making it effective as of 31st December 2017.

In 2017, the licensee continued to improve the safety of its facilities, which have been subject to reinforced surveillance by ASN since 2014. In 2017 the improvements in terms of compliance with current safety requirements as well as in terms of operating rigour were confirmed, notably for management of the criticality risk, the qualification of equipment and the performance of periodic checks and tests.

The FBFC nuclear fuel fabrication plant – BNI 98

Most of the conformity and reinforcement work on the BNI 98 installations identified during the facility's periodic safety review, has been completed. Examination of the review file for this facility however showed that further improvements were still necessary, for example concerning management of the seismic risk, the fire risk and risks associated with dangerous substances. The main safety issue for this BNI is the toxic risk. These topics will be the subject of requirements contained in the ASN resolution planned for the beginning of 2018 and defining the conditions in which BNI 98 can continue to operate.

The Cerca nuclear fuel fabrication plant – BNI 63

This plant is one of the oldest French nuclear facilities still in service. Work to ensure the conformity of the facility has started and work to improve the containment of radioactive substances and management of the earthquake and fire risks in the main building has been carried out. For this purpose, the licensee sent an authorisation application to ASN for the construction of a "new uranium zone" (area in the main building in which the uranium is in powder form) in accordance with the existing requirements, for which commissioning would be envisaged in October 2022.

Compliance with ASN resolution 2015-DC-0485 of 8th January 2015, which requires that the licensee reinforce the facility by the end of 2017, was verified during the examination of the review file, notably during site inspections.

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 irradiated fuel assemblies from nuclear reactors, are operated by Areva NC.

The various facilities of the UP3-A (BNI 116) and UP2-800 (BNI 117) plants and of the STE3 (BNI 118) effluent treatment station were commissioned from 1986 (reception and storage of spent fuel assemblies) to 2002 (R4 plutonium reprocessing 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.

Areva asked for an increase in the storage capacity for standard vitrified (CSD-V) and compacted (CSD-C) waste packages within the UP3-A plant, which was authorised on 7th November 2016. The authorisation issued by ASN defined the maximum storage duration, beyond which the conditions for this storage must be publicly reanalysed.

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 dry, in a 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. 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 extract the uranium and plutonium and leave the fission products and other transuranic elements.

After purification, the uranium is concentrated and stored in the form of uranyl nitrate $UO_2 (NO_3)_2$. It is intended for conversion in the TU5 facility on the Tricastin site into a solid compound (U_3O_8), called "reprocessed uranium".

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 metal cladding are compacted and packaged in compacted waste packages (CSD-C).

The reprocessing operations described in the previous paragraph also use chemical and mechanical processes, the operation of which generates gaseous and liquid effluents as well as solid waste.

The solid waste is 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 waste packages).

In accordance with Article L. 542-2 of the Environment Code, 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.

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 Oversight of the La Hague plants

Examination of the periodic safety review files

In 2008, ASN examined the conclusions of the periodic safety review of BNI 118 which includes the Effluent Treatment Station (STE3), the Solvents Mineralisation Facility (MDS/B) and the sea discharge pipe. ASN observes that, on the whole, Areva NC is late in meeting its undertakings resulting from this periodic safety review, in particular concerning the performance of conformity examinations on the facility and the processing of legacy waste. The licensee sent ASN a report following a new periodic safety review of this facility in November 2017.

FUNDAMENTALS

The installations at La Hague

Shut down 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 plant
  - 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

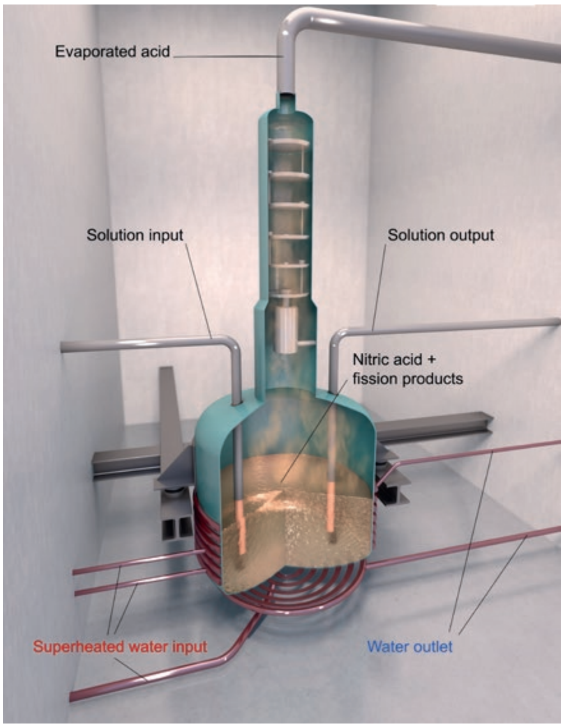
After examination of the periodic safety review report for the UP3-A plant (BNI 116), ASN ordered Areva NC on 3rd May 2016 to make safety improvements. This safety review demonstrated the need for a significant improvement in the protection of the facility against the fire and lightning risks as well as an improvement of the radioactive materials on-site transport systems.

ASN asked Areva NC to take account of experience feedback from the examination of the review file for the UP3-A (BNI 116) plant as part of the examination of the review orientation file for the UP2-800 (BNI 117) plant, in particular with regard to the completeness of the analyses provided in support of these files and in terms of methodology for identification of the Elements Important for Protection (EIP). The periodic review file for the UP2-800 plant was submitted by Areva NC at the beginning of January 2016 and is currently being examined. ASN will issue a position statement on the periodic safety review of the R1 facility at the beginning of 2018. The examination of certain technical subjects of this review should be completed in 2019.

Areva NC management of the state of the evaporation concentration containers

For the BNI 116 periodic safety review, ASN asked Areva in 2011 to examine the conformity and ageing of the fission products concentration evaporators in units T2 (BNI 116) and R2 (BNI 117). In 2014, Areva NC informed ASN that the corrosion of these items was on a scale greater than that considered in the design. During the course of 2015, Areva NC sent ASN the results of the in situ measurement campaigns. As the maintained integrity of these items has major safety implications, ASN in June 2016 specified the conditions to be met by Areva NC for continued operation of these evaporators. It is particularly attentive to the development of corrosion in this equipment and may demand shutdown of the facility in the event of excessive deterioration. In 2017, ASN carried out checks prior to each restart of this equipment following a maintenance outage.

DIAGRAM OF AN EVAPORATOR and details of the half-tubes of the heating circuit



In November 2016, ASN issued an opinion on the safety options presented by Areva NC for new evaporators. In November 2017, ASN authorised the construction of the civil engineering structures for the new buildings which are to house the future evaporators.

In addition, in 2011, following the perforation of the outer structure of an evaporator in BNI 117, the licensee sent ASN an authorisation application in 2016 for replacement and commissioning of a new evaporator, today envisaged for the 2018 time-frame.

Radiation protection

In 2017, 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 Creation Authorisation Decrees of 12th May 1981, updated in 2003 and in 2016, specify the operating domain of the plants for each type of fuel assembly. The applications for authorisation to process new types of fuels, covered by the operating domain defined in the modified Decrees of 12th May 1981, are the subject of ASN resolutions. In 2017, La Hague was authorised to receive fuels from test and research reactors, such as the "silicide" type fuels from the Siloé and Osiris reactors. Receipt of fuels from the OPAL reactors and of MOX fuel assemblies from the nuclear power plants with a plutonium and americium mass before irradiation of less than 8.78% was authorised at the beginning of 2018.

Implementation of new storage capacity for waste packages

The forecasts concerning the storage capacity for CSD-V (R7, T7 and E/EV/SE facilities) waste packages on the La Hague site demonstrated the need to double capacity by 2017.

In order to anticipate saturation of the storage capacity, the construction of the first vitrified waste storage extension on the La Hague site (E/EV/LH) began in 2007 and was completed in 2013. This extension comprises two pits, referred to as "pits 30 and 40".

Initially, only pit 30 was equipped with its storage shafts. This pit was commissioned in two stages, in September 2013 and June 2015.

On 4th June 2013, Areva NC requested authorisation to modify the UP3-A plant in order to increase storage capacity:
- creation of 4,199 additional spaces with the outfitting of pit 40 of the E/EV/LH extension;
- creation of 8,398 additional spaces with the construction of the E/EV/LH 2 extension, a facility with an identical design to that of the E/EV/LH and comprising two new pits (pits 50 and 60).

This modification was authorised on 7th November 2016. ASN authorised the introduction of CSD-V waste packages into pit 40 in November 2017.

In April 2017, Areva NC also requested a modification of the UP3-A plant creation authorisation decree so that CSD-C storage could be extended. This application is currently being reviewed by ASN.

The special fuels reprocessing unit project

With a view to obtaining authorisation to receive and reprocess spent fuels from the Phénix reactor, Areva transmitted a safety options file for a new reprocessing unit at the beginning of 2016. This was in response to an ASN requirement of March 2014 which prescribes the submission of an application before 31st December 2018 for authorisation to modify the facility, which will be the subject of a public inquiry.

Areva therefore presented ASN with a project to install a new special fuels reprocessing unit. This unit would comprise new shearing and dissolving equipment, in particular for the spent fuels from test and research reactors and from the Phénix reactor. In March 2017, ASN informed Areva NC that the safety options for this new unit were on the whole satisfactory.

ASN considers that the results of the Areva NC activities on the La Hague site are satisfactory enough with regard to nuclear safety, personnel exposure and compliance with environmental discharge limits, while noting that improvements are required with regard to the management and monitoring of handling operations and to the reliability of operational documentation (see chapter 8).

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.

In 2017, ASN observed that the safety situation in the facility is on the whole satisfactory. The containment of radioactive substances, radiation protection and criticality risk control issues are dealt with rigorously.

In 2016, the licensee applied for authorisation to produce a limited quantity of experimental fuels in order to qualify new types of fuels for possible use in fast neutron reactors. In 2017, it applied for authorisation to conduct a production campaign that could be authorised by ASN in 2018.

FUNDAMENTALS

Mélox and corresponding safety implications

The Mélox plant fabricates nuclear fuel referred to as "MOX" (mixture of plutonium and depleted uranium oxides). The plutonium, which comes from the reprocessing of spent fuels at the La Hague plant, is extremely radiotoxic for man. Tthe use of plutonium therefore requires that the licensee take appropriate measures against the risks of dispersion of radioactive substances, criticality and exposure to ionising radiation. In order to control the risk of worker contamination, the licensee carries out the fuel fabrication operations in "gloveboxes" so that the workers are not in direct contact with the plutonium. In addition, "dynamic" confinement is used, on the one hand between the gloveboxes and the rooms housing them and, on the other, between the rooms and the building containing them, in order to reduce the risk of worker or environmental contamination should there be a loss of confinement in a glovebox containing plutonium. In order to control the criticality risk (triggering of an uncontrolled fission chain reaction), «criticality control modes" (control by limiting mass, through geometry, etc.) are implemented. The risk of exposure to ionising radiation is the subject of enhanced vigilance in this facility, given the radioactive materials used there.

In 2017, ASN authorised Areva NC to begin construction work on a new emergency management building.

1.4 The back-end fuel cycle: long-duration storage

Given the anticipated time-frame identified by the review of the previous "cycle consistency" file, for saturation of spent fuel storage capacity and given the time needed to design and build a new facility, ASN asked EDF to present its strategy concerning this subject. Following on from this, Article 10 of the Order of 23rd February 2017 implementing Decree 2017-231 of 23rd February 2017, implementing Article L. 542-1-2 of the Environment Code and establishing the requirements of the National Radioactive Material and Waste Management Plan (PNGMDR) required that *"before 30th June 2017, EDF also send ASN the technical and safety options for the creation of new storage capacity."*

In 2017, EDF thus submitted a safety options file for a centralised spent fuel pool project taking account of current safety requirements. This project, for which the location has not yet been decided, should allow storage of spent fuels for which reprocessing or disposal can only be envisaged in the long-term future. The envisaged operating life for this storage facility is about a century.

ASN will issue an opinion on these safety options in early 2019.

2. Integration of experience feedback from the Fukushima Daiichi accident

Priority was given to integrating the lessons learned from the Fukushima Daiichi accident on all the fuel cycle facilities. The licensees supplied stress test reports in September 2011 for all facilities and sites, with the exception of BNI 63 in Romans-sur-Isère, for which the report was submitted in September 2012.

In June 2012, ASN set additional requirements for the Areva group facilities assessed in 2011, in the light of the conclusions of the stress tests. These requirements more specifically stipulate the deployment 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.

FOCUS

The commissioning of the first post-Fukushima emergency management buildings for the fuel cycle plants

In 2017, the Tricastin licensees were authorised to implement the revision of the On-site Emergency Plan (PUI) incorporating the hardened safety core provisions dedicated to emergency management. This authorisation more particularly allowed the site's Local Strategic Management Command Post (PCD-L) to be moved to the new emergency management building designed to be robust to the extreme hazards identified for the Tricastin site. This building more specifically contains a ventilation system with filtration enabling the personnel present to be protected against a toxic release from the site's facilities or neighbouring facilities, or a radioactive release from the neighbouring NPP.

The Tricastin site command post building.

3. Regulating the nuclear fuel cycle facilities

ASN regulates the fuel cycle facilities, more specifically with regard to:
- 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 substantial modification or make the transition to decommissioning, ASN is responsible for reviewing these modifications and proposes the draft decrees in support of these changes to the Government. ASN also establishes binding requirements for these main steps. Finally, ASN also reviews the safety files specific to each BNI.

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. Experience feedback from the examination of the periodic safety review file for the UP3-A plant on the La Hague site should enable Areva to improve its process for the future reviews. For future reviews, ASN will in particular ensure that lessons are learned from the safety review of UP3-A, completed in 2016, in particular with regard to identification of the EIP and the corresponding defined requirements, in accordance with the Order of 7th February 2012 setting the general rules for BNIs.

3.2 Particular regulatory actions conducted in consultation with the Defence Nuclear Safety Authority (ASND)

The upcoming declassification of the Tricastin DBNI to a BNI will mean that ASN will take over responsibility for oversight of these facilities. Together with the ASND, ASN ensures that consistency is maintained 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 to BNI status 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 (integrated processing of Tricastin nuclear waste) 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 takeover would be gradual, comprise as few steps as possible and be an opportunity to reorganise the oversight of the Tricastin site, so that the whole site, including soils contaminated by legacy pollution, are under the control of one or other of the safety regulators. Jointly with the ASND, ASN will propose to the Minister responsible for Nuclear Safety a reclassification of the various DBNI facilities on the site as BNIs, whether existing or new, as a result of the ongoing process to declassify the site from a DBNI to a BNI. Their safety baseline requirements will then need to be brought into line with the BNI System.

3.3 The licensee's organisation 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 a position statement regarding the chosen organisations and may issue binding requirements on specific identified points, whenever it considers that there are shortcomings in these organisations concerning internal oversight of safety and radiation protection or that they are not adequate.

ASN assesses 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 is currently examining the management processes which had not been dealt 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.

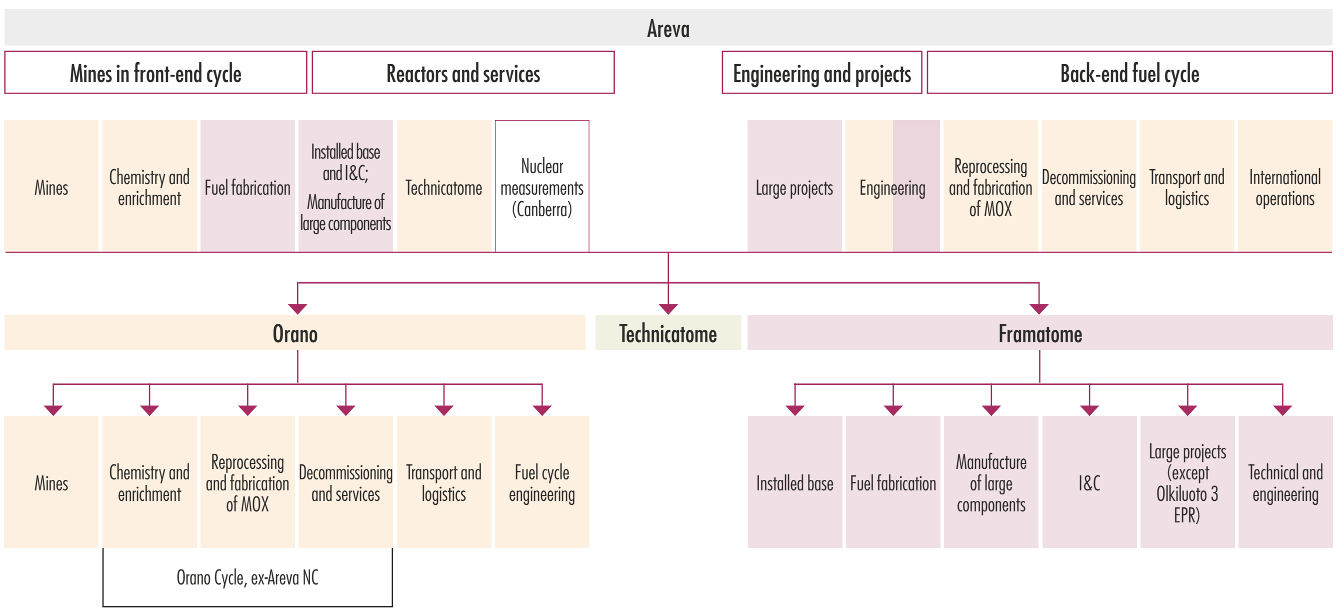
In 2018, ASN will be vigilant in ensuring that the ongoing reorganisation of the Areva group does not compromise safety management across the group. The Areva group's nuclear fuel conversion, enrichment and reprocessing activities are now grouped under Areva NAH (which more particularly owns Areva NC), while the nuclear fuel fabrication and nuclear equipment manufacturing activities are grouped within Framatome, which is an entity jointly owned by EDF and several industrial groups. In accordance with the law, the entities which, as a result of this split-up, have become licensees of BNIs of the former Areva Group (Framatome and Somanu), proved to ASN that they do in fact have the technical and financial capacity enabling them to assume their nuclear safety and radiation protection responsibilities.

In this respect, the separation of the group's engineering departments has major implications for the safety of the facilities. Although the historical ties between the two parts of Areva mean that each temporarily draws on the expertise of the other, it is essential that each party acquire the technical skills necessary to take on its responsibility as licensee.

Examining the measures taken by the Areva NAH group head office departments and Framatome in terms of safety

ASN's regulatory action also covers the head office departments which are responsible for their group's safety, radiation protection and environmental protection policy. In 2017, ASN checked the

REORGANISATION of Areva



Excluding ENR and Areva Med
Excluding support functions

process to separate the Areva group into several legal entities. Framatome and Areva NAH signed agreements for management of their inter-dependence, notably in the field of emergency management and operating experience feedback. Although this management mode can be envisaged over the short term owing to the common past of the two licensees, it is probable that they will gradually become more independent. In 2018, ASN will inspect the operational nature of the mutual provisions adopted by these licensees.

3.4 Fuel cycle consistency

ASN monitors the overall consistency of the industrial choices made with regard to fuel management and which could have an impact on safety. ASN thus periodically asks that, together with the firms in the fuel cycle, EDF provide data to demonstrate the long-term compatibility between changes to the fuel characteristics and fuel management and changes to the fuel cycle facilities and corresponding transports. EDF transmits a "Cycle impact" file in response to this request.

In 2015, ASN asked EDF to conduct an overall review of the "Cycle impact" file by 2016. The period covered by the study is from January 2016 to December 2030 and identifies the limit thresholds (capacity saturation, fuel isotope limit reached, etc.) foreseeable up until 2040.

The update of the "Cycle impact" file 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 2015-992 of 17th August 2015.
- 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.

EDF submitted the updated "Cycle impact" file to ASN on 30th June 2016. This file is currently being examined by ASN, which will issue its position statement in 2018.

4. Outlook

Restructuring of the Areva group

The new Areva NAH and Framatome entities, resulting from the separation of the Areva group, state that they wish to maintain strong operational ties in the performance of their responsibilities as nuclear licensee. These ties are to a large extent formally enshrined in various agreements. Although this management mode can be envisaged over the short term owing to the common past of the two licensees, it is probable that they will gradually become more independent of each other. In 2018, ASN will inspect the operational nature of the mutual assistance provisions adopted by these licensees and will be attentive to their remaining operational over the long-term.

Fuel cycle consistency

In 2016, ASN started an examination of the updated "Cycle impact" file covering the 2016-2030 period and aimed at anticipating the various emerging needs in order to ensure the management and consistency of the nuclear fuel cycle in France, from the viewpoint of safety. ASN is particularly vigilant with regard to the level of occupancy of the spent fuel underwater storage facilities (Areva and EDF). It asked EDF, as client, to examine the impact on the anticipated saturation dates for these storage facilities of the shutdown of one or more reactors, of a possible modification in the spent fuel reprocessing traffic, as well as the solutions envisaged for delaying this saturation. The assessment of the "Cycle impact" file submitted in 2016 is in progress and will be the subject of a joint review in May 2018 by the Advisory Committees for Laboratories and Plants, for Wastes, for Reactors and for Transports, so that ASN can issue a position statement on these subjects in 2018.

ASN will also continue to examine the files associated with fuel cycle management, 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.

The new storage capacity envisaged

ASN will issue a position statement at the beginning of 2019 on the safety options of the centralised spent fuel pool project submitted by EDF.

La Hague site

In 2018, ASN will be particularly vigilant with regard to the development of corrosion in the fission products concentration evaporators. Areva NC shall be required to consolidate its methods for inspecting this equipment and its corrosion forecasts. Areva NC has started to replace this equipment for gradual commissioning between 2020 and 2021. ASN will examine the applications concerned.

With regard to the periodic safety reviews, ASN will in 2018 be monitoring the performance of the conformity work on the UP3-A plant and compliance with the requirements of the resolution of 3rd May 2016. The implementation of the EIP identification methodology and the reassessment of the control of fire risks will be the subject of particularly close scrutiny. In addition, the examination of the periodic safety review file for the UP2-800 plant will lead to ASN's initial conclusions at the beginning of 2018 and to the examination of certain technical subjects by the Advisory Committee at the end of 2018. This examination is to continue in 2019.

With regard to future changes to reprocessing in the La Hague facility, ASN attaches particular importance to two modifications: on the one hand, the project to reprocess special fuels, which will allow the reprocessing of several fuel assemblies which hitherto could not be reprocessed, thus pushing back the saturation of the storage pools and, on the other, the replacement of the R7 evaporator, for which the particularly corrosive solutions are currently concentrated in other equipment in the plant and are liable to damage it.

With regard to the recovery and packaging of legacy waste, ASN considers that efforts must be continued (see chapter 16).

Romans-sur-Isère site

ASN will regularly check compliance with the undertakings made by the licensee in its action plan and the requirements it issues following examination of the periodic safety reviews of the BNIs on the site. Areva will in particular be required to construct a new building, referred to as the "new uranium zone", in order to continue to fabricate research fuel in accordance with current safety requirements.

Tricastin site

In December 2017, Areva NC submitted applications for a change in licensee in order to become the single licensee of the platform, which will allow a simplification of the chains of responsibility, which on the whole can only be beneficial for safety. ASN will continue to monitor the major reorganisations of the group and the reorganisation of the Tricastin platform to ensure that there is no impact on the safety of the various BNIs on the site.

In 2018, ASN will begin to examine the BNI creation authorisation application comprising new uranium storage buildings on the site, as well as the application for commissioning of the Trident unit in the Socatri facility (see chapter 14). ASN will remain particularly attentive to the reorganisation of the site with regard to nuclear waste management, pending the commissioning of the Trident unit, construction of which started in 2017.

Mélox plant

ASN will continue to monitor compliance with the licensee's undertakings and the requirements it issued following the periodic safety review of the facility in 2011, more particularly with regard to the fire risk and the monitoring of outside contractors.

In addition, the changes to fuel management for power reactors requiring adaptation of the characteristics of the MOX fuel, will be a subject of close attention for ASN. Areva NC will effectively have to demonstrate that the changes to the substances used in the BNI have no impact on the safety of the facility and it will, if need be, submit the necessary modification application files.

In addition, the licensee announced its intention to carry out experimental fabrication of new types of fuels for qualification for the Astrid project and could submit an application for modification of its operating baseline requirements accordingly.

Cross-disciplinary aspects

ASN will be continuing its review of several of the Areva Group's BNIs, notably those of La Hague, but also of EDF's inter-regional fuel stores (in Chinon and Bugey).

ASN will continue to oversee the implementation of the additional safety measures stipulated following the stress tests at the end of 2014 and beginning of 2015. This more specifically concerns the implementation of a hardened safety core of material and human resources capable of dealing with emergency situations on an exceptional scale.

Nuclear research and miscellaneous industrial facilities

14

Nuclear research or industrial facilities differ from the BNIs involved directly in the generation of electricity (reactors and fuel cycle facilities) or the disposal of waste. 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).

The variety of the activities covered by these BNIs and their past history explains the wide diversity of facilities concerned.

The safety principles applicable to these facilities are similar to those applied to power reactors and nuclear fuel cycle facilities, while taking account of their specificities with regard to risks and detrimental effects. With this in mind, ASN has divided the facilities it oversees and regulates into three categories defined by ASN resolution 2015-DC-0523 of 29th September 2015. The resolution establishes a classification of BNIs according to their risks and detrimental effects for the interests mentioned in Article L. 593-1 of the Environment Code (see chapter 3).

1. CEA installations

The CEA centres comprise facilities dedicated to research (experimental reactors, laboratories, etc.), as well as "support" facilities for the storage of waste, treatment of effluents and so on. The research carried out by CEA more particularly concerns the operating life of the NPPs, reactors of the future, nuclear fuel performance or the reprocessing and packaging of nuclear waste.

The CEA facilities undergoing clean-out or decommissioning are covered in chapter 15 and those devoted to the management of waste and spent fuels are covered in chapter 16.

1.1 The year's notable generic subjects

The inspection campaigns and analysis of the lessons learned from operation of the facilities or from examination of the safety files enable a number of priority generic topics to be defined for ASN oversight. In 2017, the generic topics concerned:
- the management of safety and radiation protection (see point 1.1.2);
- the periodic safety reviews (CEA's transmission of 16 conclusion reports at the end of 2017, see point 1.1.4);
- the new decommissioning and waste management strategy, covering all CEA facilities, implemented at the beginning of 2017.

In October 2017, the ASN commission called the CEA Chairman to a hearing concerning:
- implementation of CEA's "major commitments";
- changes to the safety organisation;
- the reorganisation of CEA implemented at the beginning of 2017 with regard to decommissioning, post-operational clean-out and management of radioactive waste;
- the progress of the work linked to the lessons learned from the Fukushima Daiichi accident;
- the future of CEA's Saclay centre.

1.1.1 Experience feedback from the Fukushima Daiichi accident

In the wake of the Fukushima Daiichi accident, ASN undertook stress tests of the 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 CEA BNIs in batch 1 and in the light of the conclusions of the stress tests, ASN ordered the implementation of appropriate organisational and material measures on 26th June 2012, referred to as the "hardened safety core" (see chapter 12).

The stress tests were continued for a second group (batch 2) of 22 facilities with lesser safety implications. These include CEA research facilities. The emergency management resources on the Cadarache and Marcoule sites underwent stress tests as part of this second batch. On 8th January 2015, ASN imposed binding requirements on CEA concerning the "hardened safety core" of its facilities, along with the implementation deadlines, which run until 2018 (see Figure 1).

Finally, for the thirty or so other facilities with lesser safety implications (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).

In 2017, ASN[1] considered that the steps taken by CEA for emergency management and for emergency situations, with regard to extreme "hardened safety core situation" type scenarios, are on the whole satisfactory. These provisions are notably presented in the On-site Emergency Plans (PUI) for the CEA centres and, with regard to long-term management, specify the interfaces between the centre affected by the event

1. *ASN resolutions of 8th January 2015.*

and the material and human reinforcements from other CEA centres, called the Nuclear Rapid Intervention Force (FARN).

At the end of 2017, for the Cadarache centre, CEA requested an additional period of five years to commission a new emergency situations management room, initially scheduled for October 2018. CEA presented the difficulties it was experiencing in taking account of the requirements concerning natural hazards in the design of its buildings and when consulting its social partners. ASN is currently examining this extension request. It will be attentive to the compensatory measures put into place.

For the Marcoule centre, CEA sent ASN the modifications adopted for reinforcement of the emergency situations management room so that it can withstand extreme natural hazards (tornado and earthquake) in accordance with the “hardened safety core” requirements prescribed by ASN. This project is currently being examined by ASN.

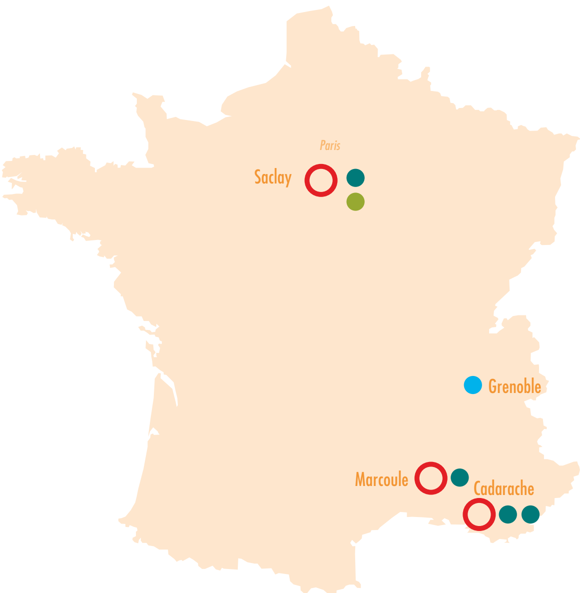
For the Saclay centre, following the review of the stress tests, ASN ordered the implementation of a “hardened safety core” for emergency management. CEA complied with the initial deadlines for the ASN requirements and forwarded additional studies and justifications concerning its ability to activate its emergency organisation in extreme situations. These elements are currently being examined by ASN.

1.1.2 Management of nuclear safety and radiation protection

ASN’s oversight of safety management is carried out at all levels within CEA, from the Chairman to the Protection and Nuclear Safety Department, but also in each centre and each BNI.

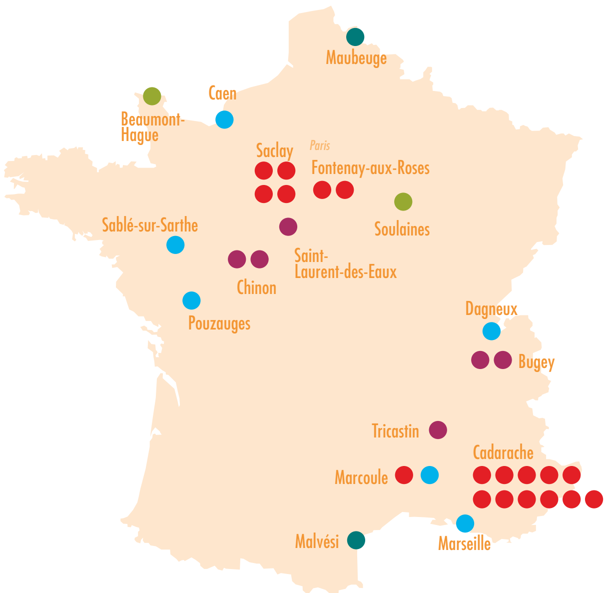
In 2016, the topics concerning decision-making and the organisation of internal monitoring, the integration of safety issues into project management, the integration of Social, Organisational and Human Factors (SOHF), skills management,

FIGURE 1: CEA centres and facilities, ILL and CIS bio international concerned by the “hardened safety core” additional requirements 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
  - 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)

subcontracting, operating experience feedback and safety in routine operations were the subject of examinations and of two ASN inspections of the Cadarache and Saclay centres. These actions enabled ASN to verify the effective implementation of the CEA measures resulting from its commitments and the ASN requests, since 2010. The implementation of these measures was considered to be on the whole satisfactory, subject to reinforcement of the SOHF and safety skills of certain personnel in charge of events analysis and project management.

In 2017, ASN summarised the investigations and observations made in 2016. The aim is to target those topics to be covered in greater depth by CEA and then incorporated into its next three-yearly review, planned for the first half of 2018. This three-yearly review will be the subject of a forthcoming examination by ASN.

ASN will also be particularly vigilant with regard to the impact of the change in CEA's safety organisation in 2018 as a result of:
- the shutdown of the "risk management" centre following the reorganisation implemented in 2016. This notably led to the "general and nuclear inspectorate" reporting directly to the Chairman;
- the "general and nuclear inspectorate" recommendations formulated in the CEA annual report, published in July 2017.

1.1.3 Monitoring of CEA's "major commitments" to nuclear safety and radiation protection

In 2006, ASN stated that it wanted to see more rigorous monitoring of the CEA subjects with the highest potential safety consequences, by means of an oversight tool at the highest level within CEA, in particular for the decision-making process. This oversight tool thus allows targeted monitoring of priority actions for which deadlines are clearly set.

In 2007, CEA therefore presented ASN with a list of "major commitments". This list is periodically updated and transmitted to ASN. Any postponement must be duly justified and discussed with ASN. The overall results of this system to date are on the whole positive.

At the end of 2017, CEA presented ASN with the update of its "major commitments" (Table 1). It should be pointed out that four "major commitments" were completed in 2017: transmission of the definition file for the BNI 37 structural reinforcements, the removal of all radioactive materials from BNI 53, the compliance of BNI 55 with the falling loads risk and reduction of the source term in BNI 56.

1.1.4 The periodic safety reviews

The Environment Code requires that the licensees carry out a periodic safety review of their facilities every ten years. This review is designed to allow an appraisal of the situation of the facility with respect to the rules applicable to it and to update the assessment of the risks or detrimental effects presented by the facility, notably taking into account the condition of the facility, acquired operating experience, changes in knowledge and the rules applicable to similar facilities. For facilities which had not yet undergone such a review, the Environment Code required that the licensees submit their first periodic safety review conclusions report no later than 1st November 2017.

