AUTORITÉ
DE SÛRETÉ
NUCLÉAIRE

ASN REPORT

on the state of nuclear safety and radiation protection in France in 2019

The French Nuclear Safety Authority presents its report on the state of nuclear safety and radiation protection in France in 2019.

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.

THE FRENCH NUCLEAR SAFETY AUTHORITY

Roles – Operations – Key figures

ASN was created by the 13 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 the citizens and regarded internationally as a benchmark for good practice.

ROLES

Regulating

ASN contributes to drafting regulations, by submitting its opinion to the Government 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 (BNIs), such as creation and decommissioning. ASN also 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 responsable for ensuring compliance with the rules and requirements applicable to the facilities and activities within its field of competence. Since the Energy Transition for Green Growth Act of 17 August 2015, ASN's roles now include protecting ionising radioactive sources against malicious acts. Inspection is ASN's primary monitoring activity. More than 1,800 inspections are thus carried out every year in the fields of nuclear safety and radiation protection. ASN has a range of enforcement and penalty powers (formal notice, administrative fines, daily penalty payments, ability to carry out seizure, take samples or require payment of a deposit, etc.). The administrative fine is the competence of the Sanctions Committee within the ASN, which complies with the principle of the separation of the examination and sentencing functions.

Informing

ASN reports on its activities to Parliament. It informs the public and the stakeholders (environmental protection associations, Local Information Committees, media, etc.) about its activities and the state of nuclear safety and radiation protection in France. ASN enables all members of the public to take part in the drafting of its decisions with an impact on the environment. It supports the actions of the Local Information Committees of the nuclear facilities. ASN's main information channel is its website *asn.fr*.

In emergency situations

ASN monitors the steps taken by the licensee to make the facility safe. It informs the public and its foreign counterparts of the situation. ASN assists the Government. More particularly, it sends the competent Authorities its recommendations regarding the civil security measures to be taken.

Regulation and monitoring of diversified activities and facilities

Nuclear power plants, radioactive waste management, fabrication and reprocessing of nuclear fuel, radioactive material packages, medical facilities, research laboratories, industrial activities, etc. ASN monitors and regulates an extremely varied range of activities and facilities.

This regulation covers:
- 57 nuclear reactors(*) producing 70% of the electricity consumed in France, as well as the Flamanville EPR reactor under construction;
- about 90 other facilities participating in civil research activities, radioactive waste management activities or "fuel cycle" activities;
- more than thirty or so facilities which have been finally shut down or are being decommissioned;
- several thousand facilities or activities using sources of ionising radiation for medical, industrial or research purposes;
- several hundred thousand shipments of radioactive substances performed annually in France.

THE SUPPORT OF EXPERTS

When drawing up its decisions and regulations, 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 its eight advisory committees of experts, who come from a variety of scientific and technical backgrounds.

** As at 3 March 2020.*

OPERATIONS

The Commission

The Commission defines ASN's general policy regarding nuclear safety and radiation protection. It consists of five Commissioners, including the ASN Chairman, appointed for a term of 6 years(*).

Bernard DOROSZCZUK Chairman	Philippe CHAUMET-RIFFAUD Commissioner	Sylvie CADET-MERCIER(*) Commissioner	Lydie ÉVRARD(*) Commissioner	Jean-Luc LACHAUME(*) Commissioner
from 13 November 2018 to 12 November 2024	from 10 December 2014 to 9 December 2020	from 21 December 2016 to 9 December 2023	from 10 March 2017 to 9 December 2023	from 21 December 2018 to 9 December 2026
APPOINTED BY the President of the Republic			APPOINTED BY the President of the Senate	APPOINTED BY the President of the National Assembly

** Pursuant to Act 2017-55 of 20 January 2017 constituting the general statutes of Independent Administrative Authorities and Independent Public Authorities, which stipulates renewal of half of the ASN Commission, except for its Chairman, every three years, Decree 2019-190 of 14 March 2019 (codifying the provisions applicable to BNIs, the transport of radioactive substances and transparency in the nuclear field) sets out the relevant interim provisions and modified the duration of the mandates of the three Commissioners.*

Impartiality

The Commissioners perform their duties in complete impartiality and receive no instructions from either the Government or 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 also terminate the duties of any member of the Commission in the event of serious breach of his or her obligations.

Competencies

The Commission takes decisions and issues opinions, which are published in ASN's *Official Bulletin*. The Commission defines ASN's oversight policy. The Chairman appoints the ASN inspectors. 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 competent committees of the National Assembly and of the Senate and to the Parliamentary Office for the Assessment of Scientific and Technological Choices.
The Commission defines ASN's external relations policy at national and international level.

The departments

ASN comprises departments placed under the authority of its Chairman. The departments are headed by a Director General, appointed by the ASN Chairman. They carry out ASN's day-to-day duties and prepare draft opinions and decisions for the ASN Commission. They comprise:

- head office departments organised according to topics, which oversee their field of activity at a national level, for both technical and transverse matters (international action, preparedness for emergency situations, information of the public, legal affairs, human resources and other support functions).
  They more specifically prepare draft doctrines and texts of a general scope, examine the more complex technical files and the "generic" files, in other words those which concern several similar facilities;
- eleven regional divisions, with competence for one or more administrative regions, covering the entire country and the overseas territories.
  The regional divisions conduct most of the oversight in the field of nuclear facilities, radioactive substances transport operations and small-scale nuclear activities. They represent ASN in the regions and contribute to public information within their geographical area. In emergency situations, the divisions assist the Prefect of the *département*(*) who is in charge of protecting the general public, and supervise, the operations to safeguard the facility affected by the accident.

** Administrative region headed by a Prefect.*

KEY FIGURES IN 2019

PERSONNEL

521 staff members

of which

321 inspectors

84% management

ASN ACTIONS

1,817 inspections
representing 4,274 days of inspection

23,420 inspection follow-up letters
available on *asn.fr*
as at 31 December 2019

22 meetings
of Advisory Committees of experts

276 technical opinions
sent to ASN
by IRSN

1,585 individual licenses
issued for facilities and activities

BUDGET

€63.97 MILLION

total budget for ASN (programme 181)

€83.4 MILLION

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

INFORMATION

More than 1,200

answers to queries
from the public and stakeholders

18

press conferences

75

information notices

8

emergency exercises

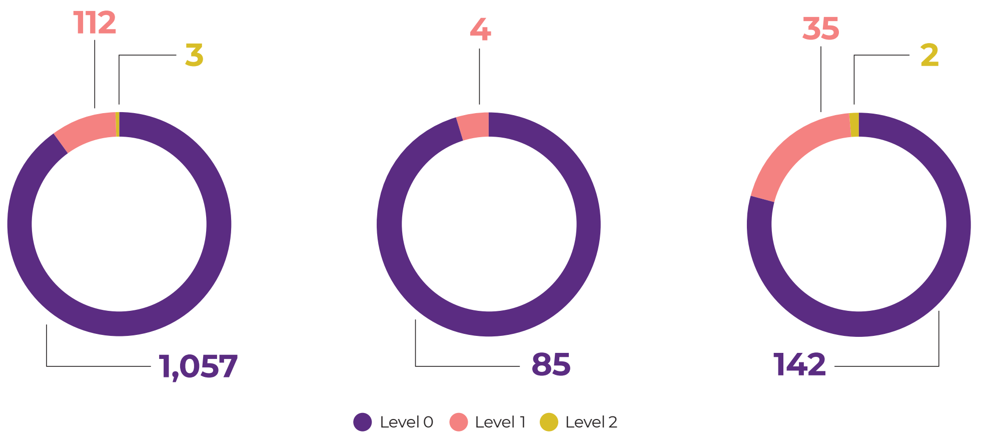
KEY FIGURES IN 2019

NUMBER OF SIGNIFICANT EVENTS RATED ON THE INES SCALE(*)

1,172 events in the BNIs

89 events in the transport of radioactive substances

179 events in small-scale nuclear facilities (medical and industrial)

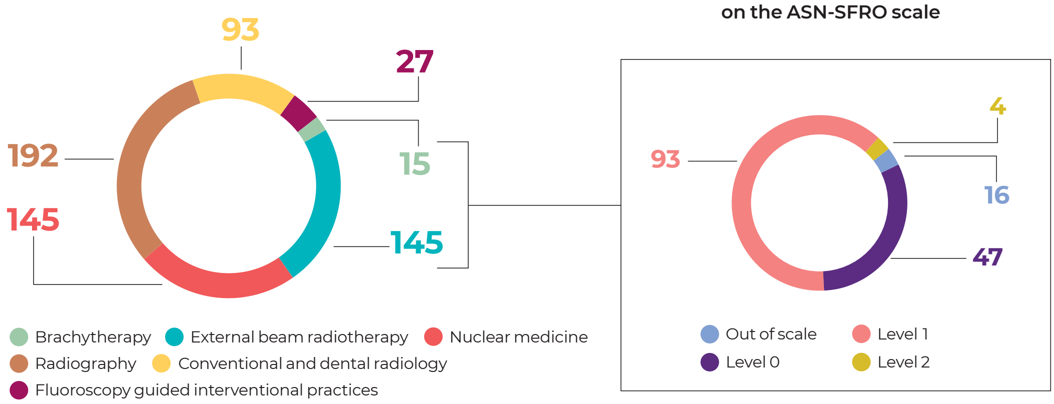


NUMBER OF SIGNIFICANT EVENTS IN THE MEDICAL FIELD(*)

617 significant events per area of exposure

160 significant events in external beam radiotherapy and brachytherapy

according to the classification on the ASN-SFRO scale



** The INES scale (International Nuclear and Radiological Event Scale) was developed by IAEA to explain to the public the importance of an event in terms of safety or radiation protection. This scale applies to events occurring in BNIs and events with potential or actual consequences for the radiation protection of the public and workers. It does not apply to events with an impact on the radiation protection of patients, and the criteria normally used to rate events (notably the dose received) are not applicable in this case.*

As it was pertinent to be able to inform the public of radiotherapy events, ASN –in close collaboration with the French Society for Radiotherapy and Oncology– developed a scale specific to radiotherapy events (ASN-SFRO scale).

These two scales cover a relatively wide range of radiation protection events, with the exception of imaging events.

ASN ORGANISATION CHART

on 3 March 2020

COMMISSION

Commissioners
Sylvie Cadet-Mercier
Philippe Chaumet-Riffaud
Lydie Évrard
Jean-Luc Lachaume

Chairman
Bernard Doroszczuk

Head of Private Office
Laurent Felber

GENERAL DIRECTORATE

Professional ethics
Alain Dorison

Deputy Directors General
Julien Collet
Daniel Delalande
Anne-Cécile Rigail

Director General
Olivier Gupta

Chief inspector
Christophe Quintin

Director of Private Office
Bastien Poubeau

DEPARTMENTS

Nuclear Power Plants Department
Rémy Catteau

Nuclear Pressure Equipment Department
Corinne Silvestri

Waste, Research Facilities and Fuel Cycle Department
Christophe Kassiotis

Transport and Sources Department
Fabien Féron

Ionising Radiation and Health Department
Carole Rousse

Environment and Emergency Department
Olivier Rivière

Legal Affairs Department
Olivia Lahaye

Information, Communication and Digital Usages Department
Céline Acharian

International Relations Department
Luc Chanial

Office of Administration
Brigitte Rouède

Management and Expertise Office
Adeline Clos

Regulation and Oversight Support Mission
Julien Husse

DIVISIONS

1 **Bordeaux Division**
Regional representative: Alice-Anne Médard
Regional head: Hermine Durand

2 **Caen Division**
Regional representative: Olivier Morzelle
Regional head: Adrien Manchon

3 **Châlons-en-Champagne Division**
Regional representative: Hervé Vanlaer
Regional head: Jean-Michel Férat

4 **Dijon Division**
Regional representative: Jean-Pierre Lestoille
Regional head: Marc Champion

5 **Lille Division**
Regional representative: Laurent Tapadinhas
Regional head: Rémy Zmyslony

6 **Lyon Division**
Regional representative: Françoise Noars
Regional head: Caroline Coutout

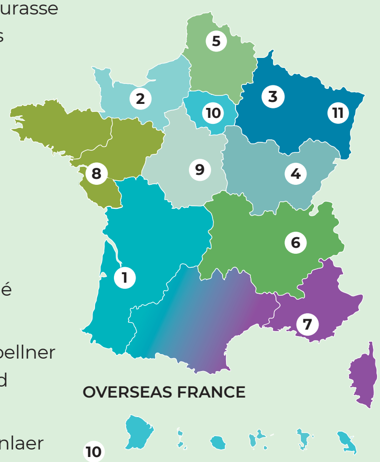
7 **Marseille Division**
Regional representative: Corinne Tourasse
Regional head: Bastien Lauras

8 **Nantes Division**
Regional representative: Annick Bonneville
Regional head: Émilie Jambu

9 **Orléans Division**
Regional representative: Christophe Chassande
Regional head: Alexandre Houlé

10 **Paris Division**
Regional representative: Jérôme Goellner
Regional head: Vincent Bogard

11 **Strasbourg Division**
Regional representative: Hervé Vanlaer
Regional head: Pierre Bois



For BNI oversight only, the Caen and Orléans divisions hold responsibility for the Brittany and Île-de-France regions respectively.

Competence
Independence
Rigour
Transparency

asn.fr

info@asn.fr

You can also follow ASN on the social media

SUMMARY

ADVICE TO THE READER

- **The control of small-scale nuclear facilities (medical, research and industry, transport) is presented in chapters 7, 8, 9.**
- **Only regulatory news for the year 2019 is present in this report. All the regulations can be consulted on *asn.fr*, under the heading "Réglementer".**

From left to right:
Philippe CHAUMET-RIFFAUD, Commissioner; Lydie ÉVRARD, Commissioner; Bernard DOROSZCZUK, Chairman; Sylvie CADET-MERCIER, Commissioner; Jean-Luc LACHAUME, Commissioner.

A commitment to quality and rigour is demanded from everyone

Montrouge, 3 March 2020

In a context where the level of safety in nuclear facilities has remained on the whole satisfactory, 2019 was marked by increased awareness on the part of the nuclear licensees of the challenges that face them as a group. The need to reinforce the quality of the work done and professional rigorousness in terms of safety has been broadly taken on board, which is essential if progress is to be made. The increase in inspections cannot be considered an appropriate response. As those with prime responsibility for safety, it is therefore up to the licensees to address these challenges.

In the medical field, the radiation protection of patients undergoing diagnostic or therapeutic procedures involving ionising radiation has been maintained at a high level. The number of significant radiation protection events reported by the health professionals remained very low in 2019 when compared with the number of procedures carried out on the patients every year and the complexity of some of these procedures. However, particular attention must be maintained, owing to the extremely sophisticated technical nature of some medical procedures and the chain of professionals involved.

Professional competence and rigour at the heart of the nuclear industry's recovery

At the end of 2018, ASN underlined the need for re‑engagement by the nuclear industry in order to maintain the key industrial skills vital to the quality of the work done and the safety of the facilities.

In 2019, in response to a request from the Government and further to the conclusions of the *Building the Flamanville EPR* report by Jean‑Martin Folz, EDF presented an action plan "*to restore the level of quality, rigour and excellence which underpinned the construction of the French NPP fleet*".

ASN considers that the orientations of the plan are a step in the right direction. Quality and professional rigour are key aspects in ensuring the safety of the facilities. They must be applied both in the performance of the activities and in their oversight by the licensees, who hold prime responsibility for safety.

ASN considers that the commitment to quality and rigour in running projects must be restated, not only for new constructions, but also for legacy waste recovery and packaging projects, decommissioning, or major maintenance works. The nuclear industry must more precisely define the conditions for implementation of this action plan, notably in terms of reinforcing the safety culture and a rigorous professional attitude.

Continued operation of the 900 MWe reactors: an EDF goal still to be achieved

With the support of the IRSN, ASN continued to examine the fourth periodic safety review of the 900 MWe reactors, in order to define the generic conditions for their continued operation, in other words those that are applicable to all these reactors. The main goals of this review concern the management of installation conformity, more particularly ageing management, as well as the facility's greater robustness to natural hazards and the mitigation of the radiological consequences in the event of an accident, notably with core melt. These goals were defined in the light of the safety objectives set for the third generation reactors, in particular the EPR.

For the fourth periodic safety review, EDF proposed installation modifications in order to achieve these goals, for example to improve the safety of the spent fuel pool, or to reduce the risk of containment basemat melt‑through with the resulting contamination of the soil and groundwater in the event of an accident with core melt. ASN will issue a resolution on the generic part of the periodic safety review of these reactors at the end of 2020, to regulate their continued operation.

ASN considers that implementation of the modifications proposed by EDF leads to significant safety improvements for the facilities and contributes to achieving the goals of the periodic safety review. However, at this stage of the examination, ASN considers that these modifications alone are unable to meet all the targets set. In the absence of any additional proposals from the licensee during the course of 2020, ASN will prescribe additional modifications.

In 2019, Tricastin reactor 1 was the first to carry out its fourth ten‑yearly outage. EDF set up a specific organisation and extensively mobilised its national engineering division to provide the site with support, before and during the outage, so that the modifications to be deployed could be fully assimilated. This organisation enabled the work to be carried out satisfactorily. ASN underlines the fact that over the next few years several reactor ten‑yearly outages will be performed at the same time and queries EDF's ability to implement such an organisation simultaneously on the sites concerned.

Questions about the operational intervention conditions

During its inspections, ASN placed greater emphasis on controlling the implementation of the operational measures planned by the licensees to deal with undesirable events in a nuclear facility. In this respect, ASN conducted exercises simulating an outbreak of fire, internal flooding, loss of containment of hazardous products, or an accident situation. For certain exercises, ASN observed that the actions required in these situations were not feasible or that the intervention times were longer than those planned by the licensee.

These findings mean that the licensee must ensure that the actions required by the operating documents are actually operationally feasible and take corrective measures where applicable.

More generally, the growing complexity of the rules to be followed and of the operational measures to be taken, demands extra vigilance on the part of all the players.

The eight EPR containment penetration welds to be repaired

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

Numerous deviations from the expected quality were found in the construction and manufacture of the EPR equipment, primarily due to a loss of experience and a lack of professional rigour, notably in the use of special processes (welding, forging, heat treatment, non‑destructive testing, etc.). These problems also revealed shortcomings in the oversight exercised by the licensee.

With regard to the deviations in the design and production of welds on the main steam letdown lines, ASN stated as early as 2018 that preference should be given to repairing all the welds. At the end of 2018, EDF however proposed an approach to justify maintaining certain welds as they were (the eight containment penetration welds). Given the nature and the particular high number of deviations which occurred in the design and production of these welds, and given that their repair is technically feasible, ASN informed EDF in June 2019 that their repair prior to commissioning of the reactor was the baseline solution.

Irregularities which should cause everyone to re-examine their activities

ASN has established an action plan to deal with the risk of fraud. The first conclusions have been reached after a campaign of fraud-targeted inspections and the analysis of fraud reports sent by whistle blowers.

The risk of fraud exists, but the number of confirmed cases at this stage is very low when compared with the volume of activities. The first findings mainly concern irregularities in the implementation of special processes (identity fraud among welders or inspectors), in internal controls at the suppliers (falsification of test results) or in the monitoring of activities (declaration of monitoring work not actually performed). Not all of these irregularities were detected by the licensee's monitoring activities.

In most cases, the analyses by the licensees and the investigations carried out by ASN further to these findings, revealed no safety risks. The manufacturers and licensees must remain vigilant, including with regard to their own personnel, and question the underlying root causes of this type of behaviour.

A new step in the consultation process for the management of radioactive materials and waste

As co-sponsor, alongside the Ministry for Energy, ASN was heavily involved in the public debate held in 2019 to prepare the next version of the French National Radioactive Material and Waste Management Plan. The conclusions of the public debate underlined the major importance of the management of high and intermediate level, long-lived waste, the need to take greater account of certain aspects (transport, environmental assessment, decommissioning issues and interaction with energy policy) as well as the central nature of the governance of the national radioactive materials and waste management system. The joint decision by the Ministry for Ecological and Inclusive Transition and the ASN Chairman, specifying how the lessons learned from the public debate are to be addressed, was published in February 2020. ASN will continue its involvement to ensure safe management of the waste and materials and will work to make an effective contribution to high-quality consultation with the stakeholders.

The permanent need to anticipate the nuclear safety and radiation protection challenges of new projects

ASN seeks to anticipate the safety challenges associated with the facilities it regulates, in particular on the basis of forward-looking analysis carried out within the framework of the National Radioactive Materials and Waste Management Plan and the guidelines of the multi-year energy programme.

In this context, ASN issued its opinion on the safety options dossier of the EDF project for a centralised storage pool, sufficiently early on so its safety requirements could be integrated into the project.

Faced with the prospect of final shutdown of the two reactors of the Fessenheim NPP, and then of several other reactors, planned under the multi-year energy programme, ASN will be attentive to ensuring that the steps taken by the licensee enable decommissioning to be carried out as rapidly as possible. ASN will aim to optimise its examination processes and learn all relevant lessons from the decommissioning of the Fessenheim NPP, for the benefit of subsequent decommissioning work.

Finally, with regard to the potential construction of new reactors, ASN issued its opinion on the safety options of the "EPR New Model" reactor project and its "EPR 2" evolution, taking account of the lessons learned from the Flamanville EPR and the reactors in operation. This opinion identifies the subjects which would need to be examined in greater depth, or the choices that would have to be justified for a possible reactor creation authorisation application, for example, the adoption of a break preclusion approach.

Vigilance to be maintained owing to the complexity of some medical procedures and the chain of professionals involved

In 2019, the number of significant radiation protection events reported to ASN in the medical field did not change significantly and remains low when compared with the number of procedures performed and the complexity of some of them. The most important challenges from the radiation protection viewpoint concern:

- for workers: fluoroscopy-guided interventional practices and nuclear medicine, where the dose limits are exceeded, notably for the hands and eyes;
- for patients: fluoroscopy-guided interventional practices, owing to the duration of certain procedures, external beam radiotherapy, notably owing to wrong-side errors

and, finally, nuclear medicine, with radiopharmaceutical administration errors;
- for the public and the environment: nuclear medicine, with radioactive source losses, leaks from pipes and radioactive effluent containment systems.

Concerning external beam radiotherapy, the number of significant radiation protection event reports stabilised in 2019. Three events were rated at level 2 on the ASN-SFRO scale (5 in 2018). The security of access to high-level sealed sources needs to be improved in brachytherapy units and will remain a priority inspection topic. The occurrence of two events in which the source remained blocked in a projector recalls the importance of staff training in the emergency measures to be taken in such a situation.

The deployment of new therapies in nuclear medicine, with high activity levels being administered to the patients, requires particular attention with regard to radioactive effluent management. In addition, personnel training efforts must be maintained and the coordination of preventive measures during work by outside contractors must be improved.

With regard to fluoroscopy-guided interventional practices, too few of the premises where they are carried out actually fully meet the regulatory requirements, although the situation is however better in the interventional radiology units. Insufficient training of the professionals in patient radiation protection and a shortfall in application of the principle of optimisation of procedures are recurring findings during the inspections. There is insufficient exploitation of the collection of the doses received by the patients during procedures in order to optimise practices. Patient follow-up –as defined by the French National Authority for Health– if the skin exposure limit is exceeded, is not very satisfactory, particularly in the operating theatres.

Similarly, in the field of external beam radiotherapy, this monitoring is also considered to be insufficient. It led ASN to request that a follow-up study be conducted by professionals on patients affected by a level 2 significant radiation protection event.

Proposals to reinforce the management of a nuclear post-accident situation

On the basis of the lessons learned from the Fukushima NPP accident and the emergency exercises, the Steering Committee for the management of the post-accident phase of a nuclear accident (Codirpa) headed by ASN, proposed a number of changes to post-accident doctrine to the Prime Minister. They primarily aim to simplify the post-accident zoning used as the basis for the population protection measures. More specifically, new criteria were proposed to define the population evacuation perimeter.

The Codirpa also drew up a public guide and created a joint Anccli/ASN/IRSN website to raise awareness of post-accident situations. This site enables elected officials, health professionals, associations, education personnel and economic players to access documents and information for preparing or managing life in a region contaminated by a nuclear accident.

New exchange framework to reinforce cross-border cooperation

ASN took the initiative of setting up a new framework of exchanges to reinforce the sharing of experience on specific subjects with its counterparts in neighbouring countries: Germany, Belgium, Luxembourg and Switzerland. In November 2019, it therefore organised the first inter-regional seminar devoted to cross-inspections, consultation with the stakeholders, emergency preparedness and response and maintaining the skill levels of the nuclear safety regulators. This format for sharing, which is broader than a bilateral meeting and more focused than a multilateral framework, showed the added value to be gained from examining these subjects in greater depth and formulating common proposals to reinforce international cooperation.

Olivier GUPTA – Director General

Efficient oversight and regulation in an unprecedented context

Montrouge, 3 March 2020

With the problems encountered on the EPR construction site, questions concerning the continued operation of the reactors and the structural shortfall in key skills in certain areas, the period through which the nuclear industry is passing at the moment could be referred to as "tense".
It is therefore perfectly legitimate to question ASN's actions, the effectiveness of its oversight and regulation and the future actions it intends to take in this unprecedented context. These actions are underpinned by four guidelines and are supported by a human resources policy appropriate to the situation.

Restoring the focus on licensee prime responsibility

When a sector is in difficulty, attention often turns towards the State or the competent Authorities. In this context, there could also be the temptation by the regulator to seek to regulate even further. However, we do not believe that the problems being experienced by the nuclear industry can be overcome by more regulation. Nor do we believe that the problem of fraud can be resolved solely by more inspections.

ASN does not hesitate to use the full range of inspection, enforcement and sanction resources at its disposal: examples of this are the reinforced surveillance in 2019 of the operating Flamanville NPP, or the new inspections deployed to prevent fraud.

In terms of nuclear safety and radiation protection however, a situation in which a licensee could "shelter behind" ASN on a long-term basis is unacceptable: the aim is always for the licensees concerned to themselves assume their prime responsibility for the protection of people and the environment in a fully satisfactory manner. And it is for this that they are accountable to ASN.

It is thus our firm conviction that the means for turning the nuclear sector around lie primarily in the hands of the industry itself.