CEA submitted 16 periodic safety review reports (see box opposite) in 2017. The examination of these 16 files will take several years, given the specific nature of each of these facilities. This review has major implications owing to the commissioning of most of these facilities in the early 1960s, to their past management but also the adoption of more recent safety standards. Once the examination has been carried out, ASN will determine the conditions allowing continued operation of these facilities.

In 2017, ASN will continue its site inspections in conjunction with the periodic safety reviews on two facilities, Rapsodie and Masurca. The review files were submitted in 2015 and the ASN examination is nearing its completion. The inspectors found that CEA had taken account of the lessons learned from the last "periodic safety review" inspections carried out by ASN in the drafting of their review files. CEA must however improve the traceability of the various measures taken following the periodic safety reviews of its facilities.

TABLE 1: New CEA "major commitments"

SITE	BNI	ACTION	DEADLINE
Marcoule	71 (Phénix)	Transmit the NOAH commissioning file for decommissioning of Phénix	2nd half 2021
	177 (Diadem)	Transmit the commissioning file	1st half 2019
Saclay	35 (Stella)	Recovery of effluents from tank MA500	2nd half 2018
	56 (Storage area)	Complete recovery of stainless steel packages from pit 6	2nd half year 2022
	72 (ZGDS)	Remove fuels from pool and block storage	2nd half year 2022
	72 (ZDGS)	Eventually stop accepting routine production of radioactive waste from Saclay. Then initiate the post-operational clean-out and decommissioning process	Redefinition of this commitment following the change in waste management strategy
Fontenay-aux-Roses	165-166 (Process-Support)	Remove from BNI 166 the LLW/ILW/HLW organic effluents resulting from R&D work in BNI 165	1st half 2019

FOCUS

The periodic safety reviews

The Environment Code requires that the licensees carry out a periodic safety review of their facilities every ten years. These periodic safety reviews are thus an opportunity for upgrades or improvements in fields in which the regulations and safety requirements have changed, in particular seismic resistance, protection against fire and confinement.

Unlike the nuclear power reactors in service, the other facilities (covered in chapters 13, 14, 15 and 16 of this report) are not generic but have implications specific to each BNI (more particularly in terms of safety, environmental protection and radiation protection). Twenty six LUDD (Laboratories, Plants, Waste and Decommissioning) facilities submitted a periodic safety review in 2017 (previously, one to six files per year).

ASN thus adapted its organisation and developed new methodologies for processing these numerous files with specific implications. In 2016, it also initiated on-site inspection campaigns specifically devoted to the periodic safety review of the facilities. A team of ASN inspectors thus supplements the analysis of a file with "field" inspections lasting several days. The aim is thus to carry out spot-checks to ensure that the licensee is effectively implementing the action plan it defined for the periodic safety review, notably with regard to regulatory compliance.

1.1.5 Revision of the prescriptions concerning water intake and effluent discharges

In July 2017, ASN completed its review of the applications for updates to the requirements concerning water intake and effluent discharges for the BNIs on the Cadarache site. It thus set limit values and defined procedures for effluent discharge and water consumption.

1.2 Facilities operations reports

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 one BNIs are sited 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 comprises facilities under construction, notably the Jules Horowitz Reactor (RJH).

In 2017, ASN carried out about fifty inspections of the BNIs in this centre. ASN considers that the level of safety remains on the whole satisfactory. It notes that the disparities previously observed between the facilities within the centre are shrinking. More specifically, the operational rigorousness applied in the facilities called STD (Solid waste Treatment Station) and STE (Effluents Treatment Station) has returned to an acceptable level. ASN will be attentive to ensuring that CEA meets the undertakings made for these BNIs.

The Cadarache centre must run several projects of varying scope, type and implications at the same time: work on decommissioning and on recovery and packaging of radioactive waste, BNI construction or redevelopment work, notably as a result of the periodic safety reviews. ASN observes greater rigorousness in the quality control of these operations and in compliance with the regulation deadlines.

Saclay Centre

The Saclay centre, covering 223 hectares, is located about 20 km south-west of Paris, in the Essonne *département*. About 6,000 persons work there. Since 2005, this centre has been primarily devoted to physical sciences, fundamental research and applied research. The applications concern physics, metallurgy, electronics, biology, climatology, simulation, chemistry and the environment. The main aim of applied nuclear research is to optimise the operation of the French NPPs and their safety. Eight BNIs are located within this centre. It also houses an office of the French national institute for nuclear science and technology (training institute) and two industrial firms: Technicatome, which designs nuclear reactors for naval propulsion and CIS bio international (see point 3.2). Since 1st February 2017, the Saclay and Fontenay-aux-Roses centres have been grouped within the same department, called the CEA Paris-Saclay Department.

ASN considers that the BNIs of the Saclay Centre are operated in satisfactory conditions of safety. A new organisation was implemented in 2017 in order to improve the management of the decommissioning projects, with the creation of the Facilities Clean-out and Decommissioning Department. During the period of consolidation of this new organisation, ASN remains vigilant with regard to the maintained control of safety and radiation protection in the Saclay BNIs.

ASN is also attentive to changes in management of BNI liquid effluents, given the fact that the room containing the front-end tanks of BNI 35 is not in use (for safety reasons), and to ensuring that their removal to the Marcoule centre continues in good conditions. CEA also changed its waste management strategy, notably by postponing the BNI 72 order (see chapter 16) owing to delays in the construction of replacement equipment.

Finally, the decommissioning and the recovery and packaging of legacy waste operations are behind schedule. ASN will examine these delays as part of the CEA decommissioning and radioactive materials and waste management strategy file and the decommissioning files for each BNI concerned (see chapters 15 and 16).

The inspections carried out in 2017 show that:

- The CEA analyses of deviations must be more systematic and carried out in greater depth.
- The long-term protection of buildings against fire requires greater surveillance on all the BNIs.
- Failures in the reactivity of the alert systems on the Saclay site were observed. ASN will thus be vigilant to the availability, upkeep and upgrading of the specific communication and alert means on the Saclay site facilities.
- CEA must reinforce the presence of its personnel in the field for the monitoring of outside contractors.

Marcoule Centre

The Marcoule centre is dedicated to the back-end fuel cycle, radioactive waste in particular. Apart from the defence-related nuclear facilities, it also houses three BNIs operated by CEA: Atalante (see this chapter), Phénix (see chapter 15) and Diadem (see chapter 16) as well as three other BNIs, not operated by CEA: the Gammatec irradiator, Melox (see chapter 13) and Centraco (see chapter 16).

In 2017, ASN carried out twelve inspections at the CEA Marcoule centre, three of which were conducted jointly with the Defence Nuclear Safety Authority (ASND).

Two inspections in particular, performed jointly with ASND, concerned the transverse organisation set up in the centre concerning the transport of radioactive substances and protection against the fire risk:

- The inspection on the fire topic aimed to check the working of the centre's Local Safety Organisation (FLS). It was shown that the coordination between this team and the centre's individual facilities needed to be improved, notably by defining and regularly carrying out exercises proportionate to the issues involved in each facility, as well as by the systematic transmission of updated facility drawings to the FLS. These drawings are an essential operational decision-making aid for the response teams.
- The centre's organisation devoted to the transport of radioactive substances for its part appeared to be satisfactory. It showed that the corrective measures decided on following significant events are implemented rapidly and are effective. However, areas for improvement were identified regarding the analysis of root causes and the preventive means to be implemented.

ASN considers that the level of nuclear safety and radiation protection in the Marcoule centre's BNIs is on the whole satisfactory.

Fontenay-aux-Roses Centre

The two BNIs in this centre are currently being decommissioned (see chapter 15).

Grenoble Centre

All the BNIs in this centre are currently being decommissioned (see chapter 15).

1.2.2 Research reactors

The purpose of nuclear research reactors is to contribute to scientific and technological research and to improve the operation of the nuclear power plants. Each of them is a specific facility, for which ASN adapts its regulation and oversight to the particular risks and detrimental effects. In recent years, the licensees have developed a more generic approach to the safety case for these facilities, derived from that used for the nuclear power reactors. This approach in particular concerns the safety assessment based on "operating conditions" and the safety classification of the equipment. It led to the identification and implementation of additional provisions which constitute safety improvements. 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 very low-power (5 kW) Masurca reactor (BNI 39), whose creation was authorised by a Decree dated 14th December 1966, is intended for neutron studies – chiefly for the cores of fast neutron reactors – and the development of neutron measurement techniques. The reactor has been shut down since 2007. In its current configuration, BNI 39 is characterised by very limited safety implications in terms of management of risks and detrimental effects. Since 2014, there have been no fissile materials in the installation.

Following the examination of the periodic safety review report transmitted by CEA in April 2015, in early 2018 ASN considered that CEA could continue to operate this BNI in its current configuration.

Moreover, in order to ensure continued operation of this BNI, CEA decided in 2016 on extensive refurbishment, notably with the construction of a New BNI Disposal and Handling Building (N-BSM). CEA thus transmitted the modification authorisation application in 2016. This application and a stress test of the facility in its refurbished configuration are currently being examined.

ÉOLE and Minerve reactors (Cadarache)

The experimental ÉOLE and Minerve reactors are very low-power (less than 1 kW) critical mock-ups, used for neutron studies, in particular to evaluate the absorption of gamma rays or neutrons by materials.

The ÉOLE reactor (BNI 42), the creation of which was authorised by the Decree of 23rd June 1965, is mainly intended for neutron studies of moderated arrays, in particular those of Pressurised Water Reactors (PWR) and Boiling Water Reactors (BWR). The Minerve reactor (BNI 95), whose transfer from the Fontenay-aux-Roses research centre to the Cadarache research centre was authorised by the Decree 77-1072 of 21st September 1977, is situated in the same hall as the ÉOLE reactor.

Teaching and research activities took place on these mock-ups until their final shutdown on 31st December 2017. The closure date for submission of the decommissioning file was set at no later than July 2018. Pending decommissioning, operations to remove radioactive and dangerous materials and preparations for decommissioning will begin in 2018. ASN will oversee these operations and subsequently examine the decommissioning file.

Irradiation reactors

Osiris and ISIS reactors (Saclay)

The Osiris pool-type reactor (BNI 40) has an authorised power of 70 megawatts thermal (MWth). It was primarily intended for technological irradiation of structural materials and fuels for various power reactor technologies. Another of its functions was to produce radionuclides for medical uses.

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 the Decree of 8th June 1965. They make up BNI 40.

Given the old design of this facility by comparison with the best available techniques for protection against external hazards and for containment of materials in the event of an accident, the Osiris reactor was shut down at the end of 2015. CEA asked to extend the December 2016 deadline for submitting the decommissioning file to March 2019. In order to comply with the provisions of the Energy Transition for Green Growth Act 2015-992 of 17th August 2015, ASN required the submission of the decommissioning file no later than June 2018. The operations to remove radioactive and dangerous materials and preparations for decommissioning are in progress. In 2018, ASN will be vigilant with regard to the licensee's control of these operations and compliance with the specified deadline.

CEA intends to continue with operation of the ISIS reactor until 2019.

The inspections carried out by ASN in 2017 demonstrated that the management of liquid effluents and wastes as well as the scheduling and monitoring of periodic tests and maintenance are on the whole satisfactory. The interpretation of the periodic tests and maintenance results does however need to be improved.

The next periodic safety review is planned for March 2019. The guidance file for this review was sent to ASN by CEA in April 2017. The ASN requests concerning this file must be taken into account in the periodic safety review report.

Jules Horowitz Reactor (RJH) (Cadarache)

The RJH, currently under construction on the Cadarache site, is a technological irradiation reactor designed to study the behaviour of materials under irradiation and of power reactor fuels. It will also allow the production of artificial radionuclides intended for nuclear medicine. The RJH will be replacing the Osiris technological irradiation reactor, located on the Saclay platform, which ceased operation in 2015. The RJH power is limited to 100 MWth. The RJH is a light water-cooled pool type reactor; its core comprises assemblies with a U_3Si_2 type fuel (with the possibility of a future UMo type fuel at a later date). The RJH offers significant developments in terms of the experiments that can be carried out as well as with regard to safety.

| Roofing work on the RJH, March 2017.

On the site, the construction work, which began in 2009, continued in 2017, notably with the roofing of the nuclear auxiliaries building, marking the end of the main civil engineering operations. Inside the buildings, the lining of the nuclear island pools is in progress, with installation of the second phase concrete and welding of the stainless steel plates. For the reactor cavity, in which the reactor block is to be installed, the plate welding operations were halted for several months owing to excessive weld shrinkage. The welding operations resumed in the autumn of 2017. According to CEA, the cavity lining should be completed in 2018, then enabling the equipment to be installed in the cavity (in particular the reactor block and the control mechanisms). With regard to the hot cells, the lining and installation of the hot cell doors is also continuing.

Off the site, equipment manufacturing is continuing. Many equipment items are being assembled, with testing to confirm their conformity. Dummy assembly of the reactor block is in progress and the regulation tests on the primary exchangers have been scheduled.

ASN carried out four inspections on the topics of the design and construction of the facility and the monitoring of outside contractors. ASN considers that the RJH construction site is managed by CEA satisfactorily, in terms of safety and that deviations are managed rigorously and effectively.

CEA asked the Minister responsible for Nuclear Safety to authorise a four-year extension to the commissioning date for its facility owing to a series of delays in the construction work. This request is currently being reviewed by ASN.

In 2018, ASN will continue to examine the progress of the actions subsequent to CEA's commitments, to monitor the facility and prepare for examination of the future commissioning authorisation application. On this point, several topics (dimensioning of the civil engineering and polar crane, civil engineering resistance to a borax type accident) will more specifically be analysed by ASN.

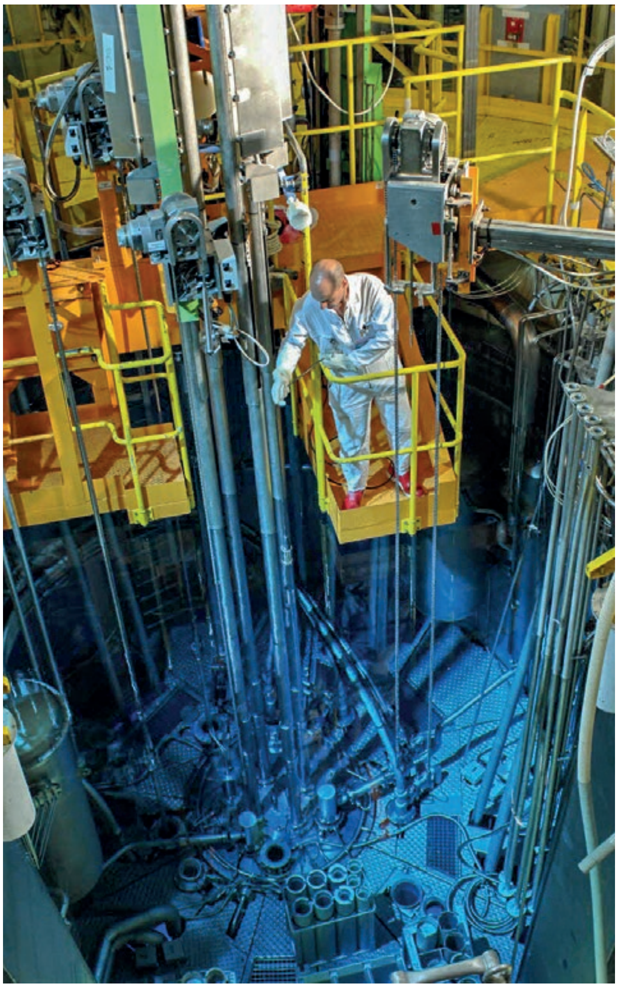
Neutron source reactors

Orphée reactor (Saclay)

The Orphée reactor (BNI 101) is a pool-type research reactor with an authorised power of 14 MWth. The highly compact core is located in a tank of heavy water acting as moderator. The reactor was authorised by the Decree of 8th March 1978 and it first went critical in 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 radionuclides or special materials. 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.

The inspections carried out in 2017 showed satisfactory operation of the facility, more particularly of the containment and ventilation systems. ASN considers that waste management and waste zoning is appropriate. However, the licensee's organisation could be improved with regard to outside contractor monitoring and its traceability. ASN will be vigilant on these points.



Orphée: work in the pool.

Finally, most of the commitments and requests resulting from the last periodic safety review have been cleared. Reactor final shutdown is scheduled for the end of 2019.

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 by Decree 2006-320 of 20th March 2006 in order to be able to run new research programmes to study the behaviour of high burn-up fraction fuel in accidental reactivity insertion situations in a PWR.

The first criticality of the modified reactor was authorised in 2015. The years 2016 and 2017 were devoted to having the operating teams familiarise themselves with the renovated reactor and preparations for the forthcoming experimental tests.

In 2017, CEA completed the post-criticality start-up tests to check correct general operation and the reactor power increase. Finally, at the end of 2017, CEA transmitted the periodic safety review file for the installation. ASN will begin its examination in 2018.

The inspections carried out by ASN in 2017 concerned fires and periodic checks and tests. They revealed no significant deviations.

FOCUS

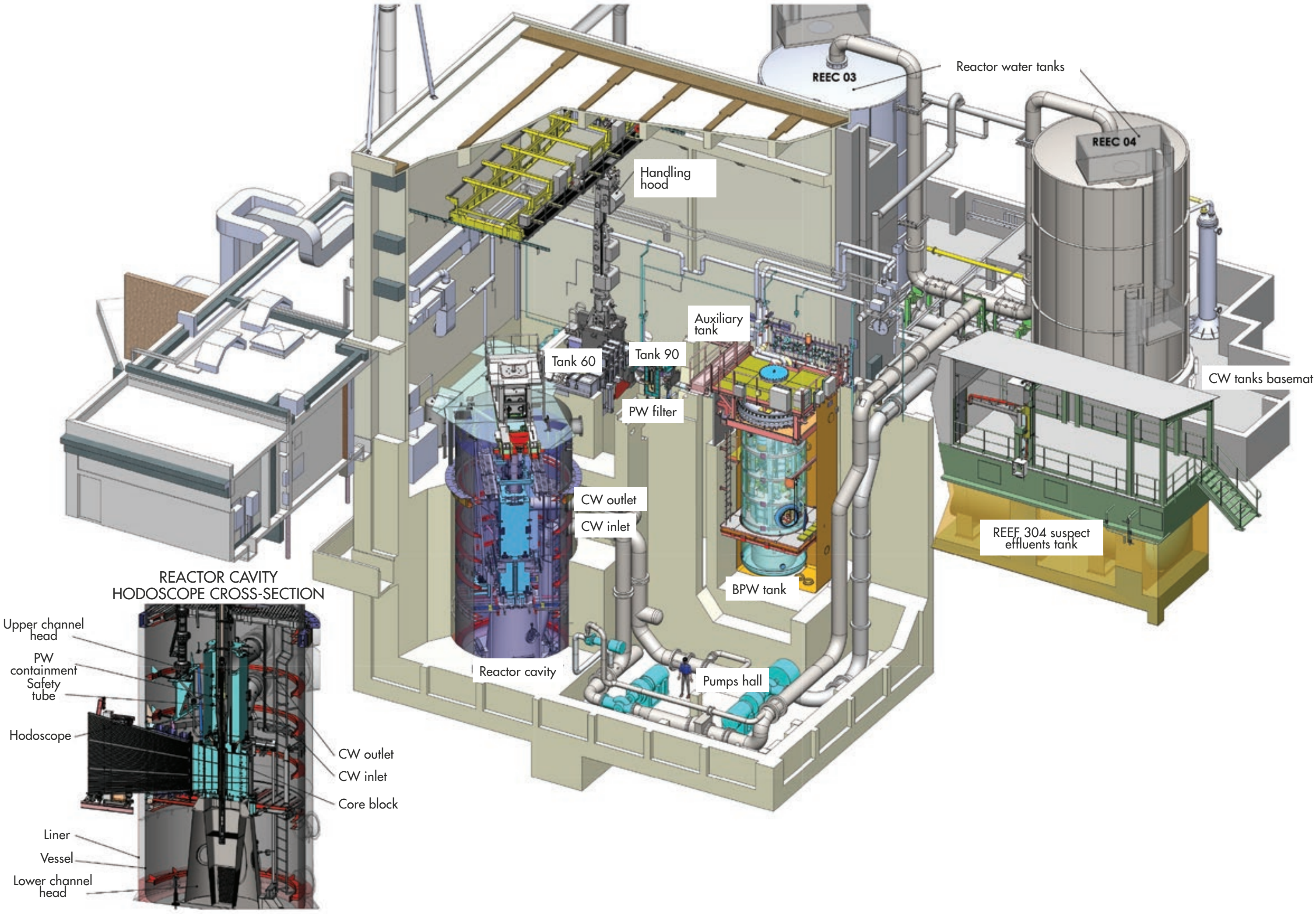
Cabri, towards the first experimental test

In 2006, CEA was authorised to modify its Cabri facility in order to replace the sodium loop by a Pressurised Water Test Loop (BEP) and carry out power excursions. The Decree provides for two authorisations, for the first criticality of the modified facility and for the first active experimental test, respectively.

Since 2015, the year its modified facility first went critical, CEA has been preparing the next project milestone, with the authorisation application for the first experimental test. For its part, in January 2016 ASN defined a technical examination programme for this application, covering the latest data concerning the safety reassessment, the start-up tests for the equipment important for safety, or equipment which could constitute a hazard and the provisions concerning nuclear pressure equipment.

The main safety issues are:
- the confinement of radioactive substances, in particular those to be introduced into the BEP;
- control of the breeder core reactivity during the experimental tests, leading to power peaks of about 25 MW for a few milliseconds;
- the handling operations required for the experiments and for exploitation of the results in the reactor hall.

ASN will issue a position statement on this file in 2018.



Source: CEA

FOCUS

Requirement for CEA submission of the decommissioning files for the Phébus reactor

Several facilities operated by CEA have been definitively shut down in recent years. This is notably the case of the Phébus reactor.

Article L. 593-24 of the Environment Code states that *"If a basic nuclear installation stops functioning for a continuous period of more than two years, its shutdown is deemed definitive"*. Pursuant to this text, on 27th July 2017, ASN ordered the submission of the Phébus decommissioning file on 29th June 2018.

Phébus reactor (Cadarache)

The Phébus reactor (BNI 92) is an experimental pool type reactor with a power of 38 MWth, situated in Cadarache, which was authorised by Decree 77-801 of 5th July 1977. This reactor was intended for the study of light water reactor severe accidents resulting from the loss of the protection and safeguard systems, as well as for the definition of operating procedures to prevent core melt, or at least mitigate its consequences.

The final tests were carried out in the Phébus facility in 2007.

In 2014, CEA transmitted a file presenting the operations in preparation for final shutdown and decommissioning, along with the reactor decommissioning plan. In 2015, it was authorised to begin the first of the scheduled decommissioning preparation operations. The deadline for submission of the Phébus reactor decommissioning file was set at 29th June 2018 (see box above). CEA also transmitted the reactor periodic safety review file in November 2017. The Phébus decommissioning file and periodic safety review file will be examined jointly.

In 2017, ASN examined several noteworthy modification files concerning the removal of Spent Fuel Elements (ECI) and the removal of fissile materials which were irradiated little if at all. The ECI removal operations should be completed by CEA in 2018. ASN notes that the initial schedule for ECI removal was not met because the receiving facility was unavailable, thus affecting the schedule for the decommissioning preparation operations. In 2018, ASN will be vigilant with regard to the resumption of the ECI removal operations.

In 2017, ASN also carried out a general inspection of the facility, which demonstrated the need to create storage zoning in the BNI for waste without an immediate disposal route.

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, although the safety approach is also proportionate to the specific risks and detrimental effects they represent.

Active Fuel Examination Laboratory (LECA) (Cadarache)

LECA (BNI 55) was commissioned in 1964 and is referred to as a "hot" laboratory, enabling CEA to carry out destructive and non-destructive examinations of spent fuel from the nuclear power, research and naval propulsion sectors.

As the facility is an old one, its seismic resistance was partially reinforced starting in 2010. During the examination of the last periodic safety review, the Advisory Committee for Laboratories and Plants (GPU) considered that the steps taken by CEA for reinforcement were unable to demonstrate the stability of the main building in the event of a Safe Shutdown Earthquake (SSE) and that the LECA should be shut down as rapidly as possible.

ASN considers that the SSE resistance of a nuclear facility is a fundamental requirement for its continued operation. It therefore asked CEA to present it with its strategy for final shutdown of the LECA in the medium term and, in the near future, to take compensatory measures to reduce the radiological consequences of a possible accident (collapse of the building followed by a fire) as a result of an SSE. In 2018, ASN will set out its requirements with regard to this strategy.

The inspections carried out in 2017 confirm that the deviations observed during the inspection have effectively been dealt with by the licensee. Nonetheless, ASN remains vigilant in the way organisational and human factors are taken into account.

The LECA extension Treatment, Clean-out and Reconditioning Station (STAR) (Cadarache)

The STAR facility (BNI 55) is a high-activity laboratory comprising shielded cells. The STAR facility is an extension of the LECA laboratory. It is 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);
- destructive and non-destructive examinations of spent fuels, performed in shielded cells.

Its creation was authorised by the Decree of 4th September 1989 and its definitive commissioning was declared in 1999.

ASN regularly checks compliance with the commitments made by CEA within the context of the facility periodic safety review, completed in June 2009. Following this review, CEA in particular made a commitment to implement a project (called STEP) for redevelopment and for installation of new equipment, in particular for handling purposes. The purpose of STEP is to improve the safety of fuel receiving and transfer to the STAR shielded cells. In May 2014 ASN prescribed the operating procedures associated with this project. The delays in this project led ASN to serve CEA with formal notice to commission STEP before 30th April 2017. During the inspection of 19th May 2017, ASN observed that STEP equipment had been commissioned.

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.

In 2014, CEA announced that it would be transferring the LEFCA R&D activities to the Atalante facility in 2017. Then, in 2017, CEA stated that the final shutdown of its facility was scheduled for 2023 and that it intended to transmit its decommissioning file in 2020.

As part of the LEFCA's packaging activities, the acceptance of new materials and the use of the "pins" warehouse for storage were authorised by ASN in 2017. Finally, in July 2017, CEA

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Safety management in a "hot" laboratory, the LECA example

A "hot" laboratory comprises equipment for handling or processing highly radioactive substances. The LECA enables CEA to carry out destructive and non-destructive examinations of spent fuels from various sectors (research reactors, power reactors, naval propulsion). These fuels are received and then transferred to shielded cells, where they undergo cutting operations, various thermal treatments and then physical characterisations.

These activities are performed using appropriate equipment, a robust organisation and trained personnel, with a view to controlling the main risks, such as irradiation and contamination of the personnel, criticality and fire.

Radiation protection is provided by:

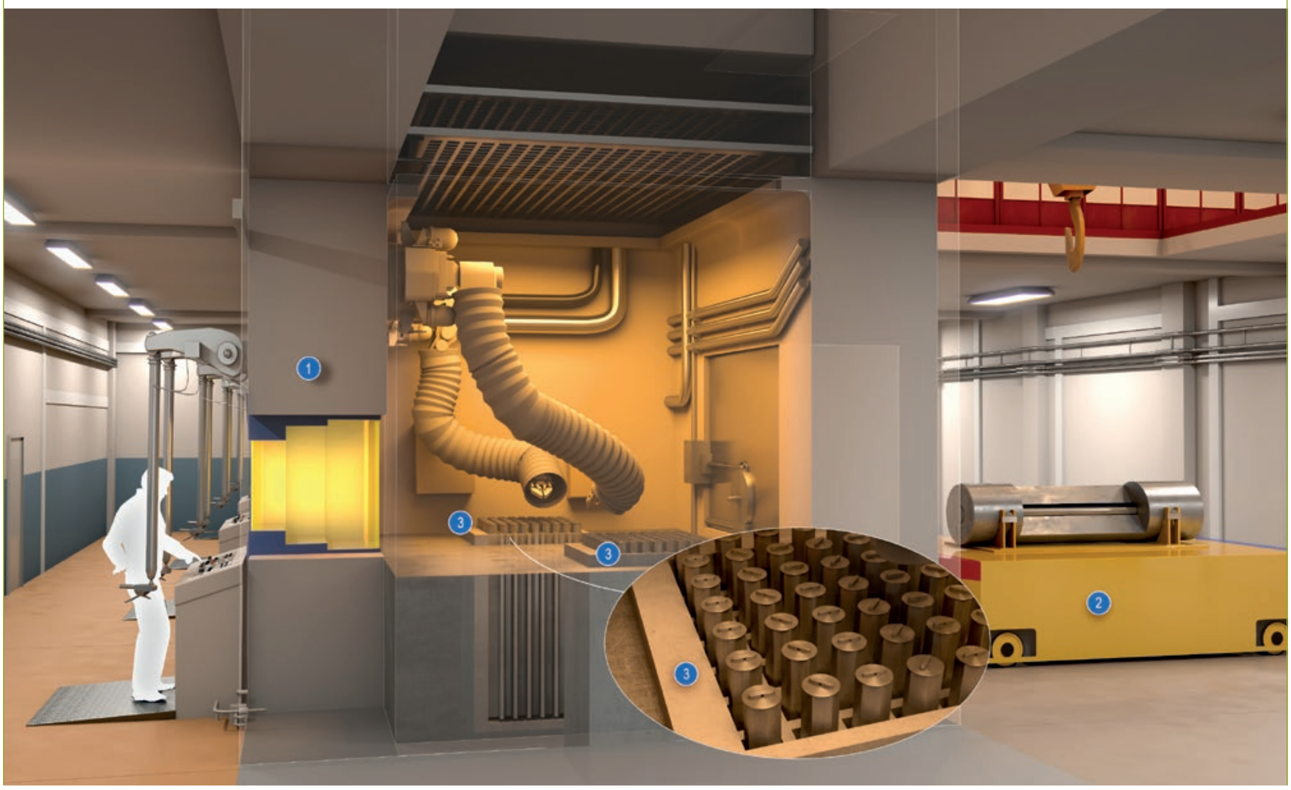
- shielded cells, for which the thickness of the walls and windows (1) offers protection against ionising radiation and controls the dispersion of radioactive substances;
- specific ventilation equipped with filters, to control the dispersion of radioactive substances;
- rolling stock (2) and instructions appropriate to the handling of fuels;
- personnel trained in the risks relevant to their tasks.

The criticality risk, present in storage cell No. 5, is controlled by means of:

- pits (3) placed under the cell to take the fuels;
- personnel trained in the storage instructions so that they respect the maximum authorised quantities and the geometrical arrangement of the fissile materials.

The fire risk is primarily controlled by means of:

- dampers, fire doors and fire walls, appropriate electrical equipment and fire-fighting equipment;
- personnel trained to deal with an outbreak of fire;
- an organisation limiting the presence of calorific materials.



deployed a groundwater drainage system to prevent the risk of soil liquefaction in the event of an earthquake, in compliance with an ASN requirement.

A level 1 significant event was notified in this facility in 2017 concerning the presence of a quantity of material in excess of the authorised quantity in the criticality unit where repackaging was to take place. This event had no impact, either on the workers, or on the environment. ASN will check the implementation of the corrective actions decided on by CEA.

In 2018, ASN will set out the conditions for continued operation of the facility, in the light of the conclusions of its periodic safety review, transmitted in December 2013.

Spent Fuel Testing Laboratory (LECI) (Saclay)

The LECI (BNI 50) was notified by CEA on 8th January 1968. An extension was authorised in 2000. The role of the LECI is to study the properties of materials used in the nuclear sector, 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. However, the 2017 inspections identified two points requiring particular vigilance: a shortage of personnel during the second half of the year with a heavier annual surveillance programme than previously, and the prevention of fire risks, more particularly during hot spot work.

Following the periodic safety review, ASN monitored the improvements plan that CEA undertook to implement. It notably required the reinforcement of the seismic resistance of building 625 before the end of the 1st half of 2021 and the removal of all objects and materials from the Célimène cell by 31st December 2023.

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 order to expand these research activities, rooms are being fitted out to host the activities and equipment from the Lefca on the CEA Cadarache centre.

In 2017, ASN considers that the level of safety of Atalante is on the whole satisfactory. However, given the activities performed in Atalante and the modifications in progress (transfer of a part of the Lefca activities), the licensee must maintain rigour in the application of the operating rules.

The inspections conducted by ASN in 2017 concerned management of the fire risk, the consideration of external hazards (lightning risk) and compliance with the licensee's commitments made following the inspections, significant events and authorisations, whether issued by ASN or by the management of the CEA Marcoule centre as part of the internal authorisation process. These inspections enabled ASN to see that these topics are dealt with satisfactorily by the licensee.

The periodic safety review conclusions report transmitted by CEA at the end of 2016 is being examined by ASN and will be presented to the GPU at the end of 2018. ASN will then rule on the continued operation of the facility.

1.2.4 Fissile material stores

Central Fissile Material Warehouse (MCMF) (Cadarache)

Built in the 1960s, the MCMF (BNI 53) is used for storage of enriched uranium and plutonium. Its main activities are the acceptance, storage and shipment of non-irradiated fissile materials pending reprocessing and intended for use in the fuel cycle.

Given the facility's insufficient seismic resistance, ASN instructed CEA to evacuate the nuclear materials stored in it before 31st December 2017, the date on which CEA definitively shut down the MCMF. In 2017, the initial version of the decommissioning plan was the subject of various ASN requests which, depending on their nature, will need to be taken into account either during the operations to prepare for decommissioning, or during the drafting of the decommissioning file.

ASN considers that operations in the MCMF facility are both well-organised and efficient. The same operational rigorousness shall be applied during the operations to prepare for decommissioning, scheduled as of 1st January 2018.