Improving nuclear safety and radiation protection through dialogue

ASN is open to proposals from licensees and professionals, who have prime responsibility for nuclear safety and radiation protection. These proposals must be based on technical arguments that will be subsequently examined by ASN, in most cases with the assistance of the IRSN. This is what we call an in-depth technical dialogue. The quality and sincerity of this dialogue constitutes one of the pillars on which safety and indeed progress in the field of safety are built.

ASN observes nuclear activities performed in the field, notably during inspections, including by questioning the various parties involved: licensees, contractors on the worksites, care personnel in hospitals and so on. These observations are the basis of ASN's annual evaluation of the nuclear safety and radiation protection situation for the main licensees and the various activity sectors.

ASN dialogues with the other stakeholders, as was the case in 2019 for the consultation on the fourth periodic safety reviews of the 900 MWe reactors and the public debate on the National Radioactive Materials and Waste Management Plan.

Listening, observing, dialoguing: this is what enables us to fully assess a situation and accurately calibrate our requirements and our oversight actions.

A clear definition of priorities

When carrying out its duties, ASN seeks to tailor its oversight actions to help the licensees and professionals focus their resources, which are by their very nature limited, on the essential nuclear safety and radiation protection issues.

In the interest of effectiveness and in order to achieve tangible progress on subjects with major implications, it is important to clearly define the priorities: this entails implementation of the principle of proportionality, on which there is an international consensus, also called the graded approach. The position statement issued by ASN and ASND in 2019 regarding CEA's waste management and decommissioning strategy was a means of validating CEA's priorities in this field. In 2020, we will be doing the same for Orano.

In the same way, it is important to clearly define oversight priorities, which must be targeted in order to address specific issues. ASN has taken initiatives in this area, for example the oversight of reactor outages. After conducting an experiment in 2019, we will be adapting this oversight in 2020, involving fewer systematic prior examinations of files and more field inspections, while increasing the responsibility of the licensee.

In small-scale nuclear facilities, this graded approach also led to the overhaul of the regulatory regimes and the reorientation of some of our inspections, so that our requirements and our inspections are more proportionate to the risks presented by the activities.

Using our powers of regulation, enforcement and sanction, whenever necessary

ASN has considerable regulatory, enforcement and sanction powers and is responsible for using them with discernment. We do of course sometimes strongly express our disagreement, as was the case this year with regard to the steam line welds on the EPR reactor. We also sometimes issue enforcement measures, such as formal notices, including in the medical sector. In total, the number of cases in which we resort to enforcement measures remains small, an indication of both the good intentions of the licensees and the strength of ASN: it is able to impose most of its positions without having to use these instruments.

In addition to the existing arsenal, the legislator has provided ASN with an additional sanction tool, the administrative fine. Its utilisation requires the creation of a Sanctions Committee, which will be set up in 2020.

A level of skills commensurate with ASN's roles

One pre-condition for being able to exercise efficient and credible oversight is to maintain the ASN personnel's level of skill and accumulated experience in the field of risks and nuclear matters. ASN must therefore have personnel with the skills enabling them to rigorously carry out their investigation and inspection duties with the necessary degree of expertise, more specifically in relation to those available at its technical support organisation, the IRSN.

In a context of State reforms, the handover from one generation to the next and the need to maintain the attractiveness of the jobs it offers, ASN has taken steps, both quantitative and qualitative, to ensure that it can call on personnel with cutting-edge skills, who will devote a sufficiently large part of their career to the regulation and oversight of nuclear safety and radiation protection, because of the recognition that their technical experience is valued.

***

The ASN teams were extensively called on in 2019 and were up to the challenge. I thank them and I thank our partners, especially the IRSN, and the members of the groups advising ASN or collaborating in its work.

The ASN teams are aware of the confidence placed in them, notably by the representative bodies of the Republic. They also know that much will be expected of them in 2020, given the scale of the challenges ahead. Through their individual commitment, they will all do everything they can to be worthy of this trust and these responsibilities.

ASN ASSESSMENTS

ASN carries out its oversight role by using the regulatory framework and individual resolutions, inspections, and if necessary, enforcement measures, in a way that is complementary and tailored to each situation, to ensure optimal control of the risks that nuclear activities represent for people and the environment. ASN reports on its duties and produces an assessment of the actions of each licensee, in each field of activity.

ASN ASSESSMENTS **PER LICENSEE**

EDF

The Nuclear Power Plants (NPPs) in operation

ASN considers that the operating rigour of the EDF NPPs regressed in 2019.

The number of significant events rated level 1 on the International Nuclear and Radiological Event Scale (INES) has been increasing steadily for several years. It has increased by more than 30% since 2017. Three significant events were rated level 2 in 2019. Two of them reveal inappropriate actions and decisions on the part of the operators and the crossing of organisational defence lines. Furthermore, as in the previous years, the verification procedures undertaken by EDF regularly reveal deficiencies in the design, installation or maintenance of equipment, calling into question their ability to fulfil their functions in all the situations considered in the nuclear safety case. These deficiencies often concern several reactors, given the similarities in the design and operation of the EDF NPPs.

The situation scenarios the EDF teams have to address during the ASN inspections show that the operational documentation is not always adapted to the reality on the ground and can contain errors, inaccuracies, and even instructions that are impossible to carry out. Analysis of the significant events moreover reveals situations in which groups of people eventually cease to be aware of the safety implications of their actions, sometimes even becoming used to non-compliant situations. ASN considers that EDF must give fresh meaning to the activities in order to federate the operators around the real safety issues.

Improvements in fire risk prevention were nevertheless observed. ASN also notes that EDF places greater importance on the conformity of its installations, which is essential for nuclear safety.

Continued operation of the reactors

The far-reaching modifications EDF plans making to the facilities and the methods of operational management within the framework of the reactor periodic safety reviews will significantly improve the safety of the facilities. EDF is deploying considerable engineering resources for these reviews. ASN notes however that these national engineering teams have reached the maximum of their capacity.

In 2019, EDF performed the first of its 4th ten-yearly outages on one of the reactors at the Tricastin NPP. EDF deployed significant resources for this ten-yearly outage which went reasonably satisfactorily. ASN wonders whether EDF has the capacity to deploy such resources in the future for the other reactors, particularly when several 4th ten-yearly outages take place concurrently.

The conformity of the facilities

As in 2018, ASN noted that, in comparison with previous years, EDF placed greater emphasis on rapidly restoring the conformity of its facility after detecting a deviation, which is satisfactory. However, as in previous years, ASN considers that the actual conformity of the facilities with the rules applicable to them needs to be significantly improved. The year 2019 was again characterised by the detection of deviations affecting equipment that call into question their ability to fulfil their function in an accident situation. Some of these deviations date back to the construction of the reactors, others have been created when implementing modifications to the facilities, including recently, or result from ageing or insufficient maintenance of the facilities. In 2019, a number of pumping stations were found to be in sub-standard condition and, once again, deviations affecting the emergency diesel generator sets were discovered. Several deviations were also linked to the manufacture of components of items important to safety. This was the case in particular with defective electrical components, which led to a significant event rated level 2 on the INES scale affecting reactor 2 of the Penly NPP. EDF must continue the targeted inspection actions it has been gradually deploying over the last few years, but must also widen their scope.

ASN notes that the necessary spare parts are not always available in sufficient quantities. In these situations, ASN is particularly attentive to the effectiveness, the efficiency and the durability of the compensatory measures implemented by EDF pending correction of the anomaly.

In order to combat the risk of fraud, EDF has adapted its inspection practices, in particular by making greater use of unannounced or cross-inspections. ASN considers that EDF must nevertheless step up its actions in order to prevent abnormalities within its own organisations.

Maintenance

As a general rule, most of the NPPs are adequately organised to successfully carry out large-scale maintenance operations.

In a context of a high maintenance workloads, due in particular to the continued operation of the reactors and the "*Grand Carénage*" major overhaul programme, ASN has in the past regularly drawn EDF's attention to the persistence of an excessively large number of maintenance quality deficiencies. Over the last few years EDF has put in place action plans to reduce their occurrence. However, ASN finds that these have not been sufficiently effective. EDF must therefore learn from this and increase its professional rigour in maintenance operations.

Several of these maintenance quality deficiencies result from operators losing sight of the fact that their actions contribute to safety, or from applying the maintenance procedures incorrectly or even applying inappropriate procedures. The operators 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.

ASN in 2019 has again noted very high levels of fouling in certain internal structures of the Steam Generators (SG) of several reactors, which could impair their operating safety. These fouling levels are the result of maintenance that was insufficient to guarantee satisfactory cleanness.

Further deterioration associated with the ageing of certain items of equipment, particularly SG internal structures, was also detected in 2019. ASN considers that EDF must therefore adapt the level of stringency of its in-service monitoring and look ahead to the development of repair processes.

ASN regularly notes EDF's difficulty in ensuring appropriate and proportional monitoring of subcontracted activities, whether the activities are performed on site or at the suppliers of goods and services. This being said, in 2019 ASN saw an improvement in the technical oversight of subcontracted operations and service provider monitoring, particularly through the use of computer aids recently deployed in the NPPs.

Operation

ASN observes organisational weaknesses on some sites and losses of know-how. These difficulties are increased on the sites which have had to carry out a ten-yearly outage due to the fact that these outages involve deploying substantial resources and lead to significant changes in the facilities and their baseline operating requirements.

In 2019, the ASN inspections highlighted the need for closer monitoring of the activities of operational control operators. At several NPPS the average time taken to detect a breach of the operational management rules is too long. Despite this, the operators seem to know the reactor operational control rules, even though they have undergone relatively frequent changes over the last few years. ASN therefore considers that the analysis of these deviations must focus on their root causes and that EDF must be particularly attentive to the verification of the actions of the operational control teams.

As in 2018, EDF encountered difficulties during the post-outage reactor restarts. Furthermore, the majority of the sites need to improve the scheduling and performance of the periodic tests and the analysis of their results. More particularly, ASN's inspectors on several occasions found incorrect conclusions regarding equipment availability following periodic testing. EDF has initiated improvement measures, the effects of which are not yet measurable.

The inspections ASN carried out in 2019 in the area of operational management in the event of an accident placed the operators in simulated accident situations. Although the operators showed that they knew the technical actions to carry out, ASN's inspections revealed that in some cases these actions cannot be accomplished within the required times, or even cannot be carried out at all due to the configuration of the facilities. In other cases, the instructions did not take into account the actual status of the facility. EDF initiated an action plan in mid-2019, and its first effects can already be seen.

In recent years, EDF has reinforced its organisation for controlling hazard-related risks, such as the organisation put into place to detect and eliminate the risk of objects falling in the event of an earthquake. However, ASN regularly observes that the steps taken by EDF to prevent hazards and mitigate their consequences need to be further improved. This is the case in particular with the provisions for explosion risks, for which some maintenance and inspection actions are not implemented satisfactorily.

As in 2018, the ASN inspections focusing on the organisation and emergency resources confirmed that the organisation, preparedness and management principles for emergency situations covered by an on-site emergency plan have been correctly assimilated.

The analyses conducted by the sites further to significant events are generally appropriate and the identification of organisational causes is getting better. However, these analyses often result only in corrective actions that are limited to one-off awareness-raising measures targeting the employees, services or companies identified as being the cause of the deviation.

Protection of the environment

EDF's organisation for controlling the detrimental effects and impact of the NPPs on the environment needs to be improved on most sites. ASN considers that the licensee needs to raise its level of vigilance on these topics. EDF must more specifically improve the integration of the regulatory provisions relating to pollution prevention, particularly regarding the containment of hazardous liquid substances. Despite some occasional weaknesses, EDF has shown a good level of control over its process for managing effluent discharges. With regard to waste management, ASN observes the continuing improvements in EDF's organisation, but remains vigilant regarding the various sites' compliance with regulations.

Worker radiation protection and occupational safety

ASN notes an overall deterioration in the way radiation protection is taken into account in the NPPs. The significant events analyses often show in particular an inadequate perception of the radiological risks. ASN has nevertheless noted improvements in the implementation of means of cordoning off worksites.

A fatal accident resulting from worksite organisation and handling problems occurred in 2019. EDF has taken actions to mitigate the main risks for workers further to inspections by the ASN labour inspectors. Certain occupational risk situations are nevertheless still worrying and must be significantly improved. They concern the risks linked to work equipment and more particularly to lifting gear, the explosion and fire risks and electrical risks.

Individual NPP assessments

The ASN assessments of each NPP are detailed in the Regional Overview in this report. Some NPPs stand out positively:
- in the area of nuclear safety: Fessenheim, Saint-Alban and, to a lesser extent, Blayais;
- in the area of environmental protection: Fessenheim, Saint-Alban and Saint-Laurent-des-Eaux;
- in the area of radiation protection: Saint-Alban.

Other sites on the contrary are under-performing in at least one of these three areas:
- in the area of nuclear safety: Flamanville, Golfech and Gravelines;
- in the area of environmental protection: Flamanville, Cruas, Dampierre-en-Burly;
- in the area of radiation protection: Flamanville, Dampierre-en-Burly and Tricastin.

The Flamanville EPR reactor under construction

ASN considers that, in view of the lack of rigour observed in the performance and monitoring of certain welding operations, EDF must extend the scale of the verifications performed to demonstrate the satisfactory condition of the facility. Beyond these verifications, ASN considers that the organisation put into place to prepare for operation of the Flamanville EPR reactor is on the whole satisfactory.

The deviations found on the main steam letdown pipes revealed a lack of control over the welding operations and a breakdown in EDF monitoring of its contractors. ASN therefore asked that the review of the quality of the Flamanville EPR reactor equipment be extended to include a broader scope of equipment and subcontractors, while adapting the depth of the review according to the implications. EDF still has to supplement this procedure. EDF must moreover be careful to ensure that the necessary repairs and worksite completion are carried out giving priority to the quality of workmanship and professional rigour.

In 2019, ASN observed improvements in equipment qualification and traceability of the startup tests. EDF must nevertheless further develop its practices concerning the demonstration of startup test representativeness.

NPPs being decommissioned and waste management facilities

ASN considers that the level of safety of the facilities being decommissioned and of waste management is on the whole satisfactory, but that the risk of worker exposure to ionising radiation, the main issue during decommissioning, must be better controlled.

With EDF facilities undergoing decommissioning from which the fuel has already been removed, nuclear safety consists in controlling the containment of the radioactive substances. Most of these substances are situated in the currently contained reactor pressure vessels which are not undergoing any decommissioning operations that could put the substances back into suspension (with the exception of Chooz A and Superphénix).

The issues that EDF has to address concern worker radiation protection and waste management. With regard to these points, in 2019, EDF continued to have difficulties in controlling the risk associated with the presence of alpha-emitting radionuclides, more particularly in the Chooz A facility. Furthermore, EDF is confronted with the problem of asbestos, which requires the suspension of work in order to establish appropriate protective measures and remove the asbestos.

As a general rule, the ongoing decommissioning operations are falling behind schedule and the major operations, which concern reactor core decommissioning, have been postponed. Managing time lines in complete safety therefore remains a major issue for EDF. ASN considers that EDF must reinforce the coordination of the Fessenheim NPP decommissioning project in order to have an overall view of the project integrating all its interactions. It also considers that EDF must improve its organisation to establish and validate fundamental decisions for the decommissioning scenario based on proven and formalised hypotheses.

Orano Cycle

ASN considers that the level of safety in the facilities operated by Orano Cycle remained at a generally satisfactory level in 2019, in a context where the group's new organisation was being put in place.

The facilities operated by Orano Cycle are located on the sites of La Hague, Tricastin and Marcoule. They present significant safety risks, but of different types, both chemical and radiological. The organisation of the Orano group is mainly decentralised, which leads to differences in practices between each site.

The Orano group has put in place a central organisation, which has improved the quality of its periodic safety reviews, particularly through its ability to report on the conformity of its facilities. The Tricastin and La Hague sites, which feature numerous Basic Nuclear Installations (BNIs), have set up dedicated organisations that enable the periodic safety reviews of the various BNIs to be conducted continuously, which improves the rigour of the reviews. Orano must nevertheless continue these improvement initiatives, particularly with regard to civil engineering where it must redouble its efforts concerning its auxiliary facilities which are not assigned to production. Orano must improve the centralised tracking of the required actions identified during these reviews in order to take them through to completion.

Orano Cycle has set up an organization to manage the effects of ageing of its La Hague facilities. The principle of the methodology deployed is acceptable. ASN observes that its deployment has improved compared with 2018. The actions to implement must be tracked more formally. Orano's organisation must be improved and be underpinned more by procedures than individual skills. Within the framework of the periodic safety reviews of the Tricastin and Marcoule facilities, ASN will check that Orano capitalises on the progress it has made in this area.

Progress remains to be made in Orano's monitoring of its service providers. ASN has observed several deviations in the execution of the periodic inspections and tests performed by outside contractors and in the way they take into account the safety requirements when carrying out new work projects.

Orano Cycle has nevertheless made progress in the implementation of its periodic inspections and tests at La Hague.

Risk control

Orano has improved its operational control teams' compliance with the instructions concerning the containment of radioactive substances at La Hague.

Compliance with radiation protection instructions in the Orano plants has also improved on the whole. Despite this, monitoring devices are not always available at the entrance to and exit from radiological areas.

Post-Fukushima

Orano Cycle has demonstrated determination in its management of the stress tests further to the Fukushima NPP accident. In 2019, Orano completed the construction of virtually all the complementary resources resulting from this exercise. These include, for example, new means designed to help cope with extreme situations in its facilities, particularly water make-up resources and new emergency response buildings that are robust to extreme hazards.

Emergency management

Orano has a robust emergency management organisation and provides its emergency response teams with appropriate training. The exercises conducted by Orano Cycle on the La Hague site in 2019 were sufficiently diverse to ensure adequate training of these teams.

Legacy waste retrieval and packaging, decommissioning and waste management

Large quantities of legacy waste at the La Hague site are not stored in accordance with current requirements and present major safety risks. The retrieval and packaging of this legacy waste govern decommissioning progress in the definitively shut down plants. ASN observes delays in Orano's waste retrieval and packaging projects, which are often complex, leading Orano to announce the pushing back –sometimes by several decades– of deadlines to which it was committed. ASN considers that the control of the retrieval and packaging projects must be improved. Thus, in 2019, ASN initiated a procedure to monitor the management of these projects, assisted by the DGEC (General Directorate for Energy and Climate). This procedure has led ASN to ask Orano to make fundamental improvements to the management of these projects and the organisation underpinning their management, in order to better meet the deadlines to which Orano has committed itself and which are prescribed in ASN resolutions or decrees. This procedure will be continued in 2020.

Furthermore, shortcomings in waste management have given rise to several significant event notifications, particularly with regard to criticality prevention. Orano must improve its waste storage conditions and monitor more systematically the drums of waste produced.

CEA

ASN considers that the safety of the facilities operated by the CEA (Alternative Energies and Atomic Energy Commission) remains on the whole satisfactory, despite a worrying budgetary situation. The safety issues concern firstly the continued operation of the facilities, designed to old safety standards, secondly the decommissioning of the definitively shut down facilities and the retrieval and packaging of legacy waste, and lastly the management of its radioactive waste and materials with no identified use.

Safety organisation and management

ASN observes that the organisation of the CEA is constantly changing. These organisational changes aim to improve the efficiency of the CEA structures, clarify roles and ensure greater involvement of the decision-making levels. ASN considers that the CEA must remain attentive to ensuring that all the safety aspects are properly taken into account at all levels of the organisation and are led by people who have the necessary resources, skills and authority. It urges the CEA to rapidly propose a strategic view of the changes under way.

ASN considers that the implementation of "major safety commitments," managed at the highest level and enabling the most important nuclear safety and radiation protection issues to be monitored, is on the whole satisfactory. It will be necessary to ensure that the reduction in resources allocated to the CEA does not affect the meeting of other commitments, particularly those governed by ASN requirements.

Facilities in operation and undergoing decommissioning

Faced with the ageing of the CEA's facilities in operation and the uncertainty of the projects to replace some of them, in 2019 the CEA developed a medium-term strategy for the utilisation of its experimental civil nuclear research facilities and its waste and material management facilities. The first conclusions reveal the need to streamline and optimise the existing facilities, as well as carry out substantial renovation work and perhaps build new facilities. ASN considers that this prioritisation is legitimate from the safety aspect and that the CEA must draw clear action plans from it and formalise precisely the options it has taken (abandoning or optimisation of operation, work to undertake, etc.).

In 2019, ASN and ASND (Defence Nuclear Safety Authority) underlined the CEA's relevant in-depth review (see Notable events) of its decommissioning strategy, its prioritisation of operations and human resources, the effectiveness of its organization, and the appropriateness of the financial resources devoted to these operations. The new organisation for decommissioning implemented in 2017 also represents a significant step forward. This progress will have to be confirmed in the medium-term by meeting the deadlines for the highest priority projects. The CEA must remain attentive to the non-redundant facilities whose unavailability could undermine the process as a whole, to the allocated financial resources, to the feasibility of the work completion deadlines and to work progress.

The conformity of the facilities

ASN observes that the CEA has embraced the periodic safety review process for its facilities by implementing a cross-cutting organisation dedicated to these activities on each site. The check of conformity, particularly with the regulatory provisions, and the action plans defined by the CEA are showing distinct improvements (efforts to be exhaustive, conclusions on conformity with the regulations or not, implementation schedules, distinguishing compliance actions from improvement actions), even if further improvements are still necessary regarding the extent of the checks on certain equipment items and the management of activities important to protection. The reassessment of control of the risks and adverse effects of each facility is also better grasped and well documented. Improvements are however required in the reassessment of the seismic and climatic risks (wind, tornadoes); the studies submitted do not allow a satisfactory assessment of the conformity of several facilities –particularly of their baseline requirements– with respect to the regulations. The CEA must be vigilant as to the proper execution of the works identified in the reassessments. ASN effectively observes that the CEA sometimes makes commitments without being able to ensure that the human or financial resources are actually available.

Management of deviations

The management of deviations within the facilities is on the whole satisfactory. Nevertheless, their analysis should be taken to further by analysing all the deviations, from the significant events down to low-level events. On the whole, the number of significant events in 2019 was stable in relation to 2018. No significant event exceeded level 1 on the INES scale. The analysis of their causes regularly reveals a technical deficiency (related to ageing or obsolescence) or an organisational or human cause (related to incorrect transposition of safety requirements in the operational documentation or to activity planning). Lastly, ASN underlines the quality of the experience feedback sheets produced by the central services for the centres and the nuclear facilities. It encourages the CEA to take steps to ensure that the measures defined in these sheets are effectively applied in the BNIs.

Management of modifications

For many years now the CEA has applied a modification management system that gives satisfaction, particularly through the quality of the files submitted to ASN when applying for authorisations for noteworthy modifications. ASN also observes that the modifications implemented on site do effectively correspond to the information provided by the CEA in its authorisation applications.

Maintenance and periodic inspections and tests

The maintenance work and the scheduling of the periodic inspections and tests, their performance and their monitoring within the CEA facilities are on the whole satisfactory. ASN does however still observe disparities between the facilities in these two areas. In addition, the traceability of the inspections performed must be further improved. ASN also expects the CEA to implement an ageing and obsolescence strategy that is harmonised for all its facilities. At present, for the facilities as a whole, ageing is often only managed through the periodic inspections and tests.

Outside contractors

ASN observes that the CEA's monitoring of outside contractors has been stepped up over the last few years, particularly by following monitoring plans and appointing CEA personnel to specifically monitor the subcontracted activities. ASN does nevertheless note that when maintenance is carried out by outside contractors whose services are governed by contracts signed with the centres and monitored by the support services, the monitoring is not always appropriate. This is because these monitoring plans are not individualised. The balance between the number of CEA employees in charge of monitoring and the number of work interventions performed can be improved, as can the appropriateness of the monitoring plans for the services they concern. ASN also notes the need for the CEA to tighten the monitoring of the chain of outside contractors, particularly their service providers' subcontractors. Lastly, there are still disparities in the quality of monitoring between the facilities operated by the CEA.

Risk control, emergency management and integration of the lessons learned from Fukushima

ASN observes significant delays in the construction of the emergency management buildings, designed to take account of the lessons learned from Fukushima, for the Cadarache, Marcoule and Saclay centres. In 2019, ASN thus gave the CEA formal notice to submit the design basis justifications for the future emergency management buildings of the Saclay centre.

The CEA's emergency organisation and resources have to be significantly improved to catch up on the lateness in meeting the current requirements. The national organisation in particular needs to be reinforced, paying very close attention to the coordination between the national level, the sites and the facilities. Coordination between the local security force and the facilities of the CEA centres is improving, particularly as regards keeping the intervention plans and instructions up to date.

ASN also considers that the CEA must continue its efforts to improve protection against the fire risk. The management of the technical devices (fire doors and fire dampers, fire detection systems, etc.) must be improved and fire loads limited, particularly when worksites are in progress. The now identified shortcomings in the lightning protection of the buildings must also be remedied within short time frames.

Personnel radiation protection

Radiation protection is satisfactorily taken into account in the various CEA centres, with the exception of the Fontenay-aux-Roses site, where shortcomings have been observed in the organisation and technical provisions in place. For all the centres, the identification of items and activities important to protection, the management of measuring instrument ageing and the monitoring of outside contractors (dealing with deviations, traceability and application of the ALARA principle) need to be improved.

Protection of the environment

CEA's organisation for controlling the adverse effects and the impact of the facilities on the environment is satisfactory, particularly with regard to the management of gaseous and liquid effluents. The management of non-radioactive liquid effluents however must be improved, as much in the quality of their analyses as in their management, and concerning storm water in particular. In view of the number of facilities in final shutdown status and undergoing decommissioning, the CEA has to engage in the substantial task of reviewing the impact studies and proposing discharge limits that are consistent with their operation. With regard to waste management, ASN expects on the part of the CEA improvements in zoning, in the cordoning-off of work areas, in collection areas and in the radioactive waste inventories.

Individual facility assessments

The ASN assessments of each centre and each nuclear facility are detailed in the Regional Overview in this report.

The Jules Horowitz research reactor (JHR), currently under construction at Cadarache

The JHR reactor, which was authorised in 2009, is currently under construction. The worksite contingencies, such as the management of safety-related deviations, are handled satisfactorily. In view of the extension of the construction work and the time required to commission the reactor, the CEA must respond to issues of project management, maintaining its technical skills over time and the conservation of already manufactured and possibly installed equipment items before they are commissioned. ASN considers that the change of organisation implemented in the second half of 2019 is on the whole satisfactory.

Andra

The French National Agency for Radioactive Waste Management (Andra) is the only licensee of radioactive waste disposal BNIs in France. ASN considers that the operation of Andra's waste disposal BNIs is satisfactory. ASN notes that the low-level long-lived waste disposal project made no progress during the 2016-2018 period, and that consequently the deadlines of the PNGMDR (National Radioactive Material and Waste Management Plan) on this subject have not been met.

Operation of Andra's existing facilities

ASN considers that safety and radiation protection in the facilities operated by Andra are satisfactory.

ASN observes a significant drop in the number of significant events reported between 2018 and 2019. It has doubts regarding Andra's reporting of events.

Alongside this, ASN considers that Andra must better integrate certain principles of the safety approach, particularly to take better account of defence in depth in the classification of certain items or activities as being important to protection.

Organisation dedicated to the *Cigéo* project creation authorisation file

Andra has set up a dedicated organisation for the preparation of the *Cigéo* project creation authorisation file, the submittal of which is planned for the end of 2020. ASN observes that this organisation is complex, which can have an impact on the management of priorities. It does nevertheless give the project team a level of visibility that is appropriate for the issues and enables the subjects to be addressed with a high standard of technical proficiency. As regards taking organisational and human aspects into account, ASN considers that Andra's organisation, which is based on outsourcing, could present weaknesses.

ASN's assessments of the other licensees are presented in the Regional Overview part and in the various chapters of this report.

ASN ASSESSMENTS **BY AREA OF ACTIVITY**

THE MEDICAL SECTOR

In radiotherapy, the safety fundamentals are in place (equipment verifications, medical staff training, quality and risk management policy). The quality initiatives are making progress. The prospective risk analyses however remain relatively theoretical and are insufficiently deployed prior to organisational or technical changes. ASN is reducing its inspection frequencies, but given the diversity of situations encountered, the centres displaying vulnerabilities or particular risks will continue to be subject to particular scrutiny and more frequent monitoring in 2020.

With regard to treatment safety, the situation **in brachytherapy** is comparable with that of external-beam radiotherapy. The radiation protection of medical staff and the management of high-activity sealed sources are considered satisfactory on the whole. This level must however be maintained through continuous training. In the current context, increased attention must be given to securing access to these sources, to prevent any unauthorised access.

In nuclear medicine, the radiation protection of patients and medical staff is satisfactory. The training efforts must be maintained in this sector as well. Moreover, the coordination of prevention measures when outside companies intervene (for machine maintenance, upkeep of the premises, etc.) must be improved. One of the radiation protection challenges is also to ensure good management of radioactive effluents, which is all the more important given that therapies administering high activities to patients are going to increase in number, leading to an increase in the discharged radioactivity.

In the area of **fluoroscopy-guided interventional practices**, ASN considers that the measures it has been recommending for several years to improve the radiation protection of patients and professionals have still not been sufficiently implemented, particularly for surgical procedures performed in operating theatres. The inspections frequently reveal deviations from the regulations, as much in the radiation protection of patients as in that of medical staff, and ASN is regularly notified of events concerning interventional practitioners who have exceeded the dose limits for the extremities. The radiation protection situation is however significantly better in the departments that have been using these technologies for a long time, such as the imaging departments performing interventional cardiology and neurology activities. Substantial awareness-raising in all the professionals is necessary to help the medical, paramedical and administrative staff of the medical centres gain a better perception of the risks, particularly for the professionals working in operating theatres.

In ASN's opinion, the continuous training of the medical staff and the involvement of the medical physicist probably constitute the two key points to guarantee control of the doses delivered to patients during interventional procedures.

The growing number of diagnostic examinations performed using **CT scanners** –computed tomography scanners– contributes very substantially to the collective dose received by the public, as medical imaging is the leading source of artificial exposure of the population to ionising radiation.

The medical justification of these procedures is still not sufficiently operational, due to the highly insufficient training of the prescribing physicians, not to mention the lack of availability of other diagnostic methods –Magnetic resonance imaging (MRI), ultrasonography. In July 2018, ASN published a second plan of action for controlling ionising radiation doses delivered to persons during medical imaging. This plan aims to reinforce the application of justification of the procedures and optimisation of the ionising radiation doses delivered to the patients.

THE INDUSTRIAL AND RESEARCH SECTOR

Among the nuclear activities in the **industrial** sector, industrial radiography and more particularly gamma radiography, are priority sectors for ASN oversight owing to their radiation protection implications. ASN considers that the risks are addressed to varying extents depending on the companies, even though worker dosimetric monitoring is generally carried out correctly. If the risk of incidents and the doses received by the workers are on the whole well managed by the licensees when this activity is performed in a bunker in accordance with the applicable regulations, ASN is still concerned by the observed shortcomings in the signalling of the operations area during on-site work and notes a deterioration in the situation compared with 2018. More generally, ASN considers that the ordering customers should favour industrial radiography services provided in bunkers and not on site. Lastly, the content of operator training should better integrate the lessons learned from the significant radiation protection events.

In the other priority sectors for ASN oversight in the industrial sector –industrial irradiators, particle accelerators including cyclotrons, suppliers of radioactive sources and devices containing them– the state of radiation protection is considered to be satisfactory on the whole. With regard to suppliers, ASN considers that preparations for the expiry of the sources administrative recovery period –which by default is 10 years– and the checks prior to delivery of a source to a customer, are areas in which practices still need to be improved.

In the field of **research**, the actions carried out in recent years have led to improvements in the implementation of radiation protection within the research laboratories. The most notable improvements concern the conditions of waste and effluent storage, particularly the setting up of pre-disposal checking procedures; nevertheless, further progress must be made, particularly in preparation for the recovery of unused “legacy” sealed radioactive sources. In addition, the registration and analysis of events which could lead to accidental or unintentional exposure of persons to ionising radiation, including as a result of insufficient traceability of the radioactive sources being held, are still not systematic enough.

With regard to the **veterinary uses of ionising radiation**, ASN can see the result of the efforts made by veterinary bodies over the past few years to comply with the regulations, notably in conventional radiology activities on pets. For practices concerning large animals such as horses, or performed outside veterinary facilities, ASN considers that the implementation of radiological zoning, the wearing of operational dosimeters and the radiation protection of persons from outside the veterinary facility who take part in the radiographic procedure, are points requiring particular attention.

TRANSPORT OF RADIOACTIVE SUBSTANCES

ASN considers that in 2019, the safety of transport of radioactive substances was on the whole satisfactory. Although a number of transport operations –mainly by road– did suffer incidents, these must be put into perspective with the 770,000 transport operations carried out each year. The incidents led neither to dispersion of the package content into the environment, nor to significant exposure of persons, with the exception of one event concerning the overexposure of a driver transporting radiopharmaceutical products (dose of nearly 28 mSv (millisieverts) received over 12 consecutive months).

The number of significant events relating to the transport of radioactive substances on the public highway remains stables (85 events reported to ASN in 2019). These were essentially:

- material non-conformities affecting a package. They had no real consequences on the radiation protection of people or the environment, although they did weaken the package (whether or not an accident occurred);
- non-compliance with internal procedures leading to the shipment of non-conforming packages, delivery errors, or packages being temporarily mislaid.

The inspections carried out by ASN also frequently identify such deviations. The consignors and carriers must therefore demonstrate greater rigour in day-to-day operations.

With regard to transport operations involved in the fuel cycle and, more generally, for BNIs, ASN considers that the consignors must further improve how they demonstrate that the contents actually loaded into the packaging comply with the specifications of the approval certificates and the corresponding safety cases.

For transport operations involving packages that no longer require ASN approval, progress is observed with respect to the previous years, along with better application of the recommendations given in ASN Guide No. 7 (volume 3). The improvements still to be made generally concern the description of the authorised contents by type of package, the demonstration that there is no loss or dispersion of the radioactive content under normal transport conditions, and that is impossible to exceed the applicable dose rate limits with the maximum authorised content.

At a time when the uses of radionuclides in the medical sector are generating a high volume of transport traffic, progress is still needed in knowledge of the regulations applicable to these transport operations and the arrangements made by certain hospitals or nuclear medicine centres for the shipment and reception of packages. ASN considers that the radiation protection of carriers of radiopharmaceutical products, who are significantly more exposed than the average worker, needs to be improved.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NOTABLE EVENTS 2019

FLAMANVILLE EPR REACTOR

Non-conformity of main secondary system welds

A significant number of deviations have been detected in the welds made on the pipes making up the main secondary systems of the Flamanville EPR reactor. These deviations led to the presence of flaws which were only belatedly detected and to mechanical properties below those initially anticipated. These deviations stem resulted from insufficient qualification of the processes, a lack of expertise in their implementation and shortcomings in EDF's monitoring of its contractors.

Some of these welds are subject to a "break preclusion" approach, which assumes mechanical properties and a level of manufacturing quality that are particularly high.

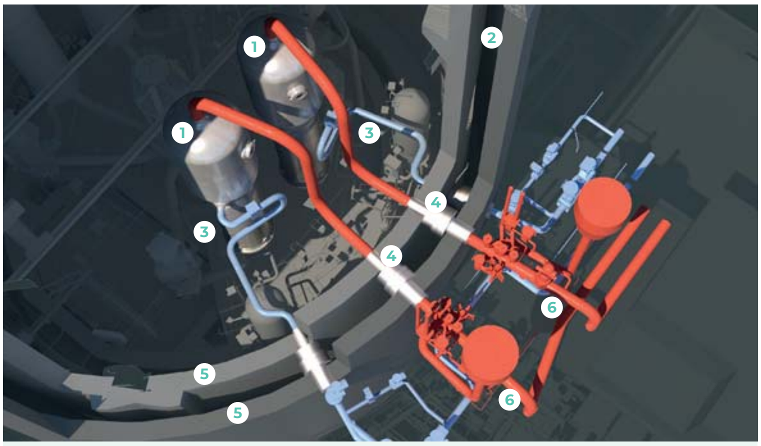
As early as 2018, ASN considered that preference should be given to repairing all the welds. EDF began to repair the main secondary systems welds, using procedures which depended on the systems concerned and the nature of the deviations.

Main steam line welds on the containment penetrations

Eight main steam line welds (VVP system) are located in the annulus between the two containment walls of the reactor building and are hard to access. EDF had hoped to be able to keep these break-preclusion welds as-is, relying on a test programme and increased in-service monitoring.

After examining the EDF file and consulting its Advisory Committee for Nuclear Pressure Equipment, ASN considered that the nature and the particularly high number of the deviations which had occurred during design and manufacture represented a major obstacle to keeping these welds as-is. In June 2019, ASN therefore indicated that repair before commissioning of the reactor remained the baseline solution.

Three repair solutions were then studied by EDF, for which ASN submitted its preliminary analysis of the risks and sensitive points. In October 2019, EDF's priority scenario was repair of the pipe from the inside, which requires the development of special intervention means. Qualification of the processes is ongoing, with EDF envisaging the end of the repair works in the second half of 2021.



1 Steam generators 2 Annulus 3 Feedwater flow control system
4 Penetrations 5 Double containment 6 Steam letdown systems (VVP)

Implementation of the orbital TIG process (weld on the main secondary system)

The other main steam line welds

In 2018, EDF decided to repair the other welds on the main steam lines. More than 50 welds are to be repaired, with the high level of quality required by the break preclusion approach.

Qualification of the welding processes and verification of the performance of the non-destructive testing means are in progress. The repair work is scheduled to start in 2020.

Steam generators feedwater system welds

In 2018, EDF began to repair the welds on the steam generators feedwater flow control system (ARE system). Six welds have been repaired.

In 2018, ASN also asked EDF to review the quality of the equipment in the Flamanville EPR reactor. In so doing, EDF revealed new deviations concerning the steam generators feedwater supply system. These deviations are currently being characterised in order to define how best to handle them. The review will continue in 2020.

IN BRIEF

Preparation for the operations to repair the eight penetration welds requires prior qualification of the welding processes, the non-destructive tests and the tools needed, notably for the pipe cutting and clamping phases, as well as for the heat treatment of the welds. Qualification of the welding process was started in 2019 and will continue in 2020.

For each weld, EDF and Framatome are thus producing a table to assess its compliance with the requirements of the technical baseline, including that associated with the break preclusion hypotheses. The organisation approved and mandated by ASN to evaluate the compliance of these welds examines their documentation and the corresponding table and evaluates whether the prerequisites for initiating their repair have been met. At the same time, ASN checks that all the actions taken by EDF, the manufacturer Framatome and the organisation result in a weld performance process that is robust.

REGULATION NEWS

Protecting NPPs from heat waves and earthquakes

In 2019, France experienced several heat wave episodes, plus the earthquake at Le Teil on 11 November 2019. The nuclear reactor safety cases take account of this type of natural hazard.

Operation of nuclear reactors during heat waves

The temperatures that nuclear reactors are required to deal with, as specified in the safety case, are regularly reassessed, notably during the periodic safety reviews. These reassessments take account of climate change.

A heat wave has three main consequences for the operation of nuclear reactors.

Operation of safety systems during a heat wave

In a heat wave, ventilation and air-conditioning systems are needed to guarantee the operation of the safety systems of the nuclear reactors.

During the heat waves of 2003 and 2006, EDF reinforced the ventilation and air-conditioning capacity of the premises containing the safety systems. These systems, which are required in the event of a heat wave, undergo preventive servicing, inspection and maintenance work. The general operating rules for the reactors indicate the steps to be taken should this equipment fail. This entails taking special measures, or even shutting down the reactor, as necessary.

In addition, EDF sets out special operating rules which, between April and October of each year, adapt the level of deployment of the internal organisations on the basis of the weather forecasts.

Reactor cooling and waste management in the event of drought or low water levels

Nuclear reactors must be permanently cooled in order to remain safe. Water is thus taken for this purpose from a watercourse or from the sea.

A period of drought can lead to a drop in the level and discharge of a watercourse. The licensee must permanently ensure that these remain sufficient to cool the safety systems. These parameters are specific to each NPP.

The discharge of the watercourse also affects the dispersal of liquid effluents from the nuclear reactors. For each NPP, ASN sets a minimum watercourse discharge value at which effluent discharges are possible.

Below this discharge rate (low water situation), effluent discharges are prohibited and the licensee has to store the effluents produced.

Controlling thermal discharges

The water intake from watercourses or the sea to cool the reactor is generally speaking discharged at a higher temperature, either directly, or after cooling in the cooling towers, enabling some of the heat to be dissipated into the atmosphere.

In the case of NPPs using a watercourse, ASN has for each site defined the conditions for discharge of the water used for cooling. In order to protect the environment, the ecosystem in particular, limit values are set for the heating of the watercourse as a result of operation of the NPP, as well as for the temperature of the water downstream of the plant. If these limit values are exceeded, the licensee shall reduce the power of the reactor or shut it down. Since 2006, ASN has incorporated measures into the regulations covering NPP discharges, to ensure advance definition of the operations of NPPs in exceptional climatic conditions leading to significant warming of the watercourse. These special provisions are however only applicable if the security of the electricity grid is at stake. Temporary relaxation of the limit values for the thermal discharges may also be authorised by ASN, at EDF's request, if needed by the electricity grid, as was the case during the heat waves of 2003 and 2006. In this case, environmental monitoring is reinforced.

During the heat waves of 2019, EDF had to shut down several reactors and reduce the power of some others.

Cruas-Meysse NPP

Designing NPPs to deal with the earthquake risk

Earthquakes form part of the natural risks that nuclear facilities must be able to withstand. Seismic protection measures are designed into the facilities and reviewed every ten years during the periodic safety reviews, to take account of changing knowledge.

In France, the characterisation of the seismic risk that each Basic Nuclear Installation (BNI) must be able to withstand is based on a deterministic approach, detailed in basic safety rule 2001-01. This rule is supplemented by ASN Guide 2/01 which defines the design provisions for the seismic protection of civil engineering structures.

The hazard characterisation method consists in:

- firstly, determining the "Maximum Historically Probable Earthquake" (MHPE) which corresponds to a return period of about 1,000 years. This level of earthquake can be considered as the most intense level "in human memory" identified in the region concerned;
- then defining the "Safe Shutdown Earthquake" (SSE) which corresponds to an increase in the magnitude of the MHPE of 0.5 on the Richter scale. Furthermore, the SSE is positioned by convention as close as possible to the nuclear site within the seismotectonic zone to which it belongs.

The SSE therefore integrates margins with respect to the historical earthquake recorded in the region in question: it is more intense and is positioned as close as possible to the nuclear site. On some sites, the consideration of paleoseismicity[1] data can supplement the movements associated with the SSEs.

Every 10 years, during their periodic safety reviews of its facilities, EDF reassess the earthquake intensity to be considered in the safety case. This reassessment is made in the light of developments in historical knowledge and any earthquakes that have occurred since the last review. As a result, EDF regularly reinforces parts of its facilities.

Without waiting for the periodic safety review, ASN may also ask that any event compromising the hypotheses used in the design of a facility be taken into consideration.

ASN therefore asked EDF to determine whether the Le Teil earthquake of 11 November 2019, once it was characterised, required a reassessment of the MHPE and thus the SSE for the Cruas and Tricastin NPPs. If so, EDF must determine whether this reassessment will oblige it to reinforce its installations. ASN will review the entire process and issue a position statement on this subject.

After the Fukushima NPP accident, ASN also asked EDF to check the robustness of its NPPs to an even higher earthquake level, the "Hardened Safety Core Earthquake" (HSCE), for which the main safety functions must continue to be guaranteed. The ground movements (accelerations) corresponding to the HSCE must be greater than those of the SSE plus 50%, and greater than those of earthquakes with a return period of 20,000 years. To meet this requirement, EDF has defined a "hardened safety core" of equipment (such as the ultimate backup diesel generator sets) that can withstand the HSCE and which is currently being deployed on its reactors.

IN BRIEF

The concept of the "hardened safety core" aims to create structures and equipment capable of withstanding events and of performing functions essential for the safety of the facilities and for management of an emergency on the site.

1. *A paleoseismicity study consists in excavating trenches through the surface trace of an active fault in order to identify earthquakes which have in the past affected the region in question.*

REGULATION NEWS

Fourth ten-yearly outage of EDF reactors: the first one at Tricastin

In 2019, EDF initiated its program of fourth ten-yearly outages for its 900 MWe reactors. Tricastin reactor 1 was thus shut down from 1 June to 23 December 2019.

This ten-yearly outage is one of the steps of its fourth periodic safety review. This periodic safety review is particularly important because the initial hypothesis used in the design of some of the reactor equipment was 40 years of operation. Extending its operation beyond this period means that these design studies must be updated or some equipment replaced. This periodic safety review is also an opportunity to complete the incorporation of the changes arising from the ASN requirements issued following the stress tests performed in the wake of the accident that struck the Fukushima Daiichi NPP.

ASN has been involving the public since 2016 in the drafting of its position statement regarding the objectives proposed by EDF. This approach continued in 2018, under the aegis of the High Committee for Transparency and Information on Nuclear Security, in the form of a consultation on the measures planned by EDF to meet these objectives. ASN will also consult the public on the position it is to adopt at the end of 2020 for the generic phase of the periodic safety review.

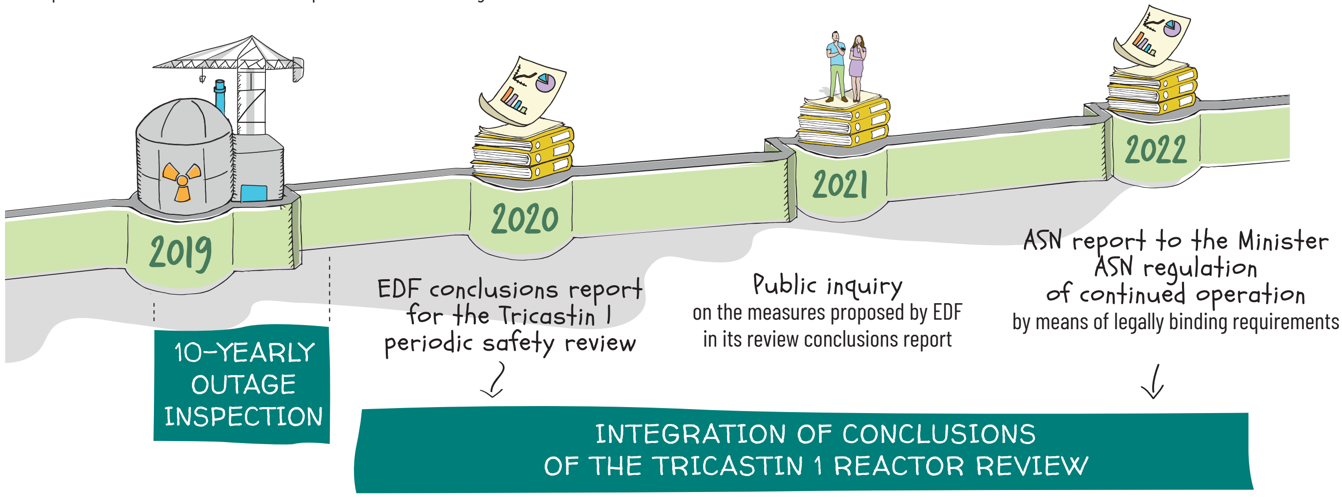
During the ten-yearly outage at Tricastin NPP reactor 1, EDF carried out tightened inspections on the compliance of equipment important for safety and ten-yearly tests on the reactor coolant system and the containment. These inspections participate in the closer attention to the compliance of the facilities requested of EDF by ASN.

EDF also made changes to its facility to improve safety. For example, EDF installed a new fuel pool cooling system and a system to remove heat from the containment in the event of an accident with fuel melt. These changes help bring the safety objectives closer in line with those of the third generation reactors.

ASN has implemented a specific inspection programme before, during and after the ten-yearly outage, entailing about ten more inspections than a conventional ten-yearly outage.

ASN considers that the performance of this ten-yearly outage was on the whole satisfactorily. It will issue a position statement on the continued operation of Tricastin reactor 1 after the public inquiry to be held in 2021, as required by law.

EDF mobilised significant human resources to prepare for and carry out this ten-yearly outage. 5,000 personnel took part in this. This effort will need to be sustained for the long-term, as of 2020 for the fourth ten-yearly outages of Bugey NPP reactors 2 and 4 and until 2030 for that of the last reactor of the Chinon NPP.



JOINT POSITION OF ASN AND ASND

CEA decommissioning and materials and waste management strategy

In France, nearly 40 CEA civil and defence nuclear facilities have been finally shut down or are being decommissioned. The ageing design of these facilities did not take account of decommissioning or radioactive waste management in accordance with current safety requirements.

Given the number and complexity of the operations to be carried out for all the nuclear facilities to be decommissioned, CEA defined priorities, based primarily on an analysis of the potential hazards, in order to mitigate the risks presented by these facilities. The highest priority operations concern some individual facilities in the Marcoule Defence Basic Nuclear Installation (DBNI), as well as the Basic Nuclear Installations (BNI) in Saclay (BNI 72) and Cadarache (BNI 56). An accident in one of these facilities could lead to unacceptable nuclear safety and radiation protection consequences.

In their opinion of 27 May 2019, ASN and the Defence Nuclear Safety Authority (ASND) confirmed the general adequacy, with constant resource levels, of the prioritisation defined by CEA, given the resources allocated by the State and the significant number of nuclear facilities being decommissioned, entailing considerable investment (creation or preliminary renovation of means for the recovery, packaging and storage of radioactive materials and waste, as well as the corresponding transportation), so that the legacy waste could be correctly managed. However, even if there are no unexpected events or delays in the projects considered by CEA to have priority, the mitigation of the risks presented by these ageing facilities will not be effective before ten or so years at best. ASN and ASND have concerns in particular about the planned human and financial resources for dealing with all of the most important situations entailing safety implications or environmental hazards over the coming 10 years. A specific investment effort, as well as the creation of engineering units and the reinforcement of the safety teams dedicated to these projects would seem to be necessary.

If these projects are to progress, they will require an increase in CEA's oversight and coordination capacity allied with rigorous and transparent State monitoring of CEA's actions, in terms of cost, time and effectiveness.

With regard to the facilities of lower priority, and owing to the limits of its human and financial resources, CEA is looking at a "two-stage" decommissioning of each facility. First of all, most of the hazard potential will be removed. Secondly, following a potentially lengthy period of interruption, the decommissioning operations will be completed on the facilities.

The resulting surveillance, upkeep and operations needed to maintain a sufficient level of safety in these facilities, once the hazard potential has been removed, possibly for decades up until delicensing, will significantly increase the final cost of the decommissioning of all the CEA facilities. **Moreover, the priority decommissioning of facilities with significant safety implications will, for those facilities for which decommissioning is postponed, lead to the modification of the regulatory requirements already issued.**

The public must be regularly informed of the progress of the programme as a whole.

IN BRIEF

CEA operated these facilities, some of them since the 1950s, in a context where *"pressing national and international needs forced it to take the necessary steps to enable France to maintain its position in the field of atomic energy research."*

PUBLIC DEBATE

National Radioactive Materials and Waste Management Plan

Planning Act 2006-739 of 28 June 2006 on the sustainable management of radioactive materials and waste stipulated the drafting of a National Radioactive Materials and Waste Management Plan (PNGMDR) every 3 years.

The PNGMDR is prepared by the General Directorate for Energy and Climate (DGEC) at the Ministry for Ecological and Solidarity-based Transition and by ASN, on the basis of the work done by a pluralistic working group in particular comprising radioactive waste producers, licensees of management facilities for these wastes, evaluation and control authorities and environmental protection associations.

In concrete terms, the PNGMDR gives a detailed inventory of radioactive materials and waste management methods, whether operational or to be deployed, and then makes recommendations or sets targets. ASN contributed to this through seven opinions issued in 2016, the main guidelines of which were incorporated into the 2016-2018 version of the PNGMDR. The Decree and Order of 23 February 2017 set out the requirements and the studies to be conducted in the coming years. There are 83 such studies, each with one or more coordinators and a completion deadline.

A similar pluralistic drafting approach will be applied for the 5th edition of the PNGMDR which was preceded, for the first time, by a public debate. Indeed, in accordance with the Ordinance of 3 August 2016, the DGEC and ASN referred to the National Public Debates Commission (CNDP) regarding the procedures to be followed for organising public participation in the drafting of this next plan. The CNDP decided to organise a public debate on the plan.