Owing to the change in the operating team on 1st January 2018, ASN considers that CEA will need to ensure the correct handover of information and to maintain the level of skills within the facility.

The periodic safety review file, received at the end of 2017, will be examined in 2018. The decommissioning file is expected by November 2018.

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.

In 2017, ASN deemed that the latest version of the Magenta safety analysis report, which was brought into line with the actual status of the facility, was applicable.

ASN underlines the considerable activity at Magenta owing to storage clearance operations at the MCMF and ÉOLE-Minerve. It considers that the Magenta facility is operated rigorously and that its level of safety is satisfactory.

1.2.5 The Poséidon irradiator (Saclay)

The Poséidon facility (BNI 77) at Saclay, authorised in 1972, is an irradiator consisting of a cobalt-60 source storage pool, partially topped by an irradiation bunker. The facility features a submersible chamber and a test cell. R&D activities on the behaviour of materials under radiation are also carried out there. The main risk in the facility is that of exposure to ionising radiation owing to the presence of very high level sealed sources.

In 2017, CEA carried out modifications on the facility - to eliminate the common mode failure risk on the cabled Pagure and Vulcain channels - and improved access control to the Poséidon and Pagure bunkers.

The very high level sources were replaced in 2017 with no noteworthy event being reported. ASN observed improvements in the preparation for the source renewal operations by comparison with the previous operation. In addition, BNI 77 is operated satisfactorily in terms of radiation protection.

In 2018, ASN will prescribe the conditions for continued operation of the facility following its periodic safety review, more specifically with regard to the monitoring of structure ageing and the seismic reinforcement of certain elements.

1.2.6 Waste and effluent storage and treatment facilities

The CEA waste and effluent storage and treatment facilities are presented in chapter 16.

1.2.7 Installations undergoing decommissioning

The CEA facilities undergoing decommissioning, as well as the CEA decommissioning strategy, are presented 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 build a technology demonstrator for a possible Generation IV electricity generating reactor. This project is supported by CEA, in association with EDF and Areva.

Astrid is a sodium-cooled fast neutron reactor project, one of the six technologies being studied by the Generation IV International Forum for the fourth generation of reactors. In anticipation of the regulatory procedures, the first guidelines envisaged for the design of Astrid were presented by CEA in a safety guidance document which underwent technical appraisal and was the subject of ASN requests in a letter of April 2014. ASN thus informed CEA of several demonstrations that would be required for the safety options file.

More generally, ASN considers that this reactor must offer a level of safety at least equivalent to that of the EPR type reactors, 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 and measures to be tested.

1.4 ASN's general assessment of CEA actions

The results of 2017 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.

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. However, ASN notes that several CEA decommissioning or waste management projects have deviated (see chapters 15 and 16). CEA's strategy in these areas is being examined by ASN and ASND and will be the subject of an opinion in 2018. ASN also considers that CEA must reinforce its surveillance and its control of the activities performed by outside contractors, in a context of extensive subcontracting.

ASN underlines that the implementation of the action plans resulting from the numerous periodic safety reviews, in association with preparation of the decommissioning files, represents a major safety challenge for the coming years.

On the topics of decommissioning and waste and materials management at CEA, ASN observed more efficient oversight in the field by the CEA central level and positive progress. However, this trend remains to be confirmed.

Finally, ASN will be vigilant with regard to the actual initiation of the decommissioning operations on the facilities finally shutdown, in accordance with the regulations.

2. Non-CEA nuclear research installations

2.1 Large National Heavy Ion Accelerator (GANIL)

The Ganil (National Large Heavy Ion Accelerator) economic interest group was authorised in 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. Exposure to ionising radiation is thus the primary risk at the Ganil.

In order to be able to produce exotic nuclei[2], the Ganil was authorised in 2012 to build phase 1 of the SPIRAL 2 project. ASN issued the partial commissioning authorisation for this project at the end of 2014. Prior to the commissioning authorisation, the Ganil undertook to answer several ASN requests no later than April 2018.

At the end of 2016, after observing that the Ganil was behind schedule in implementing several requirements of ASN resolution 2015-DC-0515 of 7th July 2015 setting limit values for discharge of effluents from the facility into the environment, ASN served the Ganil with formal notice on 21st March 2017, to restore conformity before

2. *The "exotic nuclei" are nuclei which do not exist naturally on Earth. They are created artificially in the Ganil for nuclear physics experiments on the origins and structure of matter.*

September 2017. Since then, ASN has observed that the Ganil was effectively in conformity.

The Ganil identified delays in the implementation of the measures to comply with the requirements resulting from the periodic safety review. In 2017, it therefore requested a modification of the deadlines for six of the ten requirements. This application is currently being reviewed by ASN.

In 2016, the Ganil modified its organisation by creating a team dedicated to nuclear safety studies for ongoing and future projects. ASN is remaining closely attentive to the resources devoted by the Ganil to nuclear safety, so that the requirements are met rigorously and the projects are run efficiently.

2.2 The High Flux Reactor (RHF) at the Laue-Langevin Institute

The RHF (BNI 67), located in Grenoble and operated by the Max von Laue-Paul Langevin Institute (ILL), supplies neutrons used for scientific experiments in a large variety of fields. This reactor was authorised by the Decree of 19th June 1969, modified on 5th December 1994 following the reactor block replacement. This reactor has a maximum power of 58.3 MWth and operates continuously for 50-day cycles (or about four cycles per year). 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 the safety level of the ILL installations is satisfactory, although it did however observe several deviations from the regulations in terms of safety management. ASN therefore expects ILL to reinforce its organisation with respect to the requirements of the regulations.

In 2017, the ILL continued to install “hardened safety core” back-up systems (see box opposite) and to reinforce its facility. This work is primarily in response to the undertakings made as a result of the lessons learned from the Fukushima Daiichi accident. This work, which requires shutdown of the reactor, should continue at the beginning of 2018.

In 2017, the ILL notified two significant events with no consequences for safety, workers or the environment (blockage of a spent fuel during transfer to the permanently submerged part of the spent fuel pool, with minor contamination of one level of the reactor building).

ASN is expecting ILL to significantly improve its management of the periodic checks and tests required by the regulations or by its operating baseline requirements. Since 2016, the ILL has notified seven significant safety events concerning incomplete performance of periodic checks and tests with deadline overruns.

On 6th February 2018, ASN served the ILL with formal notice to modify its organisation in order to ensure compliance with the regulatory requirements concerning the modifications of its facility. ASN will be particularly vigilant with respect to the implementation in 2018 of the new integrated management system at the ILL, for which deployment started in 2017. Significant improvements to the material modifications management process are in particular expected, with the implementation of a system for classification of material modifications and reinforcement of the corresponding preliminary risk assessments.

Finally, the ILL transmitted the facility’s periodic safety review report at the end of 2017.

2.3 European Organization for Nuclear Research (CERN) installations

The 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. ASN and the Federal Office of Public Health (OFSP), the Swiss radiation protection oversight organisation, jointly contribute to verifying safety and radiation protection requirements at the CERN. The joint actions concern transport, waste and radiation protection.

In 2017, ASN and the OFSP continued to examine new facilities and modifications submitted to them by the CERN, more particularly a facility for waste storage and sorting, as well as the experimental Medicis and n-TOF facilities. ASN also examined the methods for characterising packages of radioactive substances intended for carriage on the public highway between the various CERN sites. A joint visit by the two authorities was also carried out on the topic of waste management.

Finally, at the beginning of 2017, the licensee notified ASN and OFSP that a monthly dose received by a worker’s extremities (hands) had been exceeded during operations to recover an isotope on the GLM separator of the Isolde experiment (11.8 mSv for a limit of 10 mSv). This event is currently being examined by the OFSP.

2.4 The ITER project

ITER (BNI 174) will be 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 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 in November 2012. The facility is currently under construction on the Cadarache site (Bouches-du-Rhône *département*).

Owing to the delays in the progress of the project and certain R&D work necessary for its design, ASN set regulations for the new strategy of gradual commissioning of the facility up until 2035. ASN more particularly considered it necessary to order the updating of certain parts of the creation authorisation application, such as the safety analysis report and the notice presenting the licensee's technical and financial capacity. ASN also considers that these new deadlines will allow progress in the R&D work necessary for demonstrating the safety of ITER. In addition, ASN will be particularly vigilant with regard to compliance with the new undertakings made by the ITER Organization (lead-times and quality of files) necessary for clearing certain hold points set by ASN.

FUNDAMENTALS

The RHF "hardened safety core» back-up systems

The "hardened safety core" designates a set of structures and equipment capable of performing vital safety functions in the event of extreme events more severe than those considered in the design of the facility. These structures and equipment must thus withstand these extreme events.

Following the Fukushima Daiichi accident and the resulting stress tests, the ILL defined a "hardened safety core" consisting of active and passive equipment and structures, some of which already exist and some of which need to be created.

The active "hardened safety core" defined by the ILL comprises:

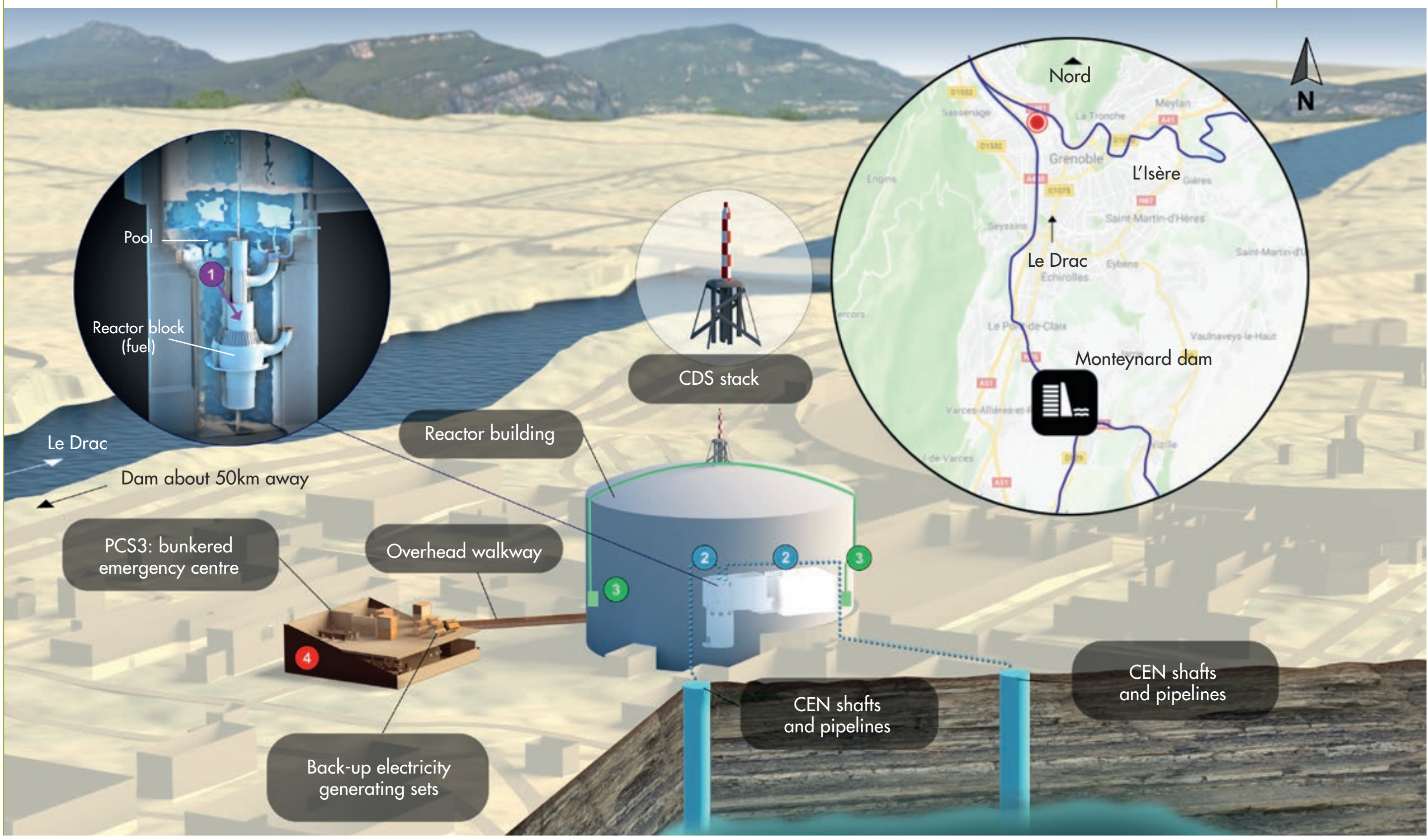
a system participating in reactivity control:
- causing Reactor Shutdown in the event of an Earthquake (ARS), by dropping the safety rods, in the event of failure of the electrical power supplies, or a lack of secondary water flow.

systems participating in cooling management, comprising:
- an Ultimate Reflooding System (CRU) (1) which, in the event of primary system breaks, enables the reactor to be resupplied with water from the pool;
- a groundwater system (CEN) (2) enabling the pools and the reactor block to be supplied with water pumped from the groundwater or from recirculation;
- a spent fuel transfer incident emergency operation (PUC).

systems participating in containment management, comprising:
- a Containment Isolation System (SIE);
- a "Seismic" Depressurisation System (CDS) (3) enabling the air to be filtered before discharge.

emergency and emergency management means, comprising:
- a Bunkered Emergency Operations Control Centre (PCS3) (4), situated high enough with regard to extreme flooding.

Technological diversity (example: different types of sensors) and the presence of channel redundancy (example: two channels for the CEN) are sought for the "hardened safety core" systems. The main work in progress or completed in recent years for implementation of the ILL's "hardened safety core" concerns the following systems: (2), (3), (1) and (4).



An inspection was carried out by ASN at the headquarters of the European domestic agency, Fusion For Energy (F4E), in Barcelona (Spain) to evaluate the means deployed by Iter Organization for its surveillance of F4E. Several points for improvement were identified by ASN, notably with regard to management of the F4E team seconded to the Cadarache site.

In 2017, work continued on the facility, more particularly with civil engineering work on the first above-ground level of the Tokamak reactor, the positioning of the overhead cranes in the assembly hall and the construction of several auxiliary buildings (utilities, cryogenic plant, etc.). The equipment necessary for the facility is currently being manufactured or procured, in particular for the vacuum chamber, the cryostat, the superconductor coils, the water detritiation system and the cooling systems. At this stage in the project, ASN considers that the worksite is being run satisfactorily.

In 2017, ASN also continued to examine the various safety files concerning the design and construction of equipment, systems, buildings, in particular the safety analysis file transmitted in 2017, detailing the envisaged modifications to the pressure limiter system in the vacuum chamber and to the facility's cooling system.

ASN inspections revealed a significant improvement in the assimilation of the safety requirements by the ITER licensee and improved dissemination down the subcontracting chain. Nonetheless, ASN wants to see more attentive monitoring of the activities important for the protection of certain batches, more specifically concerning the buildings and utilities, given the complex international organisation of the project.

Finally, in April 2017, the ASN Commission called the ITER Director General to a hearing on:
- the progress of the construction of the facility and the main upcoming milestones, notably including the assembly of the Tokamak reactor;
- changes linked to the project organisation;
- the steps taken to improve the monitoring of outside contractors.

| ASN inspection of the ITER Tokamak reactor construction site, May 2017

3. The other nuclear installations

3.1 Industrial ionisation installations

Irradiators use irradiation from sealed sources of cobalt-60 to sterilise medical devices, agro-industry products, pharmaceutical raw materials, etc. The irradiation cells are made of reinforced concrete, designed to protect persons and the environment. The sealed sources are either placed in the lowered position, stored in a pool under a height of water which protects the workers in proximity to the pool, or are placed in the raised position to irradiate the items to be sterilised. Personnel exposure to ionising radiation is thus the primary risk in these facilities.

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 level of safety and radiation protection in these installations is satisfactory. However, the licensee must continue its efforts to detect any deviations. The licensee must also ensure that it complies with the deadlines set for the submission of the files or of requests for additional information.

With regard to the Sablé-sur-Sarthe facility (BNI 154), the periodic safety review file is currently being examined by ASN, which will specify the conditions for continued operation in 2018.

With regard to the facilities at Pouzauges (BNI 146) and Dagneux (BNI 68), their files were transmitted in 2017.

The Synergy Health group operates the Gammaster (BNI 147) irradiator in Marseille and Gammatec (BNI 170) in Marcoule.

ASN considers that the level of safety and radiation protection in these installations is satisfactory. ASN does however consider that the results of the radiation protection internal checks should be more clearly formalised. ASN considers that the licensee must continue its efforts to assimilate the regulations, notably for Gammatec and must maintain sufficient human resources for operation of its facilities.

The licensee also transmitted its periodic safety review conclusions report for Gammaster (BNI 147) in 2016. This was considered to be acceptable by ASN in 2017. Examination will continue in 2018.

In 2017, the licensee was authorised to start-up an irradiation laboratory on the Gammatec site (BNI 170). This laboratory is used by CEA (agreement between the two licensees).

3.2 The radio-pharmaceuticals production facility operated by CIS bio international

BNI 29, called the "Artificial Radionuclides Production Unit (UPRA)", was commissioned in 1964 by CEA on the Saclay site, which in 1990 created the CIS bio international subsidiary, the current licensee. In the early 2000s, this subsidiary was bought up by several companies specialising in nuclear medicine. In 2017, the parent company of CIS bio international acquired Mallinckrodt Nuclear Medicine LCC thus today forming the Curium group, which owns three production sites (United States, France, Netherlands).

The Curium group is an important player on the French and international market for the production and development of radiopharmaceutical products. The products are mainly used for the purposes of medical diagnoses, but also for therapeutic uses. Until the end of 2018, the role of BNI 29 is to recover used sealed sources which were used for radiotherapy and industrial irradiation.

Generally speaking, ASN considers that the safety of the facility operated by CIS bio international must progress significantly. ASN does however observe efforts on the part of CIS bio international to make the facility's safety management more efficient, by reinforcing and modifying its organisation and its operating processes. However, despite a few improvements observed, ASN finds that the results are as yet insufficient. The increase in the number of significant events, the causes of which are almost always organisational and human failures, reflects an unsatisfactory operational safety situation. The recurrence of certain events means that certain lessons have not been learned.

ASN also observes that, in the light of the delays that have built up in recent years and despite the efforts made since the end of 2016, the licensee has difficulty in complying with the requirements resulting from the previous periodic safety review, which led it to initiate a formal notice to comply procedure at the beginning of 2018.

To conclude, ASN is expecting a lasting turnaround on the part of CIS bio international. Operating rigour, improvements to the safety culture, optimisation of the organisational structure and the workforce, oversight of operations, the transverse nature of the organisation, compliance with the facility's baseline requirements, with resolutions and with the regulations, must be reinforced.

In the light of these findings, ASN is maintaining reinforced surveillance of the licensee.

3.3 Maintenance facilities

Two BNIs operated by Areva and EDF (Somanu and BCOT) are devoted to nuclear maintenance activities in France.

The facility of the *Société de maintenance nucléaire* (Somanu) in Maubeuge

BNI 143 was authorised in 1985 and specialises in the maintenance and expert assessment of equipment from the primary systems of EDF NPP reactors.

The periodic safety review of the facility, submitted by Somanu in 2011, was completed in 2014. Owing to the priority given by ASN to monitoring the post-Fukushima actions on the facilities with the highest safety implications, ASN had temporarily suspended the examination of this review, before resuming it in 2015.

Tricastin Operational Hot Unit (BCOT) in Bollène

BNI 157, called BCOT and operated by EDF, was authorised in 1993. This facility is located in Bollène and carries out maintenance and storage of equipment and tools from PWR nuclear reactors.

The periodic safety review of the facility, submitted by EDF in 2010, was completed in 2011 and 2013. Owing to the priority given by ASN to monitoring the post-Fukushima actions on the facilities with the highest safety implications, ASN had temporarily suspended the examination of this review, before resuming it in 2015. In 2017, ASN issued a resolution covering the conditions for the continued operation of the BCOT until submission of the next periodic safety review, scheduled for 2020. This resolution takes account of EDF's June 2017 notification of the Minister in charge of Nuclear Safety, of its intention to finally shut down the facility on 30th June 2020. The decommissioning plan transmitted is currently being examined.

ASN considers that the level of safety of the BCOT is on the whole satisfactory.

The Clean-out and Uranium Recovery Facility (IARU) in Bollène

The activities of BNI 138, operated by Socatri, a subsidiary of Areva, can be divided into four sectors:
- repair and decontamination of equipment used in nuclear facilities (dismantling/reassembly, decontamination, mechanical work, maintenance for disposal or refurbishment);
- treatment, before discharge into the environment, of radioactive and industrial liquid effluents resulting from these activities and from other facilities on the Tricastin platform, via the STEU (Uranium Bearing Effluent Treatment Station) and STEF (Final Treatment Station);
- processing and packaging (sorting, crushing, compacting, disposal, etc.) of radioactive waste for disposal in approved routes, including waste from the small producers (hospitals and laboratories) on behalf of the national radioactive waste management Agency (Andra);
- storage of waste from the Tricastin platform and management of the corresponding logistics.

Before removal to approved routes, Socatri also stores contaminated items in containers, along with vessel closure heads on behalf of the EDF Tricastin Operational Hot Unit (BCOT).

ASN considers that the safety level at Socatri is satisfactory for the year 2017 and that operational rigorousness has been reinforced.

During the last periodic safety review, the need for significant improvements to the facility had been identified and these improvements were the subject of requirements issued by ASN, or undertakings on the part of the licensee. Implementation of these actions will be completed in 2018, when the licensee is required to submit the conclusions report for its next periodic safety review.

In accordance with ASN's requirements, the licensee carried out reinforced checks in 2017 on the retention basins identified as being a priority from the safety viewpoint. In 2018, ASN will check that the licensee makes repairs to the retention basins identified by these checks as being non-conforming, without delay.

4. 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 facilities as a whole and, for each type of facility, will identify best practices and encourage their implementation on all the facilities. ASN will also continue to implement an oversight approach proportionate to the risks and detrimental effects presented by these facilities, the classification of which is presented in ASN resolution 2015-DC-0523 of 29th September 2015.

The examination of the numerous periodic safety review conclusion reports (see box p. 397) submitted in 2017, and ASN's future position statements on the continued operation of the facilities concerned are particular challenges for the coming years.

Concerning CEA

ASN will remain vigilant in ensuring compliance with its commitments, both for its facilities in service and those being decommissioned. It will issue a position statement in 2018 on CEA's decommissioning and waste management strategy.

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, Orphée, MCMF, LECA, ÉOLE-Minerve). The Rapsodie reactor is also concerned, its situation being described in chapter 15, as are the following waste treatment facilities in chapter 16: the storage area (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 active preparations. Finally, ASN will monitor the operations to prepare for the decommissioning of the Osiris, Phébus, MCMF and ÉOLE-Minerve facilities.

In 2018, ASN also intends to:
- complete the examination of the authorisation application necessary for the first experimental test with the pressurised water loop of the Cabri reactor;
- continue monitoring the construction of the RJH;
- begin examination of the substantial modification authorisation application for Masurca.

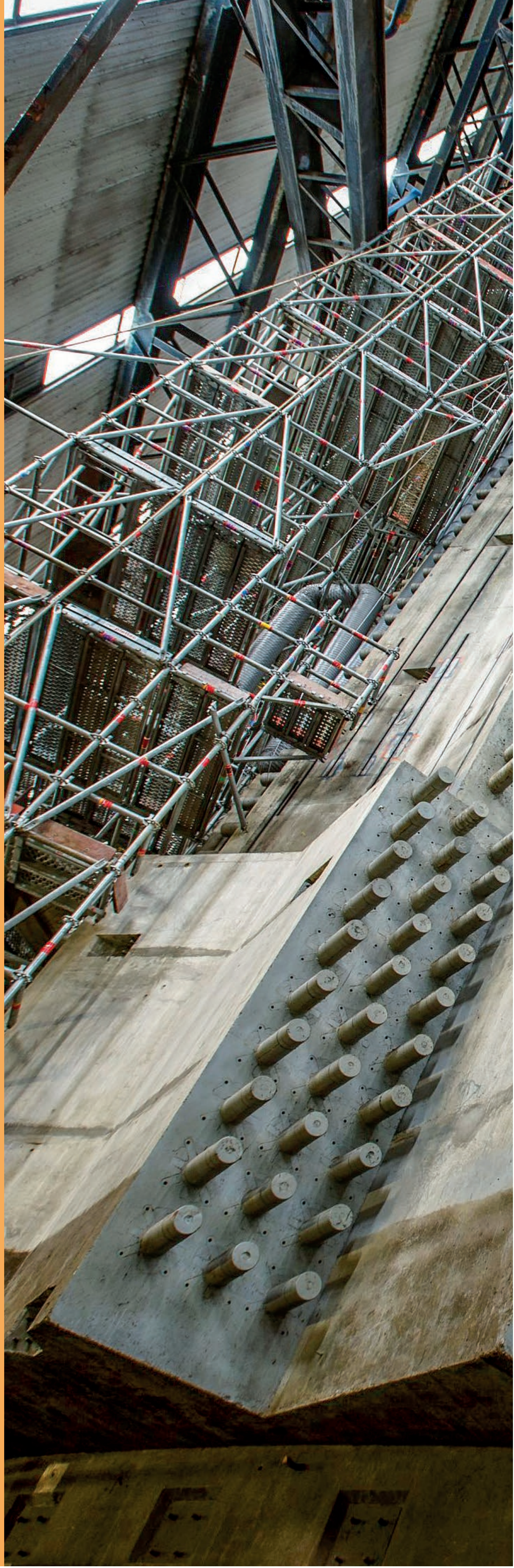
Concerning the other licensees

ASN will continue to pay particularly close attention to projects under construction, that is ITER and the Ganil extension.

ASN will remain vigilant with regard to the safety organisation put into place at Ganil and to compliance with ASN's requirements, more specifically those resulting from the last periodic safety review.

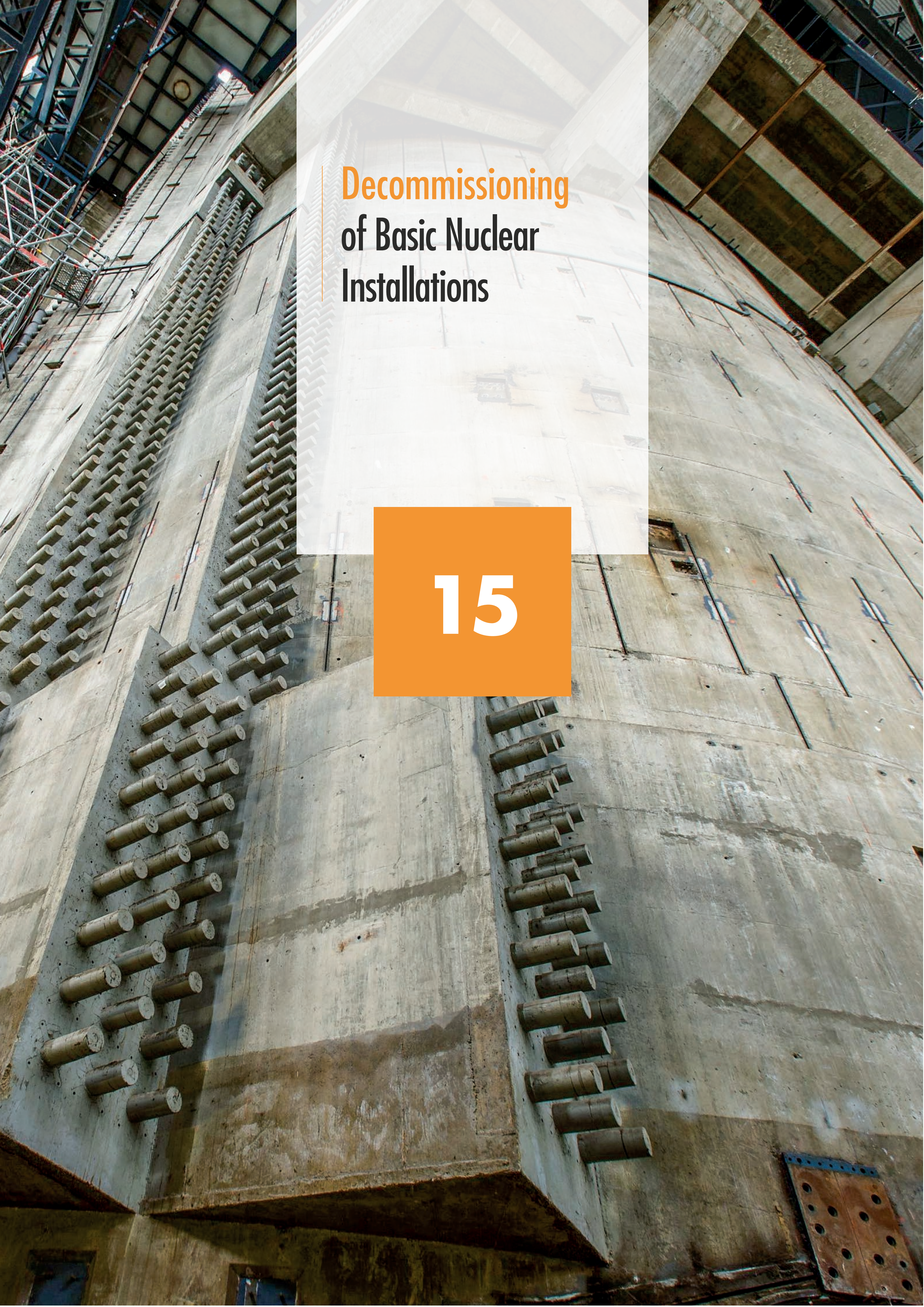
ASN will also remain vigilant with regard to the required improvements at the ILL in the management of equipment modifications, the management of periodic checks and tests and the integrated management system.

Finally, ASN will maintain its reinforced monitoring of CIS bio international in 2017 on the following subjects.
- increased operational rigour and safety culture;
- performance of the prescribed work for continued operation of the facility following its last periodic safety review;
- post-operational clean-out work on the very-high level units shut down.



Decommissioning of Basic Nuclear Installations

15



The term decommissioning covers all the technical and administrative activities carried out after the final shutdown of a nuclear installation, on completion of which the installation can be delicensed, an administrative operation which consists in removing the installation from the list of Basic Nuclear Installations (BNI). These activities include removal of the radioactive materials and waste still present in the installation and disassembly of the equipment, components and facilities used during operation. The licensee can then proceed with post-operational clean-out of the premises, remediation of the soils, and possibly the destruction of civil engineering structures. The aim of the decommissioning and Post-Operational Clean-Out (POCO) operations is to achieve a predetermined final state in which all the hazardous substances, non-radioactive substances included, have been removed from the nuclear installation.

The decommissioning of a nuclear installation is prescribed by decree issued after consulting ASN, the Nuclear Safety Authority. This phase in the life cycle of the installations is characterised by a succession of operations which are often long and costly, and produce massive amounts of waste. In the course of decommissioning, the installations undergo continuous changes which alter the nature of the risks and represent challenges for the licensees in terms of project management.

In 2017 in France, 35 nuclear installations of all types (power and research reactors, laboratories, fuel reprocessing plants, waste treatment facilities, etc.) were either shut down or undergoing decommissioning, representing more than a quarter of the BNIs in operation.

The periodic safety review conclusion reports for the majority of these installations were filed in 2017. Four decommissioning files underwent a public inquiry and were the subject of an opinion issued by the Environmental Authority of the CGEDD (General Council for the Environment and Sustainable Development), namely BNI 93 Eurodif and BNI 105 Comurhex on the Tricastin site (Areva), BNI 94 AMI Chinon (EDF) and BNI 52 ATUe at Cadarache (CEA). The examination of the decommissioning and waste management strategy files of CEA and Areva were launched jointly with ASND, the Defence Nuclear Safety Authority. EDF submitted to ASN the files supporting its change of decommissioning strategy for its Gas-Cooled Reactors (GCR) announced in 2016, and was heard by ASN on this subject. Lastly, 2017 saw the delicensing of BNI 61 LAMA (Active Materials Analysis Laboratory) in Grenoble (CEA).

1. Technical and legal framework for decommissioning

1.1 Decommissioning risks

Accomplishing the decommissioning operations – which are often long and costly – within the set time frames is a challenge for the licensees in terms of project management, skills maintenance and the coordination of the various operations which involve numerous specialist companies. Decommissioning is effectively characterised by a succession of operations rather than a production state, and therefore by changing risks. The nuclear risks generally decrease as decommissioning proceeds, but the work involved, sometimes carried out very close to the radioactive substances, present serious radiation protection implications for the workers. Other risks increase such as the risks of dispersion of radioactive substances into the environment or certain more "conventional" risks such as falling objects when handling large components on worksites situated at height, fires or burns during hot work in the presence of combustible materials, anoxia when working in confined areas, instability of partially dismantled structures, chemical risks during decontamination operations, etc.

One of the major challenges in the decommissioning of an installation lies in the very large volumes of waste produced compared with the operational waste, and the scale and associated difficulties must be assessed as early as possible in the life of the installation (from the design stage if possible) in order to ensure safe decommissioning in as short a time frame as possible.

Smooth running of the decommissioning operations is thus governed by the availability of appropriate management routes for all the types of waste likely to be produced. When the availability of the final waste disposal outlets on the stated dates is called into question, the licensees must, with due caution, organise the facilities necessary for the interim storage of their waste pending opening of the corresponding disposal route. This point moreover forms the subject of provisions in the Decree of 23rd February 2017 establishing the provisions of the French National Radioactive Material and Waste Management Plan (PNGMDR) 2016-2018 (see chapter 16).

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 decommissioning strategies and the waste management strategies established by EDF, Areva and CEA. ASN conducted an overall assessment of the EDF strategy in 2015 and after the change of strategy announced by EDF in 2016, ASN asked the company to provide justifications for this change (see point 2.1.4). The files submitted by Areva and the CEA in 2016 are currently being assessed and ASN will give its opinions on them in 2018.