Together with the Special Public Debates Commission (CPDP), ASN and the DGEC draw up a "Programme manager file", which presented the main aspects of the PNGMDR and identified the main challenges as related to the drafting of the next plan:

- the challenges of reusing stored radioactive materials;
- spent fuel storage capacity;
- the scale of the volumes of very low level (VLL) waste expected from decommissioning;
- management of the diversity of low level, long-lived waste (LLW-LL);
- the creation and operation of a deep geological disposal facility.

Furthermore, ahead of the debate, the CPDP produced a "clarifying the controversies" dossier, which aims to provide the non-specialist public with the various arguments put forward by the experts and institutional organisations concerning questions arising from the plan.

ASN and the DGEC took part in the debate in order to present the issues and answer questions from the public. The institutional representatives (nuclear licensees, associations, Local Information Committees, experts) were often present in large numbers. ASN, as did the CPDP, observed that participation by the general public was low. The participative platform received 86 questions, 442 opinions, 62 individual stakeholder presentations and 22 contributions. Of the 86 questions received, 69 were sent to ASN and the DGEC, who provided answers.

ASN notes the diversity of the subjects of concern for the debate's participants. More particularly, a large number of questions concerned the *Cigéo* project, the effective reuse of radioactive substances qualified as materials or the coverage of the costs if these materials were finally to be considered as waste, along with the management of VLL waste. These topics were already identified as being among the five issues of the debate in the Programme Manager File. Other subjects were raised by the public, such as the reprocessing of spent fuels, the separation-transmutation of radionuclides, the governance of radioactive materials and waste management, the environmental and health impacts of waste management, transports, or resorting to the use of nuclear energy.

The CNDP and the CPDP presented their conclusions following this debate in a report and a summary transmitted on 25 November 2019. For each of the topics identified by ASN and the DGEC, the CPDP concludes that the debate was able to clarify the various options and their implications. Other subjects were also raised during the public debate. For instance, the management of particular waste categories, such as those resulting from the conversion of uranium, legacy waste and mining waste, transportation, health, the economy and regional impacts, were subjects which received particular attention from the public. Elsewhere, the duration of the plan, set by law at three years, was felt to be too short and inconsistent with the nature of the issues and with the durations of the other plans related to it.

Public debate meeting on the PNGMDR in Tours – 2019

ASN considers that the debate was able to explain certain technical controversies, clarify the expectations of the public and nuclear stakeholders and inform the Programme Managers with a view to the drafting of the next PNGMDR. On 21 February 2020, the Minister for Ecological and Solidarity-based Transition and ASN communicated how they envisage following up the debate:

- transparency and the monitoring of the conditions for reuse of radioactive materials will be reinforced and characterisation of the issues involved in the reprocessing of spent fuels will be continued;
- measures to anticipate the saturation of spent fuel storage capacity and the characterisation of the challenges of dry storage, will be looked at in greater depth;
- the orientations of the previous plan concerning the management of VLL waste, notably the study of reuse solutions and the search for additional disposal solutions, will be confirmed;
- management methods tailored to the diversity of LLW-LL waste will be examined;
- cross-cutting issues in which the public expressed an interest, such as health and environmental impacts, regional issues, modes of transport and economic aspects, will be developed further in the forthcoming plan;
- the definition of the conditions for the implementation of *Cigéo* will be specified and research and development on management alternatives will be continued;
- the interaction between the PNGMDR and other management policies, such as the multi-year energy programme, will be reinforced;
- the PNGMDR will refocus on strategic orientations.

ASN opinions on radioactive materials and waste management solutions will be issued on the basis of these orientations.

The drafting of the 5th plan and its environmental assessment and public consultation will take place in 2020 and early 2021. The plan will then be made public and transmitted to the Parliamentary Office for the Evaluation of Scientific and Technological Choices for its opinion.

IN BRIEF

The debate was held from 17 April to 25 September 2019, using a variety of procedures:

- 6 general subjects meetings in large cities;
- 14 thematic meetings in the regions concerned;
- 2 discussion sessions debating an ethical approach to the management of radioactive materials and waste;
- a round-table on the question of trust and mistrust felt by the public with respect to the decisions taken or envisaged;
- information and debate stands in several towns around France;
- an on-line participative platform enabling people to express an opinion, submit comments on those already expressed, submit questions to the prime contractor and, for artificial persons, submit an individual stakeholder's presentation and contributions document.

In parallel with these participation methods open to all, the CPDP set up some innovative systems:

- a "mirror group" comprising 14 people drawn by lots drafted a joint contribution on the topic "What did we inherit and what will we leave to our children?";
- a "tomorrow's specialists workshop" brought together students from different backgrounds to explore how radioactive waste management can be informed by different disciplines.

MANAGEMENT ORIENTATIONS

Spent nuclear fuel storage capacity

ASN underlines the need for France to acquire spent fuel storage capacity and the need to start preparations for these projects without delay. In 2019, it issued its opinion on the safety options of the centralised spent fuel pool presented by EDF.

The "nuclear fuel cycle" encompasses the fabrication of the nuclear fuel used in the reactors of the power plants, its storage and its reprocessing after irradiation. ASN monitors the overall consistency of the industrial choices made concerning fuel management which could have an impact on safety.

This monitoring covers:

- the changes or problems that could be anticipated over the next decade in the facilities and transport operations involved, on the subject of which ASN issues a statement every 10 years on "fuel cycle consistency";
- the prospects, for the coming century, in terms of the management of radioactive materials and waste, for which ASN and the DGEC periodically update the National Radioactive Materials and Waste Management Plan (PNGMDR).

Identified needs

As early as 2010, ASN had identified the need for new spent fuel storage capacity by about 2030. Given the current volumes, this need can be primarily explained by the fact that, once used, the fuels resulting from a first reprocessing, called MOX, are not then again reprocessed.

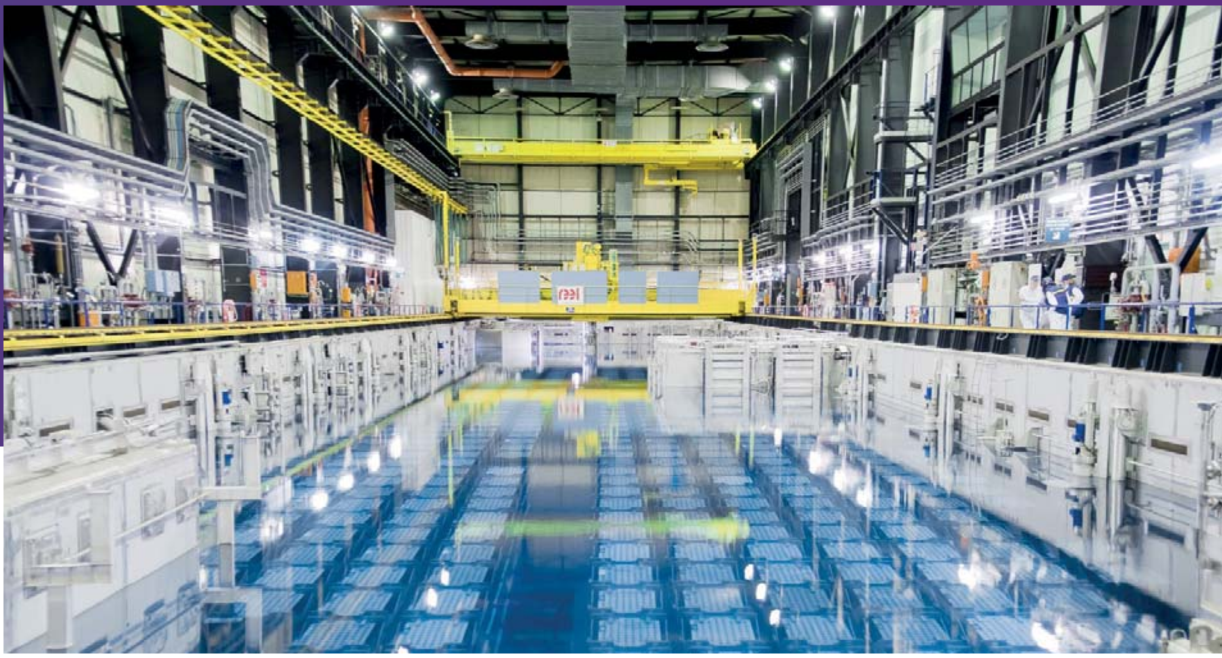
This need having been confirmed by the PNGMDR 2016-2018, the Government instructed EDF to submit applications to extend this capacity[1], more specifically an authorisation application to be submitted by EDF at the end of 2020.

An EDF project, an ASN analysis

In 2017, EDF asked ASN for its opinion on the safety options for a spent fuels centralised storage pool project. Its purpose is to store 10,000 tHM (tonnes heavy metal) in two storage ponds. In this dossier, EDF did not define a site for the location of the facility. ASN issued its opinion on this project on 23 July 2019 and considers that the general safety objectives and the design options adopted are satisfactory.

Additional demonstrations will however be required, notably concerning the design and the control of manufacturing, in order to guarantee the long-term leaktightness of the pool, as well as the contingencies selected regarding external hazards, more particularly airplane crashes, once the site of the facility has been chosen.

1. *Article 10 de of the Order of 23 February 2017 setting out the provisions of the PNGMDR requires EDF to transmit* "a creation authorisation application for a new spent fuel storage facility, or a substantial modification application, if this is an extension of an existing facility, to the Ministry responsible for nuclear safety, before 31 December 2020".



Spent fuel pool at La Hague

Anticipating confirmed needs

The public debate on the PNGMDR held in 2019 confirmed the need for new spent fuel storage capacity by about 2030 and the consistency of the choice of "wet" storage with the reprocessing strategy. This choice would also be compatible with direct disposal of the fuels.

Generally speaking, ASN underlines the need to anticipate any strategic change in the functioning of the fuel cycle by at least ten years so that this change can be designed and carried out under satisfactory conditions of safety and radiation protection. It is a question for example –given the incompressible development times for industrial projects– of ensuring that the needs for the creation of new spent fuel storage facilities or for new transport packaging designs are addressed sufficiently early.

ASN thus considers that it is important for EDF to continue its project to create new centralised storage capacity, without delay.

For the longer term, given the foreseeable shutdown of the 900 MWe reactors, which are the oldest and today the only ones using MOX fuel:

- either new storage capacity is required, well in excess of the current and planned volume;
- or MOX fuel must be usable in reactors other than the 900 MWe.

The time-frame required for the study and implementation of these options is about ten years. ASN therefore asks the industrial players to start examining these two options without delay.

IN BRIEF

MOX (mixed oxide) fuel is a nuclear fuel based on a mixture of oxides of uranium and plutonium. Its use in nuclear power generating reactors began abroad in the 1970s. It has been used in France since 1987. In 2017, of the 58 French reactors, 22 of EDF's 900 MWe nuclear reactors were using this fuel. 24 reactors are authorised to use it. In France, MOX fuel uses only civil plutonium, extracted from spent fuel.

REGULATORY NEWS

2019 was marked by considerable activity in terms of standards.

More specifically, Decree 2019-190 of 14 March 2019 published in the *Journal Officiel* (*Official Gazette*) of 16 March 2019, codifies the provisions applicable to Basic Nuclear Installations (BNIs), the transport of radioactive substances and transparency in the nuclear field. This Decree led to a wide-ranging consultation with the stakeholders and the public between September 2017 and January 2018. The High Council for the Prevention of Technological Risks (CSPRT) and then ASN issued their opinions on 13 March and 21 June 2018 respectively. It entered into force on 1 April 2019.

In addition, a number of Orders and ASN resolutions resulting from the Decrees[1] transposing Council Directive 2013/59/Euratom of 5 December 2013 laying down Basic Standards for the protection of health against the dangers arising from exposure to ionising radiation were published in 2019.

Finally, international news was marked by the revision of the regulation for the transport of radioactive materials from the International Atomic Energy Agency (IAEA).

1. National news

1.1 Acts

• Act 2019-773 of 24 July 2019 creating the French Office for Biodiversity and Hunting, modifying the duties of the hunting federations and reinforcing environmental policing

Articles 4, 6 and 22 of this Act modify the provisions of the "common core of the environmental policies" (resulting from the overhaul of these policies by Ordinance 2012-34 of 11 January 2012) on the basis of the experience acquired since 2012 and resulting from the adaptations to the procedural framework within which the personnel responsible for monitoring carry out their administrative and judicial policing duties with the aim of reinforcing the policing powers of these personnel and improving the efficiency of the monitoring services.

The ASN inspectors may use the new prerogatives created by the 24 July 2019 Act because, since Ordinance 2016-128 of 10 February 2016 introducing various nuclear provisions, the nuclear safety inspectors and radiation protection inspectors carry out their monitoring duties within the framework of the procedural rules of the "common core of environmental policies" set out by the provisions of Articles L.171-1 et seq. of the Environment Code.

For example, in the criminal field, the ASN inspectors can now, when authorised by the Public Prosecutor's office and for the purpose of technical or scientific examinations, ask qualified persons or ask any person, any establishment or any private or public organisation, for information relevant to the investigation, including data taken from a computer system or from processing of nominative data, without professional confidentiality being raised as a cause for non-compliance, if there is no legitimate reason. Furthermore, when authorised by the Public Prosecutor's office, the names and first names of the persons appearing in the copies of the citations, except for those of the offender, could be deleted when this information is liable to endanger the life or physical safety of these persons or of their family.

During the administrative inspections they carry out, the inspectors may, as was already the case in judicial police investigations, take samples or have them taken for the purposes of analysis or testing. The new provisions enable ASN to take steps (penalty payments for example) to guarantee complete performance of the enforcement measures intended to oblige the party responsible for an activity to regularise their situation and submit a notification or application for authorisation or registration.

• Act 2019-1147 of 8 November 2019 concerning energy and the climate

Article 1 of this Act more specifically modifies the date of achieving the target of a 50% share of electricity production from nuclear sources, pushing it back from 2025 to 2035. The Decree on the multi-year energy programme, which should appear in 2020, will notably detail the procedures and arrangements for achieving this target.

Article 31 of this Act modifies Article L.122-1 of the Environment Code. Under the terms of this Environment Code, as amended, "the environmental Authority" and the "authority in charge of case by case examination" to determine whether the project is subject to the environmental assessment, are separate.

V bis (new) of Article L.122-1 of the Environment Code specifies that this "*authority in charge of the case by case examination and the environmental authority should not find themselves in a position giving rise to a conflict of interest*."

However, nothing is modified for the BNIs. Since Act 2018-727 of 10 August 2018 (ESSOC Act), pursuant to the second paragraph of IV of Article L.122-1, ASN is the authority in charge of determining whether the noteworthy modification projects liable to have a significant negative impact on the environment, shall be subject to an environmental assessment.

Furthermore, in order to secure the plans and programmes subject to systematic or case by case environmental assessment, a new Article L.191-1 of the Environment Code (created by the 8 November 2019 Act) gives the administrative judge the option, when he or she finds that an illegality affecting one of these acts is liable to be regularised and provided that he or she has found that the other means are unfounded, to stay the proceedings in order to enable the administrative authority to conduct this regularisation, in order to avoid pronouncing it null and void.

1. *Decree 2018-434 of 4 June 2018 introducing various nuclear provisions and Decree 2018-437 of 4 June 2018 concerning the protection of workers against hazards arising from ionising radiation.*

1.2 Decrees and Orders

1.2.1 Radiation protection

TEXTS ISSUED PURSUANT TO THE PUBLIC HEALTH CODE

Radon

• **The purpose of the Order of 20 February 2019 concerning health information and recommendations to be issued to the population in order to prevent the effects of exposure to radon in buildings** is to act as a tool for the institutional stakeholders in charge of carrying out measures to raise awareness of the radon risk. As a priority, it concerns elected officials and inhabitants in municipalities with a significant radon potential, as identified in the Order of 27 June 2018 identifying the zones with radon potential in France. The information about the origin and health effects of radon is supplemented by recommendations on the steps to be taken according to the level of exposure measured in the home. ASN is one of the authorities designated by the Minister in charge of radiation protection to disseminate this health information and these recommendations to the public.

• **The Order of 26 February 2019 concerning the methods for managing radon in certain buildings open to the public and for dissemination of information to those persons frequenting these facilities** supplements the regulations for the management of situations in which the radon reference level, set at 300 Bq/m^3 (becquerels per cubic metre) is exceeded in buildings open to the public (ERPs). It more specifically clarifies the steps to be taken in manner that is gradual and appropriate to the situation encountered. The Order also defines the contents of the display of the radon concentration at the entrance to the buildings open to the public concerned, so that the public frequenting the buildings are made aware of this information.

Waters intended for human consumption

A health check on the quality of Waters Intended for Human Consumption (EDCH) is performed by the Regional Health Agencies (ARS) to ensure that these waters comply with the regulation quality references and entail no risk to the health of consumers. **The Order of 11 January 2019 modifying the Order of 5 July 2016 concerning the conditions for the approval of laboratories to take samples and conduct analyses to check the health quality of the waters and the Order of 19 October 2017 concerning the analysis methods used for health** checks of waters more specifically aims to share the approval procedure for laboratories measuring radioactivity in the EDCH and in natural mineral waters for the purposes of the health check. This approval, issued by the Minister in charge of health has, since 1 April 2019, been dependent on first of all obtaining national environmental radioactivity monitoring network approval, issued by ASN and mentioned in Article R.1333-25 of the Public Health Code.

TEXTS ISSUED PURSUANT TO THE LABOUR CODE

• **The Order of 26 June 2019 concerning individual monitoring of worker exposure to ionising radiation** sets out the procedures and conditions for implementation of the provisions of Article R.4451-64 to R.4451-72 of the Labour Code, more specifically:
- the implementation of individual dosimetric monitoring of workers exposed to a risk caused by ionising radiation;
- reporting to the ionising radiation exposure monitoring information system (Siseri);
- communication to Siseri of the individual dosimetric monitoring results;
- access to the individual dosimetric monitoring results and possible correction by the occupational physician;
- accreditation of the dosimetry organisations, the medical biology laboratories and the occupational health departments tasked with individual monitoring of worker exposure to ionising radiation set out in Article R.4451-65 of the Labour Code.

The Order will enter into force on 1 July 2020. On that date, the Order of 17 July 2013 concerning the individual medical monitoring form and the dosimetric monitoring of workers exposed to ionising radiation and the Order of 21 June 2013 concerning the conditions for issue of the certificate and for approval of organisations responsible for individual monitoring of worker exposure to ionising radiation will be repealed.

TEXTS ISSUED PURSUANT TO THE LABOUR CODE AND THE PUBLIC HEALTH CODE

• **The Order of 18 December 2019 concerning the training of the Radiation Protection Expert-Officer and the certification of training organisations and radiation protection organisations** defines the duties of the radiation protection advisor mentioned in Articles R.4451-126 of the Labour Code and R.1333-18 of the Public Health Code, whether they are a Radiation Protection Expert-Officer or a Radiation Protection Organisation.

This Order will enter into force on 1 July 2020 with interim provisions until 1 July 2021. It repeals the Order of 6 December 2013 concerning the training of the Radiation Protection Expert-Officer and the certification of training organisations, as well as the Order of 24 November 2009 ratifying ASN resolution 2009-DC-0147 of 16 July 2009 setting out the conditions for the performance of the duties of a Radiation Protection Expert-Officer from outside the facility as of 1 July 2021.

1.2.2 Basic Nuclear Installations

• **Decree 2019-190 of 14 March 2019 concerning BNIs and transparency in the nuclear field**

The legislative changes made to the BNI System by the TECV Act of 17 August 2015, by Ordinance 2016-128 of 10 February 2016 comprising various nuclear provisions and, concerning ASN, by Act 2017-55 of 20 January 2017 introducing the general status of independent administrative authorities and independent public authorities, entails modifications to the regulatory provisions in force.

After Decree 2016-846 of 28 June 2016 specified the provisions concerning the conditions for the modification and decommissioning of BNIs and rules regarding subcontracting, Decree 2019-190 of 14 March 2019 specified the provisions concerning Local Information Committees (CLI), the renewal of the ASN Commission, the ASN Sanctions Commission, third-party expertise and the transposition of the Industrial Emissions Directive (IED) and Seveso Directive to BNIs.

On this occasion, the Minister responsible for nuclear safety decided to codify all the regulatory provisions in force.

• **The Order of 7 February 2012 setting the general rules concerning BNIs ("BNI Order")**

Work to revise this Order began in 2019 and will continue in 2020 on the basis of feedback from more than 6 years of implementation of the Order. In 2019, ASN began to analyse the observations and proposed changes from the licensees. All the stakeholders will then be consulted on the draft modifying Order.

1.2.3 The security of radioactive sources

• **The Order of 29 November 2019 concerning the protection of ionising radiation sources and batches of category A, B, C and D radioactive sources against malicious acts** was published in the *Journal Officiel* (*Official Gazette*) on 11 December 2019. This Order clarifies the measures to be taken to protect ionising radiation sources or batches of radioactive sources against malicious acts, both in the facilities and during transport operations. This Order, to which ASN made an active contribution and which entered into force on 1 January 2020:
- is part of the Government's national security strategy, in particular to counter radiological threats;

Codification and updating of the decrees concerning BNIs and transparency in the nuclear field

Decree 2019-190 of 14 March 2019 constitutes the regulatory part of the Environment Code more specifically concerning ASN, BNIs, the transport of radioactive substances and the system of inspection and sanctions with respect to these installations and activities.

The Decree codifies and updates the following decrees:

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

The Decree also modifies the regulatory procedures relating to BNIs currently governed by the Decree of 2 November 2007 referred to as the "BNI Procedures" Decree, more specifically so that they are brought into line with the new regulatory requirements concerning the environmental assessment of projects, resulting from the Ordinance of 3 August 2016 and its implementing Decree of 11 August 2016 which transpose Directive 2011/92/EU of the European Parliament and the Council of 13 December 2011 concerning the assessment of the environmental impact of certain public and private projects, as modified by Directive 2014/52/EU of the European Parliament and the Council of 16 April 2014.

Furthermore, the Decree:

- **supplements the provisions relating to the CLIs pursuant to Article 123 of the Energy Transition for Green Growth Act (TECV) of 17 August 2015, notably with the aim of including foreign members in the CLIs concerned if the BNI site is located in a border *département*;**
- **defines the conditions of renewal of half of the ASN Commission, other than its chairperson, every three years, pursuant to Act 2017-55 of 20 January 2017 introducing the general status of the independent administrative authorities and the independent public authorities;**
- **defines the functioning of the ASN Sanction Committee instituted by Ordinance 2016-128 of 10 February 2016 introducing various provisions concerning nuclear activities and detailing the procedures giving rise to administrative fines;**
- **clarifies the System applicable to BNIs containing equipment or installations subject to Directive 2010/75/EU of 24 November 2010 relating to industrial emissions (referred to as the "IED Directive"), as well as the System of BNIs subject to Directive 2012/18/EU of 4 July 2012 concerning the control of the hazards linked to major accidents involving substances (referred to as the "SEVESO 3 Directive") pursuant to the above-mentioned Ordinance 2016-128 of 10 February 2016 containing various nuclear-related provisions.**

- is based on recommendations issued by the IAEA, which are already in effect in other countries, notably in Europe;
- adopts a graded approach, with the organisational or technical arrangements being reinforced proportionately to the danger represented by the source(s) to be protected;
- comprises interim provisions of up to two years, enabling the facilities or carriers concerned to define, plan and then implement these new requirements.

1.3 ASN Resolutions

1.3.1 Radiation protection

ASN resolution 2018-DC-0649 of 18 October 2018 pursuant to 2° of Article R.1333-109 and article R.1333-110 of the Public Health Code, defining the list of nuclear activities subject to notification and the information to be mentioned in these notifications

This resolution extended the scope of activities subject to notification, more particularly incorporating certain activities using sealed radioactive sources, and set out the generic procedures to be followed so that the activity or equipment could benefit from this system.

The activities concerned are grouped into four main areas:

- nuclear activities employing devices for medical purposes;
- nuclear activities in the industrial, veterinary or research fields involving electrical generators of ionising radiation;
- nuclear activities in the industrial or research fields involving sealed radioactive sources or devices containing them;
- activities carried out by third parties relating to the rehabilitation of sites and soils contaminated by radioactive substances.

This resolution also repeals the old resolutions concerning the notification system (resolutions 2009-DC-0146, 2009-DC-0148, 2009-DC-0162, 2011-DC-0252, 2015-DC-0531).

The resolution came into force on 1 January 2019. Until such time as they expire and if there is no modification to the nuclear activity, the existing authorisations prior to this date take the place of the notification required by the resolution.

ASN resolution 2019-DC-0660 of 15 January 2019 setting the quality assurance obligations in medical imaging using ionising radiation

This resolution defines the quality assurance obligations for medical imaging involving ionising radiation, that is to say in nuclear medicine for diagnostic purposes, in dental and conventional radiology, in computed tomography and for fluoroscopy-guided interventional practices. It obliges the person responsible for the nuclear activity to define a quality management system and to provide details:

- about the processes, procedures and work instructions associated with operational implementation of the two general radiation protection principles, namely justification of procedures and optimisation of doses;
- about the experience feedback process, by reinforcing the recording and analysis of events that could lead to accidental or unintentional exposure of persons during medical imaging procedures.

This resolution enables the quality management system to be tailored to the radiological risks inherent in medical imaging activities and the radiation protection issues.

ASN resolution 2019-DC-0667 of 18 April 2019 concerning the methods for evaluating ionising radiation doses delivered to patients during a radiology procedure, fluoroscopy-guided interventional or nuclear medicine practices, and the updating of the corresponding Diagnostic Reference Levels (DRLs)
This resolution updates and clarifies the methods for evaluating the ionising radiation doses delivered to patients during medical imaging procedures, in order to help control these doses. It updates the Diagnostic Reference Levels (DRLs) for dental and conventional radiology, computed tomography and nuclear medicine procedures. For the first time, DRLs have also been defined for certain fluoroscopy-guided interventional practices.

It specifies how the data are collected, confirms the need to analyse the dosimetry values collected, in order to optimise the doses delivered to the patients and recalls the obligation to send the data thus collected and analysed to the Institute for Radiation Protection and Nuclear Safety (IRSN). When the DRLs are exceeded, with the exception of justified special situations, the party performing the procedures takes the necessary action to reinforce optimisation.

ASN resolution 2019-DC-0669 of 11 June 2019 modifying ASN resolution 2017-DC-0585 of 14 March 2017 concerning continuing training in the radiation protection of persons exposed to ionising radiation for medical purposes
This resolution of 11 June 2019 primarily modifies the conditions for the entry into force of the resolution of 14 March 2017 (Article 15), by requiring the application:
- of the professional guides within 6 months following their approval;
- as of the day following the publication of the approval Order, in the absence of an approved professional guide, of the articles of the resolution concerning the pedagogical objectives and the methods of training for each profession or field of activity concerned, the skills of the trainers and the training organisations.

1.3.2 Basic Nuclear Installations

ASN resolution 2017-DC-0616 of 30 November 2017 concerning noteworthy modifications to BNIs
This resolution came into force in full on 1 July 2019. Noteworthy modifications include the changes made by the licensee:
- to the systems, structures and components of the installation, their authorised operating conditions, the elements which led to its authorisation or its commissioning authorisation or, as applicable, its decommissioning conditions;
- and liable to affect public health and safety or the protection of nature and the environment.

This resolution specifies the criteria for distinguishing the noteworthy modifications requiring ASN authorisation from those simply requiring notification to it. It also defines the requirements applicable to the management of noteworthy modifications, more particularly the internal check procedures to be implemented by the licensees.

The ASN resolution confirms the responsibility of the licensees for managing noteworthy modifications to their facilities, while ensuring that they are supported by an appropriate organisation, and reinforces the overall consistency of the system by making ASN's oversight more proportionate to the specific implications of each modification.

This resolution also repeals:
- ASN resolution 2008-DC-0106 of 11 July 2008 concerning the procedures for the implementation of internal authorisation systems in Basic Nuclear Installations (as at 1 January 2018);
- ASN resolution 2013-DC-0352 of 18 June 2013 concerning public access to modification project files specified in Article L.593-15 of the Environment Code (as at 1 January 2018);
- ASN resolution 2014-DC-0420 of 13 February 2014 concerning physical modifications to BNIs (as at 1 July 2019).

1.4 ASN guides

For a period of one month between 29 November and 29 December 2019, ASN submitted its draft guide on "Policy for the management of risks and detrimental effects of BNIs and the licensee integrated management system" as provided for by the Environment Code, to a public consultation.

The draft guide expresses the relevant ASN recommendations. These recommendations concern all BNIs, whether in the design, construction, commissioning, operation, final shutdown, decommissioning phases or, for radioactive waste disposal facilities, in the closure or surveillance phase.

This draft guide is part of the ASN work to integrate into the French regulatory framework a number of positions adopted by WENRA (Western European Nuclear Regulators Association), in particular the "reference levels" for the existing reactors.

The observations received will be analysed by ASN and written up in a report, which will more particularly indicate the steps to be taken to subsequent to the consultation.

1.5 The professional guides approved by ASN

With regard to Nuclear Pressure Equipment (ESPN), ASN has approved the following professional guides:
ASN resolution CODEP-CLG-2019-003685 of 22 January 2019, issued to implement the provisions of b of IV of Article 10 of the Order of 10 November 1999 concerning monitoring of the operation of the main primary system and main secondary systems of pressurised water reactors, approving the AFCEN professional guide reference RS.17.022 revision B for the design and manufacture of the main pressurised parts intended for the nuclear pressure equipment of the main primary and main secondary systems.
ASN resolution CODEP-CLG-2019003687 of 22 January 2019, implementing the provisions of the modified Order of 30 December 2015 concerning ESPN and certain safety accessories designed to protect it, approving the four professional guides:

a. **AFCEN Guide reference RS.18.003 revision A** concerning the compliance evaluation requirements and procedures for a permanent assembly of an ESPN installation subject to 4.1.a of Appendix V of the Order of 30 December 2015;
b. **AFCEN Guide reference RS.18.004 revision C** concerning the compliance evaluation of the protection against the allowable limits being exceeded at installation of an ESPN;
c. **AFCEN Guide reference RS.16.009 revision B** concerning the repairs and modifications of ESPN subject to points 1 to 4 of Appendix V of the Order of 30 December 2015;
d. **AFCEN Guide reference RS.18.006 revision A** concerning the requirements applicable to the repairs and modifications of ESPN subject to points 1 to 4 of Appendix V of the Order of 30 December 2015 and the procurement of the parts intended for it.

ASN, the French Nuclear Safety Authority, has eleven 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 31 December 2019, the ASN regional divisions totalled 230 employees, including 176 inspectors.

Under the authority of the regional representatives (see chapter 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. The divisions 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 (NPPs).

REGIONAL OVERVIEW OF NUCLEAR SAFETY AND RADIATION PROTECTION

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 emergency situation preparedness, they help draw up the emergency plans established by the Prefects and take part in the periodic exercises.

The ASN regional divisions contribute to the mission of informing the public. They take part, for example 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 section presents ASN's oversight action in the BNIs of each region and its assessment of nuclear safety and radiation protection.

Actions to inform the public and cross-border relations are addressed in chapters 5 and 6 respectively.

IMPORTANT

Oversight of small-scale nuclear activities (medical, research and industry, transport) is presented in chapters 7, 8, and 9.

Medical sector
see chapter 7

Research and industry
see chapter 8

Transport sector
see chapter 9

Auvergne-Rhône-Alpes region

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 Nuclear Power Plants (NPPs) operated by EDF:
  - Bugey (4 reactors of 900 MWe),
  - Saint-Alban (2 reactors of 1,300 MWe),
  - Cruas-Meysse (4 reactors of 900 MWe),
  - Tricastin (4 reactors of 900 MWe);
- the nuclear fuel fabrication plants operated by Framatome in Romans-sur-Isère;
- the nuclear fuel cycle plants operated by Orano Cycle on the Tricastin industrial platform;
- the Operational Hot Unit (BCOT) at Tricastin, operated by EDF;
- The High Flux Reactor (RHF) 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) for fuel storage operated by EDF;
- reactor 1 undergoing decommissioning at the Bugey NPP operated by EDF;
- the Superphénix reactor undergoing decommissioning at Creys-Malville and its auxiliary installations, operated by EDF;
- the Ionisos irradiator in Dagneux;
- the nuclear fuel fabrication plant and pelletising unit of SICN in Veurey-Voroize;
- the French Alternative Energies and Atomic Energy Commission (CEA) reactors and plants in Grenoble, waiting to be delicensed;
- the CERN international research centre located on the Swiss-French border;

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- small-scale nuclear activities in the medical sector:
  - 22 external-beam radiotherapy departments,
  - 6 brachytherapy departments,
  - 23 nuclear medicine departments,
  - about 120 centres carrying out fluoroscopy-guided interventional procedures,
  - about 120 computed tomography scanners,
  - some 10,000 medical and dental radiology devices;

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- small-scale nuclear activities in the veterinary, industrial and research sectors:
  - one synchrotron,
  - about 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;

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- activities linked to the transport of radioactive substances;
- ASN-approved laboratories and organisations:
  - 3 organisations and 8 agencies approved for radiation protection controls.

In 2019, ASN carried out 328 inspections in the Auvergne-Rhône-Alpes region, comprising 98 inspections in the Bugey, Saint-Alban, Cruas-Meysse and Tricastin nuclear power plants, 89 inspections in plants and installations undergoing decommissioning, 127 inspections in small-scale nuclear activities and 14 inspections in the radioactive substance transport sector.

ASN also carried out 47 days of labour inspections in the four nuclear power plants and on the Creys-Malville site. It took part in 13 days of meetings on this theme, including its participation in the Health, Safety and Working Conditions Committees (CHSCT).

In the exercise of its oversight duties, ASN drew up one violation report and gave one nuclear activity manager formal notice to comply with the regulations. In 2019, ASN was notified of 36 significant events rated level 1 on the International Nuclear and Radiological Event Scale (INES scale), of which 33 occurred in BNIs and 3 in small-scale nuclear activities.

BUGEY SITE

The Bugey industrial site comprises various facilities, including the Bugey NPP operated by EDF on the municipality of Saint-Vulbas in the Ain *département*, 35 km east of Lyon. It comprises four Pressurised Water Reactors (PWR), each of 900 MWe, commissioned in 1978 and 1979. Reactors 2 and 3 constitute BNI 78 and reactors 4 and 5 constitute BNI 89.

The site also accommodates Bugey 1, a graphite-moderated Gas-Cooled Reactor (GCR) commissioned in 1972, shut down in 1994 and currently undergoing decommissioning, and the Activated waste packaging and interim storage facility (Iceda) and the Inter-Regional Warehouse (MIR) for fuel storage.

Lastly, the site accommodates one of the regional bases of the Nuclear Rapid Action Force (FARN), the special nuclear rapid intervention force created by EDF in 2011 further to the Fukushima Daiichi NPP accident in Japan. Its role is to intervene in pre-accident or accident situations, on any Nuclear Power Plant (NPP) in France, by providing additional human resources and emergency equipment.

Bugey nuclear power plant

Reactors 2, 3, 4 and 5 in operation

ASN considers that the performance of the Bugey NPP with regard to nuclear safety, radiation protection and environmental protection is in line with the general assessment of EDF plant performance. The NPP maintains a high level of proficiency in its operating and maintenance activities. ASN has nevertheless noted weaknesses in the area of environmental protection.

With regard to nuclear safety, the results obtained by the Bugey NPP in 2019 must be improved, particularly regarding reactor management and the performance of periodic tests. There was also an increase in the number of reactor trips. The licensee must remain vigilant in its preparation and performance of operational control operations further to unforeseen events. Lastly, ASN noted shortcomings in the identification and handling of deviations.

With regard to environmental protection, ASN considers that the performance of the Bugey NPP, while remaining within the average for the plants operated by EDF, reveals some disparities. ASN notes a persistent weakness in the prevention of risks of leaks from buried structures (pipes and conduits) carrying radioactive and chemical fluids. ASN moreover considers that the modifications of equipment linked to environmental protection must be analysed and monitored with the same rigour as equipment associated with nuclear safety.

With regard to radiation protection, ASN notes that the dosimetric results were satisfactory.

With regard to occupational safety, despite the mobilisation of the risk prevention officers with regard to the vital risks, accidents or noteworthy near-accidents occurred in 2019, underlining the site's weaknesses, particularly regarding compliance with rules for personal protective equipment against electrical risks, compliance work on lifting equipment and on the boric acid handling stations. Although the accident indicator figures are improving, EDF must nevertheless continue the efforts requested by ASN in the application of worksite safety rules, in the context of the fourth ten-yearly outages.

Reactor 1 undergoing decommissioning

Bugey 1 is a graphite-moderated gas-cooled reactor. This first-generation reactor functioned with natural uranium as the fuel, graphite as the moderator and it was cooled by gas. The Bugey 1 reactor is an "integrated" gas-cooled reactor, whose heat exchangers are situated inside the reactor vessel beneath the reactor core.

In March 2016, in view of the technical difficulties encountered, EDF announced a complete change of decommissioning strategy for its definitively shut down reactors. In this new strategy, the planned decommissioning scenario for all the reactor pressure vessels involves decommissioning "in air" rather than "under water" as initially envisaged.

ASN considers that the Bugey 1 reactor decommissioning and vessel characterisation operations are proceeding with a satisfactory level of safety. The licensee ensures rigorous monitoring of the equipment and the ongoing decommissioning works.

Activated waste packaging and interim storage facility (Iceda)

The Iceda facility, authorised by Decree 2010-402 of 23 April 2010, is operated by EDF. It is currently in a test phase and its function will be to process and store activated waste from operation of the nuclear fleet in service and from decommissioning of the first-generation reactors and the Creys-Malville NPP.

The Iceda commissioning authorisation application file was submitted to ASN in July 2016. In its examination of this file, ASN asked for additional technical information relative to the safety case, the defining of the items and activities important to protection of people and the environment, the production quality file, the start-up tests, waste management and the operating documents. EDF submitted its reply to ASN's requests at the end of 2018. The last finishing work and the pre-commissioning tests continued in 2019.

The organisation implemented by EDF, the temporary grouping of companies to set up the equipment, and the monitoring of the tests in the facilities are ensured with rigour. The inspectors noted the good overall upkeep of the worksite. ASN nevertheless observed, as in 2018, that the test programme was significantly behind schedule. EDF now envisages commissioning the facility in 2020.

ASN has moreover continued its examination of the application file for approval of the packaging of intermediate-level long-lived waste (ILW-LL) in packages in the Iceda facility, submitted by EDF in November 2015 and supplemented in May 2016 at the request of ASN. ASN was unable to give its approval on the basis of the examination of the file as it stood. Further studies were necessary in order to rule on the suitability of this package for the waste it is designed to contain. EDF updated its file at the end of 2018 and it is currently being examined.

Inter-Regional Warehouse

The Inter-Regional Warehouse (MIR) (BNI 102) on the Bugey site operated by EDF is a storage facility for fresh nuclear fuel intended for the NPP fleet in service.

The level of safety of the MIR was satisfactory in 2019. The periodic safety review of the facility is in progress, as are the stress tests requested by ASN following the Fukushima Daiichi NPP accident.

Saint-Alban nuclear power plant

The Saint-Alban NPP, operated by EDF in the Isère *département* on the municipalities of Saint-Alban-du-Rhône and Saint-Maurice-l'Exil, 40 km south of Lyon, comprises two 1,300 MWe PWRs commissioned in 1986 and 1987. Reactor 1 constitutes BNI 119 and reactor 2 BNI 120.

ASN considers that the performance of the Saint-Alban NPP with regard to nuclear safety, environmental protection and radiation protection is well positioned in comparison with the general standard of EDF plant performance.

With regard to nuclear safety, ASN notes that in 2019 the Saint-Alban NPP maintained its good results, in keeping with the last few years. ASN notes in particular that the vigilance applied in the fight against fire outbreaks continued to bear fruit in 2019.

Concerning maintenance, ASN considers that on the whole EDF successfully managed the maintenance outage of reactor 2, which was the only maintenance outage scheduled in 2019. This outage was marked by a technical difficulty in disconnecting two control rod clusters when opening the reactor vessel closure head, an unforeseen event that was managed satisfactorily. The site must be more rigorous in its monitoring of the sensitive areas of small-diameter pipes.

ASN considers that the environmental protection performance of the Saint-Alban NPP is in line with the general assessment of the EDF plants. The organisation defined and implemented by EDF to meet the regulatory requirements concerning the monitoring of discharges and the environment seems satisfactory on the whole.

With regard to worker radiation protection, ASN notes that the operational results were satisfactory.

The results concerning health and safety at work are also satisfactory. ASN notes that no serious accidents occurred during the reactor 2 maintenance outage. During this outage, ASN noted difficulties in organising the worksites and more specifically in taking into account the occupational risks at the work station in situations with tight schedules.

Cruas-Meysse nuclear power plant

Commissioned between 1984 and 1985 and operated by EDF, the Cruas-Meysse NPP is situated in the Ardèche *département* on the municipalities of Cruas and Meysse and comprises four PWRs of 900 MWe each. Reactors 1 and 2 constitute BNI 111 and reactors 3 and 4 constitute BNI 112.

ASN considers that the performance of the Cruas-Meysse NPP is on the whole in line with the general assessment of EDF in the areas of nuclear safety and radiation protection. The site's performance in environmental protection and waste management, however, is below average.

With regard to nuclear safety, ASN considers that the Cruas-Meysse NPP is maintaining its level of performance. ASN notes in particular that the work started in 2018 on the management of deviations is bearing fruit. ASN considers that the action plan implemented by EDF meets the requirements and expects the results in this area to be consolidated in 2020. Progress has also been made in the prevention of reactor trips.

The year 2019 was also marked by the occurrence of an earthquake on 11 November 2019 on the municipality of Teil in the Ardèche *département* (see Notable events). The tremors recorded by the site's acceleration measurement system reached what are referred to as "inspection" thresholds. Reaching these thresholds led EDF to shut down reactors 2, 3 and 4 –which were in service– in order to perform inspections and tests to check that the equipment and facilities had not suffered any damage. The investigation programme and its results were submitted to ASN, which authorised their return to service. The retrospective analysis of the acceleration values recorded on the day of the earthquake shows that they were significantly below the acceleration values taken into account in the design of the nuclear power plant.

In the area of maintenance and management of the works relating to the reactor outages, ASN considers that EDF has made progress in the quality of outage preparation and the handling of unforeseen events that occur during the outages.

In the area of radiation protection, ASN takes positive note of the steps taken by the licensee, although radiological cleanliness and control of the contamination risk during reactor outages must be further improved.

With regard to protection of the environment, ASN has again noted shortcomings in waste management. In effect, despite the actions taken in this area in response to the requests issued by ASN in 2018, the year 2019 was marked by the removal of potentially pathogenic waste to a treatment facility without prior verification. During its inspections, ASN found that the waste areas concerned were not operated in accordance with the rules in force and asked EDF to stop using them until they were made compliant. With regard to environmental protection, the monitoring and treatment of the water table pollution by tritium and hydrocarbons, which occurred in summer 2018, continued in 2019.

The inspections conducted by the ASN labour inspectors in 2019 confirmed the work done by the licensee in the prevention of vital risks, the development of new protected processes for the workers and the general upkeep of worksites. The accidents or near-accidents that occurred were the subject of analyses and quality action plans, and the efforts made must be maintained, particularly for the organisational application of accident prevention in the field.

TRICASTIN SITE

The Tricastin nuclear site, situated in the Drôme and Vaucluse *départements*, is a vast industrial site accommodating the largest concentration of nuclear and chemical facilities in France. It is situated on the right bank of the Donzère-Mondragon Canal (a diversion channel of the river Rhône) between Valence and Avignon. It occupies a surface area of 800 hectares covering three municipalities, namely Saint-Paul-Trois-Châteaux and Pierrelatte in the Drôme *département*, and Bollène in the Vaucluse *département*. The site harbours a large number of installations, with a NPP comprising four 900 MWe reactors, nuclear fuel cycle facilities, and the BCOT (Operational Hot Unit) which fulfils maintenance and storage functions.

Tricastin nuclear power plant

The Tricastin NPP comprises four 900 MWe Pressurised Water Reactors (PWRs): reactors 1 and 2 were commissioned in 1980 and constitute BNI 87, while reactors 3 and 4, commissioned in 1981, constitute BNI 88.

ASN considers that the overall performance of the Tricastin NPP with regard to nuclear safety and environmental protection is in line with ASN's general assessment of EDF plant performance. ASN considers that the radiation protection performance, however, is below the national average.

With regard to nuclear safety, the NPP's performance is on the whole in line with ASN's general assessment of the EDF plants, but ASN nevertheless considers that it has deteriorated, with events such as the jamming of a spent fuel assembly when removing upper internal equipment from the reactor 2 pressure vessel, and the occurrence of multiple events significant for safety during the reactor 1 restart phase at the end of its fourth ten-yearly outage, despite restarting having begun satisfactorily. More generally, over the year 2019, ASN observed shortcomings in the application of the operating technical specifications, in the implementation of reliability-enhancement practices, the monitoring in the control room, the configuring of systems and the integrity of the first barrier made up by the fuel assembly cladding.

The processing of alarms in the control room remained at a satisfactory level further to the steps taken in 2018. With regard to maintenance, ASN considers that the standard of management of scheduled maintenance and refuelling outages dropped in 2019. The Tricastin NPP reactor 1 was shut down from June to December 2019 for its fourth ten–yearly outage, fitting in as a stage of the fourth periodic safety review (see Notable events). This is the first of EDF's 900 MWe reactors to reach this milestone.

ASN considers that the environmental protection performance of the Tricastin NPP is mixed, despite being in line with the general assessment of the EDF plants. While the licensee has taken measures to improve control of containment of liquid effluents, ASN nevertheless notes that a leak in a pipe carrying radioactive effluents led to tritium pollution of the groundwater of the water table within the site in November 2019. Along with this, ASN again notes a persistent weakness in the radioactive effluent treatment systems. Waste management has improved with respect to 2018, but further improvements can be made.

With regard to radiation protection, ASN observes that 2019 was marked by two cases of worker contamination leading to skin exposure of more than one quarter of the annual regulatory limit. Furthermore, several significant events reflect a lack of radiation protection culture in some workers. ASN therefore considers that the Tricastin NPP is below average on this subject and that the licensee must rapidly take fundamental actions to improve the radiation protection culture of the workers on the ground.

As far as worker safety is concerned, there are still problems with the regulatory compliance of the facilities, but there were no serious accidents in 2019. Thus, as in 2018, the electrical risk is still not suitably controlled, nor is the risk associated with work at height with, for example, noncompliant scaffolding.

THE NUCLEAR FUEL CYCLE FACILITIES

The Tricastin fuel cycle facilities mainly cover the upstream activities of the fuel cycle and since the end of 2018 they have been operated by a single licensee, Orano Cycle.

The site comprises:

- **the TU5 facility** (BNI 155) for converting uranyl nitrate $UO_2(NO_3)_2$ resulting from the reprocessing of spent fuels into triuranium octoxide (U_3O_8);
- **the W plant** (ICPE within the perimeter of BNI 155) for converting depleted UF_6 into U_3O_8;
- **the former Comurhex facility** (BNI 105) **and the Philippe Coste plant** (ICPE within the perimeter of BNI 105) for converting uranium tetrafluoride (UF_4) into uranium hexafluoride (UF_6);
- **the Georges Besse I plant** (BNI 93) for the enrichment of UF_6 by gaseous diffusion;
- **the Georges Besse II plant** (BNI 168) for centrifuge enrichment of UF_6;
- **the uranium storage areas at Tricastin** (BNI 178 and 179) for storing uranium in the form of oxides or UF_6;
- **the maintenance, effluent treatment and waste packaging facilities** (formerly Socatri) (BNI 138);
- **the Atlas process samples analysis and environmental monitoring laboratory** (BNI 176);
- **a Defence Basic Nuclear Installation** (DBNI) which accommodates the nuclear materials storage areas in particular, virtually all of which are for civil uses.

Following the inspections it conducted in 2019, ASN considers that the level of safety of the Orano Cycle facilities on the Tricastin site has remained stable. The industrial commissioning of new facilities with reassessed safety standards nevertheless encountered several difficulties and some components will have to be replaced. In 2019, ASN authorised the application of a new version of the on-site emergency plan, adapted to the new site organisation, under the responsibility of Orano Cycle as sole licensee.

The unannounced inspections conducted by ASN simultaneously on BNIs 93, 105, 138, 155 and 168 in 2019 found the rigour of the patrol inspections to be quite satisfactory. ASN also conducted an inspection focusing on the waste management organisation of the Orano platform on the Tricastin site in 2019. ASN noted that this organisation needs to be better formalised and that the licensee must increase the rigour of the ultimate inspections of conventional waste leaving the site.

In 2020, ASN will ensure that Orano continues to deploy its action plans for monitoring outside contractors, the retention structures and the control of liquid discharges in order to improve and harmonise the practices of the platform's BNIs. ASN will also check that the internal inspection body is properly put in place, in accordance with the resolution of 30 November 2017 concerning noteworthy modifications of BNIs.

Orano Cycle uranium chemistry plants TU5 and W

BNI 155, called TU5, can handle up to 2,000 tonnes of uranium per year, which enables all the uranyl nitrate ($UO_2(NO_3)_2$) from the Orano Cycle plant in La Hague to be processed for conversion into U_3O_8 (a stable solid compound that can guarantee storage of the uranium under safer conditions than in liquid or gaseous form). Once converted, the reprocessed uranium is stored on the Tricastin site. The W plant situated within the perimeter of BNI 155 can process the depleted UF_6 from the Georges Besse II plant, to stabilise it as U_3O_8.

ASN considers that the facilities situated within the perimeter of BNI 155 are operated with a satisfactory level of safety.

For the TU5 plant, ASN continued to monitor the implementation of the commitments made further to the periodic safety review of the facility. The progress with these commitments and the organisational setup for tracking them are satisfactory.

To follow up ASN's waste management inspections of 2017 and 2018 which had revealed and then confirmed an unsatisfactory situation, a two-day unannounced inspection was carried out on this theme in July 2019. This inspection revealed a significantly improved situation, particularly with regard to the identification of the waste and the storage areas, the traceability and the condition of the waste storage areas, which are now less congested. More generally, the licensee must continue its efforts to increase its operational rigour, particularly through the detection and management of deviations.

Orano Cycle uranium fluorination plants

Pursuant to the ASN requirement, the oldest fluorination facilities were shut down definitively before 31 December 2017. The shut down facilities have since been emptied of the majority of their hazardous substances and are now in the decommissioning preparation phase.

In 2019, ASN completed its examination of the decommissioning file for BNI 105 (formerly Comurhex) submitted by Orano Cycle in February 2014 and which underwent a public inquiry in 2017. The decommissioning of BNI 105 is now authorised by Decree 2019-1368 of 16 December 2019. The main issues associated with decommissioning concern the risks of dissemination of radioactive substances, of exposure to ionising radiation and of criticality, on account of the residual uranium-bearing substances present in some items of equipment.

Furthermore, in 2019 ASN authorised and inspected work conducted within this facility on a storage area for drums of uranium-bearing materials with the aim of providing static and dynamic containment and suitable climate control, in order to prevent a repeat of the loss-of-containment event resulting from the pressure increase in the drums caused by the hot summer temperatures in 2018.

ASN also inspected the industrial commissioning of the majority of the units of the Philippe Coste plant, whose facilities are classified Seveso high threshold and replace those of BNI 105 (formerly Comurhex). Only the second fluorine production unit is still at the tests stage with a view to commissioning in 2020.

ASN has also checked the licensee's management of numerous significant design, construction and operating anomalies detected in this plant. ASN has more specifically monitored (1) the sealing defects in the crystallizing containers used to cool down and heat the UF_6 for its purification and transfer to the transport tanks, (2) widespread corrosion of the fluorine pipes, and (3) the gaseous discharge limit values which were exceeded several times.

ASN checked that in response to these anomalies the licensee had put in place appropriate operating instructions, technical modifications and tightened monitoring procedures for the equipment items concerned, pending their replacement or the implementation of lasting technical solutions.

Alongside this, the inspections conducted in the Philippe Coste plant in 2019 aimed in particular at ensuring that the licensee had remedied the shortcomings in rigour identified during the inspections in 2018. In 2020, ASN will be attentive firstly to the commissioning of new and replaced equipment and of the new fluorine production unit of the Philippe Coste plant, and secondly to the repackaging and processing of the uranium-bearing materials present in the BNI in preparation for the decommissioning of BNI 105.