Furthermore, the decommissioning of the old installations of the CEA and the first-generation plants of Areva (especially the plants that played a role in the French deterrence policy, such as the gaseous diffusion plants of the Pierrelatte Defence Basic Nuclear Installation (DBNI) at Tricastin and the UP1 plant of the Marcoule DBNI) is going to produce extremely large quantities of Very Low Level (VLL) waste. This massive production of waste, which was not anticipated during the installation operating phases and which is incompatible with the current capacities of the VLL disposal route, was addressed by a PNGMDR working group resulting in several lines of reflection relative to the possible recycling or on-site storage of this waste (see chapter 16).

The French policy for the management of very low level radioactive waste does not provide for release thresholds, but requires that it be managed via a specific route to guarantee its isolation and traceability. This policy is based on the waste zoning of the installations, which has often been established conservatively by the licensees for operational reasons and has been partly responsible for the difficulties mentioned during the work of the abovementioned working group. Nevertheless, this work conducted in collaboration with the licensees and stakeholders, shows that the French waste management policy with no release threshold remains appropriate for the decommissioning needs, even if some aspects could be further improved. More specifically, the operations that generate very large volumes of VLL waste are now examined at a very early stage (this is the case for BNI 93 Eurodif, see point 2.3.3). Furthermore, points of application have been detailed in ASN Guides No. 6, 14 and 24 published in 2016, enabling the particular situations of certain installations to be taken into account (massive objects, for example).

1.2 The ASN doctrine concerning decommissioning

1.2.1 Immediate dismantling

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.

In 2014, the International Atomic Energy Agency (IAEA) 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.

Today, in accordance with IAEA recommendations, French policy aims to ensure that BNI licensees adopt an immediate dismantling strategy.

This principle now figures in the regulations applicable to BNIs (Order of 7th February 2012 setting the general rules relative to basic nuclear installations). It has been included in the doctrine established by ASN for BNI decommissioning and delicensing since 2009 and has been taken up at legislative level in Act 2015-992 of 17th August 2015 relative to Energy Transition for Green Growth. 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.

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 and sends the decommissioning application file before it stops operating the installation.
- The decommissioning operations are carried out "in as short a time as possible" after shutting down the installation, a time frame 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 or deposition phenomena, and any migrations of contamination in the structures of the installation premises or even 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. 7-2012 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 doctrine 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 reasonably possible. ASN therefore considers that the defining of thresholds cannot be envisaged. More specifically, achieving a threshold with exposure leading to an effective annual dose of 300 microsieverts for the public (i.e. one third of the annual dose limit of 1 millisievert for the public) is only acceptable after demonstrating the integration of an optimisation process, in accordance with the IAEA texts on the unconditional release of a site contaminated by radioactive substances.

In 2016, ASN thus updated and published a technical guide relative to structure clean-out operations (Guide No. 14, available on *www.asn.fr*). The provisions of this Guide have already been implemented on numerous installations with diverse characteristics, such as research reactors, laboratories, fuel manufacturing plant, etc. ASN also published in 2016 a guide relative to the management of polluted soils in nuclear installations (Guide No. 24, available on *www.asn.fr*).

1.3 Decommissioning regulatory framework

Once a BNI is definitively shut down, it must be decommissioned and therefore the end-purpose for which its creation was authorised changes since 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.

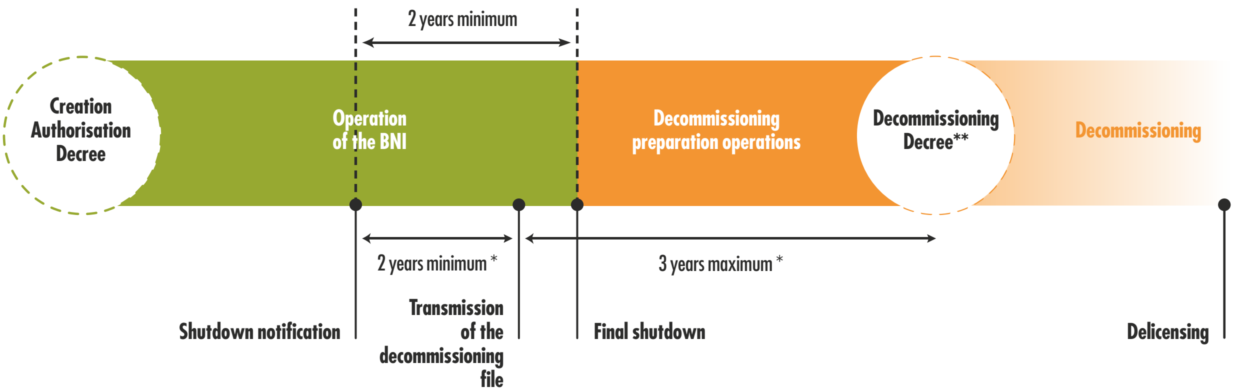
Given the fact that installation decommissioning operations are often very long, the decommissioning decree can stipulate that a number of steps will, when the time comes, be subject to prior approval of ASN on the basis of specific safety analysis files.

The Diagram below illustrates the corresponding regulatory procedure.

The licensee must prove in its decommissioning file that the decommissioning operations will be carried out in as short a time frame 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.

PHASES in the life of a BNI



** Deadline extendable by 2 years in certain cases*
*** The decommissioning decree takes effect on the date ASN approves the revision of the general operating rules and no later than one year after publication of the decree*

ASN shall be attentive to ensuring that the licensee remains compliant with its operating baseline requirements until the decree authorising it to perform the major decommissioning operations is issued. ASN recommends that the licensee inform the Local Information Committee (CLI) of the planned work 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 directed 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, and at least every 10 years. ASN's objective with these safety reviews is to ascertain that the installation complies with the provisions of its decommissioning decree and the associated safety and radiation protection requirements through to its delicensing by applying the principles of defence in depth specific to nuclear safety.

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 delicencing application, the licensee must, among other things, provide a file containing a description of the state of the site after decommissioning (analysis of the state of the soils, remaining buildings or facilities, etc.) and demonstrating that the planned final state has been reached. 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 relative to securing the funding of the nuclear costs and by the Order of 21st March 2007 relative to securing the funding 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 on these costs 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 the necessary measures should it be found to be insufficient or inappropriate. Whatever the case may be, 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 Retrieving 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 1) an analysis of the options that could be reasonably envisaged for the operation, 2) a conservative choice of a reference strategy, 3) consideration of residual technical uncertainties and performance contingencies, and 4) 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 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 of the same Decree.

1.4.2 Review of the reports submitted by the licensees

On 8th June 2017, ASN gave the DGEC its opinion on the three-yearly reports concerning the securing of provisions to cover the long-term financial costs.

As in the previous years, ASN underlines the lack of details in the EDF report, making it impossible for ASN to adopt a position on the completeness of the financial costs evaluation.

ASN recommends that the licensees evaluate the cost of cleaning out the civil engineering structures and the soils, as few licensees take them into account in their cost evaluation.

ASN also recommends that third-party audits be carried out on the sums provisioned for the management of spent fuel from the EDF facilities and management of the repackaging of legacy waste from the Areva plant in La Hague and for its decommissioning.

Lastly, the BNI licensees duly transmitted the three-yearly report update notices during 2017. These notices are currently being examined.

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 on their installations, including those undergoing decommissioning.

With regard to EDF, the stress test reports for the BNIs undergoing decommissioning (Bugey 1, Chinon A1, A2 and A3, Saint-Laurent-des-Eaux A1 and A2, 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 (GCRs), and the flood risk in the GCRs. The first answers from EDF were examined in 2016, while those still to be received will be examined as part of the periodic safety reviews of the GCR installations.

With regard to the CEA installations, the Plutonium Technology Facility (ATPu) (Cadarache) currently undergoing decommissioning was the subject of the ASN resolution 2012-DC-0296 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. The quantities of material have greatly decreased in the last few years with the decommissioning and material removal operations.

ASN resolution 2012-DC-0293 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 which aim to reinforce the robustness of the installation against extreme situations, notably by establishing a "hardened safety core". ASN resolution 2015-DC-0480 of 8th January 2015 also sets additional stipulations specifying the requirements applicable to the "hardened safety core" of the Phénix reactor and the management of emergency situations. In 2017, ASN examined the licensee's study of the flood risk in the event of beyond design-basis rainfall, which should be supplemented in 2018, and authorised the licensee to put in place information transfer from the NPP to the emergency centre of the Marcoule site.

ASN has not issued requirements for the Rapsodie reactor (Cadarache), for which the stress test report was issued on 13th September 2012. Nevertheless, at the request of ASN, the CEA has studied the scenario of a sodium-water reaction induced by rainfall occurring after an extreme earthquake causing devastation of the BNI buildings. ASN considered there was no need to establish additional requirements if the sodium tanks were removed to the Phénix BNI 71 at Marcoule for treatment before the end of 2018. This end-of-removal deadline was stipulated by ASN resolution CODEP-CLG-2017-0222587 adopted on 8th June 2017.

The stress test 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, provided that the quantity of radioactive substances present in the installation was reduced in the short term.

Lastly, with regard to the Areva facilities, after discovering the inadequate earthquake resistance of the Donzére-Montdragon Canal embankment, the systems to mitigate the consequences of a toxic discharge in case of flooding at the Comurhex facility (BNI 105) have been reinforced so that they fulfil their functions in the event of an earthquake (see box in chapter 13, page 381).

On the La Hague site, the licensee has put in place provisions to extinguish a fire following an earthquake of the "hardened safety core" design standards in silo 130 and examined their potential deployment in silo 115. ASN will monitor performance of the work to protect silo 115 in 2018.

The experience feedback from the Fukushima Daiichi accident for the facilities presenting lower risks will be assessed by ASN later on, more specifically during the next periodic safety reviews of the Procédé and Support BNIs (Fontenay-aux-Roses).

The stress tests are not applicable to installations in which decommissioning has reached a stage where such studies would not be justified, or to installations very close to delicensing whose potential source term is very low.

1.6 The international action of ASN in the area of decommissioning

ASN participated in various international initiatives relating to decommissioning in 2017.

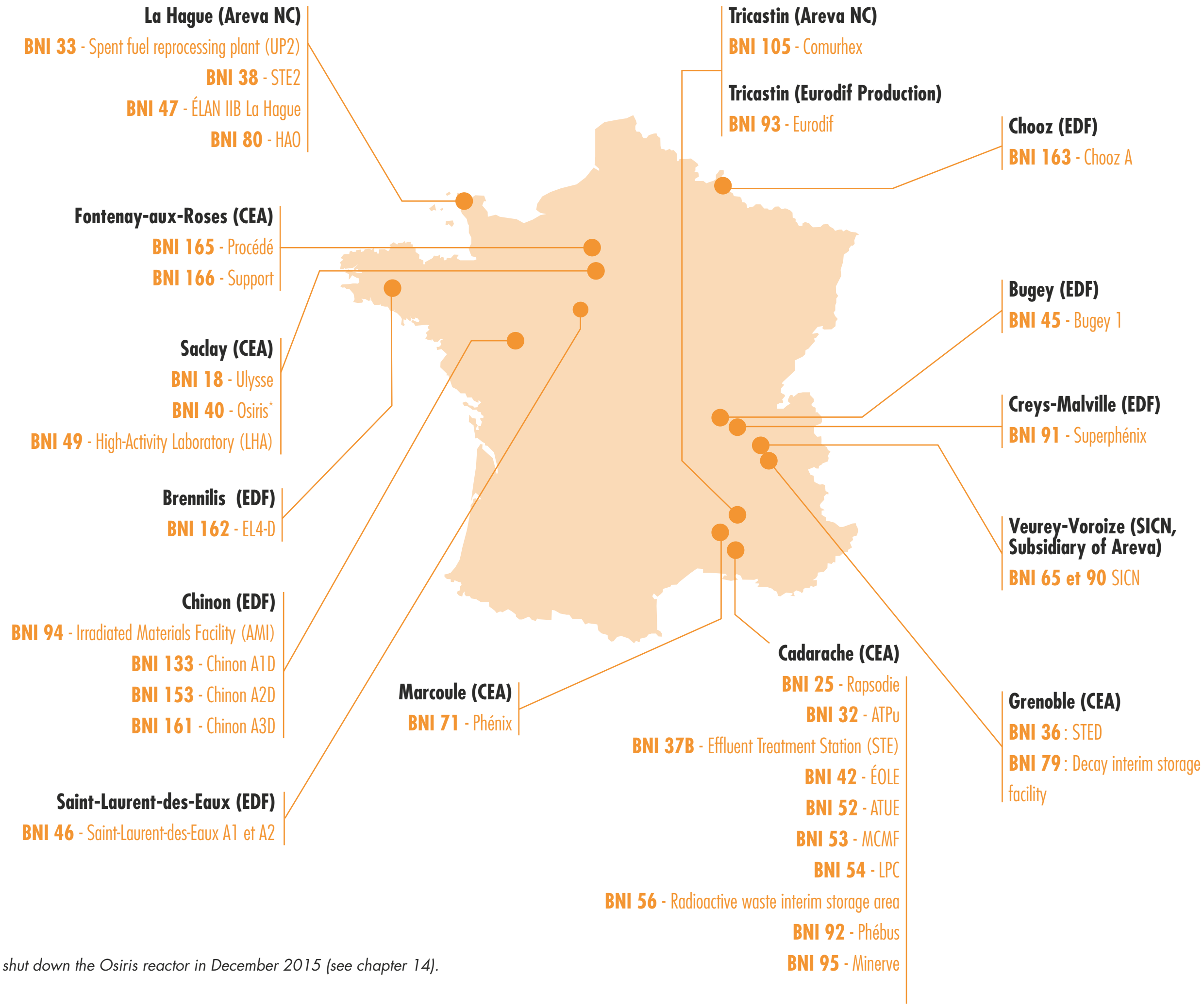
It is involved more specifically in the multilateral work of WENRA (Western European Nuclear Regulators Association), the IAEA and the NEA (Nuclear Energy Agency).

ASN takes part in bilateral exchanges between safety Authorities on subjects relating to decommissioning and legacy situations (particularly the retrieval and packaging of legacy waste and polluted sites and soils), the scale of which is growing on the international scene. In 2017, ASN had exchanges more specifically with the NRC (Nuclear Regulatory Commission, United States), the NRA (Nuclear Regulation Authority, Japan) and the ONR (Office for Nuclear Regulation, United Kingdom). A joint visit by ASN-ASND to the main facilities in question (silos, pools) on the Sellafield site in the United Kingdom took place in April 2017, while the ONR visited facilities on the DBNI of Marcoule (spent fuel reprocessing plant UP1, APM pilot unit at Marcoule, etc.) in May 2017, leading to fruitful discussions on the monitoring and verification of the progress of decommissioning projects and on decommissioning preparation work. The three regulators have regular audioconferences on these subjects. A visit to La Hague addressing the same theme is planned in April 2018

2. Situation of nuclear installations undergoing decommissioning

Thirty five nuclear installations in France are definitively shut down or undergoing decommissioning. It is planned to shut down some ten more installations in the coming years (see map on following page).

INSTALLATIONS definitively shut down or in the process of decommissioning as at 31st December 2017



** The CEA shut down the Osiris reactor in December 2015 (see chapter 14).*

FUNDAMENTALS

Technical difficulties associated with the decommissioning of the Gas-Cooled Reactors (GCR)

The EDF GCRs, which have been shut down for several decades, were designed and built in accordance with the safety requirements of the time. They were not built to function over a very long time scale.

Nowadays, the most significant safety issues concern:
- the behaviour of the reactor pressure vessels in the event of an earthquake;
- the resistance of the internal structures that support the graphite bricks of the "integrated" reactors, in normal and earthquake situations.

Several factors can effectively call into question the resistance of the reactor, such as the ageing of materials (anti-seismic pads) or the corrosion of steel structures.

The behaviour of EDF's gas-cooled reactors had been considered acceptable from an immediate dismantling viewpoint, which might not be the case with deferred dismantling.

In 2017, EDF submitted the files to justify the change of strategy proposed in 2016 and to make safe the reactors whose decommissioning is deferred.

The reasons put forward by EDF for its change of strategy concern difficulties in maintaining the leak-tightness of the reactor pressure vessel when decommissioning under water, and in treating large quantities of effluents. The improvements in remotely-operated handling equipment mean that it is now possible to carry out dismantling "in air" from a distance, reducing the radiation protection problems. The lack of a disposal route for the low-level long-lived graphite waste from the GCRs is a problem. The first file sent to ASN in March 2017 put these difficulties into the balance for the change of strategy. A second file was sent to ASN at the end of 2017 to demonstrate that it is possible to make these reactors safe for long periods of time. These two files will undergo an in-depth technical examination in 2018 and ASN will adopt a position on the matter as of 2019.

2.1 EDF nuclear installations

2.1.1 The decommissioning strategy of EDF

The first decommissioning strategy for definitively shut down EDF reactors was transmitted in 2001 at the request of ASN. This strategy has been updated regularly, for example, to adjust the decommissioning schedule or incorporate the complementary studies requested by ASN and elements concerning the future decommissioning of the reactor fleet in service. These updates did not call into question either the decommissioning scenarios or the pace of decommissioning. In March 2016, EDF informed ASN of a complete change in strategy for its Gas-Cooled Reactors (GCRs) which pushes back their decommissioning by several decades. With this new strategy, EDF wants to start with complete decommissioning of the Chinon A2 reactor pressure vessel "in air", without filling it with water as was initially planned for the Bugey 1, Saint-Laurent-des-Eaux A1 and A2 and Chinon A3, then to decommission the other reactors, also "in air".

ASN heard EDF on this strategy in June 2016 and asked that the files justifying this change be submitted to it in order verify that the new strategy meets the regulatory requirements obliging the decommissioning of nuclear installations in the shortest times possible. EDF submitted the requested files to ASN in March and December 2017. ASN will examine these files in 2018, with a view to adopting a position in 2019. ASN also inspected EDF on this subject in December 2017. This inspection shows that the process applied for the "under water" decommissioning of Bugey was rigorous and effectively took into account the questions of nuclear safety and radiation protection. The inspectors found that the decision to change strategy seems to result primarily from project management difficulties (costs, technical aspects, control of project risks).

On the other hand, the decommissioning strategy for the other reactors, namely Brennilis, Chooz A and Creys-Malville, has not been significantly modified.

2.1.2 The Brennilis NPP

The Brennilis NPP on the Monts d'Arrée site (BNI 162), called EL4-D, is an industrial prototype heavy water moderator nuclear power reactor cooled with carbon dioxide which was definitively shut down in 1985. EDF has been the nuclear operator of this installation since 2000. 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.). The Decree of 27th July 2011 authorised part of the decommissioning operations with the exception of reactor block decommissioning. The Decree of 16th November 2016, issued after consulting ASN, extended the time frame for carrying out the decommissioning operations authorised by the Decree of 27th July 2011, and more specifically:
- decommissioning of the heat exchangers;
- clean-out and demolition of the effluent treatment station.

These operations are to be completed before 28th July 2018.

During 2017, EDF continued firstly the operations to clean and rehabilitate the equipment present in the reactor containment following the September 2015 fire on the heat exchanger decommissioning worksite, and secondly decommissioning of the effluent treatment station.

In 2018, the major issues involved are associated with completion of decommissioning of the heat exchangers and the effluent treatment station, including remediation of the soils situated beneath this building, and performance of the periodic safety review, the conclusions of which shall be submitted at the end of 2018.

Furthermore, ASN resolution CODEP-CLG-2017 of 21st August 2017 makes it necessary to obtain the prior consent of ASN before taking samples from the Brennilis reactor block.

The Decree of 16th November 2016 stipulates that EDF must submit a complete decommissioning file for the installation before 31st July 2018. ASN shall start examining this file in 2018.

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ASN is preparing for the decommissioning of the Pressurised Water Reactors (PWR) and Fessenheim in particular.

In 2017, Decree 2017-508 of 8th April 2017 repealing the license to operate the Fessenheim NPP, makes this repeal conditional on commissioning of the Flamanville 3 EPR reactor, insofar as this repeal would be necessary to avoid exceeding the authorised maximum total production capacity for nuclear-generated electricity, set at 63.2 gigawatts by the Energy Code

EDF is therefore preparing to definitively shut down the two Fessenheim reactors should the above conditions be satisfied.

The final shutdown notification provided for in Article L. 593-26 of the Environment Code has not yet been sent for the Fessenheim reactors.

ASN has nevertheless continued discussions with EDF on the in-service reactor decommissioning files, particularly regarding the applicable administrative procedures and the preparatory operations to be carried out before the decommissioning decree is obtained.
Coordination between the various ASN and EDF departments is effectively necessary to control the interim period between final shutdown and decommissioning of the reactors, so that their decommissioning can be carried out in the shortest time possible as required by law in Article L. 593-25 of the Environment Code.

2.1.3 The Gas-Cooled Reactors

Bugey 1, Chinon A1, A2 and A3, Saint-Laurent-des-Eaux A1 and A2 constitute the Gas-Cooled Reactors (GCR). These first-generation reactors functioned with natural uranium as the fuel and graphite as the moderator. They were cooled by gas.

There are two types of GCR: "integrated" reactors, whose heat exchangers are situated beneath the reactor core inside the pressure vessel, and "non-integrated" reactors whose heat exchangers are situated on either side of the reactor pressure vessel.

Bugey 1 reactor (BNI 45)

The Bugey 1 reactor is an "integrated" GCR. Complete decommissioning of the installation, for which final shutdown became effective in 1994, was authorised by Decree of 18th November 2008. The corresponding scenario involved decommissioning the reactor pressure vessel "under water". If the change of scenario envisaged by EDF ("in air" instead of "under water") is accepted, a new decree will be necessary: the Bugey 1 reactor was to be the first EDF reactor of the GCR type to be decommissioned, but EDF wants to change decommissioning strategy, which will push back the end of decommissioning of the Bugey 1 reactor by about fifty years with respect to the initially prescribed date. ASN is examining EDF's new strategy for the decommissioning of its gas-cooled reactors (see point 2.1.1).

ASN considers that the current decommissioning work on the Bugey 1 reactor is proceeding with a satisfactory level of safety over the short term. However, the event in 2107 where a package fell during handling shows that EDF must be particularly attentive to the handling of components and packages.

In 2017, EDF did not resubmit its file concerning the operations to extract operational waste from the reactor pressure vessel, in which radiation protection was to be explicitly taken into account. During its inspection of the head office departments on 14th December 2017, ASN asked EDF to provide justifications for this postponement.

In 2017, ASN examined the periodic safety review guidance file for Bugey 1, for which the conclusions report must be submitted before the end of 2018. The main demands of ASN concern the ageing of the structures and their behaviour over time, and the behaviour of the reactor pressure vessel with respect to seismic stresses.

Chinon A1, A2 and A3 reactors (BNIs 133, 153 and 161)

The Chinon A1, A2 and A3 reactors are "non-integrated" GCRs. They 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 EIG (Economic Interest Grouping) (robots and machines for intervening on accident-stricken nuclear installations).

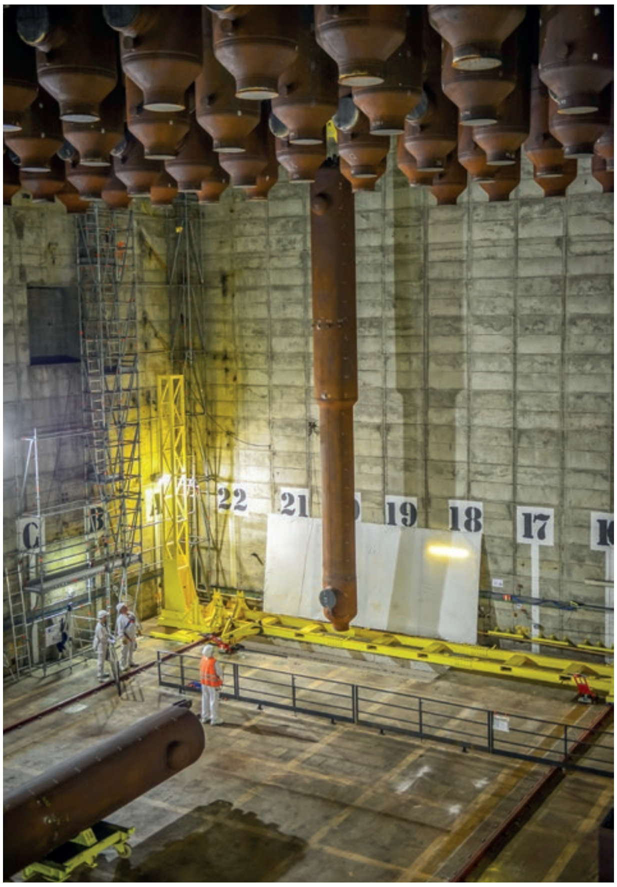
The complete decommissioning of the Chinon A3 reactor was authorised by the Decree of 18th May 2010 with an "under water" decommissioning scenario.

The change of scenario envisaged by EDF will necessitate a new decommissioning decree. This is because the Chinon A reactors were initially to be decommissioned last, whereas with the new strategy, Chinon A2 would be decommissioned first. EDF considers that the decommissioning of a "non-integrated" GCR would present fewer difficulties than that of an "integrated" GCR. ASN is currently analysing the overall acceptability of this change of strategy (see point 2.1.1).

Decommissioning of the heat exchangers (first step in the decommissioning of the facility) of the Chinon A3 reactor began several years ago and is now continuing after an interruption of several months due to the presence of asbestos.

With regard to the Chinon A2 reactor, further to the results of the first analyses of the components removed from the reactor systems, additional analyses are going to be carried out to determine the treatment strategy for this waste.

The depollution of chemically polluted soils is in progress. Groundwater monitoring has been stepped up and completion of the complementary characterisation of the gaseous discharges is planned for early 2018.



Decommissioning of the Chinon A3 heat exchangers.

ASN considers that the level of safety of the nuclear installations undergoing decommissioning on the Chinon site (Chinon A1, A2 and A3) is satisfactory over the short term.

In 2018, ASN will examine the periodic safety reviews of the Chinon A1 and Chinon A2 reactors, for which the conclusions reports were received at the end of 2017.

Saint-Laurent-des-Eaux A1 and A2 reactors (BNI 46)

Complete decommissioning of the facility, which comprises two reactors whose final shutdown was declared in 1990 and 1992 respectively, was authorised by the Decree of 18th May 2010. The prescriptions regulating the water intakes and effluent discharges are set by ASN resolutions published in 2015.

EDF wants to change decommissioning strategy, which would push back the end of decommissioning of the Saint-Laurent-des-Eaux A reactors to beyond 2100.

ASN is examining the files submitted by EDF concerning its GCR decommissioning strategy (see point 2.1.1). Pending decommissioning of the pressure vessel of the reactors, other operations are performed outside the pressure vessel or to prepare for its decommissioning.

Some worksites presenting a risk of contamination by alpha radionuclides (emptying tanks, characterising sludge, removing the source term from the Saint-Laurent-des-Eaux A2 pool) had been suspended since 2016 following the discovery of confirmed cases of internal contamination of personnel working on these sites. An operating rigour action plan was thus initiated by EDF and presented to ASN, which asked that worker training and monitoring be stepped up. ASN conducted several inspections to check that this risk had been adequately taken into account. Operations on these worksites resumed in 2017.

ASN observes improvements in the nuclear safety and radiation protection of these installations in view of the results obtained on the first worksites to have resumed their activity. ASN will ensure that EDF restarts the other worksites with similar diligence and will check implementation of the specified actions in 2018.

Lastly, in 2018 ASN will examine the periodic safety reviews of the Saint-Laurent-des-Eaux reactors A1 and A2, for which the conclusions report was received at the end of 2017.

2.1.4 Chooz A reactor

The reactor of the Ardennes NPP (BNI 163) was the first pressurised water reactor built in France. It was shut down in 1991. Its decommissioning work foreshadows the future decommissioning of pressurised water reactors, the technology of the French nuclear power reactors currently in operation.

In 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.

Decommissioning work on the reactor pressure vessel has been underway since 2016.

The licensee must be particularly attentive to the risk of internal contamination by alpha-emitting radionuclides, given the recurrent internal contamination events on the Chooz A decommissioning worksite.

With regard to nuclear safety and the environment, ASN considers that the decommissioning operations are being carried out correctly.

Lastly, in 2018 ASN will examine the periodic safety review conclusions report for the Chooz A reactor which it received at the end of 2017.

2.1.5 The Superphénix reactor and the Fuel storage facility

The Superphénix fast neutron reactor (BNI 91), a 1,200 MWe sodium-cooled industrial prototype is situated at Creys-Malville. It was definitively shut down in 1997. The reactor has been unloaded and the majority of the sodium is neutralised in concrete. Neutralisation of the remaining sodium-potassium eutectic is in progress. Superphénix is associated with another BNI, the APEC fuel storage facility (BNI 141). The APEC essentially comprises a pool containing the fuel unloaded from the reactor pressure vessel and the area for storing the soda concrete packages resulting from the neutralisation of sodium from Superphénix.

In 2017, the licensee finished neutralising the reactor pressure vessel and filling it with water prior to the decommissioning of its internal structures. The licensee also continued setting up the cutting and packaging worksites inside the reactor building.

The periodic safety review of the two facilities has been carried out. EDF sent the files and conclusions reports to ASN within the prescribed deadlines, namely end of December 2015 for BNI 141 and end of March 2016 for BNI 91. After prior discussions, ASN started the in-depth technical examination of these files in 2017. At the same time, in May 2017 the licensee sent the application file for authorisation to start decommissioning the reactor pressure vessel internal structures, corresponding to the start of the stage 2 of the Superphénix decommissioning decree, which ASN has started examining.

ASN considers that the decommissioning operations in 2017 on the whole were conducted with satisfactory safety standards. ASN did however instruct EDF to bolster its organisation for ensuring compliance with commitments and the management of deviations. ASN's inspections also revealed deficiencies in the monitoring of subcontracted activities, the management of sodium waste and the related risks, and the emergency management organisation.

2.1.6 Irradiated Material Facility

The Irradiated Material Facility (AMI), which was declared and commissioned in 1964, is situated on the Chinon nuclear site and operated by EDF. This installation (BNI 94) is not yet undergoing decommissioning even if it has stopped functioning. It was intended essentially for performing examinations and analyses and expert assessments on activated or contaminated materials from Pressurised Water Reactors (PWR).

The analysis and expert assessment activities were entirely transferred in 2015 to a new facility on the site, the Lidec (Ceidre integrated laboratory).

With decommissioning of the installation in view, the activities at AMI essentially concern decommissioning preparation operations and surveillance.

The decommissioning file was submitted in June 2013. At the end of 2014, ASN asked EDF for further information concerning the planned state of the facility in 2018 (projected time frame for publishing the decommissioning decree). This additional information was provided by the licensee in 2016 and deemed satisfactory; consequently, the decommissioning file underwent a public inquiry in early 2017 and ASN is continuing to examine it.

ASN considers that waste treatment management and in-service equipment monitoring are satisfactory. Particular attention must however be focused on operating rigour. In a context where the facility's activities are undergoing significant changes, ASN will be attentive to the management of these changes. Furthermore, the organisation of the facility changed substantially at the beginning of 2017, with internal transfer of operational operating responsibility to another of the licensee's departments. ASN will be particularly attentive to the licensee's compliance with the baseline requirements of the facility.

Lastly, in 2018 ASN will examine the periodic safety review conclusions report for the AMI, which it received in November 2017.

2.2 CEA installations

ASN and ASND (Defence Nuclear Safety Authority) have noted that the decommissioning operations and the retrieval and packaging of the CEA legacy waste are significantly behind schedule. The forecast duration of the decommissioning and legacy waste retrieval operations has been very significantly increased (about fifteen years for the Fontenay-aux-Roses installations and for the UP1 plant of the Marcoule DBNI (Defence Basic Nuclear Installation), and there is considerable lateness in the transmission of decommissioning files. Consequently, ASN and ASND asked the CEA to present in 2016 the new decommissioning strategy it envisaged for all the BNIs and individual installations situated inside DBNIs. ASN and ASND have asked the CEA to draw up decommissioning programmes for the next fifteen years based on ranked priorities of safety, radiation protection and environmental protection, taking particular account of the total potential activity of the radioactive and hazardous substances present in each installation. ASN and ASND have also asked the CEA to conduct an overall review of the CEA's radioactive material and waste management strategy. ASN and ASND have also asked the CEA to increase the human resources assigned to decommissioning operations and to the organisation of its decommissioning and waste management programmes, and to review the financial resources assigned to the decommissioning operations.

The file submitted at the end of 2016 was deemed admissible. ASN and ASND nevertheless asked for several additions to it. The ongoing examination should lead the authorities to adopt a position on this strategy in 2018.

2.2.1 The Fontenay-aux-Roses Centre

Created in 1946, the Fontenay-aux-Roses site - CEA's first research centre - is continuing to move away from nuclear activities and towards 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 Procédé installation (BNI 165) and Support installation (BNI 166)

The decommissioning of these two installations was authorised by two Decrees of 30th June 2006. The initial planned duration of the decommissioning operations was about ten years. The CEA informed ASN that, due to strong presumptions of radioactive contamination beneath one of the buildings, to unforeseen difficulties and to a change in the overall decommissioning strategy of the CEA's civil centres, the decommissioning operations would extend beyond 2030, and in June 2015 it filed an application to change the prescribed decommissioning time frames.

ASN deemed that the first versions of these files were not admissible. In 2017, the CEA undertook to provide a new more complete version of these files in 2018.

In the light of its inspections and the incidents reported in 2017, ASN considers that the standard of safety of the Fontenay-aux-Roses BNIs is improving. Nevertheless, control of the fire risk remains a major issue and there appears to be room for improvement in the emergency management organisation. ASN will closely monitor the CEA's commitments in terms of manpower and training in these two areas.