Georges Besse I enrichment plant

The Georges Besse I (Eurodif) uranium enrichment facility (BNI 93) consisted essentially of a plant for separating uranium isotopes by the gaseous diffusion process.

After stopping production at this plant in May 2012, the licensee carried out, from 2013 to 2016, the Eurodif "Prisme" process of "intensive rinsing followed by venting", which consisted in performing repeated rinsing of the gaseous diffusion circuits with chlorine trifluoride (ClF_3), a toxic and dangerous substance, which allowed the extraction of virtually all the residual uranium deposited in the diffusion barriers. These operations are now finished.

The licensee submitted its application for final shutdown and decommissioning of the facility in March 2015. Examination of the file continued in 2019 and the decree instructing Orano Cycle to proceed with the decommissioning of the Georges Besse 1 plant was published on 5 February 2020.

The decommissioning challenges concern the volume of very low-level (VLL) waste produced, which includes 160,000 tonnes of metal waste, and the decommissioning time frame, which must be as short as possible (currently estimated at 30 years), considering the best scientific and technical knowledge available, and under economically acceptable conditions.

ASN has checked the operation of the facility for hydraulic containment and treatment of the alluvial water table situated beneath BNI 93 which has been polluted with perchloroethylene and trichloroethylene. This facility enables the water to be pumped out of the water table at one point, treated and then reinjected into the water table upstream of the pumping point, thereby containing and depolluting the water table. ASN has observed that since its commissioning in March 2014, the water table treatment facility has functioned very little due to several failures and substantial technical problems, including in particular a scaling phenomenon leading to the clogging of the facility's components. ASN has therefore asked Orano to propose technical solutions to allow sustained operation of the facility and treatment of the pollution.

In 2020, ASN shall endeavour to check the effective operation of the hydraulic containment and alluvial water table treatment facility. The main residual risk in the facility now is associated with the UF_6 containers in the storage yards, which are still within the facility perimeter. These yards should ultimately be attached to the Tricastin uranium storage yards (BNI 178).

Georges Besse II enrichment plant

The Georges Besse II plant (BNI 168), which was operated by *Société d'enrichissement du Tricastin* (SET) until 2018 and is now operated by Orano Cycle which has become the sole licensee on the Tricastin site, constitutes the site's new enrichment facility since the shutdown of Eurodif. It uses the centrifuge process to separate uranium isotopes.

The standard of safety of the plant's facilities in 2019 was satisfactory. The technologies utilised in the facility enable high standards of safety, radiation protection and environmental protection to be reached. ASN considers that the licensee is proactive in the detection of deviations from its baseline requirements and duly meets the commitments made to ASN.

In 2020, ASN will be attentive to the frequency of the patrol inspections and the completeness of the modification authorisation application files submitted by the licensee.

Maintenance, effluent treatment and waste packaging facilities

The effluent treatment and uranium recovery facility, constituting BNI 138 (formerly Socatri), ensures the treatment of liquid effluents and waste, as well as maintenance operations for various BNIs. ASN considers that in 2019 the licensee made efforts to improve the level of operational safety and the rigour of operation of this facility and that these efforts must be continued.

Decree 2019-113 of 19 February 2019 authorised substantial modifications to the BNI, in particular to create "Trident", a facility for treating the site's waste. ASN has inspected the fitting-out work for this facility. It is currently examining the commissioning authorisation.

In 2020, ASN will be attentive firstly to the Trident facility startup tests and secondly to the continuation of the licensee's actions to increase operating rigour.

Tricastin uranium-bearing material storage yards

Following the delicensing of part of the Pierrelatte Defence BNI by Decision of the Prime Minister, BNI 178 –Tricastin uranium-bearing materials storage yards, has been created. This facility groups the uranium storage areas and the new emergency management premises of the Tricastin platform. ASN registered this facility in December 2016 and ascertained, with the Defence Nuclear Safety Authority (ASND), the continuity of oversight of the nuclear safety of this facility. The facility baseline requirements are currently being upgraded to be in conformity with the regulatory texts applicable to BNIs.

ASN notes that the storage yard facilities are well kept. The licensee must nevertheless still deal with several damaged legacy packages. Following its inspections in 2019, ASN asked the licensee to review the retention structure inspection practices, to improve the monitoring of the anomalies observed during the patrol inspections and to ascertain that all nuclear materials are correctly labelled in accordance with the regulations.

ASN is expecting the licensee to make progress with regard to the emergency management building and the equipment it contains. The facility baseline requirements must effectively be upgraded to guarantee operation of the emergency centre and mobile equipment.

P35 facility

Following on from the delicensing process of the Pierrelatte DBNI by Decision of the Prime Minister, BNI 179 "P35" has been created. This facility comprises ten uranium storage buildings.

ASN registered this facility in January 2018 and has ascertained, with ASND, that there will be continuity in the oversight of the nuclear safety of these storage areas.

ASN considers that safety of operation of the P35 storage facilities was on the whole satisfactory in 2019. However in 2019, following an inspection, ASN asked that the integration of all the defined requirements for equipment important to the protection of people and the environment be clarified. ASN had effectively noted in particular that the inspection frequencies had been reduced without a documented analysis.

New uranium storage facility project

In February 2015 Orano Cycle informed ASN of its wish to create a new BNI on the Tricastin site for the storage of uranium-bearing materials resulting from fuel reprocessing. Orano Cycle undertook work to optimise the existing storage facilities on the site in order to push back their saturation date from 2019 to 2021 and in November 2017 submitted a creation authorisation application for new storage buildings. In 2018, ASN informed the Minister responsible for nuclear safety that the content of the creation authorisation application was sufficient to enable its examination to continue in 2019. The public inquiry should be held in 2020.

Tricastin analysis laboratories (Atlas)

Atlas (BNI 176) was authorised by Decree 2015-1210 of 30 September 2015 and commissioned in May 2017. The facility represents a significant improvement in safety compared with the old laboratories it replaces.

Two of the three UF_6 analysis and sampling benches have been functioning since February 2018 following validation of the preliminary test results. The start-up of the last bench, which will finalise the complete commissioning of the facility, was planned for 2019. However, substantial difficulties were encountered with the sealing of the bench. These difficulties led Orano Cycle to carry out sealing reinforcement operations under conditions that ASN, after inspection, considered inappropriate.

More generally, ASN considers that the licensee must continue its efforts to increase its operational rigour in this facility. The licensee must also improve its oversight of the teardown of worksites entrusted to outside contractors.

In 2020, ASN will be extremely vigilant regarding the reconditioning of the third UF_6 analysis and sampling bench before any active tests are performed.

Tricastin Operational Hot Unit (BCOT)

The BCOT constitutes BNI 157. Operated by EDF, it is intended for the maintenance and storage of equipment and tooling, fuel elements excluded, coming from contaminated systems and equipment of the nuclear power reactors.

In a letter dated 22 June 2017, EDF declared the final shutdown of the BCOT by 30 June 2020 at the latest. The storage and maintenance operations shall now be carried out on the Saint-Dizier maintenance Base (Bamas). Activity transfer and tooling disassembly continued in 2019.

ASN considers that the level of safety of the BCOT is on the whole satisfactory.

In 2019, ASN verified the modifications the BCOT made to its facility for cutting up the used RCC guide tubes of the pressurised water reactors operated by EDF.

In 2020, ASN will be attentive to the resumption of these operations and the last equipment removal operations.

ROMANS-SUR ISÈRE SITE

Framatome operates two BNIs on its Romans-sur-Isère site in the Drôme *département*, namely the research reactor fuel fabrication unit (BNI 63) and the PWR nuclear fuel fabrication unit (BNI 98), and an Installation Classified for Protection of the Environment (ICPE) called the "cavities" facility which manufactures specific components such as the "cavities" or "LHC collimators" for the European Organization for Nuclear Research (CERN).

Framatome nuclear fuel fabrication plants

The fabrication of fuel for the nuclear power reactors necessitates transforming the UF_6 into uranium oxide powder. The pellets fabricated from this powder in Framatome's Romans-sur-Isère plant, called "FBFC" (BNI 98), are placed in zirconium metal clads to constitute the fuel rods, then brought together to form assemblies for use in the NPP reactors. In the case of experimental reactors, the fuels used are more varied, with some of them using, for example, highly-enriched uranium in metal form. These fuels are also fabricated in the Romans-sur-Isère plant, formerly called "Cerca" (BNI 63).

In 2019, Framatome kept up an ambitious work programme within the two plants in order to meet the commitments made further to the periodic safety reviews. Investments have been made ("New Uranium Zone - NZU", new oxidation furnace CAPADOX), along with reinforcements of existing buildings (fire risk management, paraseismic reinforcements, improvement in material containment). The way in which the commitments are tracked and fulfilled is on the whole satisfactory.

The inspections conducted in 2019 confirmed satisfactory performance of the work and the putting in place of new organisational measures. An improvement was observed in the qualification process for new equipment important to the protection of people and the environment. The monitoring of service providers must nevertheless be further improved, particularly on the New Uranium Zone worksite. Several significant events relating to control of the criticality risk and rated level 1 on the International Nuclear and Radiological Event Scale (INES scale) were reported in 2019.

A storage bunker adjoined to a laboratory (L1) was commissioned in summer 2019. This arrangement represents a major improvement in safety, as it enables the mass of uranium in the laboratory to be limited to 600 grams, in accordance with the ASN resolution of 4 June 2019.

With regard to environmental protection, ASN considers that the Romans-sur-Isère site must further improve its control of the waste management routes, particularly by making a clear distinction between radioactive waste and conventional waste.

In 2020, ASN will be particularly attentive to the running of the New Uranium Zone worksite project, linked to the events of 2019. It will also closely monitor restarting of the Triga facility of BNI 63 and entry into service of the new waste treatment facility (Geode).

THE INDUSTRIAL AND RESEARCH FACILITIES

High Flux Reactor of the Laue-Langevin Institute

The Laue-Langevin Institute (ILL), an international research organisation, accommodates a 58 MWth heavy-water High-Flux neutron Reactor (RHF) which produces high-intensity thermal neutron beams for fundamental research, particularly in the areas of solid-state physics, neutron physics and molecular biology.

The RHF, which constitutes BNI 67, accommodates the European Molecular Biology Laboratory (EMBL), an international research laboratory, within its perimeter. Employing some 500 persons, this BNI occupies a surface area of 12 hectares situated between the rivers Isère and Drac, just upstream of their confluence, near the CEA Grenoble centre.

ASN considers that the safety of the RHF is managed relatively satisfactorily, but in 2019 it once again observed deviations concerning the operating organisation, particularly in the areas of waste management, environmental monitoring and periodic inspections.

ASN notes the substantial efforts the ILL has made in deploying its integrated quality and safety management system in order to meet the requirements of the BNI Order of 7 February 2012. During 2019, the licensee finished implementing all these processes and trained the personnel involved. The licensee had been given formal notice by ASN resolution of 6 February 2018 to modify its organization in order to comply with the regulatory provisions concerning physical modifications to its facilities. An inspection at the end of 2018 had revealed that the measures planned by ILL to comply with this notice had not been fully deployed and that they seemed not to have been made sufficiently known to the personnel. The ASN Director General's Office then had a meeting with ILL senior management so that the ILL could present immediate provisional measures and lasting measures to prevent recurrence of the observed deviations. During summer 2019, the ILL finished updating its modifications management process. The inspections carried out by ASN in 2019 enabled the compliance notice to be lifted in October 2019.

ASN tested the ILL's emergency organisation and resources during an inspection with an unannounced exercise outside working hours. ASN noted appropriate responsiveness, good knowledge of the facility and of the actions to take in an accident situation, and fluidity in the actions of the response teams.

The periodic safety review concluding report is currently being examined. The licensee's responsiveness and the quality of the information provided for the purpose of the examination are considered satisfactory. ASN carried out a tightened inspection focusing on the hypotheses and the conclusions of the ILL periodic safety review and the defining and implementation of its plan of action.

ASN will continue its examination of the safety review report in 2020 and will be attentive to the various action plans implemented by the ILL as a follow-up to the inspections of 2019 and lifting of the compliance notice.

Ionisos irradiator

The company Ionisos operates an industrial irradiator in Dagneux, situated in the Ain *département*. This irradiator, which constitutes BNI 68, uses the radiation from cobalt-60 sources for purposes such as sterilising medical equipment (syringes, dressings, prosthesis) and polymerising plastic materials.

The level of safety of the facility was found to be satisfactory in 2019. The ASN inspection focused specifically on the sealed source requalification operations carried out within the facility; these operations were conducted properly. An inspection targeting the periodic safety review was also carried out in 2019, and highlighted points requiring particular attention in the assimilation of the studies and conclusions of the safety review and the experience feedback analysis.

CERN accelerators and research centre

Following the signing of an international agreement between France, Switzerland and CERN on 15 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.

Two joint visits by the Swiss and French Authorities took place in 2019 on the theme of fire prevention and radiation protection of workers. These visits revealed satisfactory practises.

FACILITIES UNDERGOING DECOMMISSIONING

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 in the Isère *département*. It was definitively shut down in 1997. The reactor has been unloaded and the majority of the sodium has been neutralised in concrete. 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 neutralisation of the sodium from Superphénix.

ASN considers that the safety of Superphénix decommissioning operations and of APEC operation is on the whole satisfactory.

ASN has authorised commencement of the second Superphénix decommissioning phase, which consists in opening the reactor pressure vessel to dismantle its internal components, in dedicated facilities constructed in the reactor building, by direct or remote manipulation. The safety and radiation protection measures implemented by EDF for these operations are on the whole satisfactory.

In December 2018 and June 2019, the site experienced a total loss of its electrical power supplies and the failure of one equipment important to the protection of the installations (emergency diesel generator set), which gave rise to two significant events rated level 1 on the INES scale. EDF reported difficulties in procuring certain obsolete items of equipment and long lead times for the replacement and repair of parts. ASN asked the licensee to perform a diagnosis covering the entire site and establish an action plan for managing equipment obsolescence. More generally, ASN notes that EDF was good about meeting its various commitments in 2019, but will remain attentive to the way defence in depth is taken into account and to the implementation of the plan addressing equipment obsolescence.

Siloette, Siloé, LAMA reactors and effluents and solid waste treatment station – *CEA Centre*

The CEA Grenoble centre (Isère *département*) 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. The Grenoble centre now carries out research and development in the areas of renewable energies, health and microtechnology. In 2002 the CEA Grenoble centre began a site delicensing process.

The site accommodated six nuclear installations which have gradually stopped their activities and are now in the decommissioning phase with a view to delicensing. Delicensing of the Siloette reactor was declared in 2007, that of the Mélusine reactor in 2011, of the Siloé reactor in January 2015 and of the LAMA in August 2017.

The last BNIs on the site are the effluents and Solid Waste Treatment Station and the decay storage facility (STED) (BNI 36 and 79). All the buildings have been dismantled, in accordance with their decommissioning decree.

The technical discussions between ASN and CEA concerning the radiological and chemical remediation of the soil of the STED continued in 2018. All the operations that can be technically achieved at a reasonably acceptable cost have been carried out. In view of the presence of residual chemical and radiological contamination, the licensee submitted a delicensing file along with a file for the establishing of active institutional controls in December 2019.

SICN plant in Veurey-Voroize

The former nuclear fuel fabrication plant in Veurey-Voroize (Isère *département*), operated by *Société industrielle de combustible nucléaire* (SICN, Orano Group) comprised two nuclear installations, BNI 65 and 90. The fuel fabrication activities were definitively stopped in the early 2000's. The decommissioning operations were authorised by Decrees 2006-190 and 2006-191 of 15 February 2006. The decommissioning work has been completed.

The site presents residual contamination of the soils and the groundwater. 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. The SICN submitted this file to the Isère Prefect's Office in March 2014, and the delicensing application file for the two BNIs to ASN.

A public inquiry concerning the request to implement active institutional controls was held in January 2019. The order instituting the institutional controls was issued by the Prefect of Isère in September 2019. Delicensing of BNI 65 and 90 was declared by two ASN resolutions, approved by Order of 12 December 2019.

Bourgogne Franche-Comté region

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:

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- small-scale nuclear activities in the medical sector:
  - 8 external-beam radiotherapy departments,
  - 4 brachytherapy departments,
  - 14 nuclear medicine departments, 3 of which practice internal targeted radiotherapy,
  - 36 centres carrying out fluoroscopy-guided interventional procedures,
  - 53 computed tomography scanners for diagnostic purposes,
  - about 800 medical radiology devices,
  - about 2,000 dental radiology devices;

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- small-scale nuclear activities in the veterinary, industrial and research sectors:
  - about 300 veterinary practices, 3 of them equipped with scanners,
  - about 400 industrial and research centres, including 32 companies with an industrial radiography activity,
  - 1 industrial irradiator per radioactive source,
  - 1 computed tomography scanner dedicated to research,
  - 2 accelerators, one for industrial irradiation, the other for research and the production of drugs for medical imaging;

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- activities linked to the transport of radioactive substances;
- ASN-approved laboratories and organisations:
  - 3 organisations approved for radiation protection controls,
  - 5 organisations approved for measuring radon,
  - 1 laboratory approved for taking environmental radioactivity measurements.

ASN conducted 74 inspections in small-scale nuclear activities in the Bourgogne-Franche-Comté region in 2019, comprising 28 inspections in the medical sector, 36 inspections in the industrial research and veterinary sectors, 2 inspections concerning radon exposure, 1 inspection in the area of polluted sites and soils, 2 inspections to monitor the activity of approved organisations and laboratories, and 5 inspections specific to the transport of radioactive substances.

One significant event rated level 1 on the INES scale was reported to ASN in 2019.

ASN inspectors issued one violation report in the exercise of their oversight duties.

ASN also devoted particular attention to the Framatome manufacturing plants situated in the Bourgogne-Franche-Comté region. The actions conducted by ASN in this context are described in chapter 10. ASN performed 8 inspections in these plants in Bourgogne-Franche-Comté in 2019.

Bretagne region

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 NPP (Brennilis), undergoing decommissioning;

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- small-scale nuclear activities in the medical sector:
  - 10 external-beam radiotherapy departments,
  - 5 brachytherapy departments,
  - 10 nuclear medicine departments,
  - 39 centres using interventional procedures,
  - 54 computed tomography scanners,
  - some 2,500 medical and dental radiology devices;

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- small-scale nuclear activities in the veterinary, industrial and research sectors:
  - 1 cyclotron,
  - 15 industrial radiography companies, including 4 performing gamma radiography,
  - some 450 industrial and research equipment licenses;

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- activities linked to the transport of radioactive substances;
- ASN-approved laboratories and organisations:
  - 8 agencies approved for radiation protection controls,
  - 18 organisations approved for measuring radon,
  - 4 head-offices of laboratories approved for taking environmental radioactivity measurements.

In 2019, ASN carried out 45 inspections, comprising 2 inspections at the Monts d'Arrée NPP undergoing decommissioning, 40 in small-scale nuclear activities and 3 in the transport of radioactive substances.

In 2019, 2 significant events in the medical sector were rated level 1 on the International Nuclear and Radiological Event Scale (INES scale). One event also concerned a worker in a non-nuclear activity and was rated level 2 on the INES scale.

ASN inspectors issued one violation report in the exercise of their oversight duties.

The Brennilis nuclear power plant

The Brennilis NPP is situated in the Finistère *département*, on the Monts d'Arrée site 55 km north of Quimper. Baptised EL4-D, this installation (BNI 162) was an industrial electricity production prototype (70 MWe) moderated with heavy water and cooled with carbon dioxide, and it was definitively shut down in 1985. The Decree of 27 July 2011 authorized the decommissioning operations with the exception of those concerning the reactor block. The Decree of 16 November 2016 extended the time frame for the decommissioning operations, particularly those concerning:

- decommissioning of the heat exchangers;
- the clean-out and demolition of the effluent treatment station.

In July 2018, EDF submitted an application file for the complete decommissioning of its installation. This file, which should enable decommissioning of the reactor block to be prescribed by decree, is currently being examined.

During 2019, EDF continued the preliminary work (preparation of access points and erection of scaffolding) and the safeguarding and removal of asbestos from the reactor containment in preparation for taking samples in the reactor block. These sampling operations were authorised by ASN by resolution CODEP-DRC-2019-039420 of 20 September 2019. EDF also carried out preparatory tests in 2019 so that these sampling operations could be carried out at the beginning of 2020.

With regard to the decommissioning of the Effluent Treatment Station (STE), the basemat demolition operations that began in August 2016 took longer than expected and were completed in early 2018. The licensee then proceeded with the removal of the contaminated soils subjacent to the STE after approval of its soils management plan by ASN in April 2018. ASN conducted checks in the presence of all the parties after removal of the soils, the results of which will be known in 2020.

Furthermore, following the detection of a contaminated water leak in a room situated within the reactor containment in March 2017, EDF conducted investigations in 2019 to identify the origin of the leak and prepared the complementary investigations to be carried out prior to the reactor block decommissioning work. ASN considers that the licensee conducts its work in compliance with the safety and radiation protection requirements, but must improve its management of the time taken to perform the authorised operations.

In 2020, ASN will continue its examination of the complete decommissioning file and of the concluding report on the Brennilis installation periodic safety review submitted at the end of 2019.

Polluted sites and soils and mining sites

ASN backs up the Regional directorates for the environment, planning and housing (Dreal) on polluted sites and soils and on mining sites. With regard to the places in the public domain where uranium-bearing mining waste rock was reused, the ten areas in Bretagne concerned by the priority works have been treated (partial or complete removal of the mining waste rock). The materials have been transferred to the former mining site of Prat-Mérien (Morbihan *département*). Five areas containing sludge and sediments radiologically contaminated by mine water from the former uranium mines have also been treated. The materials have been removed and transported to the Écarpière site (Loire-Atlantique *département*) for disposal.

Centre-Val de Loire region

The Orléans division regulates 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:

- Basic Nuclear Installations:
  - 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 in operation (2 reactors of 900 MWe), and 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);

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- small-scale nuclear activities in the medical sector:
  - 8 external-beam radiotherapy departments,
  - 3 brachytherapy departments,
  - 11 nuclear medicine departments,
  - 32 centres using fluoroscopy-guided interventional procedures,
  - 38 computed tomography scanners,
  - some 2,700 medical and dental radiology devices;

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- small-scale nuclear activities in the veterinary, industrial and research sectors:
  - 10 industrial radiography companies,
  - about 330 industrial, veterinary and research radiography devices;

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- activities linked to the transport of radioactive substances;
- ASN-approved laboratories and organisations:
  - 2 organisations approved for radiation protection controls,
  - 4 laboratories approved for taking environmental radioactivity measurements.

In 2019, ASN carried out 134 nuclear safety and radiation protection inspections: 106 inspections of the nuclear installations on the EDF sites of Belleville-sur-Loire, Chinon, Dampierre-en-Burly and Saint-Laurent-des-Eaux, and 28 inspections in small-scale nuclear activities in the Centre-Val de Loire region.

ASN also ensured 60 days of labour inspection in the Nuclear Power Plants (NPPs).

In 2019, 16 significant events rated level 1 on the International Nuclear and Radiological Event Scale (INES scale) were reported by licensees of the EDF nuclear facilities in the Centre-Val de Loire region. In small-scale nuclear activities, 1 event concerning a brachytherapy patient was rated level 2 on the ASN-SFRO scale.

ASN inspectors issued one violation report in the exercise of their oversight duties.

Belleville-sur-Loire nuclear power plant

The Belleville-sur-Loire NPP is situated in the north-east of the Cher *département*, on the left bank of the river Loire, at the crossroads of four *départements* (Cher, Nièvre, Yonne and Loiret) and two administrative regions (Bourgogne-Franche-Comté and Centre-Val de Loire). The NPP comprises two reactors of 1,300 MWe, which were commissioned in 1987 and 1988 and constitute BNIs 127 and 128 respectively.

ASN considers that the performance of the Belleville-sur-Loire NPP is in line with the general assessment of EDF in the areas of radiation protection, the environment and nuclear safety.

The operational control of the installation has significantly improved compared with the preceding years, even if it is still below the level expected. The licensee has identified the few weaknesses that persist and is continuing to implement its action plan. More specifically, ASN considers that the licensee must make further progress in communication within and between the operational control teams, in the robust analysis of periodic test results and in monitoring the reactor parameters. By way of example, EDF reported a significant event rated level 1 on the INES scale due to two excursions from the operating envelope authorised by the installation's safety rules.

In addition to this, significant improvements can be made in fire risk management.

In the area of radiation protection, ASN finds that the situation is satisfactory and has remained so for several years. The service competent in radiation protection has made improvements in the traceability and monitoring of actions to optimise the dosimetry of worksites where there are major radiation risks.

Lifting tightened monitoring

In the light of the results of the tightened monitoring of the Belleville-sur-Loire NPP decided in September 2017, ASN observes that the condition of the installations and the practices with regard to safety have, broadly speaking, significantly improved. After the progress noted by ASN in 2018, the specific inspections carried out in 2019 revealed an improvement in the site's performance in the areas of deviation management and operating control of the installations.

Consequently, in January 2020 ASN decided to lift the tightened monitoring of the Belleville-sur-Loire NPP. ASN nevertheless insists on the need for the site to maintain this level of rigour so that the improvements observed since 2017 are sustained over the long term.

The environmental performance of the Belleville-sur-Loire NPP is satisfactory, even though the licensee must be particularly attentive to the management of on-site transport of hazardous materials, an area in which improvements are required in 2020.

With regard to labour inspection, inspections were carried out in the areas of health and safety at work, particularly during the maintenance outages. Inspections were carried out in particular in relation to the sealing work on the reactor containment wall. The observations addressed to the NPP and the subcontractor companies necessitated corrective actions which were checked during performance of the services. In addition, regular meetings took place with the bodies representing the personnel at meetings of the Committee for Health, Safety and Working Conditions (CHSCT) and when specifically requested by the personnel representatives, on subjects essentially addressing application of the Labour Laws.

Dampierre-en-Burly nuclear power plant

The Dampierre-en-Burly NPP is situated on the right bank of the Loire river, in the Loiret *département*, about 10 km downstream of the town of Gien and 45 km upstream of Orléans. It comprises four 900 MWe nuclear reactors which were commissioned in 1980 and 1981. Reactors 1 and 2 constitute BNI 84, and reactors 3 and 4 BNI 85. The site accommodates one of the regional bases of the FARN (Nuclear Rapid Intervention Force), the special emergency response force created by EDF in 2011 following the Fukushima Daiichi NPP accident. Its role is to intervene in pre-accident or accident situations, on any NPP in France, by providing additional human resources and emergency equipment.

ASN considers that the nuclear safety performance of the Dampierre-en-Burly NPP is in line with the general assessment of the EDF plants.

This being said, its environmental and radiation protection performance are below the national average. These assessments are exactly the same as those formulated for the year 2018.

With regard to safety, the results are on the whole satisfactory, with a good level of involvement of the independent safety organisation and the operational control teams in the significant events analyses. ASN does nevertheless observe an upsurge in organisational weaknesses between the operational control teams and the other services of the NPP which have been the cause of several significant events. Weaknesses in the monitoring actions in the control room are still observed regularly. ASN moreover again noted incomplete control of the fire risk on the site.

With regard to the maintenance of the facilities, ASN considers that the monitoring of outside contractors, application of the maintenance baseline requirements and the physical conformity of the facilities with the applicable requirements must be improved. Several inspections and significant events also reveal maintenance errors following preventive and curative maintenance operations (on the emergency diesel generator sets in particular).

The site must make further improvements in radiation protection. Despite the plan of rigour deployed by the site in 2019, which brought some improvements, ASN regularly detects significant malfunctions in the control of radiological cleanliness and contamination dispersion on the sites. To give an example, recurrent deviations are noted in the monitoring and the working condition of the equipment for placing the systems under negative pressure to limit contamination dispersion.

Lastly ASN considers that the site must make further progress in environmental protection, particularly with waste management and the containment of liquids. ASN also regularly notes shortcomings in control of the risk of dispersion and proliferation of legionella in the tertiary circuit.

With regard to labour inspection, substantial work was carried out on the electrical risk, focusing in particular on management of the regulatory checks of electrical installations, authorisations and application of the lockout/tagout rules. Labour inspection also asked for complementary verifications on certain electrical systems. Improvement actions are expected of the licensee to ensure better control of the electrical risk. Following the occurrence of a serious handling and lifting-related accident, specific inspections were conducted to analyse the circumstances of the accident and check the corrective actions implemented by the licensee.

CHINON SITE

Situated in the municipality of Avoine in the Indre-et-Loire *département*, on the left bank of the river Loire, the Chinon site accommodates various nuclear installations, some in operation, others shut down or undergoing decommissioning. On the south side of the site, the Chinon B NPP comprises four in-service 900 MWe reactors; the first two constituting BNI 107 were commissioned in 1982-1983, while the second two constituting BNI 132 were commissioned in 1986-1987. To the north, the three old graphite-moderated GCRs designated Chinon A1, A2 and A3, are currently being decommissioned. The site also accommodates the Irradiated Materials Facility (AMI), designed for the expert assessment of activated or contaminated materials, whose activities have now been entirely transferred to a new laboratory –the LIDEC– and the MIR (Inter-regional fresh fuel warehouse).

Chinon nuclear power plant

Reactors B1, B2, B3 and B4 in operation

ASN considers that the performance of the Chinon NPP is in line with the general assessment of EDF in the areas of safety, radiation protection and the environment. Although this assessment is identical to that of 2018 in the areas of safety and the environment, the radiation protection performance in 2019 is poorer than that observed in 2018.

ASN considers that the NPP is maintaining a satisfactory level with regard to safety. Progress has been made in management of the alignment activities and performance of the periodic tests, both identified as weak points in the last few years. Continued progress is nevertheless required because these activities remain the cause of a large number of significant events. An improvement in the quality of the risk analyses and the traceability of maintenance operations was observed in 2019. In view of the deviations from regulations discovered during the inspections conducted in 2019, ASN considers that the licensee must significantly improve its management of risks related to fire and explosion.

The radiation protection performance of the Chinon NPP is satisfactory, leading to good results in terms of dosimetry and radiological cleanliness. The year 2019 was nevertheless marked by a rise in significant radiation protection events due to shortcomings in preventing contamination dispersion and a loss of robustness in the general organisation of the site in this respect.

Although comparable with the national average, the environmental performance of the Chinon NPP must be improved. Despite compliance with the discharge limits for gaseous and liquid effluents, and no observed exceeding of limits for legionella and amoebae in 2019, numerous deviations from regulations were noted concerning waste management (a finding already made in 2018) and the containment of hazardous substances. The licensee must take priority actions to address these deviations.

With regard to labour inspection, inspections were carried out in the areas of health and safety at work, particularly during the NPP maintenance outages. Thematic inspections were also carried out, particularly on management of the explosion risk. Improvements are expected of the licensee for the demonstration of control of conformity of facilities situated in identified explosion-risk areas.

Reactors A1, A2 and A3 undergoing decommissioning

The graphite-moderated GCRs series comprises six reactors, including Chinon A1, A2 and A3. These first-generation reactors used natural uranium as the fuel, graphite as the moderator and were cooled by gas. This plant series includes “integrated” reactors, whose heat exchangers are situated under the reactor core inside the vessel, and “non-integrated” reactors, whose heat exchangers are situated on either side of the reactor vessel. The Chinon A1, A2 and A3 reactors are “non-integrated” GCR reactors. 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 11 October 1982 and 7 February 1991 respectively. Chinon A1 D is partially decommissioned at present and has been set up as a museum –the Museum of the Atom– since 1986. Chinon A2 D is also partially decommissioned and houses GIE Intra (which operates robotised machines for interventions on accident-stricken nuclear installations.

Complete decommissioning of the Chinon A3 reactor was authorised by the Decree of 18 May 2010, with a decommissioning "under water" scenario.

In March 2016, EDF announced a complete change of decommissioning strategy for its definitively shut down reactors. In this new strategy, the planned decommissioning scenario for all the reactor pressure vessels involves decommissioning "in air" and the Chinon A2 reactor pressure vessel would be decommissioned first. This new strategy has been examined by ASN (see chapter 13).

ASN considers that the level of safety of the Chinon nuclear installations undergoing decommissioning (Chinon A1, A2 and A3) is satisfactory. The inspections conducted in 2019 revealed in particular that EDF's monitoring of outside contractors is well managed.

Decommissioning of the heat exchangers in the South hall of Chinon A3 ended in June 2018, with the removal of all the heat exchangers. Despite the measures taken as a result of experience feedback from the operations in the South hall, decommissioning of the heat exchangers in the North hall was interrupted due to the presence of asbestos. Restarting these operations in 2020 is under consideration.

THE NUCLEAR FUEL CYCLE FACILITIES

Inter-Regional fresh Fuel Warehouse

Commissioned in 1978, the Chinon Inter-Regional Fuel Warehouse (MIR) is a facility for storing fresh fuel assemblies pending their utilisation in the EDF reactors. It constitutes BNI 99, and along with the Bugey MIR, it contributes to the management of flows of fuel assembly supplies for the reactors.

The facility was emptied of all the fuel assemblies in early 2018 to allow the replacement of the handling crane in 2019. ASN considers that the work went well and during an inspection it noted the good upkeep of the premises.

Nominal operation shall resume in early 2002 with the restarting of reception of fuel assemblies with updated baseline requirements, authorised by ASN.

RESEARCH FACILITIES UNDERGOING DECOMMISSIONING

Irradiated materials facility

The AMI, which was declared and commissioned in 1964, is situated on the Chinon nuclear site and operated by EDF. This facility (BNI 94) has stopped operating and is waiting to undergo decommissioning. It was intended essentially for performing examinations and expert assessments on activated or contaminated materials from pressurised water reactors.

The analysis and expert assessment activities were entirely transferred in 2015 to a new facility on the site, the Lidec (Ceidre Integrated Laboratory).

With a view to decommissioning the facility, the activities in the AMI are now essentially decommissioning preparation and monitoring operations. The year 2019 was chiefly marked by the continuation of the treatment and removal of legacy waste and various unused equipment items, along with standard operating and monitoring operations and preparation for the future decommissioning activities.

ASN continued its examination of the decommissioning file and issued its opinion on the draft decommissioning decree in early 2020.

ASN considers that the management of the waste treatment operations, the performance of the periodic checks and tests and the monitoring of pressure equipment are satisfactory. Particular attention must be paid to the measures for controlling the fire risk. Shortcomings have been observed in the application of the operating rules and particular attention is required in the implementation of measures to prevent their recurrence.

In a context where the facility's activities involve numerous specific work projects, ASN will be attentive to the management of the facility developments and the announced schedules.

SAINT-LAURENT-DES-EAUX SITE

The Saint-Laurent-des-Eaux site, situated on the banks of the river Loire in the municipality of Saint-Laurent-Nouan in the Loir-et-Cher *département*, comprises various nuclear installations, some of them in operation and others undergoing decommissioning. The Saint-Laurent-des-Eaux NPP comprises two operating reactors, B1 and B2, which were commissioned in 1980 and 1981 and constitute BNI 100. The site also features two old GCRs, A1 and A2, currently in the decommissioning phase, and two silos for storing the graphite sleeves from the operation of reactors A1 and A2.

Saint-Laurent-des-Eaux nuclear power plant

Reactors B1 and B2 in operation

ASN considers that the performance of the Saint-Laurent-des-Eaux NPP is in line with the general assessment of the EDF plants in the areas of environment and safety, but underlines a drop in the rigour of operational control of the facilities. The radiation protection performance, however, is below the national average.

With regard to nuclear safety, ASN considers that the NPP has not improved its performance with respect to 2018 despite putting in place a "safety rigour plan". ASN nevertheless underlines the good overall upkeep of the worksites and satisfactory condition of the inspected equipment. This being said, shortcomings in operating rigour and operational control of the facilities were again observed in 2019. Numerous events highlight deficiencies in the management of changes of reactor state and in the application of the general operating rules. Shortcomings have been observed in the NPPs organisation for detecting deviations during maintenance work on the primary and secondary systems. Determined action regarding compliance with the facility operational control rules is expected of the licensee in 2020. ASN does however note that performance of the periodic tests is well managed.

Broadly speaking, the radiation protection performance of the Saint-Laurent-des-Eaux NPP dropped in 2019. Management of the storage areas must be improved and the containment rules must be more clearly defined and more closely monitored by EDF. Lastly, although its inspections identified several good practices, ASN considers that the site must consolidate its process for optimising doses prior to operations with radiation exposure risks.

The NPPs organisation to meet the environmental regulatory requirements is considered satisfactory. The various facilities inspected are well kept. An exercise simulating a hazardous substance discharge showed that the site was well organised, had a sound knowledge of the response actions and implemented them calmly. The management of retention structures showed some weaknesses however, with noncompliant equipment storage areas and undetected run-offs.

With regard to labour inspection, an in-depth inspection was conducted on the subject of fire, personnel evacuation and sheltering in the event of an incident or accident. Further to the labour inspection's observations, improvement actions are expected on the part of the licensee regarding the use and maintenance of the evacuation systems and the site's response organisation. Labour inspection will assess the measures taken in subsequent inspections. Particular attention must be focused on the audibility of the sirens inside the buildings.

Reactors A1 and A2 undergoing decommissioning

The former Saint-Laurent-des-Eaux NPP constitutes a BNI comprising two "integrated" GCRs, the Saint-Laurent-des-Eaux reactors A1 and A2. These first-generation reactors used natural uranium as the fuel, graphite as the moderator and were cooled by gas. Their final shutdown was declared in 1990 and 1992 respectively. Complete decommissioning of the installation was authorised by the Decree of 18 May 2010.

In March 2016, EDF announced a complete change of decommissioning strategy for its definitively shut down reactors (see chapter 13).

ASN, which is examining the periodic safety review concluding report for Saint-Laurent-des-Eaux A submitted at the end of 2017, carried out a specific inspection in 2019. ASN noted that the organisation put in place by EDF for this safety review is satisfactory, but nevertheless observed that the justification for certain conformity analyses could be improved.

Work on the decommissioning sites continued in 2019, but several of them fell behind schedule due to organisational and technical difficulties, or issues related to the presence of asbestos. EDF also continued its efforts to remove the liquid and solid waste.

ASN considers that the level of safety of the Saint-Laurent-des-Eaux A reactors is satisfactory. ASN's inspections found that the overall upkeep of the premises and worksites was good. In addition, the organisation and tools in place for monitoring deviations and outside contractors are satisfactory. However Saint-Laurent-des-Eaux A must improve its organisation for the management of emergency situations in order to better integrate the particularities of installations undergoing decommissioning. ASN will also be attentive to the management of liquid waste, and more specifically to the solutions proposed by EDF further to the loss-of-containment event concerning two drums on a nuclear waste storage area in summer 2019.

Saint-Laurent-des-Eaux silos

The facility, authorised by Decree of 14 June 1971, consists of two silos whose purpose is the storage of irradiated graphite sleeves coming from the operation of Saint-Laurent-des-Eaux A GCRs. Static containment of this waste is ensured by the concrete bunker structures of the silos, which are sealed by a steel lining. In 2010, EDF installed a geotechnical containment around the silos, reinforcing the control of the risk of dissemination of radioactive substances, which is the main risk presented by the installation.

Operation of this BNI (BNI 74) is limited to surveillance and maintenance measures (inspections and radiological monitoring of the silos, checking there is no water ingress, checking the relative humidity, the dose rates in the vicinity of the silos, the activity of the water table, and monitoring the condition of civil engineering structures). These actions are carried out satisfactorily on the whole.

In the context of its new decommissioning strategy for the GCRs, EDF announced in 2016 its decision to start removing the graphite sleeves from the silos without waiting for the graphite waste disposal route to become available. To this end, EDF envisages creating a new graphite sleeve storage facility on the Saint-Laurent-des-Eaux site.

EDF has postponed by one year –that is to say until the end of 2021– submission of the decommissioning file which will take into account the emptying, post-operational clean-out and demolition of the current existing.

Corse (Corsica) Collectivity

The Marseille division regulates radiation protection and the transport of radioactive substances in the Corse collectivity.

THE INSTALLATIONS AND ACTIVITIES TO REGULATE COMPRISE:

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- small-scale nuclear activities in the medical sector:
  - 2 external-beam radiotherapy departments,
  - 2 nuclear medicine departments,
  - 7 centres performing fluoroscopy-guided interventional procedures,
  - 9 computed tomography scanners,
  - about 330 medical and dental radiology devices;

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- small-scale nuclear activities in the veterinary, industrial and research sectors:
  - some 40 veterinary surgeons using diagnostic radiology devices,
  - some 40 industrial and research centres;

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- activities linked to the transport of radioactive substances;
- ASN-approved laboratories and organisations:
  - 2 organisations approved for measuring radon.

In 2019, ASN carried out 5 inspections in Corse, of which 4 were in the medical sector and 1 in the industrial sector.

Overseas *départements* and regions

The regulation of radiation protection and the transport of radioactive substances in the 6 overseas *départements* and regions (Guadeloupe, Guyane, La Réunion, Martinique, Mayotte, Saint-Pierre-et-Miquelon) is ensured by the Paris division. The Paris division also acts as expert to the competent authorities of Nouvelle-Calédonie and French Polynesia.

THE INSTALLATIONS AND ACTIVITIES TO REGULATE COMPRISE:

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- small-scale nuclear activities in the medical sector:
  - 4 external-beam radiotherapy departments,
  - 1 brachytherapy department,
  - 5 nuclear medicine departments,
  - 20 centres performing fluoroscopy-guided interventional procedures,
  - about 30 centres in possession of at least one computed tomography (CT) scanner,
  - about 100 medical radiology devices,
  - about 1,000 dental radiology devices;

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- small-scale nuclear activities in the veterinary, industrial and research sectors:
  - more than 70 users of veterinary radiology devices,
  - 2 industrial radiography companies using gamma radiography devices,
  - 1 cyclotron;

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- activities linked to the transport of radioactive substances.

19 inspections were carried out in the small-scale nuclear activities sector in the French Overseas *départements* and regions in 2019. Three on-site inspection campaigns were carried out by the ASN Paris division.

In 2019, one event concerning workers was rated level 1 on the INES scale.

Grand Est region

The Châlons-en-Champagne and Strasbourg divisions jointly regulate 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:

- Basic Nuclear Installations:
  - 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, of which 1 is in final shutdown status since 22 February 2020),
  - the Nogent-sur-Seine NPP (2 reactors of 1,300 MWe),
  - the CSA storage centre for short-lived low- and intermediate-level radioactive waste located in Soulaines-Dhuys in the Aube *département*;
- the *Cigéo* geological disposal project for long-lived high- and intermediate-level radioactive waste;

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- small-scale nuclear activities in the medical sector:
  - 15 external-beam radiotherapy departments,
  - 5 brachytherapy departments,
  - 20 nuclear medicine departments,
  - 83 computed tomography scanners,
  - some 80 centres performing fluoroscopy-guided interventional procedures,
  - some 2,100 medical and dental radiology devices;

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- small-scale nuclear activities in the veterinary, industrial and research sectors:
  - about 85 veterinary clinics,
  - about 250 industrial activities coming under the licensing system,
  - about 50 research laboratories situated primarily in the universities of the region;

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- activities linked to the transport of radioactive substances;
- ASN-approved laboratories and organisations:
  - 5 organisations approved for radiation protection controls.

In 2019, ASN conducted 182 inspections in the Grand Est region, of which 71 were in the NPPs, 7 in radioactive waste disposal facilities, and on the site of the Chooz A NPP currently being decommissioned, 85 in the small-scale nuclear activities sector, 5 in the transport of radioactive substances and 14 concerning approved organisations or approved laboratories.

ASN also carried out 23 days of labour inspections in the NPPs.

During 2019, 18 significant events reported by nuclear installation licensees in the Grand Est region were rated level 1 on the International Nuclear and Radiological Event Scale (INES scale).

In small-scale nuclear activities, 3 significant events in the industrial sector were rated level 1 on the INES scale.

Cattenom nuclear power plant

The Cattenom NPP is situated on the left bank of the river Moselle, 5 km from the town of Thionville and 10 km from Luxembourg and Germany.

It comprises four 1,300 MWe Pressurised Water Reactors (PWRs) commissioned between 1986 and 1991. Reactors 1, 2, 3 and 4 constitute BNIs 124, 125, 126 and 137 respectively. Along with the Paluel and Gravelines NPPs, it is one of the world's largest NPPs in terms of installed power.

ASN considers that, despite a relative improvement in 2018, the year 2019 was marked by a new deterioration in the Cattenom NPP's performance with regard to operation and maintenance, but nevertheless without the safety measurement indicators falling significantly below the average for the EDF plants.

The environmental protection results revealed satisfactory control in a context marked by a heatwave. Lastly, the radiation protection results remain contrasted despite the efforts made.

Several events highlighted a lack of rigour in the preparation or performance of reactor operating activities, and technical deviations or document anomalies were observed during work in the field. With regard to maintenance, 2019 was marked by a heavy schedule, with three reactors concerned by maintenance outages, two of which partially overlapped, mainly due to delays caused by unforeseen events during restarting. In this high industrial workload situation, weaknesses emerged in the performance of the technical actions in some maintenance activities (leading to maintenance errors) or in equipment requalifications. The ability to manage unforeseen events, and significant event reporting times and quality of analysis remain satisfactory.

The licensee took stock of the drop in performance and in late 2019 initiated an action plan to improve operating rigour.

With regard to the environment, 2019 was marked by the effects of the heatwave, with the water level of the River Moselle remaining very low for a long period. The site thus had to resort to operation by recirculating water from the adjacent Mirgenbach reservoir. Furthermore, substantial volumes of water were released from the Vieux-Pré reservoir into the River Moselle to compensate for the water intakes necessary for operation of the cooling towers. No accidental discharges were reported in 2019, but two events related to the control of discharges into water and the atmosphere were recorded.

With regard to radiation protection, 2019 was marked by deviations concerning compliance with the basic rules of access to classified areas and the control of contamination dispersion, in a context of intense activity linked to the reactor outages. This being said, the site's commitments made since 2017 to improve radiation protection have been widely met.

Lastly, regarding occupational safety, ASN has observed a drive on the theme of control of explosive atmosphere risks and this must be continued.

An inspection into the legality of the conditions of operation of foreign companies on the French territory was carried out jointly with the inspectors of the Regional unit supporting and monitoring the fight against illegal work (Uracti) of the Regional directorate for enterprises, competition, consumption, labour and employment (Direccte). This inspection detected irregularities concerning subcontractor companies during the provision of their services.

Chooz nuclear power plant

The Chooz NPP operated by EDF is situated in the municipality of Chooz, 60 km north of Charleville-Mézières, in the Ardennes *département*. The site accommodates the Ardennes NPP, called Chooz A, comprising reactor A (BNI 163), operated from 1967 to 1991, for which the final shutdown and decommissioning operations were authorised by Decree 2007-1395 of 27 September 2007, and the Chooz B NPP, comprising two 1,450 MWe reactors (BNI 139 and 144), commissioned in 2001.

Reactors B1 and B2 in operation

ASN considers that the performance of the Chooz B 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 nuclear safety, ASN observes that momentum driving progress has been maintained despite the context of intense activity on account of the ten-yearly outage of reactor 2. As far as operation of the reactors is concerned, particular attention must nevertheless be paid to the quality of the risk analyses relating to work interventions in periods of heightened activity.

In the area of maintenance, deficiencies in spare parts procurement were the cause of several significant events. The quality of the operational documentation can be further improved. Efforts must also be made in personnel training, particularly for activities that are complex or involve several specialities.

Alongside this, all the actions contributing to optimisation of worksite radiation protection, from the preliminary risk analysis through to compliance with instructions, must be improved. The licensee must moreover maintain its vigilance in the control of radiological cleanliness of the facilities and increase the rigour of individual behaviour.

ASN considers that the sites organisation for environmental protection is on the whole satisfactory. It notes in particular satisfactory and prompt management of the main events in this area.

Lastly, the oversight ensured through the labour inspections revealed no major nonconformities, but regularly highlighted shortcomings in the optimisation of occupational radiation protection.

Reactor A undergoing decommissioning

The reactor vessel decommissioning work continued in 2019, culminating in the packaging of the reactor vessel head and its shipping to the Aube disposal centre.

On a more general note, ASN considers that the licensee must make progress in the areas of radiation protection, the monitoring of service providers and the environment.

In the area of radiation protection, providing for the risk of alpha particle contamination is a major challenge for the site.

A surge in the cases of on-site contamination was observed in 2019. These findings were made in particular during labour inspection missions on the decommissioning worksites. The licensee must make particular efforts to improve the situation in this respect, and that also includes the monitoring of service providers.

With regard to the environment, ASN considers that the licensee must be particularly attentive to ensuring compliance with waste disposal routes.

Fessenheim nuclear power plant

The Fessenheim NPP comprises two PWRs, each with a unit power of 900 MWe. It is situated 1.5 km from the German border and about 30 km from Switzerland. The two reactors were commissioned in 1977 and will be definitively shut down in 2020.

ASN considers that the nuclear safety performance of the Fessenheim NPP remains satisfactory, as much in the operation of the reactors as in the implementation of the facility maintenance programmes; the facility is situated above the national average in the areas of safety and the environment, and in the average for radiation protection.

Thus, following a good year 2018, operation in 2019 revealed a number of events related to the reliability of maintenance interventions and operational control, but did not call into question the generally positive judgement of ASN. The good results in the number of reactor trips indicate the continued rigour of prevention actions in this respect. The site also displays excellent performance in the off-site and on-site transport of radioactive substances. The site's organisation for the deployment of the On-site Emergency Plan (PUI) is found to be robust, and the responsiveness of the response teams and the personnel in charge of deploying the local emergency resources was noted very positively during the ASN inspections.

ASN observed several events in 2019 that indicate a relative weakness in the site's management of the fire risk, such as with configuring the systems, monitoring the fire protection equipment, or the capacities of the response resources present on the site.

However, no deviations were observed with regard to fire permits, sectorisation or the fire loads, which appear to be well managed.

The maintenance programme for 2019 was rather particular, with two reactor shutdowns for maintenance outages, scheduled belatedly due to the postponement of the initially planned final shutdown date, and with worksites adapted to the context of the forthcoming closure. This programme was carried out satisfactorily. ASN noted the strong determination of the site to maintain the facilities in exemplary condition, with a good degree of involvement of the personnel and management in the maintenance and condition of the facilities.

With regard to environmental management, there were no events that called into question the generally positive judgement of the preceding years.

Lastly, in the area of radiation protection, 2019 witnessed a few events concerning accesses to classified areas and the control of the risk of contamination dispersion. This latter point reveals a potential weakness in the atypical decontamination activities, which will require particular vigilance in the context of the site's future activities. A few deviations were noted with respect to the fire regulations for worker safety, but the site's occupational safety performance remains satisfactory.

Preparation for final shutdown of the Fessenheim site

In September 2019, EDF transmitted the declaration of final shutdown of the Fessenheim NPP, which constitutes BNI 75, to the Minister responsible for nuclear safety and to ASN, in accordance with Article L. 593-26 of the Environment Code. Reactor 1 was shut down on 22 February 2020 and reactor 2 will be shut down on 30 June 2020. In accordance with the Environment Code, EDF enclosed with its shutdown declaration a decommissioning plan describing the planned decommissioning strategy for the NPP. EDF shall then have to submit a decommissioning file with the aim of obtaining a decree authorising it to start the decommissioning operations. This decommissioning file shall undergo a technical examination and a public inquiry.

There is already considerable international feedback on the decommissioning of PWR. In France, the Chooz A reactor in the Ardennes uses the same technology and is also undergoing decommissioning. For the Fessenheim NPP, EDF today plans for five years of decommissioning preparation, which will extend from final shutdown through to obtention of the decommissioning decree. These preparatory operations include in particular the removal of the fuel from the reactor core and removal of the spent fuel stored in the pools. Once the decommissioning decree has been issued, EDF estimates that the decommissioning operations will take 15 years to achieve the final status, followed by delicensing of the BNI.

Considered as a whole, the decommissioning plan submitted by EDF for the Fessenheim NPP is not sufficiently detailed for a facility that is so close to final shutdown. Consequently, in December 2019 ASN asked EDF to justify and further clarify its strategy, particularly regarding the decommissioning time frames and waste management. In this context, ASN observes that EDF plans sending the old steam generators –which are currently stored on site– to Sweden, for recycling in its Cyclife Sweden plant, whereas the conditions for this type of recycling have not yet been determined with regard to French Law.