ASN also considers that the reorganisation of the centre has led to job vacancies. This has caused delays in the revising of the on-site emergency plan, which has still not been completed, and in the files currently being examined (decommissioning and post-operational clean-out files). ASN expects the licensee to be more responsive.

Lastly, the high-level effluents from the Circé facility in BNI 166 have been duly removed.

The periodic safety review of the two facilities has been completed and the CEA sent the files and conclusions reports to ASN at the end of 2017. ASN will examine these reports in 2018, along with the submitted decommissioning authorisation modification application files.

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, that of the Siloé reactor in January 2015 and that of the LAMA in 2017.

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 2017.

Radioactive Effluent and Solid Waste Treatment Station (STED) and Decay Storage Facility (BNIs 36 and 79)

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 Decree. The main operations still to be carried out concern decontamination of the soil.

The technical discussions between ASN and CEA concerning the radiological and chemical remediation of the soil of the STED continued in 2017. All the operations technically achievable at an economically acceptable cost have been carried out and should lead to the establishing of Active Institutional Controls (AIC). Once the AICs are established, the licensee shall submit a delicensing application for the installation to ASN.

Storage of uranium-bearing substances and waste pending transfer to area 79 of the Comurhex plant at Tricastin.

Active Material Analysis Laboratory (LAMA) (BNI 61)

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.

In accordance with the provisions of this Decree, CEA carried out the decommissioning of BNI 61 (LAMA) from 2008 to 2015.

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Delicensing of the LAMA

The CEA sent ASN a delicensing application for the Active Materials Analysis Laboratory (LAMA, BNI 61) in March 2015. ASN sent the CEA a request for additional information in March 2016 in order to clarify certain points. The CEA transmitted the additional information between March and June 2016. On the basis of its inspections and its analysis of the elements provided by the licensee, ASN considered that the LAMA had been properly decommissioned and the set objectives had been met. The decommissioning and post-operational clean-out work has reduced the radioactivity-related risks to a very low level. The final state attained on completion of decommissioning prevents public health and safety risks and ensures the protection of nature and the environment. In view of the very low radiological impact of the site, it was not deemed necessary to implement active institutional controls.

In July 2016 ASN asked the Isère département Prefect's Office, the 18 municipalities concerned and the CLI for their opinion on the delicensing application for BNI 61. Six municipalities gave favourable opinions in the consultation on the facility delicensing application. The other 12 municipalities did not respond. The CLI deemed that the lack of a response within the allotted time constituted a favourable opinion.

ASN therefore prepared the draft resolution for delicensing the BNI. The draft resolution and the licensee's file were made available for public consultation in March 2017. The draft resolution was then approved and ASN finally delicensed BNI 61 by a resolution of 24th August 2017. This resolution was approved in September 2017.

The CEA sent ASN a delicensing application for the installation in 2015.

Considering the clean-out objectives to have been achieved, ASN delicensed the LAMA on 24th August 2017 after consulting the stakeholders.

2.2.3 The Cadarache Centre installations undergoing decommissioning

Rapsodie reactor and Fuel Assembly Shearing Laboratory (LDAC) (BNI 25)

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, the sodium-containing waste was transferred at the end of 2016 to the Phénix installation (BNI 71) on the Marcoule site for treatment. At present 2.5 tonnes of sodium are still in storage and must be transferred to the Phénix installation by the end of 2018.

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. The Environmental Authority of the CGEDD gave its opinion on the file in August 2017. Examination of these files will continue in 2018 with, among other things, a public inquiry.

The operations carried out by the CEA at present mainly involve removing waste containing sodium. These operations are 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. The licensee is currently decommissioning the LDAC cells and making good progress. Final clean-out is included in the decommissioning project for the entire BNI.

ASN considers that the CEA must improve the quality of the analyses furnished for the decommissioning of Rapsodie and prepare its responses more promptly. ASN will finish examining the decommissioning decree in 2018 and will be attentive to the completion of removal of the sodium-containing waste.

Enriched Uranium Processing Facilities (ATUEs) (BNI 52)

Until 1995, the ATUEs converted uranium hexafluoride from the enrichment plants into sinterable oxide (UF_6), and ensured the chemical reprocessing of waste from the manufacture of fuel elements. The facility included an incinerator for slightly contaminated organic liquids. 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 observing that the decommissioning operations had stopped and that CEA had not applied for a new authorisation with a view to completing decommissioning as requested by ASN, ASN gave the CEA formal notice on 6th June 2013 to submit a new file. In February 2014 CEA submitted a new application for authorisation to complete the decommissioning and clean-out operations. The technical examination continued in 2017 with, among other things, a public inquiry in the first quarter.

ASN observed that the licensee has met the commitments made in 2016, particularly regarding the upgrading of the last containment barrier, which is the building, and the management of the slightly contaminated soils outside the buildings.

Lastly, the periodic safety review has been carried out and the CEA submitted its conclusions report to ASN within the prescribed time at the end of 2017.

ASN will examine the periodic safety review in 2018 and complete the technical examination of the decommissioning authorisation modification application.

The Plutonium Technology Facility (ATPu) (BNI 32) and the Chemical Purification Laboratory (LPC) (BNI 54)

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.

Since 1994 Areva NC had been the industrial operator responsible for operation of the facilities and for their decommissioning until CEA took over this latter activity completely in early January 2017.

The year 2017 enabled the CEA to take ownership of the facilities, redefine the contracts with outside contractors and continue removing waste resulting from the operations carried out in 2016.

With regard to the cryogenic treatment unit for plutonium-bearing waste, the decommissioning operations authorised by ASN in 2011 resumed in the second half of 2017.

ASN will remain attentive to the organisational situation of these two BNIs in 2018, due to the resuming of decommissioning activities by the CEA, and will ensure that the decommissioning operations continue.

2.2.4 The Saclay Centre installations undergoing decommissioning

The decommissioning operations carried out on the Saclay 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 for Protection of the Environment), 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) (BNI 49)

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 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 cell clean-out operations continued in 2017, with dismantling of the Totem shielded line in particular.

ASN's inspections have found improvements in the management of the waste storage areas, but particular attention must be focused on the management of waste in general.

ASN also evidenced the need for the last filtration level manifolds to function during the future work. Dismantling of these manifolds has therefore been postponed.

Lastly, the treatment of the radioactive contamination of the soils in certain interior courtyards will not be able to be carried out before the 18th September 2018 deadline set by the LHA decommissioning authorisation decree. The licensee must produce a deadline modification file. In 2018, ASN will be attentive to the justification for pushing back this deadline and to the future operations schedule.

ASN considers that the level of safety of BNI 49 undergoing decommissioning is satisfactory.

Ulysse reactor (BNI 18)

Ulysse was the first French university reactor. The facility has been definitively shut down since February 2007 and has contained 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 presenting limited safety risks.

Following the ASN authorisation granted in early 2017, the cutting up of the concrete reactor block – the final stage in the nuclear worksites – began in July 2017. Some one hundred concrete blocks resulting from the cutting up will be removed in accordance with the provisions of the file for the clean-out of the structures and soils, for which the authorisation was delivered on 4th September 2017.

In 2018, ASN will monitor these removal operations and examine the modification application relative to the conventional decommissioning of the pool, following the discovery of a lens of water (small quantity coming from perched water tables) behind one of the pool walls.

ASN will be attentive to compliance with the decommissioning deadline of August 2019.

2.2.5 The Marcoule Centre installations undergoing decommissioning

Phénix NPP (BNI 71)

The Phénix reactor, built and operated by CEA and EDF, is a sodium-cooled fast neutron-breeder reactor demonstrator. Phénix was a research-dedicated power reactor with an electrical power of 250 MWe. It was definitively shut down in 2009. The Decree of 2nd June 2016 instructed the CEA to proceed with the decommissioning operations.

In 2017, the licensee continued the withdrawal of fuel from the core under liquid sodium, the removal of the large components (pumps, heat exchangers) and the construction of the NOAH building. NOAH is dedicated to the neutralisation of the sodium from Phénix and other CEA facilities prior to discharge. The licensee has also undertaken a renovation of the NPP fire detection and alarm system and has asked ASN for authorisation to build airlocks for accessing the main buildings, in accordance with the instructions of the decommissioning decree.

The inspections carried out by ASN in 2017 on control of the fire risk, the transport of radioactive substances and the monitoring of pressure equipment, revealed no particular problems.

2.3 Areva installations

2.3.1 The decommissioning strategy of Areva

Decommissioning the old installations is a major challenge for Areva, which has to manage several large-scale decommissioning projects (UP2-400 facility at La Hague, Eurodif Production plant, individual facilities of the DBNI at Pierrelatte, etc.). Furthermore, the decommissioning preparation or actual decommissioning operations may necessitate the removal of the operational waste that is still present in the installation. In some cases, especially with the old waste storage facilities on the La Hague site, specific legacy waste retrieval and packaging operations must be carried out.

In June 2016, at the request of ASN and ASND, Areva transmitted its 10-year decommissioning strategy for the installations for which it is the licensee. This file, for which additional elements were received in 2017, is currently being reviewed. The last review of Areva's waste management strategy dates back to 2005 and only focused on Areva NC La Hague. ASN will rule on the Areva group's strategy in 2018, and in particular on its application to the La Hague and Tricastin sites.

2.3.2 The UP2-400 spent fuel reprocessing plant and associated facilities

Commissioned in 1996, the former UP2-400 facility (BNI 33) has been in final shutdown state since 1st January 2004. Final shutdown also concerned three BNIs associated with the UP2-400 facility (see chapter 13, point 1.2.1): BNI 38 (STE2 facility and AT1 plant), BNI 47 (ÉLAN IIB facility) and BNI 80 (HAO facility). The ongoing operations in the four BNIs concern waste retrieval and packaging and decommissioning.

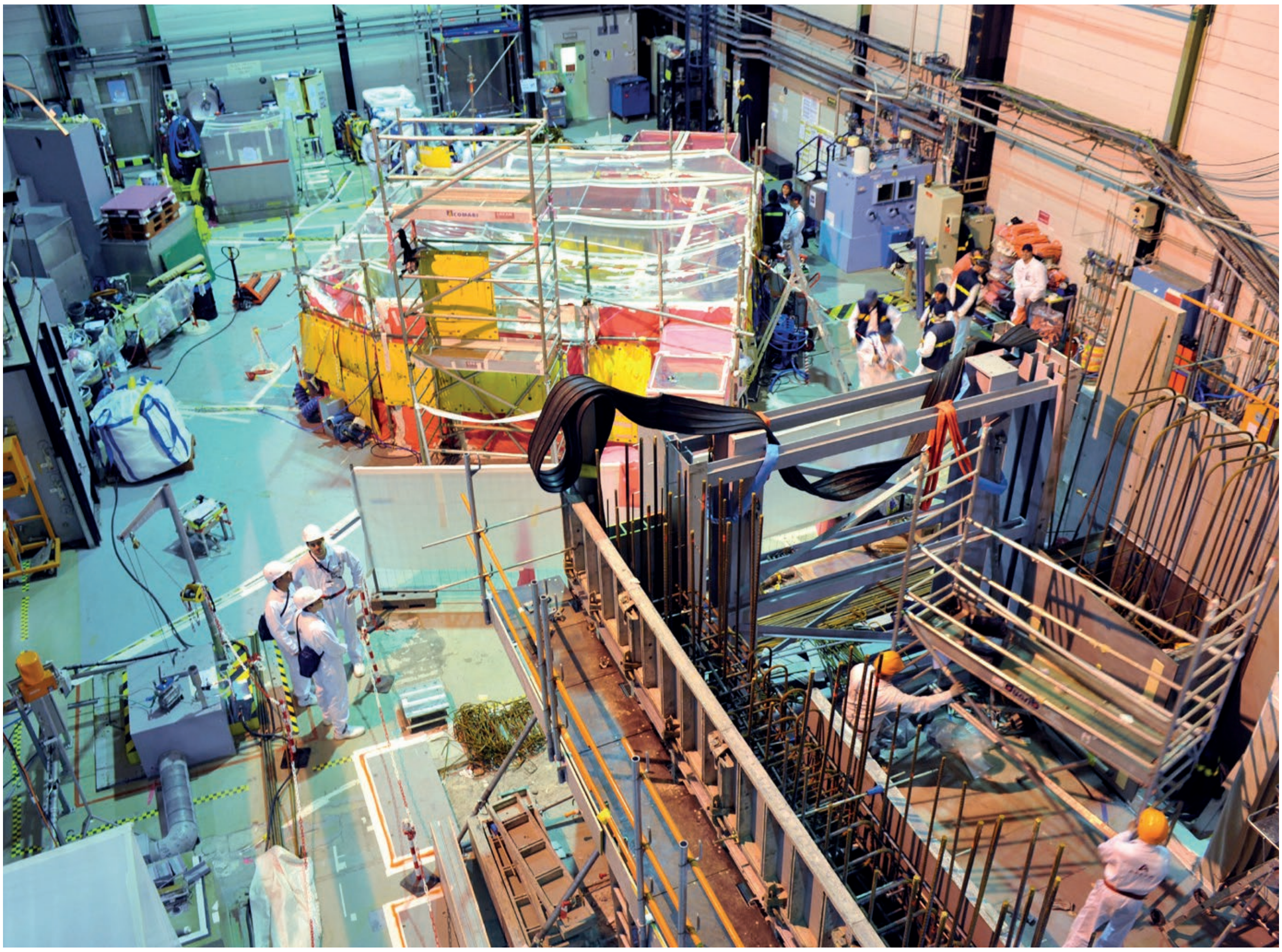
Retrieval and packaging of legacy waste (RCD)

Unlike the waste produced by the new UP2-800 and UP3-A plants at La Hague that is packaged directly on-line, most of the waste produced by the first UP2-400 plant was stored in bulk without any final packaging. The operations involved in retrieving 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 retrieval 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 retrieval 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 retrieval of legacy waste from the La Hague site therefore presents major concerns for nuclear safety and radiation protection which ASN monitors with particular attention. Furthermore, retrieval 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) at the beginning of the 1990s.

Over the years, retrieval of this waste has fallen considerably behind the initial schedule and continued to do so in recent years. ASN considers that the deadlines can no longer be pushed back given that the buildings in which this legacy waste is stored are ageing and no longer comply with current safety standards. ASN considers in particular that Areva NC must recover the legacy waste produced by operation of the UP2-400 facility as rapidly as possible, and more specifically the sludges stored in the STE2 silos, the waste from the HAO facility and silo 130 and the fission products solutions stored in the SPF2 unit.

Disposal routes or new interim storage facilities must be definitively decided upon, 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 medium-level long-lived waste produced before 2015 must package it by 2030 at the latest (see the video on the *Rules for recovery*



Decommissioning work on the slab of the HAO South facility silo of the UP2-400 plant. Areva spent fuel reprocessing plant on the La Hague site.

and packaging of legacy waste at La Hague on the ASN website, *www.asn.fr*).

ASN issued prescriptions regarding all the legacy waste recovery and packaging programmes in resolution 2014-DC-0472 of 9th December 2014. This resolution defines the priorities regarding the safety of waste retrieval and packaging operations and sets milestones for each of the programmes concerned. At the end of 2016 ASN also carried out an in-depth inspection of the waste retrieval and packaging projects.

STE2 sludges

The scenario presented in 2010 concerning the recovery and packaging of STE2 sludges is split into three steps:
- recovery of sludges stored in silos in STE2 (BNI 38);
- transfer and treatment by drying and compacting in STE3 (BNI 118);
- packaging of the pellets obtained into C5 packages for deep geological disposal.

ASN authorised the first phase of recovery of the STE2 sludges in 2015. During 2017, Areva NC provided additional elements relating to the first phase of the works, along with an authorisation application concerning the procedure for recovering the sludges from STE2 and transferring them to STE3. This file is currently being examined.

The Creation Authorisation Decree for the STE3 effluents treatment station was modified by the Decree of 29th January 2016 to allow the installation of the STE2 sludges treatment process.

Moreover, in a resolution of 4th January 2011, ASN made production of the C5 package, for which the risk of radiolysis leading to the production of hydrogen must be considered as of the design stage (see chapter 16, point 1.4.2), subject to prior ASN consent.

However, at the end of 2016, Areva NC informally notified ASN that the process adopted for the treatment of the sludge in STE3 could lead to more complex equipment operating and maintenance conditions. The licensee confirmed this information in 2017 and presented the alternative scenario it intends implementing along with results of an internal audit of the STE2 sludge recovery and packaging project. This information makes it difficult to conceive that time frame targets defined by the law for packaging the legacy waste can be met.

ASN will be particularly vigilant in ensuring that Areva NC does everything in its power to meet the deadlines prescribed for the recovery of the STE2 sludges.

Silo 130

Silo 130 is a reinforced concrete underground storage facility, with carbon steel liner, used for dry storage of solid waste from the reprocessing of Gas-Cooled Reactor (GCR) fuels, and the storage of technological waste and contaminated soils and rubble. The silo received waste of this type from 1973 until 1981, when a fire forced the licensee to flood the waste. The tightness of the silo thus filled with water is today ensured by means of a single containment barrier consisting of a steel "skin". Silo 130 is monitored by a network of piezometers situated nearby. The scenario for retrieving and packaging this waste comprises four stages:
- retrieval and packaging of the solid GCR waste;
- retrieval of the liquid effluents;
- retrieval and packaging of the residual GCR waste and the sludge in the bottom of the silo;
- retrieval and packaging of the soils and rubble.

Areva NC is currently building a retrieval unit above the pit containing the waste and a new building dedicated to the packaging operations. ASN had set 1st July 2016 and 31st December 2023 as the deadline dates for starting and ending of the recovery operations for all the waste. During an inspection in July 2016, ASN found that Areva NC had not actually begun to recover the waste stored in silo 130. In view of the justifications provided by Areva NC concerning the technical difficulties encountered and considering that the final deadline of 31stDecember 2023 was not called into question, ASN pushed back the date of start of retrieval to 30th April 2018.

The authorisation applications for the first retrieval phases will be examined in 2018.

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 a standard UMo vitrified waste package (CSD-U).

The use of the cold crucible with legacy solutions was authorised by a resolution of 20th June 2011. The first CSD-U packages were produced in 2013, but the cold crucible experienced a number of technical problems in 2014 and 2015. CSD-U packages were produced during short production campaigns. In view of the technical contingencies, Areva NC was unable to meet the end-of-retrieval deadlines of 31st December 2017 set by ASN resolution 2011-DC-0229 of 14th June 2011 and undertook to complete retrieval by the end of March 2019.

Other legacy waste recovery and packaging projects

With regard to other lower-priority legacy waste recovery and packaging projects, the following events in 2017 are worthy of note:
- completion of retrieval of the waste stored in room 107 of the MAPu facility at La Hague (BNI 33);
- continuation of the R&D studies on the packaging processes for the operational waste from GCR reactors and low granulometry wastes.

Final shutdown and decommissioning operations

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.

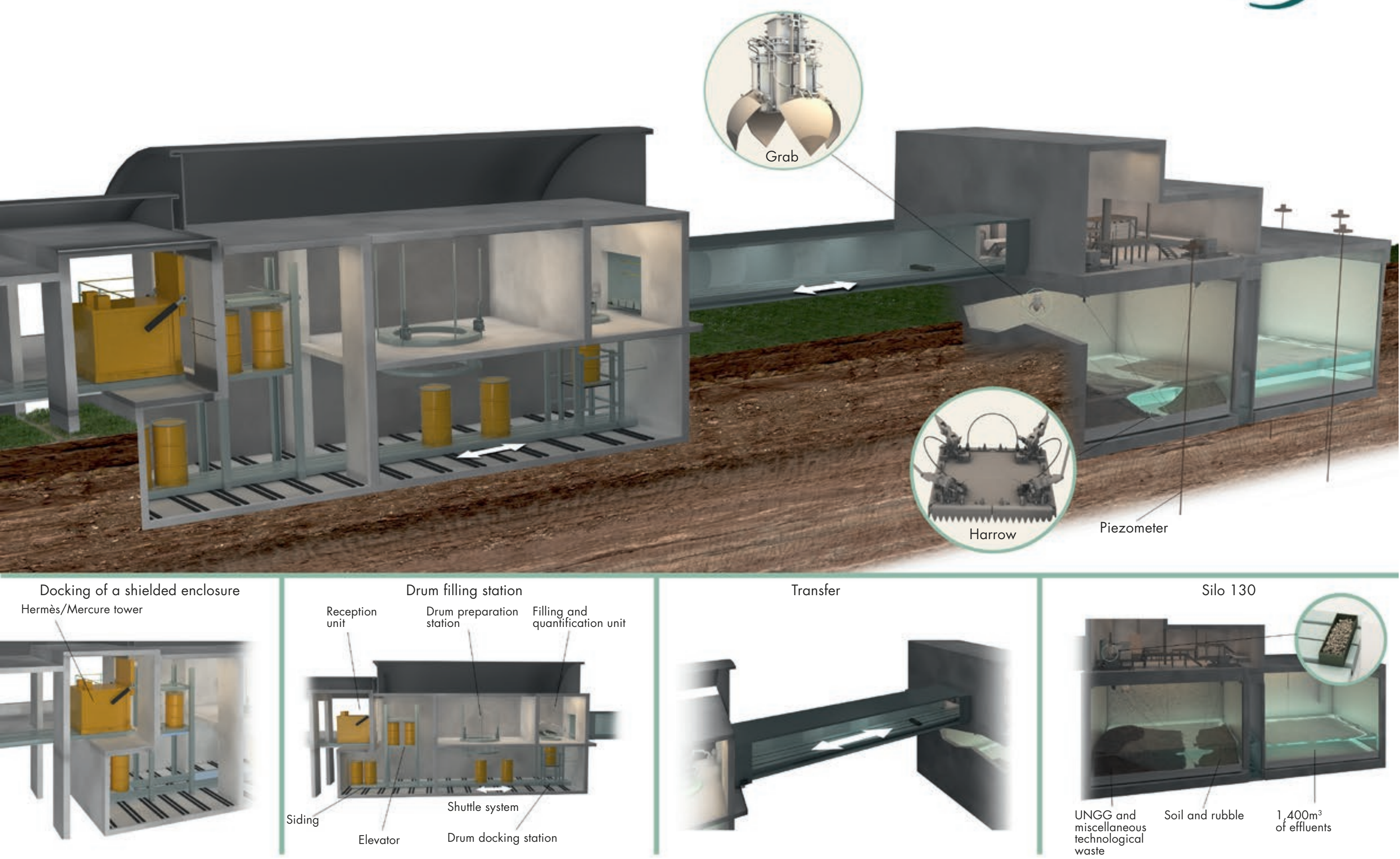
FUNDAMENTALS

The nuclear safety issues associated with silo 130

Silo 130 was designed and built in compliance with the nuclear safety requirements in force in the 1960's. The structure of the silo 130 civil engineering is today weakened by ageing and by the fire of 1981. Furthermore, the waste, which was initially stored dry, is now submerged in a large volume of water resulting from the extinguishing of the 1981 fire. The water is therefore in direct contact with the waste and can contribute to the corrosion of the carbon steel lining, which today is the sole containment barrier. One of the major risks therefore concerns the dispersion of radioactive substances into the environment (infiltration of the contaminated water into the water table).

Another factor that can compromise the safety of silo 130 is linked to the nature of the substances present in the waste, such as magnesium, which is pyrophoric. Hydrogen, a highly inflammable gas, can also be produced by the phenomenon of radiolysis or corrosion (presence of water). These elements contribute to the fire and explosion risks.

SCHEMATIC OF RETRIEVAL AND PACKAGING OF THE WASTE FROM SILO 130



BNI 80 comprises five facilities:

- HAO North, spent 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 (fuel element cladding and ends) in bulk, fines coming essentially from shearing, resins and technological waste 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.

FUNDAMENTALS

Shut down installations undergoing decommissioning on the La Hague site

BNI 80: Oxide High Activity facility (HAO)
- HAO North: Facility for underwater unloading and spent fuel storage
- HAO South: Facility for shearing and dissolving spent fuel elements

BNI 33: UP2-400 facility, 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: ÉLAN II B facility, CEA research installation currently being decommissioned

Decommissioning of the HAO was authorised by Decree of 31st July 2009.

The waste retrieval and packaging project currently under way in the HAO silo and in the SOC, represents the first hold point in the decommissioning of the installation. Areva NC has expressed its difficulties in meeting the prescribed deadlines for retrieval of the waste contained in the HAO silo and the SOC. Pushing back the deadlines will necessitate a modification of the Decree of 31st July 2009. In 2018 the licensee will continue construction of the unit for the waste retrieved from the silo with the installation of the various equipment items.

BNI 80 has also undergone a periodic safety review. Following examination of the review, ASN set additional requirements in a resolution of 4th January 2018.

The UP2-400 (BNI 33) plant, the effluent treatment plant STE2 (BNI 38) and the ÉLAN IIB installation (BNI 47)

Areva submitted 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. Examination of the periodic safety review files jointly with the decommissioning files allows, among other things, verification of 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. A meeting of the Advisory Committee for Laboratories and Plants held in April 2017 concluded that, on the whole, the risk control provisions for the decommissioning operations were appropriate. The licensee must nevertheless carry out additional studies on the earthquake resistance of the LCC (Central Quality Control Laboratory). The examination is to continue in 2018 with the opinion of the Environmental Authority of the CGEDD and the public inquiry. ASN will take the results of the examination into account and prescribe additional measures.

The licensee has started the decommissioning operations in BNI 33 and decommissioning preparation work in BNIs 38 and 47. ASN notes that decommissioning of BNI 33 is proceeding satisfactorily while that of BNI 38 seems to be facing difficulties, primarily due to uncertainties about the radiological and chemical content of the cells. With regard to

FOCUS

Examination of the decommissioning application files for Areva's first-generation plants

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 (ÉLAN IIB). ASN's examination revealed the need for a large number of additional studies. Consequently, for BNIs 33 and 38, only those operations for which the safety case was documented could be authorised.

The Decrees of 8th November concerning BNIs 33 and 38 only authorise partial decommissioning, whereas the Decree of 8th November concerning BNI 47 authorises complete decommissioning of the installation.

Areva NC submitted the complete decommissioning files for BNIs 33 and 38 in July 2015. These file were reviewed by the Advisory Committee of Experts in April 2017. Areva NC wishes to keep in service some of the facilities that provide support for the decommissioning and operation of the site's installations and has asked to attach them to the installations in operation. In the absence of sufficient proof concerning the hazard resistance of the civil engineering structures of these buildings and considering the potential consequences in the event of an accident, ASN is not in favour of a change of the scope of these facilities. To prevent any delay in the decommissioning work already planned, Areva NC shall submit an update of the files in 2018 so that the examination of the scope of decommissioning described in the file can continue, with the opinion of the Environmental Authority of the CGEDD and then the public inquiry. Once Areva NC has provided the necessary supporting information, ASN will rule on the possibility of attaching these facilities to the installations in operation.

BNI 47, further characterisations are necessary before starting decommissioning; they will be available in 2018. ASN does note however that Areva NC is endeavouring to define action plans to control drifts in the schedule.

2.3.3 BNI 105 at Tricastin

Operated by Areva NC, BNI 105 mainly produced uranium hexafluoride (UF_6) for the fabrication of nuclear fuel. Alongside this main activity, BNI 105 produced various fluorinated products such as chlorine trifluoride.

The fabrication of UF_6 from natural uranium was carried out in a part the plant governed by the ICPE regulations, while the fabrication of UF_6 from reprocessed uranium was carried out in a part of the plant classified as a BNI. This latter part, BNI 105, which was definitively shut down in 2009, 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.

Areva NC filed a decommissioning decree application in February 2014. The expert technical assessment of the file was completed in May 2016 and the Environmental Authority of the CGEDD issued its opinion on the file in September 2016. The examination continued in 2017 with the public inquiry and drafting of the draft decree which will be made available for consultation in 2018. The licensee submitted the first periodic safety review file for its facility at the end of 2017; examination of this review which start in 2018.

Three events rated level 1 on the INES scale were reported by the licensee in 2017. These events concerned environmental dispersion of potassium contaminated with uranium and anomalies in the packaging of nuclear waste and materials present in the storage areas. In 2018, ASN will check the effectiveness of the measures implemented by the licensee further to these events.

2.3.4 Eurodif plant at Tricastin

The Eurodif facility (BNI 93), licensed in 1977, consisted primarily of a plant for separating 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, the licensee – Eurodif Production – was authorised in May 2013 to implement the operations of the Eurodif project for intensive rinsing followed by "air-filling" (operation "Prisme"), which consisted in repeatedly rinsing the gaseous diffusion circuits with chlorine trifluoride (ClF_3), a toxic and hazardous substance which allowed the extraction of virtually all the residual uranium deposited in the diffusion barriers[1].

1. The Eurodif plant used the process of gaseous diffusion through a cascade of diffusers. Further to the production stoppage in 2012, decommissioning preparation operations have been undertaken: these operations (baptised "Prisme") consist firstly in intensive rinsing with ClF_3 to extract the large majority of the residual uranium from the equipment and secondly in injecting moist air to cause a hydrolysis chemical reaction in order to extract the gaseous effluents.

In accordance with the Decree of 24th May 2013, the licensee filed its final shutdown and decommissioning application for the installation in March 2015. The initial examination by ASN revealed that further information was required before the examination could proceed. This additional information concerned 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. On 31st March, the Prefect coordinating the public inquiry issued a favourable opinion on the final shutdown and decommissioning application for the Eurodif plant.

The decommissioning challenges concern the volume of very low-level (VLL) waste produced (including 180,000 tonnes of metallic VLL waste) and the reduction in the decommissioning time frame which must be as short as possible (currently estimated at 30 years).

Operations to prepare for final shutdown and decommissioning of the Eurodif plant were started in 2017. Once they are completed, ASN will authorise the shut down installations to enter a surveillance phase pending starting of the first decommissioning operations. Before delivering its authorisation, ASN will ascertain that the installations in are in a safe state compliant with that described in the application file submitted by the licensee, particularly regarding the removal of operational waste and the addressing of the events that led to pollution in the past.

Examination of the final shutdown and decommissioning file will continue in 2018 with the preparation of the draft decree governing decommissioning.

2.3.5 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 and the decommissioning work has now been completed.

The site nevertheless displays residual contamination of the soil and groundwater, the impact of which is compatible with 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. Initiated at the end of 2017, this procedure will continue in 2018.

3. Outlook

ASN's key actions in 2018 will concern the monitoring of decommissioning and waste management project progress, and especially the retrieval and packaging of the legacy waste of CEA and Areva, where the delays are particularly detrimental to the safety of the sites concerned. More specifically, ASN will adopt a position on the examination of the strategy files of these two licensees, submitted in 2016.

In 2018, ASN will examine the elements supporting the change of EDF's decommissioning strategy for the first-generation GCR reactors, and the elements concerning the safety of these reactors during the period pending decommissioning. ASN will adopt a position on EDF's change of strategy request after completing all the technical and regulatory examinations.

The periodic safety reviews of the installations undergoing decommissioning, for which the majority of the conclusions files were submitted by the licensees in 2017, will also be the subject of attentive examinations tailored to the risks and inconveniences these installations represent.

Lastly, in order to clarify the decommissioning and waste management regulations updated by Ordinance 2016-128 of 10th February 2016, ASN will continue to develop new guides in these areas as well as in the area of polluted sites and soils in the BNIs.

Thus in 2018, ASN plans to:
- examine the decommissioning strategy of EDF, and more particularly for the GCRs;
- continue the coordination with the EDF teams regarding the shutdown of the Fessenheim reactors;
- adopt a position on the decommissioning strategies of Areva and the CEA.

ASN also plans to:
- continue the examination of the decommissioning files submitted by the licensees, particularly those for the Tricastin and La Hague sites (Areva) and the Fontenay-aux-Roses site (CEA) and the corresponding periodic safety reviews;
- start or continue examining the conclusions of the periodic safety reviews of the installations undergoing decommissioning;
- continue examining the delicensing applications, particularly those for the STED in Grenoble and the SICN in Veurey-Voroise ;
- detail the structuring and requirements associated with the BNI decommissioning plans;
- continue capitalising on international decommissioning experience feedback by participating in the work of WENRA, the IAEA and the NEA.

Appendix

LIST of Basic Nuclear Installations delicensed and undergoing decommissioning as at 31st December 2017

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
Melusine Grenoble	(Former BNI 19)	Reactor (8 MWth)	1958	1988	2011: removed from BNI list	Cleaned-out
Siloé Grenoble	(Former BNI 20)	Reactor (35 MWth)	1963	2005	2015: 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 (**)

LIST of Basic Nuclear Installations delicensed and undergoing decommissioning as at 31st December 2017

INSTALLATION LOCATION	BNI	TYPE OF INSTALLATION	COMMISSIONED	FINAL SHUTDOWN	LAST REGULATORY ACTS	CURRENT STATUS
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	(Former BNI 34)	Processing of liquid and solid waste	Before 1964	2006	2006: removed from BNI list	Integrated into BNI 166
STED Cadarache	(Former BNI 37)	Transformation of radioactive substances	1964	2015	2015: removed from BNI list	Integrated into BNIS 37 A and 37-B
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 (**)
Strasbourg university reactor	(Former BNI 44)	Reactor (100 kWth)	1967	1997	2012: 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 BNI 165 and 166
LCPu FAR	(Former BNI 57)	Plutonium chemistry laboratory	1966	1995	2006: removed from BNI list	Integrated into BNI 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 BNI 165 and 166
LCAC Grenoble	(Former BNI 60)	Fuels analysis	1975	1984	1997: removed from BNI list	Decommissioned
LAMA Grenoble	(Former BNI 61)	Laboratory	1968	2002	2017: removed from BNI list	Cleaned-out
STEDs FAR	(Former BNI 73)	Radioactive waste decay storage	1971	2006	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
LURE	(Former BNI 106)	Particle accelerators	From 1956 to 1987	2008	2015: removed from BNI list	Cleaned out institutional controls (***)
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 (**)
Miramas uranium warehouse	(Former BNI 134)	Uranium-bearing materials warehouse	1964	2004	2007: 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 (**)
Ulysse Saclay	18	Reactor (100 kWth)	1967	2007	2014 : Final shutdown and Decommissioning decree	Decommissioning in process
Rapsodie Cadarache	25	Reactor (40 MWth)	1967	1983		Preparation for decommissioning
ATPu Cadarache	32	Fuel fabrication plant	1962	2003	2009 : Final shutdown and Decommissioning decree	Decommissioning in process

Appendix

LIST of Basic Nuclear Installations delicensed and undergoing decommissioning as at 31st December 2017

INSTALLATION LOCATION	BNI	TYPE OF INSTALLATION	COMMISSIONED	FINAL SHUTDOWN	LAST REGULATORY ACTS	CURRENT STATUS
Spent fuel reprocessing plant (UP2) (La Hague)	33	Transformation of radioactive substances	1964	2004	2013: Final shutdown and partial decommissioning degree	Decommissioning in process
Sted and High level waste Storage unit (Grenoble) 36 and 79	36 & 79	Waste treatment and storage facility	1964/1972	2008	2008: Final shutdown and decommissioning decree	Decommissioning in process
STE Cadarache	37-B	Effluent treatment facility (non-permanent part of former BNI 37)	2015	2016		Preparation for decommissioning
STE2 (La Hague)	38	Effluent treatment facility	1964	2004	2013: Final shutdown and partial decommissioning decree	Decommissioning in process
Osiris	40	Reactor (70 MWth)	1966	2015		Preparation for decommissioning
ÉOLE	42	Reactor (1 kWth)	1965	2017		Preparation for decommissioning
Bugey 1	45	Reactor (1,920 MWth)	1972	1994	2008: Final shutdown and decommissioning decree	Decommissioning in process
Saint-Laurent-des-Eaux A1	46	Reactor (1,662 MWth)	1969	1990	2010: Decommissioning decree	Decommissioning in process
Saint-Laurent-des-Eaux A2	46	Reactor (1,801 MWth)	1971	1992	2010: Decommissioning decree	Decommissioning in process
ÉLAN IIB La Hague	47	Manufacture of caesium-137 sources	1970	1973	2013: Decommissioning decree	Decommissioning in process
High Activity Laboratory (LHA) Saclay	49	Laboratory	1960	1996	2008: Final shutdown and decommissioning decree	Decommissioning in process
ATUE Cadarache	52	Uranium processing	1963	1997	2006: Final shutdown and decommissioning decree	Decommissioning in process
MCMF	53	Storage of radioactive substances	1968	2017		Preparation for decommissioning
LPC Cadarache	54	Laboratory	1966	2003	2009: Final shutdown and decommissioning decree	Decommissioning in process
SICN Veurey-Voroize	65 & 90	Fuel fabrication plant	1963	2000	2006: Final shutdown and decommissioning decree	Decommissioning in process
Phénix Marcoule	71	Reactor (536 MWth)	1973	2009	2016: Decommissioning decree	Decommissioning in process
Hao (High Level Oxide) facility (La Hague)	80	Transformation of radioactive substances	1974	2004	2009: Final shutdown and decommissioning 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
Phébus	92	Reactor (40 MWth)	1978	2017		Preparation for decommissioning
Eurodif	93	Transformation of radioactive substances	1979	2012		Preparation for decommissioning
AMI Chinon	94	Utilisation of radioactive substances	1964	2015		Preparation for decommissioning
Minerve	95	Reactor (100 Wth)	1977	2017		Preparation for decommissioning
Comurhex Tricastin	105	Uranium chemical transformation plant	1979	2009		Preparation for decommissioning

LIST of Basic Nuclear Installations delicensed and undergoing decommissioning as at 31st December 2017

INSTALLATION LOCATION	BNI	TYPE OF INSTALLATION	COMMISSIONED	FINAL SHUTDOWN	LAST REGULATORY ACTS	CURRENT STATUS
Chinon A1D (Former Chinon A1)	133 (Former BNI 5)	Reactor (300 MWth)	1963	1973	1982: Chinon A1 confinement decree and creation of the Chinon A1 D storage BNI	Partially decommissioned, transformed into storage BNI for waste left in place decommissioning file to submit
Chinon A2 D (Former Chinon A2)	153 (Former BNI 6)	Reactor (865 MWth)	1965	1985	1991: Partial decommissioning decree for Chinon A2 and creation of the storage BNI Chinon A2 D	Partially decommissioned, transformed into storage BNI for waste left in place decommissioning file to submit
Chinon A3 D (Former Chinon A3)	161 (Former BNI 7)	Reactor (1,360 MWth)	1966	1990	2010: Decommissioning decree	Decommissioning in process
EL4-D (Former EL4 Brennilis)	162 (Former BNI 28)	Reactor (250 MWth)	1966	1985	1996: Decree ordering decommissioning and creation of the EL-4D storage BNI 2006: Final shutdown and decommissioning 2007: Decision of the conseil d'état (state council) cancelling the 2006 decree 2011: Partial decommissioning decree	Partially decommissioned, transformed into storage BNI for waste left in place decommissioning file to submit
Chooz AD (Former Chooz A)	163 (Former BNI 1, 2, 3)	Reactor (1,040 MWth)	1967	1991	2007: Final shutdown and decommissioning decree	Decommissioning in process
Procédé FAR	165	Grouping of former research installations (BNI 57 and 59) concerning reprocessing processes	2006	2006	2006: Final shutdown and decommissioning decree	Decommissioning in process
Support FAR	166	Grouping of former installations (BNI 34 and 73) for packaging and treating waste and effluents	2006	2006	2006: Final shutdown and decommissioning decree	Decommissioning in process

** Attila: reprocessing pilot located in a unit of BNI 57*
*** Passive institutional controls*
**** Active institutional controls*

Radioactive waste and contaminated sites and soils

16

This chapter presents the role and actions of ASN, the French Nuclear Safety Authority, in the management of radioactive waste and the management of sites and soils contaminated by radioactive substances. It describes in particular the steps taken to define and determine the main radioactive waste management routes and the controls carried out by ASN with respect to nuclear safety and radiation protection in facilities involved in the management of this waste.

According to Article L. 542-1-1 of the Environment Code, radioactive waste consists of radioactive substances for which no subsequent use is planned or envisaged or which have been re-qualified as such by the administrative authority in application of Article L. 542-13-2. The waste comes from nuclear activities involving artificial or natural radioactive substances, from the moment this radioactivity justifies the implementation of radiation protection controls.

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 present risks for health and the environment. Contamination by radioactive substances can result from industrial, craft, medical or research activities.

The year 2017 saw the adoption of the French National Radioactive Material and Waste Management Plan (PNGMDR) 2016-2018, which was transmitted to Parliament in February. This three-yearly plan takes stock of the radioactive substances management policy nationwide, identifies the new needs and determines the objectives to be achieved, more specifically in terms of studies and research to develop new waste management solutions. It is supplemented by Decree 2017-231 of 23rd February issued in application of Article L. 542-1-2 of the Environment Code and establishing the requirements of the PNGMDR and the Order of 23rd February 2017 issued in application of the Decree of 23rd February 2017.

On 8th June 2017, ASN gave its opinion on the fourth three-yearly reports submitted by the licensees in 2016. These reports describe the assessment of the costs associated with decommissioning and waste management, the methods applied to calculate the provisions corresponding to these costs and the choices made regarding the composition and management of the assets assigned to ring-fence these provisions. ASN considers that the level of detail in the content of the licensees' reports is variable and that the EDF file does not contain sufficient information for ASN to adopt a position on the completeness of its evaluation of the financial costs.

2017 was marked by the examination of the safety options file for the deep geological repository project, *Cigéo*, submitted by Andra, the French National Agency for Radioactive Waste Management, in 2016. ASN gave its opinion on this file in January 2018, considering that these safety options constitute significant progress and detailing the additional justifications that will be necessary for a future creation authorisation application.

Lastly, ASN published resolution No. 2017-DC-587 of 23rd March 2017 relative to the packaging of radioactive waste and the conditions of acceptance of waste packages in the disposal Basic Nuclear Installations (BNIs).

1. Radioactive waste

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. Radioactive waste must be managed in accordance with specific procedures. 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 types of radioactive waste differ widely in their radioactivity (specific activity, nature of the radiation, half-life) and their form (scrap metal, rubble, oils, etc.).

Two main 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 hand, 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 The legal framework for radioactive waste management

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 radioactive waste management, and then by Planning Act 2006-739 of 28th June 2006 on sustainable management of radioactive waste, which gives a legislative framework to management of all radioactive materials and waste. These Acts are codified in Book V, Part IV, Chapter II of the Environment Code.

The Act of 28th June 2006 more specifically sets a 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 increases the missions of Andra. 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 the Ordinance 2016-128 of 10th February 2016 introducing various provisions with regard to nuclear activities 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, without calling into question Article L. 542-2 of the Environment Code which prohibits the disposal in France of radioactive waste from foreign countries and of radioactive waste resulting from the reprocessing of spent fuel and the treatment of radioactive waste from abroad, and to detail 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.

The conditions for creating a reversible deep geological repository for HL and IL-LL radioactive waste are detailed in Act 2016-1015 of 25th July 2016.

1.1.1 Production of radioactive waste in installations overseen by ASN

ASN oversees the activities associated with the management of radioactive waste from Basic Nuclear Installations (BNI) or small-scale nuclear activities, other than those linked to national defence which are overseen by ASND and those relative to Installations Classified for Protection of the Environment (ICPE), which are placed under the oversight of the Prefects.

Decree 2014-996 of 2nd September 2014, amending the nomenclature of the ICPEs, defines the division of authority with regard to the oversight of installations which hold radioactive substances or manage radioactive waste. Consequently, 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 non-sealed radioactive substances and of radioactive waste, however, is governed by the Environment Code if the volume present in the facility exceeds $10m^3$ for either of these categories, and by the Public Health Code if not.

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.

The absence of release thresholds[1] is a particularity of the French regulations. In concrete terms, application of this doctrine leads, in BNIs, to the establishing 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 dedicated routes. Waste from other areas, once confirmed as being free of radioactivity, is sent to authorised routes for the management of hazardous, non-hazardous or inert waste, depending on its properties.

The regulations also oblige the licensees to conduct waste management studies setting out the licensee’s targets for limiting the volume and the radiological, chemical and biological toxicity of the waste produced in its facilities and to reduce, by recycling and treating this waste, the final disposal volume reserved for ultimate waste. This study shall consider the installations’ waste management routes through to disposal.

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.

ASN Guide No. 23 presents the conditions of application of this resolution with regard to the drawing up and modification of the waste zoning plan.

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.*

Production of radioactive waste by a nuclear activity authorised under the Public Health Code

Article R. 1333-12 of the 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. This Article could change in 2018 (see chapter 3).

ASN resolution 2008-DC-0095 of 29th January 2008 lays out the technical rules applicable for the disposal of effluents and waste contaminated or potentially contaminated by radionuclides owing to a nuclear activity. ASN published a guide (Guide No. 18) to the application of this resolution in January 2012. ASN will update this guide to make it consistent with the new regulations.

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 dates from 2015. It more specifically presents 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.

The national inventory will be updated in 2018. ASN sits on the steering committee that supervises preparation of the inventory.

1.1.3 The French National Plan for the Management of Radioactive Materials and Waste

Article L.542-1-2 of the Environment Code, as instituted by the Act of 28th June 2006 and supplemented by Ordinance 2016-128 of 10th February 2016, 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, determine the objectives to be met. This Plan is produced by a pluralistic working group co-chaired by ASN and the Ministry responsible for Energy and is revised every three years. The main provisions of the Plan are set by decree.

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 PNGMDR 2016-2018 was submitted to Parliament at the beginning of 2017, then made public. ASN contributed to it more specifically through seven opinions issued in 2016, the main lines of which were included in the plan. The Decree and Order of 23rd February 2017 set out respectively the prescriptions of the Environment Code and the studies to conduct in the coming years.

The Plan is accompanied by a concise and educational summary presenting an overview of the management of radioactive materials and waste and the main recommendations.

An English version of the PNGMDR and its summary has also been published.

In 2017, ASN kept track of the progress of the initial work on the PNGMDR 2016-2018 through its participation in the PNGMDR working group among other things. In this context, ASN and the DGEC (General Directorate for Energy and the Climate) presented their first thoughts for the development of the next PNGMDR, in which new conditions of public participation, including the possibility of a prior public debate, will be applicable in accordance with Ordinance 2016-1060 of 3rd August 2016, which reforms the procedures for informing the public and ensuring its participation in the preparation of certain decisions that could have an impact on the environment.

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 a 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 fundamental 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 inspecting the installations and 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. This approach must take into account all the issues relating to safety, radiation protection, minimisation of the volume and harmfulness of the waste, while ensuring satisfactory traceability.

Finally, ASN considers that this management approach must be conducted in a manner that is transparent for the public and involves all the stakeholders, in a framework that fosters the expression of different opinions. The PNGMDR is thus developed within a pluralistic working group co-chaired by ASN and the 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 plan and the associated ASN opinions on its website.

1.2.1 Oversight of the BNIs

With regard to radioactive waste management, ASN's oversight aims 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 treatment, 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 resolution 2017-DC-0587 of 23rd March 2017 specifies the requirements regarding waste packaging for disposal and the conditions of acceptance of waste packages in the disposal BNIs.

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), HLW or ILW-LL waste.

Under these conditions, the production of waste packages for a disposal facility currently being studied is subject to ASN approval on the basis of a file called "packaging baseline requirement". This file must demonstrate that the packages display no unacceptable behaviour with respect the requirements regarding 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 packaging approvals.

FOCUS

Publication of ASN resolution 2017-DC-0587 of 23rd March 2017 relative to the packaging of radioactive waste and the conditions of acceptance of the radioactive waste packages in the disposal basic nuclear installations.

The management of the radioactive waste produced during the operation and subsequent decommissioning of a BNI comprises successive and interdependent stages (pre-treatment, treatment, packaging, storage, transport and disposal). These stages constitute a management route.

Each stage must be compatible with the stages that follow. More specifically, radioactive waste packages must be compatible with the safety case of the disposal facility to which they are directed. Furthermore, the packaging operations can imply radioactive waste transformations that would be hard to reverse. Consequently, their compatibility with the subsequent steps in the management route must be verified before they are performed.

As the packaging operations can be carried out by a licensee other than the producer of the waste or the disposal facility operator, it is essential to design and produce radioactive waste packaging in compliance with the requirements of the disposal facilities.

The aim of this new resolution is to specify the safety requirements in the various stages of a management route. This resolution sets out the provisions of the Order of 7th February 2012, especially Articles 6.7 and 6.8, and transposes several reference levels established by the Western European Nuclear Regulators Association (WENRA). It also details the responsibilities of the radioactive waste producer, of the licensee that packages the waste and the licensee of the disposal facility to which the waste is directed, in order to apply the notion of *"compatibility of radioactive waste packages with the planned conditions for their subsequent management"* mentioned in Article 6.7 of the Order of 7th February 2012. Lastly, it provides a framework for the specifications that Andra must adopt in application of 4° of Article L. 542-12 of the Environment Code: *"provide, in compliance with the rules of nuclear safety, the specifications for the disposal of radioactive waste and give the competent administrative authorities an opinion on the waste packaging specifications"*. This resolution was approved on 13th June 2017 and shall be applicable as from 1st July 2018.

ASN also ensures through inspections that Andra takes the necessary measures 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 waste package producers is vital in guaranteeing package quality and compliance with the safety case of the waste repositories.

1.2.3 Developing recommendations for sustainable waste management

ASN gives opinions on the studies submitted in application of the Decree setting the requirements of the PNGMDR. ASN also gives 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 ASN regulations. Thus, the provisions of the Order of 7th February 2012 which concern the management of radioactive waste have been set out in ASN resolutions mentioned earlier relative to waste management in BNIs and the packaging of waste. Other ASN resolutions may detail, among other things, the requirements applicable to the storage of radioactive waste and to the facilities intended for its disposal.

ASN has also published two guides concerning waste management: Guide No.18 relative to the management of radioactive effluents and waste produced by a nuclear activity licensed under the Public Health Code, and Guide No. 23 relative to the BNI waste zoning plan (see point 1.1.1).

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 website.

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 monitoring 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 which aims to harmonise nuclear safety practices in Europe by defining "reference safety levels" which must be transposed into the national regulations of its member countries. In this respect, the WGWD (Working Group on Waste and Decommissioning) is tasked with developing reference levels for the management of radioactive waste and spent fuel. In 2017, following the work already carried out on storage, disposal and decommissioning, ASN participated in finalising the development of reference levels for the packaging of radioactive waste in 2017. The ASN resolutions enable, among other things, these reference levels to be transposed into the general regulations applicable to BNIs. ASN also tracks the transposition of the reference levels in the WENRA member countries.

ASN participates in the International Atomic Energy Agency's (IAEA) Waste Safety Standards Committee (WASSC), whose role is to draft 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 responsible for subjects relative to radioactive waste management.

ASN also participates in projects of a technical nature conducted with the European Union and the IAEA, particularly on the deep geological disposal of radioactive waste.

In 2017, 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 approved in 2000. The French report was submitted to the IAEA in October 2017. It will undergo a peer review in May 2018 in Vienna. 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 and in the spent fuel and radioactive waste management policies, along with 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 for the fuel cycle and radioactive waste management facilities.

ASN's international actions are presented more generally in chapter 7.

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 *département* and operated by Andra, includes a disposal facility for Very-Low-Level (VLL) waste. This facility, which has ICPE status, has been operational since August 2003.

At the end of 2017, the volume of waste in the Cires repository was about 352,300 m^3, or 54.2% 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.

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 in guiding future choices in the overall optimisation of the management route. As authorised disposal capacities are expected to have been reached 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 the corresponding modification application as soon as possible.

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 VLL waste producers must engage 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.

ASN considers moreover that the management of VLL radioactive waste in France must continue to be based on the place of origin of the waste and guarantee its traceability, by means of specific routes, from production to disposal. ASN also considers that the possibilities of recycling very-low-level materials within the nuclear sector must studied exhaustively before considering other outlets. These positions are formalised in ASN opinion 2016-AV-0258 of 18th February 2016.

1.3.2 Disposal of Low and Intermediate-Level, Short-Lived (LL/ILW-SL) waste

The majority of LL/ILW-SL waste is placed in surface disposal facilities operated by Andra. Once these facilities are closed, they are subject to monitoring for a period set by convention at 300 years. The facility safety analysis reports – which are updated periodically, including during the monitoring phase – must show that at the end of this phase the residual activity contained in the waste will have reached a residual level 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.

FUNDAMENTALS

The periodic safety review of the CSA

Andra carried out the periodic safety review of the Aube Waste Repository (CSA) until August 2016 when it submitted the conclusions report to ASN. ASN conducted an initial analysis of this file, which resulted in the licensee being asked for additional information and referral to the Advisory Committee for Laboratories and Plants (GPU) and the Advisory Committee for Waste (GPD). The identified issues concern the safety functions to be fulfilled by the civil engineering structure and the CSA equipment: control of chain nuclear reactions, containment of harmful substances (radioactive substances in particular) and protection of people and the environment against ionising radiation. The Advisory Committees gave their opinions on 8th February 2018.

The periodic safety reviews provide the opportunity to assess the conformity of the facility, the upgrades or improvements proposed by the licensee or requested by ASN, taking into account the ageing of the facility and its equipment, particularly in the areas in which the regulations and safety requirements have evolved. The subjects examined with particular scrutiny in the periodic safety review of the CSA are:

- control of the risks associated with internal and external hazards:
  - fire, particularly in the Waste Packaging Unit (ACD);
  - earthquake, particularly the levels of seismic risk proposed by Andra during operation and during the surveillance phase for the various CSA buildings, and the resulting reinforcement of certain premises in the ACD;
- the long-term impact of the chemical substances, particular those contained in the stored packages;
- the technical characteristics of the long-term cover of the repository;
- the reassessment of the ultimate inventory of the waste;
- the positioning of the disposal structures with respect to the highest water level;
- the package acceptance specifications, particularly for sealed sources.

The CSA periodic safety review takes into consideration the technical particularities of the disposal facilities and the risks during the operating phase and after closure of the repository. It has induced Andra to define measures to reinforce the safety of the repository, and to prevent and mitigate its environmental impacts.

ASN is preparing a resolution to be issued in 2018 governing the continued operation of the CSA; this resolution will modify the current provisions applicable to the CSA if necessary.

ASN will transmit an analysis report to the Minister responsible for Nuclear Safety on the fitness of the repository for continued operation after its periodic safety review, and more specifically until the next one.

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. The CSM stopped accepting waste in July 1994.

In application of Decree 2016-846 of 28th June 2016 relative to the modification, final shutdown and decommissioning of BNIs and subcontracting, the CSM is no longer considered to be in the monitoring phase but in decommissioning (operations prior to its closure) until the long-term cover has been definitively put in place. An ASN resolution will specify the duration of the operations in question and the minimum duration of the monitoring phase.

ASN considers that the state and the operation of the CSM are satisfactory. Andra must however 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. Furthermore, the examination of the periodic safety review guidance file led ASN to remind Andra of the additional technical information required for the dimensioning of the long-term cover, initially requested for 1st September 2017, and that in 2018 Andra was to submit the progress of the work to preserve and transmit the memory of the site, and information on analyses of the impact of the BNI.

In 2016, Greenpeace France lodged a complaint concerning tritium contamination of the water table, which resulted to a large extent from the disposal in 1976 of waste with a high tritium content. The complaint was dismissed by the public prosecutor in June 2017.

With regard to the updating of the regulatory baseline, a new version of the on-site emergency plan was authorised by ASN in April 2017. Examination of Andra's request to modify the BNI perimeter of the facility in order to extend the perimeter to the limits of ownership of the facility continued in 2017 and should be completed in 2018.

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 at the same time from its experience. 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 2017, the volume of waste in the repository was about 325,600 m^3, or 32.6% of the authorised capacity. According to the estimates Andra made in the concluding report on the periodic safety review of the CSA in 2016, the CSA could be filled to maximum capacity by 2062 instead of 2042 as initially forecast, this new estimate being based on better knowledge of the future waste and the waste delivery schedules.

In 2017, Andra continued the modification work on the package inspection facility aiming to give the site more efficient means for checking the quality of the packages received at the CSA. The last additional information was provided by Andra in 2017. The commissioning of this facility, planned for 2018, will require an ASN authorisation. In 2017, Andra also sent ASN an application for a license to receive disused sealed sources from the licensees CIS bio international and the CEA.

The technical examination of the CSA periodic safety review, for which the concluding report was submitted in 2016, continued in 2017. It formed the subject of an inspection on 1st and 2nd June 2017 and an opinion from the GPD and the GPU on 8th February 2018. ASN will rule on the conditions for continued operation of this repository in 2018.

ASN considers that the CSA is operated satisfactorily, in line with previous years.

1.3.3 Management of High-Level and Intermediate-Level, Long-Lived (HL/ILW-LL) waste

The Act of 28th June 2006, in continuity with the Act of 30th December 1991, states that research into the management of HL/ILW-LL waste shall be pursued in three complementary directions: separation and transmutation of long-lived radioactive elements, storage, and reversible disposal in a deep geological repository.

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 and the harmfulness 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.

On the basis of the interim report on the industrial prospects of the separation/transmutation processes submitted by the CEA in 2015 under the PNGMDR, ASN issued its opinion on 25th February 2016. It 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 same gains do not eliminate the need for a deep disposal repository and could only bring a tangible reduction in the footprint of a future repository on the assumption of hundreds of years of operation of a sufficiently large fleet of fast-neutron breeder reactors to ensure the consistency of the cycle as a whole.

Storage

A second line of research and studies in the Act of 28th June 2006 concerns the storage of waste.

The long-term storage of waste has not been retained as a solution for the final management of radioactive waste.

Storage facilities are nevertheless indispensable pending commissioning of the deep geological disposal facility, to allow the cooling of certain types of waste and then to accompany the industrial operation of the disposal facility, which will develop in stages. Furthermore, if operations to remove emplaced packages were to be decided on in the context of the reversibility of the repository, storage facilities would be needed. Reception of the first radioactive waste packages for deep geological disposal is now planned for around 2030.

The Act of 28th June 2006 tasked Andra with coordinating the research and studies on the storage of HL and ILW-LL waste, which are therefore part of the approach of complementarity with the reversible repository. The law stipulated more specifically that the research and studies on storage should, by 2015 at the latest, allow new storage facilities to be created or existing facilities to be modified to meet the needs identified by the PNGMDR, particularly in terms of capacity and duration.

The progress made

In early 2013 Andra submitted a report on all the research and studies carried out. This report more particularly presented a survey of future storage needs, the exploration of the complementarity between storage and disposal, studies and research on engineering and on the phenomenological behaviour of the warehouses and a review of innovative technical options.

From 2013 to 2015, Andra conducted more in-depth studies into storage concepts linked to repository reversibility. This concerns hypothetical future installations which, if necessary, would accept packages removed from the repository. For such installations, Andra looked for versatility which would allow simultaneous or successive storage of packages of various types in their primary form or placed in a disposal overpack. In its study submitted in 2013, Andra states that it has ceased research on near-surface storage facilities owing more specifically to the greater complexity – linked in particular to the management of groundwater and ventilation in the case of exothermal waste – of civil engineering monitoring (limited accessibility to the outer surface of the structures in contact with the rock) and reduced operational flexibility.

On the basis of the results of research and studies, Andra issued recommendations in 2014 for the design of future installations to complement disposal.

These recommendations are also based on industrial experience feedback and the continued research on the durability of materials and on monitoring and surveillance systems. They focus in particular on the measures that foster the durability of the facilities (up to one hundred years or so), their monitoring, and the modularity of the future warehouses, allowing additional modules to be added to a storage facility while it continues to operate.

Jointly with Andra, Areva has integrated certain advances into the design of the extension of the HLW waste storage facility on the La Hague site, commissioned in 2013. This enables a longer operating life to be envisaged for this facility.

Within the framework of the PNGMDR 2013-2015, and after presenting the inventory of HLW and ILW-LL waste packages intended for *Cigéo* as at the end of 2013 and the status of the existing storage locations, the producers more specifically analysed the core elements enabling waste package storage needs to be identified.

In its opinion 2016-AV-0259 of 25th February 2016 concerning the studies on the management of high-level and intermediate-level long-lived waste (HL and ILW-LL) submitted in application of the PNGMDR 2013-2015, with a view to preparing the PNGMDR 2016-2018, ASN considers that the producers of HL and ILW-LL waste must supplement the study carried out under the PNGMDR 2013-2015 and define the following for each family of HL and ILW-LL waste:
- the existing storage capacities, specifying their availability;
- the forecasts for these filling to capacity or the obsolescence of these storage facilities and the needs for new storage capacity, some of which are already confirmed, for the next twenty years;
- the time needed to commission new storage capacity.

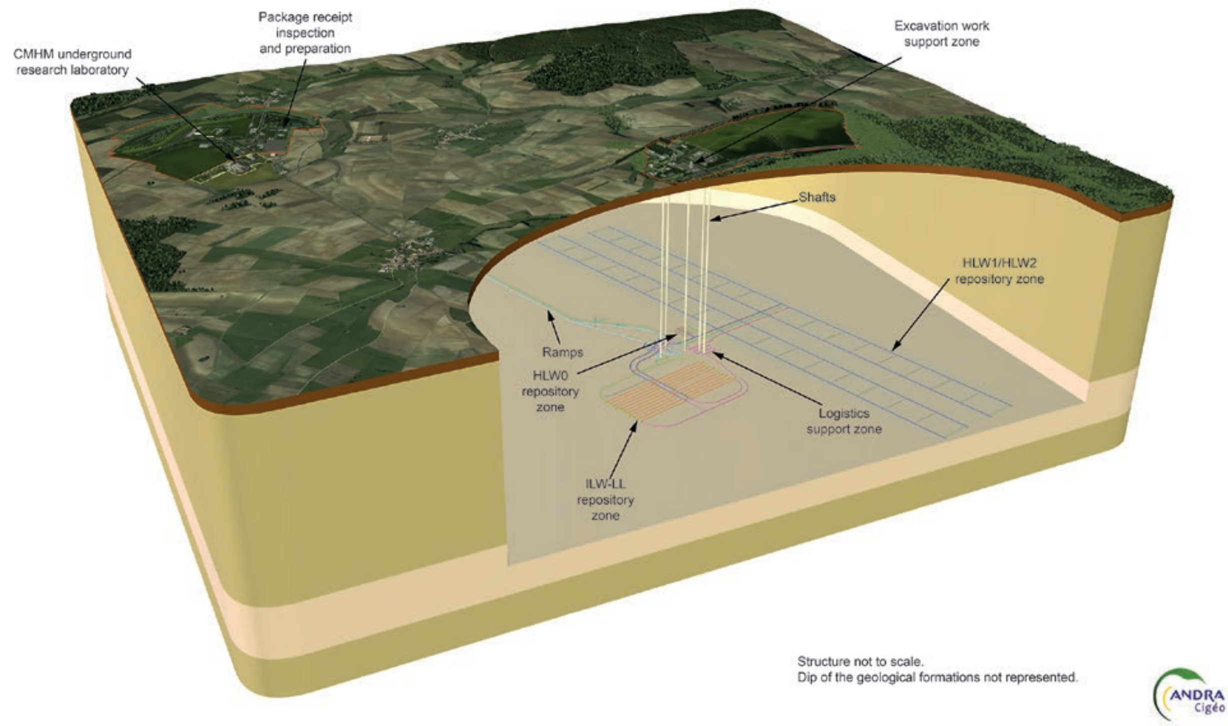
The sensitivity of the storage needs to shifts in the *Cigéo* project development schedule must be analysed in order to identify any threshold effects with regard to future storage needs or extensions to the operating time of existing storage facilities. This analysis must be based on the assumptions used by the licensees for the decommissioning of their installations over the next twenty years.

ASN recommends that the PNGMDR should, after identifying the foreseeable needs for storage facilities, set the time frames associated with the key stages in the procedures for their creation and commissioning.

In the abovementioned opinion, ASN considers that at the present stage, generic studies into storage concepts complementary to disposal will provide no further significant advances. Studies could be carried out in the future as part of the licensee-led storage facility projects.

ASN considers the following to be necessary.
- The licensees must take the recommendations given in the PNGMDR 2016-2018: into account in the design of new storage facilities, and, insofar as possible, in the periodic safety review of existing facilities.
- Andra is studying the management of degraded primary packages of ILW-LL waste, which could have been removed from the repository, in particular concerning the dimensioning of the means for repackaging degraded primary packages in the *Cigéo* surface installations.
- Andra must specify the technical elements on which it based its decision to definitively abandon the near-surface storage facilities design option, as the document submitted by Andra contains insufficient technical details to rule on the appropriateness of the abandonment decision.

SCHEMATIC diagram of the *Cigéo* repository showing the surface and underground facilities



Outlook

The studies of the PNGMDR 2016-2018 focus on the analysis of the storage needs for HL and ILW-LL waste packages and take up the broad lines of the ASN opinion.

According to Article D. 542-79 of the Environment Code (introduced by the Decree of 23rd February 2017) relative to the provisions of the PNGMDR 2016-2018, the holders of spent fuel and HL and ILW-LL radioactive waste must keep up to date the availability status of the storage capacities for these substances by waste category and identify the future storage capacity needs, at least for the next twenty years.

According to Article 53 of the Order of 23rd February 2017, EDF, the CEA and Areva must define, before the end of 2017, the future storage needs for all families of HL and ILW-LL waste, covering at least the next twenty years. Within this context, EDF, CEA and Areva are studying how sensitive the storage needs are to shifts in the *Cigéo* project development schedule.

Article 52 of the Order of 23rd February 2017 requires Andra to communicate, before the end of 2017, the technical data on the basis of which it ruled out the near-surface storage facilities design option.

The challenges now concern the continuation of the construction of storage facilities for HL and ILW-LL waste in accordance with the design recommendations set forth in the PNGMDR, pending commissioning of the deep geological repository. These facilities shall more specifically be capable of storing the ILW-LL waste produced before 2015 which will have been packaged before 2030.

Reversible deep geological disposal

Deep geological disposal is required by the provisions of Article L. 542-1-2 of the Environment Code, which stipulates 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 Act of 28th June 2006 assigns Andra the task of devising a project for a deep geological disposal facility which shall be a BNI and therefore subject to ASN oversight.

The principle of this type of disposal

Deep geological disposal of radioactive waste consists in emplacing the radioactive waste in an underground facility specially designed for this purpose, complying with the principle of reversibility. The characteristics of the geological layer are intended to confine the radioactive substances contained in this 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 oversight, 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.

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.

The conditions for creating a reversible deep geological repository for HL and ILW-LL radioactive waste are detailed in Act of 25th July 2016.

This Act also defines reversibility as *"the ability, for successive generations, to either continue the construction and then the operation of successive sections of a disposal facility, or to reassess previous choices and change the management solutions. Reversibility is materialised by the progressive nature of the construction, the adaptability of the design and the operational flexibility of placing radioactive waste in a deep geological repository which can integrate technological progress and adapt to possible changes in waste inventory following a change in energy policy. It includes the possibility of retrieving waste packages from the repository under conditions and during a period of time that are consistent with the operating strategy and the closure of the repository."*

In its opinion 2016-AV-0267 of 31st May 2016 relative to the reversibility of the deep geological disposal of radioactive waste, ASN had considered that the principle of reversibility implied a requirement for adaptability of the facility and retrievability of the packages during a period governed by law.

The Decree of 23rd February 2017 relative to the provisions of the PNGMDR details certain principles applicable to *Cigéo*, and more particularly in Articles D. 542-88 to D. 542-96 of the Environment Code. Article D. 542-90 stipulates in particular that *"The inventory to be considered by the French National Agency for Radioactive Waste Management (Andra) for the studies and research conducted for the design of the repository provided for in Article L. 542-10-1 shall comprise a reference inventory and a reserve inventory. The reserve inventory shall take into account the uncertainties associated more specifically with putting in place new waste management routes or changes in energy policy. The repository shall be designed to accommodate the waste of the reference inventory. It shall also be designed by Andra, in consultation with the owners of the substances of the reserve inventory, to be capable of accommodating the substances figuring in that inventory, provided that changes in its design can be implemented if necessary during operation of the repository at an economically acceptable cost"*.

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. A fatal accident caused by a structural collapse occurred in 2016. A judicial inquiry is in progress.

In the context of the studies on the deep geological disposal, ASN issues recommendations concerning the research and experiments conducted in the laboratory, and ascertains through follow-up inspections that they are carried out using processes that guarantee the quality of the results.

Technical instructions

Pursuant to the Act of 30th December 1991, and then pursuant to the Act of 28th June 2006 and the PNGMDR, Andra has carried out studies and submitted reports on the deep geological repository. These 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 primarily examined the overall files submitted by Andra in 2005 and at the end of 2009. It issued opinions on these files on 1st February 2006 and 26th July 2011.

Andra is continuing its work and has submitted various files to ASN presenting the progress of the studies and work carried out.

ASN issued a position statement:
- in 2013, on the documents produced between 2009 and 2013 – the year of the public debate, and on the intermediate design milestone at the outline stage presented by Andra in 2012;
- in 2014, on the safety components of the closure structures and the expected content of the safety options dossier for the facility;
- in 2015, on the control of operating risks and the cost of the project;
- in 2016, on the components development plan.

In this latter opinion ASN once again underlined the need for Andra to make sure that the research and development work is well coordinated with the planned project development phases in order to ensure the availability of the data necessary for the facility's safety case.

The authorisation process

The examination of a creation authorisation application for a deep geological disposal facility has not been started. It will not begin until Andra has filed such an application. In 2017 Andra stated that the application was pushed back to mid-2019.

Further to the conclusions of the public debate, Andra decided to set up an industrial pilot phase before operating the facility at industrial rates. The Board of Directors of Andra also decided to submit a Safety Options Dossier (DOS) for the *Cigéo* repository project to ASN before applying for the facility creation authorisation.

ASN welcomed this decision which is in keeping with the stepwise development promoted in the ASN Safety Guide relative to radioactive waste disposal in deep geological formations, and informed Andra of its expectations regarding the content of this dossier by letter dated 19th December 2014.

FOCUS

ASN's position on the *Cigéo* DOS

General observations

ASN considers that:

- the project has on the whole reached satisfactory technological readiness at the DOS stage:
  - Detailed understanding of the Meuse/Haute-Marne site has been acquired, confirming the suitability of the chosen area.
  - Considerable knowledge has been compiled concerning the various components of the repository.
  - The disturbances that could affect the host rock and those that will occur during the transients (thermal, hydraulic, mechanical, etc.) that will result from the construction of the repository have been properly identified. The results presented tend to indicate that their extent should be limited, given the thickness of the host rock.
  - The principles adopted in the safety approach are consistent with the ASN safety guide of 2008 and the recommendations made by the international bodies.
- the DOS is documented and supported and has made significant progress with respect to the files of 2005 and 2009.

Safety options to supplement

Additions are required for the facility's creation authorisation application with regard to:

- the radioactive waste inventory;
- the bituminised waste packages and control of the fire risks;
- certain subjects which could lead to design changes:
  - justification of the repository architecture;
  - dimensioning of the facility to withstand hazards;
  - monitoring the installations
  - post-accident situations.

Examination of the *Cigéo* Safety Options Dossier (DOS)

The filing of a DOS marks the start of a regulatory process[2].

ASN received the DOS for *Cigéo* in April 2016. Experts were consulted for their opinion at two key stages in its examination: the IAEA peer review from 7th to 15th November 2016 and the meeting[3] of the GPD and the GPU on 18th and 19th May 2017. ASN published its draft opinion on the *Cigéo* DOS in July 2017. This draft opinion was subject to public consultation from 1st August to 15th September 2017. ASN issued its opinion on the *Cigéo* DOS on 11th January 2018. ASN also detailed in a letter the safety options to prevent or mitigate the risks and asked Andra for complementary studies and substantiations (corrosion phenomena, low-pH concretes, representativeness of the hydrogeological model, etc.).

The examination of the *Cigéo* DOS highlighted several issues relating to specific aspects (see box above). Andra will continue to prepare the Creation Authorisation Decree (DAC) application file in 2018. ASN and IRSN will make regular progress assessments to check that the key issues identified in the examination of the previous Andra files have been properly taken into account.

2. *Article 6 of the Decree of 2nd November 2007 stipulates that* "any person who plans to operate a BNI can, before initiating the creation authorisation procedure provided for by Article 29 of Act 2006-686 of 13th June 2006, ask ASN for an opinion on all or part of the options it has chosen to ensure the safety of that installation. ASN, through an opinion rendered and published under the conditions determined by ASN, indicates the extent to which the safety options presented by the applicant are appropriate for preventing or mitigating the risks for the interests mentioned in I of Article 28 of the Act of 13th June 2006, given the prevailing technical and economic conditions. It may indicate the additional studies and justifications that will be required for a prospective creation authorisation application. It can set a validity period for its opinion. This opinion is communicated to the applicant and to the Ministers responsible for Nuclear Safety."

3. *It relies on the technical expertise of IRSN with regard to the Cigéo DOS and the conclusions of the IAEA peer review.*

The cost of the project

On 15th January 2016, in accordance with the procedure stipulated in Article L. 542-12 of the Environment Code and after consideration of ASN's opinion of February 2015 and the comments of the radioactive waste producers, the Minister responsible for Energy issued an Order setting the reference cost of the *Cigéo* disposal project *"at €25 billion 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 "industrial pilot phase", periodic safety reviews), in accordance with ASN opinion of 10th February 2015 concerning the evaluation of the costs of the *Cigéo* project for deep geological disposal of radioactive waste.

1.3.4 Low-Level Long-Lived Waste (LLW-LL) management

Low-level long-lived waste (LLW-LL) comprises two main categories: graphite waste resulting from the operation of the Gas-Cooled Reactor (GCR) 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 spent sealed radioactive sources.

Putting in place a definitive management solution for this type of waste is one of the objectives defined by the Act of 28th June 2006. Finding such a management solution necessitates firstly having greater knowledge of LLW-LL waste and secondly conducting safety studies on the associated disposal solution. The successive editions of the PNGMDR have set out this objective. ASN also issued a notice in 2008 giving general safety guidelines concerning the search for a site capable of accommodating LLW-LL.

The PNGMDR 2013-2015 required the various players 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;
- preliminary design studies covering the disposal options referred to as "intact cover disposal" and "reworked cover disposal"[4] ;
- the inventory of the waste to be emplaced in it and the implementation schedule.

ASN issued an opinion on Andra's interim report on the disposal project for LLW-LL waste on 29thMarch 2016. In 2018, Andra must submit a progress file detailing the design assumptions for the LLW-LL repository, an assessment of the safety of the repository during its operation and after closure, the quality and performance of the chosen geological formation and the consolidation of the inventory of waste that could be emplaced on the studied site.

1.4 The radioactive waste management strategies of the nuclear licensees

ASN requires BNI licensees to define a management strategy for all the radioactive waste produced in their facilities and it 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 in this chapter.

The waste management procedures adopted by the three main waste producers are presented below.

1.4.1 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.

4. *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 protective layer of planted vegetation reconstituting the site's natural level.*

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 (cement-, sodium-, magnesium- and mercury-bearing waste);
- waste resulting from final shutdown and decommissioning of the facilities (graphite waste, rubble, contaminated soils, etc.).

The contamination spectrum of this waste is also wide with, in particular, the presence of alpha emitters in activities relating to fuel cycle research and beta-gamma emitters in operational waste from the experimental reactors.

CEA has specific facilities for managing this waste (processing, packaging and storage). Some of them are shared between all the CEA centres, such as the liquid effluent treatment station in Marcoule or the solid waste treatment station in Cadarache.

The issues and implications

The two main issues for CEA with regard to radioactive waste management are:
- the renovation of existing facilities or commissioning of new facilities for the processing , packaging and storage of the effluents, spent fuel and waste under satisfactory conditions of safety and radiation protection and within time frames compatible with the commitments made for shutting down old facilities which no longer meet current safety requirements;
- the management of legacy waste retrieval and packaging projects.

ASN notes the difficulty CEA has in fully managing these two issues and conducting all the associated projects, especially decommissioning projects, at the same time.

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 examination carried out in 1999. ASN nevertheless observed that aspects of the strategy required improvement, particularly with regard to the management of intermediate-level long-lived solid waste and low or intermediate-level liquid waste, which therefore had to be consolidated.

Very significant increases in the projected duration of decommissioning operations declared by the CEA after the review of 2012, along with the quantity, the non-standard nature and difficulty in characterising certain substances or waste that will be removed from storage or produced during the decommissioning operations, led ASN and ASND to jointly ask the CEA to conduct an overall review of its decommissioning and radioactive materials and waste management strategies for the next fifteen years. The CEA report was received in December 2016 and is currently being examined by ASN and ASND so that the two authorities can have an overall view of the subject and establish a joint position on CEA's strategy. ASN will issue an opinion on this strategy in 2018.

Facilities operated by CEA to support this strategy

Facilities under construction

▪ Diadem - BNI 177

By Decree 2016-793 of 14th June 2016, the CEA was authorised to create the BNI called Diadem on the Marcoule site.

This facility is intended for the storage of containers of irradiating waste emitting beta and gamma rays or rich in alpha emitters, pending their disposal in *Cigéo*, or low and intermediate level short-lived (LL/ILW-SL) waste whose characteristics – dose rate in particular – cannot be accepted as is in the CSA. The maximum storage duration for each radioactive waste container is set at fifty years.

Diadem occupies an important position in CEA's management strategy for ILW-LL and LL/ILW-SL radioactive waste. Its entry into service will allow the decommissioning of certain installations, especially the Phénix reactor (BNI 71), and the retrieval and packaging of legacy waste held by CEA (at the Fontenay-aux-Roses Centre in particular) to be carried out.

Diadem construction worksite, September 2015.

At the end of 2017, the civil engineering work was almost completed, the lining of the disposal vault compartments and the installation of the storage stands was in progress, as was the finishing work (masonry and sealing).

ASN resolution of 17th November 2016 supplements the provisions of the creation authorisation application and stipulates the elements of the commissioning authorisation application file for which the date of submission remains to be confirmed by the CEA.

These stipulations concern the radioactive waste packages, the facility safety functions, the dimensioning of the facility – particularly the civil engineering, and the integration in the safety baseline requirements of the general requirements relative to defence in depth and the elements important for protection of the interests mentioned in Article L. 593-1 of the Environment Code.

They also concern the updating of the on-site emergency plan design study and taking into account the conclusions of the stress tests, particularly the defining of a "hardened safety core" for the facility. These stipulations also take account of ASN resolution 2015-DC-0532 of 17th November 2015 relative to the BNI safety analysis report applicable to the Diadem facility as soon as the commissioning authorisation application file has been submitted.

CEA has not yet defined the procedures that will be adopted to adapt the waste packaging to the acceptance specifications of the receiving disposal facilities.

In application of Article 6.7 of the Order of 7th February 2012, as of 2019, the CEA plans to stagger the packaging approval applications for intermediate packages, as defined in ASN resolution of 23rd March 2017 relative to packaging.

Since the start of the worksite at the end of 2014, ASN has carried out inspections to verify the quality of construction of the structure and that the commitments made by CEA following the technical examination of the BNI creation authorisation application have been met. These inspections showed that this worksite was proceeding under satisfactory conditions.

Installations in operation

On the Cadarache site

▪ Agate facility (BNI 171)

The function of the Agate facility, which was authorised by Decree 2009-332 of 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 through its resolution of 29th April 2014. An end-of-start-up file was communicated by CEA on 30th October 2015. ASN considers that the end-of-start-up test results for the facility and the integration of experience feedback are satisfactory on the whole.

These elements will have to be supplemented by those relative to the tests carried out since this file was submitted.

ASN moreover conducted an inspection of the static and dynamic containment of the facility in 2017.

ASN's opinion on the safety of operation of the Agate facility is generally positive.

- **Cedra facility (BNI 164)**

The Cedra facility, which was authorised by Decree 2004-1043 of 4th October 2004, processes intermediate-level, long-lived waste (ILW-LL) and stores packages of low and medium irradiating waste pending the creation of an appropriate disposal route. The package storage duration is limited to fifty years.

ASN authorised commissioning of the first phase of the storage facility for low-irradiating (LI) waste (two storage halls) and medium irradiating (MI) waste (one storage hall) in April 2006.

At the end of December 2017, the filling rate was 39.6% for the LI halls and 36.5% for the MI hall. According to the CEA's projections, the FI and MI halls should be filled to capacity as of 2029, but this time frame is strongly dependent on the rate at which the waste stored in BNI 56 is removed. The third storage phase (two additional storage buildings for the FI waste and seven additional compartments for storing MI waste) will then have to be put into operation.

Further to the ASN opinion of 2017 on the Cedra periodic safety review guidance file, the CEA sent ASN the safety review conclusions report in November 2017. This safety review does not concern the second phase (phase b: intermediate processing buildings) because in June 2017 the CEA submitted to the Minister responsible for Nuclear Safety an application to modify its creation authorisation decree with the aim of cancelling it.

In the periodic safety review, ASN will be particularly attentive to the scope and method adopted by CEA to review the conformity of the installation and the stored packages in particular. In 2017, the CEA implemented an action plan to clarify the acceptance specifications applicable to the packages received at Cedra to ensure they are handled and stored with all necessary safety precautions. 2016 was effectively marked by significant event notifications concerning noncompliance with package acceptance specifications. The work relating to this action plan was discussed during the inspections held on the facility in 2017.

An auxiliary building intended for the storage of equipment was commissioned in 2017. Commissioning of the examination unit authorised by ASN in January 2016 has been pushed back to the end of the first half of 2018.

The corrective actions further to the fall of an MI waste bin in October 2016 were deemed satisfactory and authorised by ASN in 2017. However, it was observed during inspections in 2017 that their implementation had taken a long time. ASN will be attentive that their implementation continues properly 2018. In addition, the reception of packages from the alpha waste packaging unit (Marcoule) with heterogeneous fissile material distribution was authorised by ASN in July 2017. This work will continue in 2018.

ASN considers that Cedre must be operated with greater rigour and that the measures to clarify the specifications of the packages and waste bins received at the facility must be continued.

- **Cascad facility (BNI 22)**

The Cascad facility, authorised by a Decree of 4th September 1989 modifying the Pégase facility and operated since 1990, is dedicated to the dry storage of spent fuel canisters in wells.

Unlike Pégase, from which all the radioactive substances must be removed as soon as possible, Cascad displays a satisfactory level of safety.

Through a resolution of 8th July 2014, ASN authorised a further ten years of storage for the spent fuels already present in the facility. This resolution is without prejudice to the conclusions of the facility's next periodic safety review for which the file was submitted on 30th October, the same date as that for Pégase. The examination of this file will focus in particular on the way the site effects are taken into account in the evaluation of the seismic resistance of the facility.

The CEA is considering pushing back to 2025 the decoupling of the two facilities to avoid any concomitant activity that would penalise removal of the araldite-coated spent fuel from Pégase. ASN will examine this change-of-strategy request.

As at 13th September 2017, 268 pits out of 315 usable pits were occupied and contained a total of 3,616 containers.

On condition that the removal of fuel from the Phénix NPP takes place before 2023, the CEA estimates that the Cascad pits will have reached 90% filling capacity in 2026.

ASN's opinion on the safety of operation of the Cascad facility is generally positive. Two inspections were carried out in 2017 on BNI 22 (Cascad and Pégase), one a general inspection, the other concerning the periodic checks and tests. The responses were on the whole satisfactory.

- **Chicade (BNI 156)**

The Chicade facility (chemistry, waste characterisation), the creation of which was authorised by the Decree of 29th March 1993, conducts research and development work on low and intermediate level waste and objects. 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;
- the assessment and monitoring of waste packaged by the waste producers.

The CEA informed ASN in 2015 of its project to extend the facility's activities to the packaging of waste within a time frame of 7 to 10 years. ASN considers that the CEA must ensure that the facility is appropriately dimensioned to be able to operate with the envisaged extensions. As part of the facility's research and development activities, the CEA in mid-2017 submitted a license application to ASN for the development of packages for disused ILW-LL sealed sources and to produce a limited number of them. This application is currently being examined.

The CEA has undertaken to apply to ASN at the end of 2018 for the creation authorisation decree to be modified to take into account the improved performance of the measuring equipment quantifying the radioactivity in the gaseous effluents from the Cadarache centre.

The periodic safety review report of the facility was submitted by the CEA in March 2017 and is currently being examined by ASN. The analysis of the consequences of an earthquake on the facility and the methods of reinforcing the resistance of the FA building represent major issues in this examination.

Moreover, two inspections were carried out, one on waste management and one general inspection, and their overall conclusions were positive.

ASN considers that the Chicade facility was operated satisfactorily in 2017.

On the Saclay site

- **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 2004-25 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 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 produced 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. The CEA has since progressed in defining its packaging solution for all the effluents of the installation (package 12H); Andra is now examining the validity of this solution. The CEA however had not obtained approval of the 12H package by the initial deadline of mid-2017. The CEA has asked for this deadline to be pushed back to 2018. ASN is currently examining the elements provided to justify this request.

The complementary investigations concerning the stability of the walls of the LL liquid effluents storage room (room 97) structure, which have led the CEA to suspend the acceptance of effluents from other BNIs, have not yet been completed. ASN remains attentive to the development of this situation and more specifically to any impacts it might have on the safety of the facility, on the legacy effluent retrieval programmes and the on management of the Saclay centre's liquid waste. Given this context, the CEA must monitor the safety of this facility with particular attention and take the necessary measures to resolve the operating difficulties encountered (see page 454) and to compensate for the unavailability of this room and ensure a regular management solution for the liquid waste from the Saclay centre.

ASN moreover carried out two inspections of the facility in 2017, one on commitment monitoring, and the other on the periodic tests. ASN considers that significant progress has been made in the routine management of waste, but major issues subsist in the management of the legacy effluents stored in pit 99, which must be cleaned out. The licensee must also finalise the updating of the safety analysis report within the times to which it has committed itself.

Renovation or shutdown of old facilities

On the Cadarache site

- **Solid Waste Treatment Station (STD) - BNI 37-A and Effluent Treatment Station (STE) - BNI 37-B**

BNI 37 of CEA Cadarache historically comprised the Effluent Treatment Station (STE) and the Waste Treatment Station (STD). The STE definitively stopped functioning on 1st January 2014 and must be decommissioned. Continued operation of the STD over the long term necessitates renovation work which was prescribed on completion of its second periodic safety review.

The STD and the STE were registered respectively as BNI 37-A and 37-B on 5th July 2015, in order to distinguish the part of the facility to be sustained from the part to be decommissioned. The registrations were made after defining the perimeters of these two BNIs by Orders of 9th June 2015. The registration resolutions for these two BNIs act as a Creation Authorisation Decree.

- **Solid Waste Treatment Station (STD) - BNI 37-A**

At present, the STD is CEA's only civil BNI licensed to package ILW-LL radioactive waste before it is stored in the Cedra facility (BNI 164) pending transfer to a deep geological repository (*Cigéo* project).

The last safety review of the STD showed that for its activity to continue over the long term, substantial renovation work was necessary and that pending performance of this work, whose completion is planned for 2021, protective measures would have to be implemented in the short term.

To govern operation of the facility until the renovation work is completed, ASN instructed the licensee – through its resolution of 18th April 2016 – to update the baseline requirements of the facility before the end of 2016 and to put in place protective measures covering the period from April 2016 until the end of 2017, concerning in particular the restriction of the quantities of radioactive substances in the facility and fire protection. The ASN instructions also govern the renovation work, particularly increasing the earthquake resistance of the waste treatment zones and the protective measures against fire and flooding and their completion deadline in 2021.

In the course of 2017, ASN started examining the update of the BNI's baseline safety requirements submitted by the CEA at the end of 2016, and also examined the authorisation applications for significant modifications concerning the implementation of protective measures.

The work to disassemble the unused equipment of the BNI prior to the BNI renovation work is continuing: the injection line, the 250-tonne press and its handling unit are disassembled; the ongoing disassembly worksites concern the incinerator and the MI storage area; the worksites which have not yet started concern the removal of the hydraulic unit of the 250-tonne press, disassembly of the decommissioning unit (breakup room) and that of the injection cell.

The instruction relative to submission of the safety case of the facility in its final state by the end of 2017 represents an important milestone in the renovation project. ASN will be attentive to ensure that this deadline is met.

In application of Article 6.7 of the Order of 7th February 2012, the CEA transmitted, on 20th November 2015, a packaging approval application file for the 500 L MI and 870 L alpha-Pu FI packages of BNI 37-A, which is currently being examined.

Further to persistent shortcomings in the management of deviations on BNIs 37-A and 37-B, ASN gave CEA formal notice in July 2016 to put in place an organisation designed to better detect deviations, analyse them, define appropriate corrective actions, implement them and measure their effectiveness in order to comply with the BNI Order.

The observed malfunctions concerned in particular the management of the inspections and periodic tests, the conditions of waste storage in the facilities, equipment lockouts/tag-outs and management of the fire risk.

The inspections carried out during 2017 to check compliance with the formal notice requirements confirmed the improvements in operating rigour and the management of deviations.

ASN nevertheless remains vigilant with regard to these points and compliance with the commitments made further to the periodic safety review, particularly compliance with the completion deadlines for the facility renovation project.

- **Effluent Treatment Station (BNI 37-B)**

The periodic safety review file for the STE was submitted to ASN in late October 2017. CEA planned to submit the STE decommissioning file in 2017 at the same time as the safety review file. The CEA has pushed back submission of the decommissioning file until 2021. As the STE has been stopped since 1st January 2014, its shutdown can be considered definitive since 1st January 2016 in accordance with the provisions of Act 2015-992 of 17th August 2015 relative to the Energy Transition for Green Growth. In its resolution of 27th July 2017, ASN has set 29th December2019 as the deadline date for submitting the decommissioning file, that is to say almost six years after the facility stopped operating and four years after its final shutdown, to take into account the complexity of the facility.

As part of the preparation of the decommissioning file, the CEA is continuing to characterise the soils and tanks in order to establish the initial state of the facility.

The inspections carried out in 2016 and the formal notice decision of 5th July 2016 led the CEA to produce an action plan to improve the handling of deviations and in particular to characterise the tanks, and to define measures for the inspection and maintenance of the retention structures and the removal of the waste stored in unauthorised premises.

The inspections conducted in 2017 show that the actions taken to bring this facility into compliance are on the whole satisfactory. Progress must nevertheless continue to be made over the longer term and ASN will be vigilant regarding compliance with this action plan.

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, is used for waste storage and packaging as well as for waste retrieval from small-scale nuclear activities[5] (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 and the commitments made during the periodic safety review or after inspections. ASN has asked the CEA to put in place the appropriate organisation and means, particularly the means necessary for decommissioning the facility.

These retrieval and packaging projects necessitate substantial technical and human resources and ASN verifies, through periodic meetings with the licensee, the progress of these projects and CEA's compliance with its commitments.

ASN notes that some waste removal worksites which had fallen behind schedule after discovering package contents that did not meet the safety baseline requirements for these operations (cans damaged or missing), have resumed and are continuing under suitably safe conditions. Removal of the first spent fuel from the storage blocks has begun.

5. *Small-scale nuclear activities represent all facilities using ionising radiation but not covered by the BNI system. Small-scale nuclear activities concern many fields such as medicine (radiology, radiotherapy, nuclear medicine), human biology, research and industry.*

ASN does however observe that several removal from storage operations have not started. The progress of these operations is behind the projected schedule. Compliance with certain deadlines set by ASN for removing from storage the drums in the 40 non-drained pits of building 114 and the fuel stored in the pool and in the concrete blocks is compromised, which led the CEA in 2017 to request that these deadlines – set by ASN resolution of 22nd July 2010 – be pushed back by five years. This request is currently being examined.

ASN shall be attentive to the justification of the new time frames requested and the plan of action proposed by the CEA to complete the removal from storage operations in a schedule compatible with maintaining the facility in suitably safe conditions.

Despite these delays, ASN considers that the safety of the facility such as it is ensured today is on the whole satisfactory.

The decommissioning authorisation application file submitted in December 2015 was lacking in many respects. ASN asked for additional information, which the CEA submitted in September 2017. This included more specifically the safety case for the operations planned in the next ten years (removal from storage operations, EPOC in particular).

In November 2017 the CEA filed the concluding report for the periodic safety review of BNI 72 to ASN.

On 7th October 2017, CEA stated that shutdown of BNI 72 was pushed back from 31st December 2017 to 31st December 2022 in order to continue its activities during the transition phase between the initially planned shutdown date and the entry into effect of the decommissioning decree.

In the context of the periodic safety review and examination of the decommissioning file, ASN will check whether partial operation of BNI 72 can continue in complete safety and it will ensure that the decommissioning preparation operations, particularly those concerning the removal of radioactive and hazardous substances, are carried out under optimum conditions of safety and radiation protection and with adequate resources.

ASN carried out four inspections of the facility in 2017. They led to several requests for corrective action and additional information. The licensee must in particular step up the monitoring of outside contractors responsible for waste management.

Lastly, with the prospect of the scheduled final shutdown and decommissioning of BNI 72, ASN will be attentive to the proposed organisation and the means deployed by the CEA for the future treatment of solid waste from the Saclay site.

■ **Liquid effluent management zone (BNI 35)**

Decree 2004-25 of 8th January 2004 authorising the creation of Stella required the CEA to remove old effluents stored in the MA500 and HA4 tanks of BNI 35 within ten years. The 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 gigabecquerels in 2004) as at 8th January 2014. Nevertheless, all the radioactive organic effluents contained in tank HA4, which presented the greatest safety risks, had been removed by the end of 2013.

Through resolution 2014-DC-0441 of 15th July 2014, ASN prescribed new retrieval deadlines for these effluents and obliged the CEA to have them removed by the end of 2018, with intermediate milestones at the end of 2014, 2015 and 2016. These intermediate milestones were met. The CEA nevertheless informed ASN in 2017 that it was having difficulties in completing the emptying of the last tank within the prescribed of end-of-2018 deadline. ASN is attentive to the measures taken by the CEA to keep these difficulties under control and to start the clean-out of the building accommodating these effluents.

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 facility comprises six pits, five trenches, three pools and hangars containing primarily intermediate-level, long-lived waste (ILW-LL) from the operation or decommissioning of the CEA's installations which cannot be disposed of at the CSA repository. The facility also comprises storage areas of legacy very low level (VLL) waste compatible with disposal at the Cires facility.

The waste present on the facility 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. The VLL waste will be characterised and packaged at the STARC ICPE, situated in Epothémont (Aube *département*), then transferred to the Cires repository.

The report presenting the conclusions of the periodic safety review of the facility was submitted in April 2017. At the same time, the CEA submitted an application for registration of the BNI perimeter of the facility because the regulatory framework in force when it was created did not provide for a BNI perimeter to be explicitly defined. A joint examination is being conducted on the two subjects. During the inspections of the facility in 2017 it was observed that the management and monitoring of the equipment for ensuring the containment of materials with respect to the soils and surface and groundwater could be improved, and this issue will be addressed specifically in the examination of the periodic safety review of the facility. The CEA plans to submit the facility decommissioning file in the second half of 2018.

ASN considers that significant improvements have been made in safety management at this installation over the last few years. The CEA completed waste retrieval and packaging projects in 2017 in accordance with its commitments (retrieval of the T2 trench). In addition, the CEA has restored an operating pace that exceeds its targets for pits 5 and 6 for the year 2017. As for the "legacy" VLL waste, its removal from storage should be completed by 2019. However, delays are observed in emptying the pools and retrieving the low-level waste from the pits, given the complexity of the operations with regard to project management and implementation of the technical retrieval solutions.

ASN will also be attentive to the progress of the retrieval of the waste packages stored in the hangars, especially those that are currently undergoing additional characterisation investigations to determine whether they can be accepted in the downstream storage routes (Cedra in particular).

Pégase (BNI 22)

The Pégase reactor entered service on the Cadarache site in 1964 and was operated for about ten years. By the Decree of 17th September 1980, the CEA was authorised to reuse the Pégase facilities to store radioactive substances, particularly spent fuel elements in a pool.

This facility does not meet current storage standards and since 2008 it has received no further radioactive substances for storage. Its source term has significantly decreased since 2004, falling from $2.5x10^{17}$ becquerels (Bq) as at 31st December 2004 to $9.8x10^{15}$ Bq as at 31st December 2016. It is now only located in the pool.

The removal from storage of the 2,714 plutonium-containing waste drums stored in the premises baptised DRG was completed at the end of 2013. Furthermore, out of the 865 cans of fuel elements surplus to requirements initially present in the pool in 2004, there remained 123 on 16th June 2017 (119 araldite-coated cans and four non-araldite-coated cans containing water and recategorised). Removal of the non-araldited fuel surplus to requirements was completed on 16th November 2016.

Removal from storage of the araldite-coated fuel surplus to requirements necessitates the development of a heat treatment process which is currently underway at the STAR (Spent Fuel Reprocessing Clean-out and Repackaging Station) facility (BNI 55). Given the fact that STAR is unavailable until 2022-2023 and the time required to set up such a process, the CEA is currently studying alternative solutions.

One solution being studied is removal of the fuel to the pools of the RES (test reactor) installation for subsequent processing in STAR, while another is examining their repackaging in Pégase to allow direct removal to Cascad. CEA plans making a decision in 2018.

The other radioactive substances and items to be removed comprise beryllium reflector elements, boron carbide absorbing elements and irradiating materials from decommissioning of the Pégase reactor.

The CEA plans storing the Be and B_4C elements in Diadem after their packaging in ISAI (individual facility for monitoring irradiated assemblies) at the Marcoule Defence Basic Nuclear Installation (DBNI), which can accept large-capacity packages and has a large modular cell with systems for placing in welded containers.

With regard to the irradiating waste from the Pégase reactor, the CEA plans to treat it in the Pégase shielded unit before sending it to STAR to make up ILW bins which will be processed in BNI 37-A before being stored in Cedra.

The examination of CEA's request to push back the deadline for removal of the radioactive substances from the Pégase pool from 2015 to 2025 led ASN to stipulate on 10th February 2017 that the removal from storage and removal of all the radioactive substances present in the installation was to be completed by the end of 2018. This deadline may nevertheless be revised in the light of the safety review file which was submitted late October 2017 and is currently being examined.

At the end of 2017, the CEA declared that Pégase would be finally shut down at the end of 2023 and adopted the partial decommissioning option in order to continue operating Cascad.

Despite these delays, ASN's assessment of the operating safety of BNI 22 is positive on the whole. It will remain vigilant with regard to the schedule for removing the radioactive substances from the Pégase pool and the choice of solution for removing the araldite-coated fuel surplus to requirements in order not to delay the removal from storage.

1.4.2 Areva waste management

ASN's opinion on Areva's waste management strategy

The spent fuel reprocessing plant at La Hague produces a large proportion of Areva's radioactive waste. The waste on the La Hague site comprises on the one hand waste resulting from reprocessing of the spent fuel, which generally comes from nuclear power plants but also from research reactors, and on the other, 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 front end activities of the cycle, essentially contaminated by alpha emitters.

In mid-2016 Areva submitted to ASN and ASND a file presenting the decommissioning and waste management strategy for the group's installations in France and its practical application on the La Hague and Tricastin sites. This file, for which additional elements were received in 2017, is currently being examined. ASN will give an opinion on this strategy in 2018. The last review of Areva's waste management strategy dates back to 2005 and only focused on the Areva NC La Hague site.

The issues and implications

The main issues relating to the management of waste from the licensee Areva concern:
- the safety of the facilities for storing the legacy waste present on the La Hague site, which requires planning for and implementing appropriate retrieval and storage solutions. ASN has effectively observed recurrent lateness in the retrieval of legacy waste at La Hague (see chapter 15);
- 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 time frames that enable 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 associated 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. This site is presented in chapter 13 covering fuel cycle installations.

- **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 high-threshold ICPE System.

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.

It comprises two sludge storage ponds (B1 and B2) for sludge from the Areva NC plant on the Malvési site. These ponds alone 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.

Areva applied for commissioning authorisation on 15th October 2015. This application was supplemented on 2nd June 2016 and is currently being examined by ASN. ASN will adopt a position on this application in 2018, provided that Areva NC has submitted the last additional information requested.

ASN is particularly attentive to the stability of the embankments and their earthquake resistance, and the safety of the work involved in the transfer of the sludge, the filling of the compartment and the laying of the bituminous cover.

Within the framework of the PNGMDR, ASN asked Areva to study the different long-term disposal options for the waste contained in the Ecrin BNI. These studies are currently being examined.

1.4.3 EDF waste management

EDF waste management strategy

The waste produced by EDF Nuclear Power Plants (NPP) is activated waste (from reactor cores) and waste resulting from their operation and maintenance. Some legacy waste and waste resulting from ongoing decommissioning operations can be added to this. 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.

Operational 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 in 2015. Further to this examination, ASN asked EDF more specifically in 2017 to continue its measures to reduce the uncertainties concerning the activity of the waste sent to the CSA, to improve its organisational arrangements to guarantee the allocation of adequate resources to radioactive waste management, and to present the most appropriate process for the treatment of used steam generators.

The issues and implications

The main issues related to the EDF waste management strategy concern the management of legacy waste and changes linked to the fuel cycle.
- The management of legacy waste 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 waste (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 are involved in EDF's fuel use policy (see chapter 12) which 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 for Nuclear Reactors and the Advisory Committee for Laboratories and Plants 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 or treatment (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 2010-402 of 23rd April 2010, will be to process and store activated waste from operation of the nuclear fleet in service and from the decommissioning of the first-generation reactors and of the Creys-Malville NPP.

The main risks and inconveniences associated with the facility are the dispersion of radioactive substances and hazardous substances, the release of heat, the radiolysis of waste and the exposure of persons to ionising radiation.

The construction site was suspended in January 2012 for more than three years due to cancellation of the building permit by the Appeal Court of Lyon. Work resumed in April 2015.

Building work on the facility has continued since that date. The commissioning of the facility, which EDF had initially scheduled for early 2014, fell behind schedule due to the worksite suspension.

The Iceda commissioning authorisation application file was submitted to ASN in July 2016. Pursuant to the examination of this file, ASN asked for complementary technical information concerning the safety case, the definition of Elements Important for Protection (EIP) and Activities Important for Protection (AIP), the start-up tests, waste management and the operating documents.

Examination of the commissioning application file, for which the maximum time is set at one year by Article 4 of the Decree of 2nd November 2007, is suspended until all these elements have been received. Discussions are in progress with EDF on subjects such as the definition of the EIPs and AIPs and the associated requirements, particularly for the collective measures for occupational radiation protection.

In 2017, ASN continued examining the application file for approving the packaging of ILW-LL waste in C1PG packages in the Iceda facility, submitted by EDF in November 2015 and supplemented at the request of ASN in May 2016. The first conclusions of the examination do not allow the C1PG package to be authorised in its current state. Complementary studies will be necessary in order to rule on the suitability of this package for the waste it is designed to contain.

Iceda construction worksite, 2017.

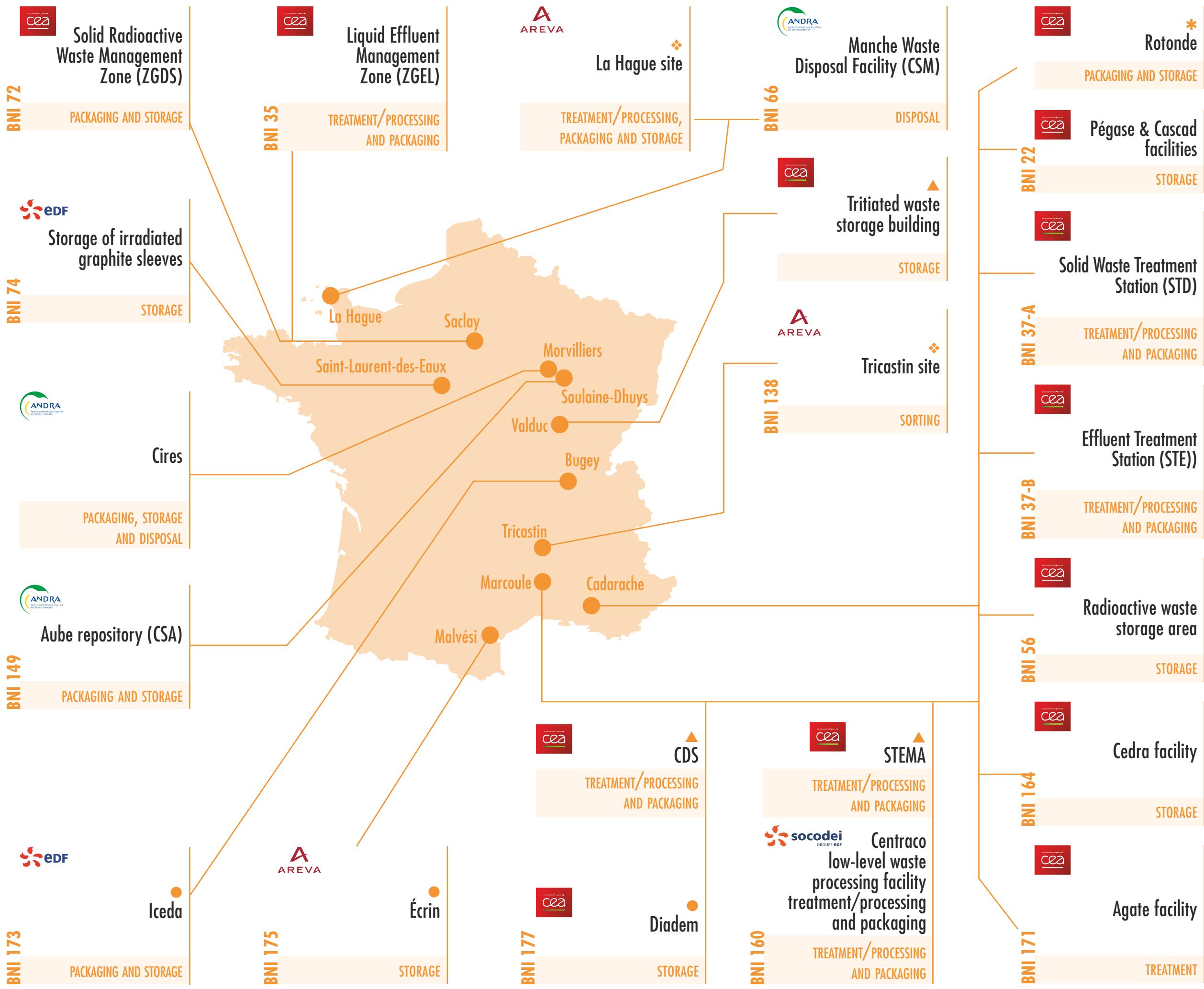
During the two inspections carried out in 2017, ASN found that EDF has a rigorous organisation for monitoring the worksite and its subcontractors. The inspectors also observed the progress of the work, particularly the fitting out of the hot cells and underlined the good overall upkeep of the worksite. The finishing work and the end-of-assembly verifications are in progress, particularly on the networks. The facility construction quality file must nevertheless be supplemented. The test programme is about six months behind schedule.

FUNDAMENTALS

The challenges concerning Iceda

They consist in:
- ensuring safety for the projected duration of operation of the facility under normal, incident and accident conditions;
- defining and checking the acceptance specifications for incoming waste;
- ensuring the quality of the package packaging operations;
- maintaining the packages in a state of conservation that allows them to be managed in complete safety throughout the storage period and ensures their compatibility with the planned conditions for their subsequent management. The condition of the package must be subject to a monitoring programme on this account. It must be possible to retrieve the packages at the end of the storage period or if deterioration is detected; the treatment of nonconforming packages must be planned for. Lastly, a programme for monitoring the ageing of the civil engineering structures and the means of package retrieval must be put in place, along with, in particular, a maintenance programme for the lifting and handling equipment.

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 DBNIs

In 2018, ASN will be attentive to the quality of the content of the commissioning authorisation application and to the satisfactory performance of the tests.

■ **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 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 of this BNI is limited to surveillance and maintenance measures (inspections and radiological monitoring of the silos, checking there is no water ingress, checking relative humidity, dose rates in the vicinity of the silos, the activity of the water table, monitoring the condition of civil engineering structures). These actions are on the whole performed satisfactorily.

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 the silos are respected.

The file concerning the stress tests conducted as part of the Fukushima Daiichi accident experience feedback process, submitted at the end of 2015, has been examined by ASN. The measures implemented by EDF are satisfactory on the whole.

In the context of its new decommissioning strategy for the Gas-Cooled Reactors (GCR) presented to ASN and the local information committee in 2016, EDF announced its decision to start removing the graphite from the silos without waiting for the graphite waste disposal route to become available. To this end EDF is considering creating a new facility for storing sleeves on the Saint-Laurent-des-Eaux site and submitting a decommissioning file in 2025 with a view to starting the emptying of the silos in 2029. EDF will present the progress of the removal-from-silo and storage studies to ASN in 2018. ASN will examine these studies along with the periodic safety review of the silos in 2019.

1.4.4 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.

ASN conducted four inspections on the Centraco site in 2017. ASN considers that the current organisation of the facility enables the installations to function with a suitable level of safety.

1.5 Management of waste from small-scale nuclear activities

1.5.1 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, remains from meals served (uneaten foodstuffs, containers, and cutlery) to patients who have received injections for diagnostic or therapeutic purposes, etc. Radioactive liquid effluents also come from source preparation as well as from patients who eliminate the administered radioactivity 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 produced 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). Once they have been used, and if their suppliers do not envisage their reuse in any way, they are considered to be radioactive waste and must be managed as such.

The management of sealed sources considered to be waste, and their disposal in particular, must take into consideration the dual constraint of concentrated activity and a potentially attractive appearance in the event of human intrusion after loss of the memory of a disposal facility. This dual constraint therefore limits the types of sources that can be accepted in disposal facilities, especially surface facilities.

Further to the PNGMDR 2013-2015, the CEA submitted to the State in late 2014 a summary report of its work concerning:
- continuation of Andra's study of the conditions of acceptance of these sealed sources in disposal facilities;
- consolidated batching of disused 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 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 small-scale 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. Since 2012, Cires – situated in the municipalities of Morvilliers and La Chaise – is Andra's collection centre and storage facility for waste from small producers other than nuclear power plants. 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.

Nevertheless, the tritiated solid waste will have to be managed along with the waste from ITER (Intermed project) in a storage facility operated by the CEA.

However, the delays in the ITER project schedule are impacting the Intermed project schedule and the management strategy for tritiated waste from small producers. In its opinion of 24th November 2016, ASN asked the CEA to take into account the shift in the projected date of Intermed commissioning in the studies to compare tritiated waste management solutions carried out for the PNGMDR and to define, before 31st December 2017, a revised strategy for the storage of tritiated waste from installations other than ITER.

1.5.2 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 products, residues or waste resulting from these materials. This is known as technologically enhanced natural radioactivity. The majority of these activities are (or were) regulated by the ICPE System 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 waste disposal facilities are authorised by Prefectural Order to receive waste containing enhanced natural radioactivity, namely the hazardous waste disposal facilities of:
- Villeparisis in Ile-de-France, authorised until 31st December 2020, for an annual capacity of 250,000 tonnes per year (t/year);
- Bellegarde in Occitanie, 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 Normandie, authorised until 2023, for an annual capacity of 30,000 t/year.

The PNGMDR 2013-2015 identified the need for regulatory changes in order to improve knowledge of the deposits of enhanced naturally radioactive waste and improve their traceability.

The transposition of Directive 2013/59/Euratom of 5th December 2013 setting the basic standards for radiation protection (see chapter 3) 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. The activities of industries involving enhanced natural radioactivity are therefore concerned. The scope of application of the reinforcements 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 radiation protection verification. Consequently, the currently applicable regulations concerning activities involving enhanced natural radioactivity will change in 2018 in the transposition of this directive, while maintaining the same management principles for this type of waste.

1.5.3 Management of mining residues and mining waste rock from former uranium mines

Uranium mines were worked in France between 1948 and 2001, producing 76,000 tons of uranium. Some 250 sites in France were involved in exploration, extraction and processing activities. The sites were spread over 27 *départements* in the eight regions of Nouvelle-Aquitaine, Bretagne, Pays de la Loire, Auvergne-Rhône-Alpes, Bourgogne-Franche-Comté, Provence-Alpes-Côtes d'Azur, Grand Est and Occitanie. 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. These sites are ICPEs and their environmental impact is monitored.

The regulatory context

The uranium mines, 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. They are not under ASN oversight.

Furthermore, the Minister responsible for 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 reuse of waste rock in the public domain has been traced since 1984, knowledge of reuses prior to 1984 remains incomplete. ASN and the Ministry responsible for the Environment, in the framework of the action plan drawn up further to the Circular of 22nd July 2009, asked Areva Mines to inventory the mining waste rock reused in the public domain in order to verify compatibility of the 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 Ministry responsible for the Environment defined the procedures for managing cases of confirmed presence of mining waste rock in an Instruction to Prefects of 8th August 2013. Some work has been carried out since 2015 on sites classified as priorities, 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 millisieverts per year (mSv/year) on the basis of a radiological impact study.

Within the framework of the PNGMDR 2016-2018 Areva submitted in January 2018 an assessment of the actions taken for the inventorying of mining waste rock in the public domain. 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 assists the Prefects with regard to the radiation protection of workers and the public and the review of 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 reference 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 such cases. 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 geochemical and radiological 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 PNGMDR 2013-2015, based on ASN opinion 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;
- the doctrine for assessing the long-term integrity of the embankments surrounding tailings disposal sites;
- the comparison of the surveillance data and the results of modelling;
- 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.

As required by the ASN opinion of 9th February 2016, these studies are continuing as part of the PNGMDR 2016-2018 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.

Thus, in January 2017, Areva supplemented its study on the relation between the discharged flows and the accumulation of marked sediments in the rivers and lakes. This study is currently being examined by ASN. Two other Areva studies are expected at the beginning of 2018, addressing:
- the result of the actions taken to inventory the waste rock in the public domain;
- the progress in the modelling of long-term transfer of uranium and radium in certain residue disposal sites.

With regard to mining waste rock, sites containing waste rock outside the perimeter of the former uranium mining sites must continue to be treated. The consultation process must also be continued with the stakeholders on all these subjects, within the framework of the PNGMDR as well as at the local level.

The Pluralistic Expert Group (GEP), involvement and informing of the stakeholders

Set up in 2005, the Limousin Pluralistic Expert Group (GEP) submitted two reports to the Minister responsible for the Environment and to the Chairman of ASN in 2010 and 2013. The first report proposes recommendations for the short-, medium- and long-term management of former uranium mining sites in France. ASN and the Ministry responsible for the Environment are thus engaged in a plan of action dedicated to the implementation of these recommendations.

The second report 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.

ASN is moreover continuing its involvement in the steering committee for the national inventory of uranium mining sites, baptised Mimausa (Memory and impact of uranium mines: summary and archives, available on *www.irsn.fr)*.

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 finalised under the coordination of the Ministry for Ecological and Inclusive Transition. It shall more particularly respond to several recommendations resulting from the GEP report of September 2010 on the Limousin uranium mining sites: 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.

2. Management of sites and soils polluted by radioactive substances

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 result from industrial, craft, 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 have been the seat of 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 that generated the radioactive contamination identified today 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, which necessitates having a precise diagnosis of the site.

Article L.125-6 of the Environment Code provides for the State to create Soil Information Sectors (SIS) in the light of the information at its disposal. These sectors must comprise land areas in which the knowledge of soil contamination justifies – particularly in the case of change of use – carrying out soil analyses and taking contamination management measures to preserve safety, public health and the environment. Decree 2015-1353 of 26th October 2015 defines the conditions of application of these measures.

The Regional Directorates for the Environment, Planning and Housing (Dreal) coordinate the SIS development process under the authority of the Prefects. The ASN regional divisions contribute to the process by informing the Dreals of the sites they know to be contaminated by radioactive substances. Ultimately these sites are to be registered in the urban planning documents.

The SIS development process is progressive and is not intended to be exhaustive.

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 Ministry responsible for the Environment's databases dedicated to contaminated sites and soils *(www.georisques.gouv.fr/dossiers/pollution-des-sols-sis-et-anciens-sites-industriels)*.

In October 2012, ASN finalised its doctrine specifying the fundamental principles it has adopted for the management of sites contaminated by radioactive substances. In the event that, depending on the characteristics of the site, this procedure would be difficult to apply, it is in any case necessary to go as far as reasonably possible in the remediation process and to provide elements, whether technical or economic, proving that the remediation operations cannot be taken further and are compatible with the actual or planned use of the site.

The ASN doctrine defines the measures to take if complete remediation is not achieved.

ASN considers moreover that the stakeholders and audiences concerned must be involved as early as possible in the process to rehabilitate a site contaminated by radioactive substances.

ASN also points out that in application of the "polluter-pays" principle written into the Environment Code, those responsible for the contamination finance 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.

2.1 Regulatory framework

In reference to Article L. 542-12 of the Environment Code (see point 1.5.1), Andra receives a State subsidy to help fund its assigned missions of general interest. The French National Funding Commission for Radioactive Matters 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.

The commission met four times in 2017, more specifically to decide on the allocation of public funds for the management of contaminated sites considered to be priority cases, such as the sites of Champlay, Limoges and Orléans, as well as those of the Radium Diagnosis operation.

The Circular of 17th November 2008 of the Minister responsible for the Environment relative to the management of certain radioactive wastes 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 in default. Whatever the case, the Prefect relies on the opinion of the classified installations inspectorate, of ASN and the ARS (Regional Health Agency), to approve 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 Prefect and the classified installations inspectors to give its opinion on the clean-out objectives of a site.

The currently applicable regulations concerning contaminated sites and soils (excluding ICPE and BNIs) shall be modified and supplemented in 2018 pursuant to the transposition of Directive 2013/59/Euratom of 5th December 2013 (see chapter 3).

When contamination is caused by an installation that is subject to special policing (BNI, ICPE or nuclear activity governed by the Public Health Code), the sites are managed under the same oversight system. Otherwise, the Prefect oversees the management of the contaminated site.

Chapter 8 details the various demands concerning contaminated sites and soils to which the ASN regional divisions responded.

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 craft 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.

A non-exhaustive list drawn up in late 2014 of addresses having accommodated such activities counts more than 160 sites in France.

For the occupants of these sites, this operation – free of charge – consisted in performing a diagnosis and rehabilitating the site if radiological contamination was found.

The diagnoses carried out by IRSN since the operation began have resulted in 25 premises being rehabilitated and then renovated (21 in Ile-de-France and four in Annemasse).

The feedback more than five years after launching the operation shows that the large majority of premises diagnosed are free of radiological contamination. The contamination levels recorded are low and confirm that there is no health risk.

The initiation of further diagnosis operations was suspended in 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 continues to monitor the sites on which rehabilitation work is still in progress.

Aerial view of the formerly contaminated Orflam-Plast site in Pargny-sur-Saulx after rehabilitation.

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[6] (RSLS) 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 needs in terms of management and means for preventing the creation of future legacy sites. ASN took part in the forum's technical seminar held in October 2017 in Bessines-sur-Gartempes. In 2018, the IAEA plans to publish a "Tecdoc" technical document tracing back the interchanges between the countries.

ASN also 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 2018, ASN will continue 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.

3. Outlook

ASN considers that the French radioactive waste management system, built around a specific legislative and regulatory framework – a National Plan (the PNGMDR) and an Agency (Andra) for managing radioactive waste which is independent of the waste producers – is capable of regulating and implementing a structured and coherent national waste management policy. ASN considers that there must ultimately be safe management routes for all waste, and more specifically a disposal solution.

The French National plan for the Management of Radioactive Materials and Waste

ASN will monitor the progress of the studies submitted under the PNGMDR 2016-2018, more specifically within the pluralistic working group that it co-chairs with the DGEC. Depending on the decision of the French national public debate commission, which will be consulted on the methods of organising public participation in the preparation of the PNGMDR 2019-2021, ASN will work alongside the Ministry for Ecological and Inclusive Transition to enable the public to be involved in the draft plan. ASN will also prepare the production of the future PNGMDR through the opinions

6. *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.*

it will issue, as of 2018, on the analyses of the PNGMDR 2016-2018.

Lastly, ASN will participate in the working group of the HCTISN (French High Committee for Transparency and Information on Nuclear Security) on the management of VLL waste.

The regulations concerning the management of radioactive waste

In 2018, ASN will continue to prepare draft resolutions relative to the radioactive waste disposal and storage facilities. These draft texts will be made available for consultation by the stakeholders and the public.

ASN will also be vigilant with regard to the transposition of Directive 2013/59/Euratom of 5th December 2013.

The radioactive materials and waste management strategies of the licensees

In 2018, ASN will continue to monitor the legacy waste and spent fuel retrieval and packaging operations, focusing on those presenting the most significant safety risks.

ASN will complete its joint examination with ASND of the waste management strategy of Areva, submitted in mid-2016, and of the CEA, submitted at the end of 2016. ASN and the ASND will present their conclusions in 2018.

In 2018, ASN will continue its oversight actions to ensure that the CEA meets its commitments concerning its old facilities which do not comply with current safety requirements. ASN will also keep track of the progress of the CEA's strategic waste management projects (Diadem, BNI 37-A, solid and liquid waste management on the Saclay site) and the preparation of the decommissioning files for the old storage facilities (BNI 56, Pégase, BNI 37-B).

Low-Level, Long-Lived Waste (LLW-LL)

With regard to LLW-LL, ASN considers it essential to make progress in setting up management solutions. The analysis of the file submitted by Andra in 2015 under the PNGMDR has shown that it will be difficult to demonstrate the feasibility – in the investigated area – of a disposal facility for all the LLW-LL waste. In its opinion of 29th March 2016, ASN asked Andra to submit by mid-2019, under the PNGMDR, a report presenting the technical and safety options for this disposal facility and an industrial scheme for managing the LLW-LL waste established through consultation with the producers of this waste. Andra has also undertaken to submit an interim report to ASN in 2018.

Depending on the conclusions of this report, the waste producers will, if necessary, have to firstly create new storage capacity to avoid delaying decommissioning operations, and secondly speed up the deployment of alternative strategies if their waste is not compatible with the Andra project.

In 2018, ASN will work on revising the safety guide relative to the disposal of low-level long-lived radioactive waste.

HLW and ILW-LL waste

With regard to the *Cigéo* disposal project for HLW and ILW-LL waste, in 2018 ASN will monitor Andra's preparation of the DAC application, and in particular the measures taken further to its demands concerning the safety options dossier. ASN urges Andra to be vigilant with regard to the industrial development times associated with the results of Andra's research and development programme and the regulatory deadlines that govern the *Cigéo* facility authorisation process.

ASN underlines the importance it attaches to the progress the waste producers must make in the packaging of their waste, particularly waste resulting from waste retrieval and packaging operations.

The periodic safety reviews of the radioactive waste management BNIs

In 2018, ASN will continue examining the nine periodic safety review conclusions reports for the waste management facilities received in 2016 and 2017. It will continue monitoring the progress of the action plans defined by the licensees for the BNIs whose files have already been examined.

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

ASN will continue to assist the public authorities with the Areva Mines action plan relative to the management of uranium mining waste rock. Its work will focus in particular 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.

With regard to contaminated sites and soils, in 2018 ASN will continue its analysis of the contaminated site remediation projects, on the basis of the principles of its doctrine published in October 2012.

ASN will also continue to monitor the ongoing rehabilitation worksites, in collaboration with the relevant administrations and the other stakeholders.

International actions

ASN will also continue to participate in the international work on the themes relative to the management of radioactive waste and contaminated sites and soils, particularly with the IAEA, ENSREG and WENRA, and in bilateral exchanges with its counterparts. It will participate in particular in the IAEA Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management that will be held in May 2018.

List of Basic Nuclear Installations as at 31st December 2017

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 Caen and Orléans divisions are responsible for BNI regulation in the Bretagne (Brittany) and Ile-de-France regions respectively. The Paris division oversees the overseas regions and the *département* of Mayotte, while the Marseille division oversees radiation protection and radioactive substance transport in the Corse territorial collectivity.

A BNI is an installation which, due to its nature or the quantity or activity of the radioactive substances it contains, is subject to a specific regulatory system as defined by the Act 2006-686 of 13th June 2006 (the "TSN Act") codified in Books I and V of the Environment Code by Ordinance 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. 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 comprise 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.

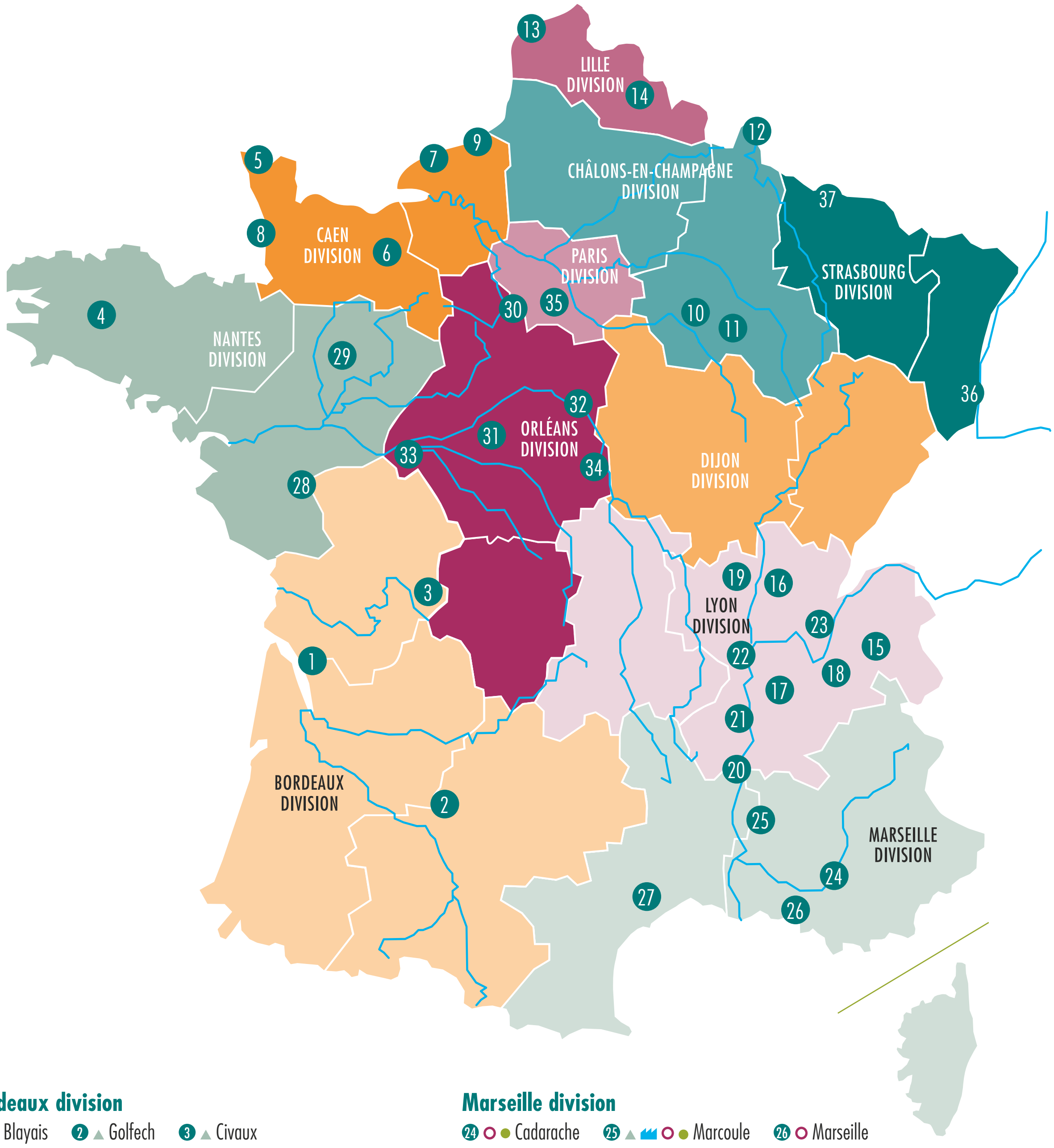
The following are subject to the BNI System:
- facilities under construction, provided that they are the subject of a Creation Authorisation Decree;
- facilities in operation;
- facilities shut down or undergoing decommissioning, until they are delicensed by ASN.

As at 31st December 2017, there were 127 BNIs (legal entities).

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 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 🏭 ■ 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 🏭 Romans-sur-Isère
18 🏭 Veurey-Voroize 19 ○ Dagneux 20 ▲ 🏭 ○ Tricastin
21 ▲ Cruas-Meysse 22 ▲ Saint-Alban/Saint-Maurice
23 ○ ▲ Creys-Malville

Marseille division

24 ○ ● Cadarache 25 ▲ 🏭 ○ ● 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
● Research installations
■ Disposal of waste
○ Others

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 29530 Loqueffret	EDF	Reactor (decommissioning in progress)	162
5 LA HAGUE	SPENT FUEL REPROCESSING PLANT (UP2-400) 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 (decommissioning in progress)	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 Paluel	EDF	Reactor	103
7 PALUEL	PALUEL NUCLEAR POWER PLANT (reactor 2) 76450 Paluel	EDF	Reactor	104
7 PALUEL	PALUEL NUCLEAR POWER PLANT (reactor 3) 76450 Paluel	EDF	Reactor	114
7 PALUEL	PALUEL NUCLEAR POWER PLANT (reactor 4) 76450 Paluel	EDF	Reactor	115
8 FLAMANVILLE	FLAMANVILLE NUCLEAR POWER PLANT (reactor 1) 50340 Flamanville	EDF	Reactor	108
8 FLAMANVILLE	FLAMANVILLE NUCLEAR POWER PLANT (reactor 2) 50340 Flamanville	EDF	Reactor	109
8 FLAMANVILLE	FLAMANVILLE NUCLEAR POWER PLANT (reactor 3 - EPR) 50340 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

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⑩ NOGENT-SUR-SEINE	NOGENT-SUR-SEINE 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 (decommissioning in progress)	163
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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 (SOMANU) 59600 Maubeuge	SOMANU	Nuclear maintenance	143
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⑮ GRENOBLE	HIGH FLUX REACTOR (RHF) 38041 Grenoble Cedex	Max von Laue Paul Langevin Institute	Reactor	67
⑮ GRENOBLE	DECAY INTERIM STORAGE FACILITY (STD) 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 (decommissioning in progress)	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 (MIR) BP 60120 - 01155 Lagnieu Cedex	EDF	Storage of new fuel	102
⑯ BUGEY	ACTIVATED WASTE PACKAGING AND STORAGE INSTALLATION (ICEDA) 01150 SAINT-VULBAS	EDF	Packaging and interim storage of radioactive substances	173
⑰ ROMANS-SUR-ISÈRE	NUCLEAR FUELS FABRICATION UNIT (CERCA) 26104 Romans-sur-Isère	New NP	Fabrication of radioactive substances	63
⑰ ROMANS-SUR-ISÈRE	NUCLEAR FUELS FABRICATION UNIT (FBFC) 26104 Romans-sur-Isère	New 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
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SITE NAME	NAME AND LOCATION OF THE INSTALLATION	LICENSEE	TYPE OF INSTALLATION	BNI
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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 (IARU) 26130 Saint-Paul-Trois-Châteaux	SOCATRI	Factory	138
20 TRICASTIN	TU5 and W FACILITIES BP 16 - 26701 Pierrelatte	AREVA NC	Transformation of radioactive substances	155
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20 TRICASTIN	GEORGES BESSE II PLANT FOR CENTRIFUGAL SEPARATION OF URANIUM ISOTOPES (GB II) 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
20 TRICASTIN	TRICASTIN URANIUM-BEARING MATERIAL STORAGE YARD 26700 Pierrelatte	AREVA NC	Storage of radioactive materials	178
20 TRICASTIN	P35 26700 Pierrelatte	AREVA NC	Storage of radioactive materials	179
21 CRUAS-MEYSSE	CRUAS-MEYSSE NUCLEAR POWER PLANT (reactors 1 and 2) 07350 Cruas	EDF	Reactors	111
21 CRUAS-MEYSSE	CRUAS-MEYSSE NUCLEAR POWER PLANT (reactors 3 and 4) 07350 Cruas	EDF	Reactors	112
22 SAINT-ALBAN/ SAINT-MAURICE	SAINT-ALBAN/SAINT-MAURICE NUCLEAR POWER PLANT (reactor 1) 38550 Le Péage-de-Roussillon	EDF	Reactor	119
22 SAINT-ALBAN/ SAINT-MAURICE	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 (decommissioning in progress)	91
23 CREYS-MALVILLE	FUEL STORAGE FACILITY 38510 Morestel	EDF	Storage of radioactive substances	141
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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
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SITE NAME	NAME AND LOCATION OF THE INSTALLATION	LICENSEE	TYPE OF INSTALLATION	BNI
㉔ CADARACHE	ACTIVE FUEL EXAMINATION LABORATORY (LECA) AND SPENT FUEL REPROCESSING, CLEAN-OUT A ND REPACKAGING STATION (STAR) 13115 Saint-Paul-lez-Durance Cedex	CEA	Utilisation of radioactive substances	55
㉔ CADARACHE	SOLID RADIOACTIVE WASTE STORAGE YARD 13115 Saint-Paul-lez-Durance Cedex	CEA	Storage of radioactive substances	56
㉔ CADARACHE	PHÉBUS 13115 Saint-Paul-lez-Durance Cedex	CEA	Reactor	92
㉔ CADARACHE	MINERVE 13115 Saint-Paul-lez-Durance Cedex	CEA	Reactor	95
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㉕ MARCOULE	PHÉNIX 30205 Bagnols-sur-Cèze	CEA	Reactor	71
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SITE NAME	NAME AND LOCATION OF THE INSTALLATION	LICENSEE	TYPE OF INSTALLATION	BNI
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30 SACLAY	HIGH-ACTIVITY LABORATORY (LHA) 91191 Gif-sur-Yvette Cedex	CEA	Utilisation of radioactive substances (decommissioning in progress)	49
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32 DAMPIERRE-EN-BURLY	DAMPIERRE-EN-BURLY NUCLEAR POWER PLANT (reactors 1 and 2) 45570 Ouzouer-sur-Loire	EDF	Reactors	84
32 DAMPIERRE-EN-BURLY	DAMPIERRE-EN-BURLY NUCLEAR POWER PLANT (reactors 3 and 4) 45570 Ouzouer-sur-Loire	EDF	Reactors	85
33 CHINON	IRRADIATED MATERIAL FACILITY (AMI) 37420 Avoine	EDF	Utilisation of radioactive substances	94
33 CHINON	CHINON INTER-REGIONAL WAREHOUSE (MIR) 37420 Avoine	EDF	Storage of new fuel	99
33 CHINON	CHINON NUCLEAR POWER PLANT (reactors B1 and B2) 37420 Avoine	EDF	Reactors	107
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