Furthermore, EDF submitted a safety review guidance file for the Fessenheim reactors in June 2018. In effect, EDF must submit the safety review concluding report for the first reactor before 10 September 2020 and for the second reactor before 28 August 2022.

This guidance file serves to set the bounds of the conformity analyses and safety reassessments which are required for the periodic safety review. In December 2019, ASN also asked EDF for clarifications, particularly concerning the scope of the conformity review proposed by EDF, the justification for the methodologies used and the unforeseen events considered for the safety review. The safety review reports must enable ASN to ascertain that the safety of the facility will be maintained during the decommissioning preparation phases and decommissioning itself.

In November 2019, an in-depth inspection was carried out at the EDF's Department of dismantling projects and waste (DP2D), and on the Fessenheim site. ASN found project work packages that are insufficiently detailed and progress in the technical studies that is insufficient given the present stage of the decommissioning project.

EDF must reinforce the coordination of the Fessenheim decommissioning project in order to have an overall view of the project integrating all its interactions. It also considers that EDF must improve its organisation to establish and validate fundamental decisions for the decommissioning scenario based on proven and formalised hypotheses.

With regard to local operational aspects, the site has already started the planning and preparation of the reactor shutdown operations in 2020, and the management of the workforce and skills during the period prior to decommissioning. ASN has observed the maintaining of a highly satisfactory level of personnel involvement and considers that the management of the organisational and human challenges entailed by the prospective closure of the site, has been excellent.

Furthermore, a number of regulatory requirements, particularly those associated with the implementation of safety improvements further to the lessons learned from the Fukushima Daiichi accident, need to be adapted to the configuration of a site which will no longer be generating power but waiting for decommissioning. Consequently, ASN has started to amend certain requirements, particularly the requirement to build ultimate backup diesel generator sets and the designation of the resources required for the "hardened safety core" (see chapter 10, point 2.9).

Nogent-sur-Seine nuclear power plant

Operated by EDF and situated in the municipality of Nogent-sur-Seine in the Aube *département*, 70 km north-west of Troyes, the Nogent-sur-Seine NPP comprises two PWRs, each of 1,300 MWe, commissioned in 1987 and 1988. Reactor 1 constitutes BNI 129 and reactor 2 BNI 130.

ASN considers that the performance of the Nogent-sur-Seine site with regard to nuclear safety, radiation protection and environmental protection is in line with the average for the plants operated by EDF.

As far as nuclear safety is concerned, the licensee must maintain its efforts to be rigorous in the operation of the reactors. ASN notes in particular that the restarting phase of reactor 1 was subject to an unusual number of events and observes that the operator vigilance, particularly in the control room, must be maintained, including in situations of increased activity. Particular attention must also be paid to the system configuring operations.

With regard to maintenance, ASN considers that the situation is generally satisfactory, in a context of intense activity linked to the ten-yearly outage of reactor 1. ASN notes the progress in monitoring work operations, but the monitoring is still not sufficiently relevant and appropriate for the facility modification activities. The licensee must also ensure rigorous traceability in the processing of anomalies observed on the equipment.

With regard to radiation protection, ASN considers that the licensee has managed to continue correcting the malfunctions in worker protection measures observed in the previous years. The loss of control of radiological cleanliness on a worksite with exposure risks during the ten-yearly outage of reactor 1 nevertheless underlines the need for vigilance in this area on the future similar worksites.

ASN notes a positive trend in environmental protection, but considers that the licensee must remain vigilant regarding the on-site management of effluents and the containment of liquid substances.

Lastly, the oversight ensured through the labour inspections revealed no major nonconformities: ASN focused particular attention on the conformity of the fuel handling machine during the ten-yearly outage of reactor 1, further to the corrections made by the licensee.

Aube waste disposal facility

Authorised by a Decree of 4 September 1989 and commissioned in January 1992, the Aube repository (CSA) took over from the Manche repository which ceased its activities in July 1994, while benefiting from the experience gained with the latter. This facility, situated in Soulaines-Dhuys, has a disposal capacity of one million cubic metres of low and intermediate level, short lived waste (LL/ILW-SL). It constitutes BNI 149. The operations authorised in the facility include the packaging of waste, either by injecting mortar into metal containers of 5 or 10 m^3 volume, or by compacting 200-litre drums.

At the end of 2019, the volume of waste in the facility had reached about 345,000 m^3, or 34.5% of the authorised capacity. According to the estimates made by Andra in 2016 in the concluding report on the CSA periodic safety review, the CSA could be completely filled by 2062 rather than 2042 as initially forecast, this new estimate being based on better knowledge of the future waste and the waste delivery schedules.

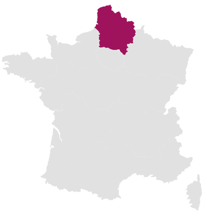
ASN considers that the CSA is operated under satisfactory conditions with regard to safety, radiation protection and environmental protect.

In 2019, with the authorisation of ASN, the CSA commissioned the package inspection facility which gives it more effective means of checking the quality of the received packages. The CSA has moreover started the construction of new waste disposal structures.

The technical analysis of the CSA's periodic safety review report, intended in particular to assess the safety of the facility according to the planned development of its activities over the next ten years, continued in 2019. ASN shall give its opinion on the conditions of operation of the CSA in 2020.

Deep geological disposal facility project

ASN considers that the scientific experiments and work conducted by Andra in the underground laboratory at Bure continued in 2019 with a good standard of quality, comparable with that of the preceding years.



Hauts-de-France region

The Lille division regulates 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:

- one Basic Nuclear Installation:
  - the Gravelines NPP (6 reactors of 900 MWe) operated by EDF;

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- small-scale nuclear activities in the medical sector:
  - 19 external-beam radiotherapy departments,
  - 3 brachytherapy departments,
  - 28 nuclear medicine departments,
  - 92 centres using fluoroscopy-guided interventional procedures,
  - 126 computed tomography scanners,
  - some 4,600 medical and dental radiology devices;

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- small-scale nuclear activities in the veterinary, industrial and research sectors:
  - 1 accelerator intended for the inspection of freight trains (see chapter 8),
  - 600 industrial and research establishments, including 29 companies exercising an industrial radiography activity, 3 particle accelerators of which 2 are cyclotrons, 38 laboratories situated mainly in the universities of the region and 19 companies using gamma ray densitometers,
  - 340 veterinary surgeries or clinics practising diagnostic radiology;

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- activities linked to the transport of radioactive substances;
- ASN-approved laboratories and organisations:
  - 4 organisations approved for radiation protection controls.

In 2019, ASN's carried out 126 inspections in the Hauts-de-France region, of which 22 were in the Gravelines NPP, 96 in small-scale nuclear activities and 8 in the transport of radioactive substances.

ASN also carried out 41 labour inspection operations in the Gravelines NPP.

During 2019, 6 significant events rated level 1 on the INES scale were reported by the Gravelines NPP.

In small-scale nuclear activities, 5 events were rated level 1 on the INES scale.

Gravelines nuclear power plant

The Gravelines NPP operated by EDF is located in the Nord *département* on the shores of the North Sea, between Calais and Dunkerque. This NPP comprises six 900 MWe pressurised water reactors, representing a total power of 5,400 MWe. Reactors 1 and 2 constitute BNI 96, reactors 3 and 4 BNI 97 and reactors 5 and 6 BNI 122.

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 perceived in 2018, especially during the in-depth inspection carried out from 14 to 18 May 2018, did not continue in 2019. ASN notes more specifically a downturn in the results concerning the reliability enhancement of practices. The licensee must also remain attentive to the availability of systems associated with the cooling function.

On the maintenance front, 2019 was marked by problems affecting the pumps and pipes carrying seawater. Furthermore, some items of equipment providing protection against external hazards display corrosion phenomena that could call into question their effectiveness. The licensee must respond to the recurrent problems of corrosion on the facilities.

As regards environmental protection, ASN considers that the Gravelines NPP must improve its management of the maintenance of the facilities for treating the radioactive effluents produced by the operation of the reactors.

With regard to radiation protection, ASN continues to find weaknesses in the control of access to certain areas presenting radiological exposure risks. Improvements are also expected in the monitoring of worksites involving internal contamination risks which were the cause of significant radiation protection events in 2019.

Forty-one labour inspection operations were carried out in the Gravelines NPP in 2019. The inspections are divided between inspections conducted on the maintenance worksites, particularly during reactor outages, and thematic inspections (exposure to chemical risks, lifting risks). Meetings were also organised with senior management, members of the Health, Safety and Working Conditions Committee (CHSCT) and personnel representatives. ASN requested the organisation of technical meetins on specific subjects, such as the risks involved in replacing the steam generators on reactor 5 or the site's organisation for the management of risks and safety at work. ASN effectively remains attentive to the training of operators working at height and to the precautions to be taken when lifting loads. No serious accidents occurred in 2019. The ASN labour inspector did however order a temporary work stoppage after observing a dangerous situation on the ultimate backup diesel generator set worksite.

Polluted sites and soils and mining sites

ASN continued its action and assisted the Dreal with safety recommendations concerning radiation protection for a clean-up project for the PCUK (*Produits Chimiques Ugine-Kuhlmann*) brownfield site, on which phosphogypsum residues are stored.

Île-de-France region

The Paris division regulates radiation protection and the transport of radioactive substances in the 8 *départements* of the Île-de-France region. The Orléans division regulates nuclear safety in the BNIs of this region.

THE INSTALLATIONS AND ACTIVITIES TO REGULATE COMPRISE:

- Basic Nuclear Installations regulated by the Orléans division:
  - the CEA Saclay site, which belongs to the CEA Paris-Saclay centre,
  - the UPRA (Artificial Radionuclide Production Plant) operated by CIS bio international in Saclay,
  - the CEA Fontenay-aux-Roses site which belongs to the CEA Paris-Saclay centre;

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- small-scale nuclear activities in the medical sector regulated by the Paris division:
  - 226 external-beam radiotherapy departments,
  - 14 brachytherapy departments,
  - 40 *in vivo* nuclear medicine departments and 16 *in vitro* (medical biology) nuclear medicine departments,
  - 153 centres performing fluoroscopy-guided interventional procedures, more than 200 centres in possession of at least one computed tomography (CT) scanner,
  - about 850 medical radiology devices,
  - about 8,000 dental radiology devices;

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- small-scale nuclear activities in the veterinary, industrial and research sectors under the oversight of the Paris division:
  - some 650 users of veterinary radiology devices,
  - 9 industrial radiography companies using gamma radiography devices,
  - some 160 licenses concerning research activities involving unsealed radioactive sources;

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- activities linked to the transport of radioactive substances;
- ASN-approved laboratories and organisations:
  - 9 bodies for radiation protection oversight.

ASN carried out 196 inspections in the Île-de-France region in 2019, of which 42 were in the field of nuclear safety, 148 in small-scale nuclear activities and 6 in the transport of radioactive substances.

Nine safety-related significant events were rated level 1 on the INES scale in Ile-de-France, 3 in the area of transport and 6 concerning BNIs.

CEA SACLAY SITE

The Saclay research centre, covering an area of 223 hectares, is located about 20 km south-west of Paris, in the Essonne *département*. About 6,000 people 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 and enhance the safety of the French Nuclear Power Plants (NPPs). The Saclay centre accommodates eight BNIs. Nearby are also located an office of the French National Institute for Nuclear science and Technology (INSTN) –a training institute– and two industrial firms: Technicatome, which designs nuclear reactors for naval propulsion, and CIS bio international, which produces radiopharmaceuticals for nuclear medicine.

THE INDUSTRIAL AND RESEARCH FACILITIES

Osiris and ISIS reactors – *CEA Centre*

The Osiris pool-type reactor has an authorised power of 70 MWth (megawatts thermal). 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 purposes.

Its critical mock-up, the ISIS reactor with a power of 700 kWth (kilowatts thermal), was essentially used for training purposes. These two reactors, which constitute BNI 40, were authorised by the Decree of 8 June 1965.

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. The ISIS reactor was definitively shut down in March 2019. In October 2018, the French Alternative Energies and Atomic Energy Commission (CEA) submitted its decommissioning file for the complete facility: the Osiris reactor and the ISIS reactor. The decommissioning file admissibility analysis carried out by ASN in 2019 revealed the need for a more detailed description of the operations planned for each stage of decommissioning, to better justify the envisaged initial state at the start of decommissioning, and to provide clarifications on the results of the impact study.

Since the Osiris reactor was shut down, the operations to remove the radioactive substances and hazardous materials and to prepare for decommissioning are under way, with an organisation that is adapted to this new reactor status. Removal of the spent fuels continued in 2019 and a new generator set was commissioned.

The inspections conducted by ASN in 2019 showed that the facility is operated under satisfactory conditions as regards the transport operations and the electrical equipment. However, the emergency organisation and operational management for accident situations must be improved, particularly through the updating of the operational documents and tightened monitoring of the training programmes. Management of the decommissioning preparation operations is satisfactory in the technical aspects, but some delays are observed. Management of baseline requirement updating deadlines needs to be improved.

Lastly, some of the significant events reveal organisational and human weaknesses, particularly in the relations with the centre's technical services. Consequently, the licensee must be vigilant regarding maintaining of operating rigour and the safety culture and in the analyses of periodic checks and tests results.

Orphée reactor – *CEA Centre*

The Orphée reactor (BNI 101), a neutron source reactor, is a pool-type research reactor with a licensed power of 14 MWth. The highly compact core is located in a tank of heavy water acting as moderator. Creation of the reactor was authorised by the Decree of 8 March 1978 and its first divergence took place in 1980. It is equipped with nine horizontal channels tangential to the core, allowing the use of 19 neutron beams. These beams were used for conducting experiments in areas such as physics, biology and physical chemistry. The reactor also has ten vertical channels allowing the introduction of samples to irradiate for the manufacture of radionuclides or the production of special materials. The neutron radiography facility, for its part, is intended for the performance of non-destructive tests on certain components.

The Orphée reactor was definitively shut down at the end of 2019. The licensee is preparing the decommissioning file for the facility.

Based on the inspections carried out in 2019, ASN considers that the level of safety of the Orphée reactor is on the whole satisfactory. Operation of the cooling towers has improved since 2018, when numerous deviations were observed. However, the fire risk control measures must be improved, as must emergency management preparedness. Lastly, the robustness of some of the nuclear pressure equipment management provisions must be increased.

Following reactor shutdown, the phase of decommissioning preparation pending issuing of the decommissioning decree shall be subject to particular scrutiny by ASN, notably the adaptation of the organisation and the personnel skills to manage new activities while maintaining the level of safety of the facility.

Spent fuel testing laboratory – *CEA Centre*

The Spent Fuel Testing Laboratory (LECI) –BNI 50– was built and commissioned in November 1959. It was declared a Basic Nuclear Installation on 8 January 1968 by the CEA. An extension was authorised in 2000. The LECI is an expert assessment aid for the nuclear licensees. Its role is to study the properties of materials used in the nuclear sector, whether irradiated or not.

This facility must meet the same safety requirements as the fuel cycle nuclear installations, but the safety approach is proportional to the risks and drawbacks it presents.

Further to the last periodic safety review, ASN issued the resolution of 30 November 2016 (amended on 26 June 2017) regulating the continued operation of the facility through technical prescriptions relating in particular to the improvement plan that CEA had undertaken to implement. Some of CEA's commitments have not been fulfilled within the deadlines. In particular, the demonstration of the behaviour of the structures with respect to the fire risk is behind schedule: a complementary study must be carried out to finalise the list of work to be carried out along with the corresponding deadlines. ASN shall be attentive to the proposed schedule and the CEA's firm commitment to meet it.

The reinforcement work to ensure the earthquake resistance of building 625 was authorized in February 2019. ASN shall be particularly attentive to the meeting of the deadlines for this work (end of the second quarter of 2021).

The inspections carried out by ASN in 2019 revealed operation of the facility to be satisfactory. More particularly, safety management was found to be well ensured. Improvements are however expected in the management of the periodic checks and tests with, among other things, the updating of the operating documents and a clearer definition of the criteria to be satisfied during the tests.

Poséidon irradiator – *CEA Centre*

Authorised in 1972, the Poséidon facility (BNI 77) is an irradiator comprising a storage pool for cobalt-60 sources, partially surmounted by an irradiation bunker. The BNI moreover includes another bunkered irradiator baptised Pagure, and the Vulcain accelerator.

This facility is used for studies and qualification services for the equipment installed in the nuclear reactors, notably thanks to an immersible chamber, as well as for the radiosterilisation of medical products.

The main risk in the facility is of personnel exposure to ionising radiation due to the presence of very high-activity sealed sources.

Examination of the periodic safety review report for the facility was completed with the publication of resolution CODEP-CLG-2019-048416 of 22 November 2019. The major themes addressed include the resistance of the building to seismic and climatic hazards (snow and wind in particular), and the ageing of the Poséidon storage pool.

In the light of the inspections carried out in 2019, ASN considers that the facility is operated satisfactorily and that the radioactive source renewal operations are properly managed. It underlines the steps taken by the CEA to clean out the premises by removing the items that are no longer used, thereby minimising the fire loads, and to improve the facility's equipment or put it back into service. Greater rigour is however required in filling out the operating documents.

SOLID WASTE AND LIQUID EFFLUENT TREATMENT FACILITIES

The CEA operates diverse facilities: laboratories associated with fuel cycle research as well research reactors. The CEA also carries out numerous decommissioning operations. Consequently, it produces diverse types of waste. The CEA has specific processing, packaging and storage facilities for the management of this waste.

Solid radioactive waste management zone – *CEA Centre*

The solid radioactive waste management zone (BNI 72) was authorized by the Decree of 14 June 1971. Operated by the CEA, this facility processes, packages and stores the high, intermediate and low-level waste from the Saclay centre facilities. It also stores legacy materials and waste (spent fuels, sealed sources, scintillating liquids, ion-exchange resins, technological waste, etc.) pending disposal.

Considering the "Potential Source Term" (TSM)[1] currently present in the facility, BNI 72 is one of the priorities of the CEA's decommissioning strategy which has been examined by ASN, which stated its position on the so-defined priorities in May 2019 (see Notable events in the introduction to this chapter and chapter 13).

The commitments made further to the preceding safety review in 2009 aimed to guarantee an acceptable level of safety of the facility for the next ten years. They concerned in particular the removal of the majority of the potential source term from the facility and stopping the reception of new waste from the Saclay centre in order to concentrate the facility's resources on the retrieval and packaging of the legacy waste and on the decommissioning.

In 2017, in view of the delays in the removal from storage operations, the CEA requested that the deadlines prescribed in ASN resolution 2010-DC-0194 of 22 July 2010 for removal of the irradiated fuel from storage and removal of the waste stored in the "40 wells" area be pushed back by several years.

In order to be able to continue using the BNI for managing the radioactive waste from the Saclay BNIs, the CEA in 2017 asked for a change in the date of final shutdown of the facility, postponing it until the first of the following two terms was reached: either the effective date of the decommissioning decree or the date of 31 December 2022.

In the context of the periodic safety review, for which the report was submitted at the end of 2017, and the decommissioning file, ASN has examined the conditions of continued operation of BNI 72 with a view to its decommissioning. These two files have been examined jointly by ASN and IRSN, ASN having requested the latter's opinion. ASN shall be particularly vigilant with regard to rigorous application of the action plan proposed by the CEA, and meeting of the commitments made during the examination. Alongside this, the examination of the decommissioning file shall continue in 2020.

*1. The Potential Source Term (TSM is the French acronym for "*terme source mobilisable*") corresponds to the quantity of radioactive activity that could be involved in an incident or accident.*

ASN considers that the safety of the facility is acceptable, while at the same time noting numerous delays in the operations to remove the fuel and waste from storage. ASN shall be particularly attentive to the monitoring of the intermediate deadlines and the CEA's commitments. ASN underlines the delay in the construction project for a new facility that is necessary for the retrieval and packaging of priority waste drums. ASN expects of the CEA both rigorous management of this project and compliance with the corresponding deadlines. ASN underlines that projects that contribute to reducing the potential source term within facilities constitute priorities for safety.

Floor and metal structure refurbishment work was carried out in various buildings of the BNI in 2019. ASN has observed during inspections that the management of the facility's sources is suitably organised, with internal instructions and procedures that allow satisfactory implementation of the regulatory provisions.

The year 2019 was nevertheless marked by several significant events concerning noncompliant use of the waste or package storage areas. These events reveal the lack of a questioning attitude on the part of the outside contractors, and a lack of monitoring on the part of the CEA. Lastly, ASN observes shortcomings in the ageing management of the facility and in particular a lack of preventive measures.

The liquid effluents management zone
– *CEA Centre*

The liquid effluents management zone constitutes BNI 35. Declared by the CEA by letter of 27 May 1964, this facility is dedicated to the treatment of radioactive liquid effluents. CEA was authorised by a Decree of 8 January 2004 to create "Stella", an extension in the BNI 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 French National Radioactive Waste Management Agency (Andra) above-ground waste disposal centres.

The concentration process was put into service in 2010, but the appearance of cracks in the first packages led ASN to limit the packaging operations. The CEA has thus only packaged some of the effluents from one of the installation's tanks that contains 40 m^3 of concentrates. The CEA has since made progress in defining its packaging solution for all the facility's effluents. Thus, in June 2018, Andra authorised the packaging of these concentrates in accordance with the 12H package approval. In April 2019, ASN received the CEA's request for authorisation to commission these packages and finalised its examination at the year end.

Complementary investigations concerning the stability of the structure of the low-level liquid effluents storage room (room 97) have led the CEA to suspend, since 2016, the acceptance of effluents from other BNIs. The majority of the low- and intermediate-level (LL and IL) radioactive effluents produced by the Saclay site production sources are now directed to the Marcoule Liquid Effluent Treatment Station (STEL), a Defence BNI.

In November 2018, in accordance with its commitment, the CEA submitted to ASN a file presenting the management strategy for the liquid radioactive effluents from the CEA Île-de-France and the overall strategy concerning BNI 35. In this file the CEA has set out deadlines for the cementation of the legacy concentrates stored on the site, which is a priority for the facility.

Alongside this, the situation of pit 99 containing old tanks of organic effluents, with the presence of contaminated sludge in the bottom of the tanks and the bottom of the pit, remains a major clean-out challenge. The clean-out and tank removal studies have been carried out, but ASN is still waiting for an authorisation application file to be submitted for these operations.

The Decree of 8 January 2004 authorising the creation of Stella also provided that the CEA must, within 10 years, remove the legacy effluents stored in the eight tanks called MA500 and in tank HA4 of BNI 35. Due to the technical difficulties encountered in their retrieval and packaging, these operations lasted longer than planned. The operations to empty the last MA500 tank have progressed significantly and the residual sludge in the bottom of the tanks must now be treated.

The inspections carried out by ASN on this facility in 2019 revealed proficiency and a robust organisation with regard to "instrumentation and control", and satisfactory implementation of maintenance. Shortcomings were however observed in the monitoring of ageing of civil engineering structures.

THE CEA SACLAY CENTRE FACILITIES UNDERGOING DECOMMISSIONING

The decommissioning operations performed on the Saclay site concern two finally shut down BNIs (BNI 18 and 49) and three BNIs in operation (BNI 35, 40 and 72), parts of which have ceased activity and in which operations in preparation for decommissioning are being carried out. They also concern two Installations Classified for Protection of the Environment –ICPEs– (EL2 and EL3), previously classified as BNIs but which have not been completely decommissioned due to the lack of a disposal route for the low-level long-lived waste. Their downgrading from BNI to ICPE status in the 1980's, in compliance with the regulations of that time, could not be done today.

Broadly speaking, the CEA's decommissioning and waste management strategy has been examined by ASN, which stated its position on the defined priorities in May 2019 (see Notable events in the introduction to this report and chapter 13).

Ulysse reactor – *CEA Centre*

Ulysse is the first French university reactor. The facility, which constitutes BNI 18, has been in final shutdown status since February 2007 and has contained no fuel since 2008. The BNI Decommissioning Decree was published on 21 August 2014 and provides for a decommissioning duration of five years. This facility presents limited safety risks.

On 8 August 2019, the CEA announced the end of the decommissioning operations provided for in the decommissioning decree, with the completion of final post-operational clean-out. The facility therefore no longer has any areas regulated

Control of urbanisation around the Saclay site

The CEA –Saint-Aubin station project, on the route of the future line 18, is situated at the "*Le Christ de Saclay*" roundabout. This project is not compatible with the town-planning restrictions currently in effect.

At present, the control of urbanisation around Saclay is based on hazard zones resulting from studies that used hypotheses that are no longer relevant, given the changes in the Basic Nuclear Installations (BNIs) of the CEA and CIS bio international. ASN had therefore asked the CEA and CIS bio international to update these studies to assess the impacts of these BNIs on the line 18 project.

These updates, which take into account the shutdown of the Orphée reactor and removal of the iodine-131 from the CIS bio international facility, do not show any hazard zones reaching the station. The examination carried out by ASN confirms these results. In 2020, ASN will state its position on the effective reduction of the risks induced by the site's BNIs, which enable the provisions for controlling urbanisation to be revised.

on account of radiation protection, or areas where nuclear waste can be produced.

Some one hundred blocks of concrete resulting from the cutting-up phase of the "conventional" part of the reactor block are still present in the facility. Samples were taken from these blocks at the end of 2019 to check that the planned clean-out targets has been met. When the analysis results are received, which should be during the first half of 2020, and provided they are satisfactory, the last concrete blocks from the Ulysse reactor will be able to be removed.

In 2020, the CEA will start the procedures aiming to delicence the facility and withdraw it from the BNI System.

High-level Activity Laboratory – *CEA Centre*

The High-level Activity Laboratory (LHA) comprises several laboratories intended for research work or the production of various radionuclides. It constitutes BNI 49. On completion of the decommissioning and clean-out work authorised by Decree of 18 September 2008, only two laboratories –currently in operation– should ultimately remain under the ICPE System. These two laboratories are the laboratory for the chemical and radiological characterisation of effluents and waste, and the packaging and storage facility for the retrieval of unused sources.

Despite the progress of the clean-out and decommissioning operations, the accumulated delays have prevented the CEA from meeting the deadline of 21 September 2018 set by the decree authorising LHA decommissioning. The discovery of pollution in certain "intercell yards" in 2017 also led to changes being made in the operations to be carried out. Investigations into the radiological status of the soils were carried out during 2019, with results expected in 2020. The licensee must submit a decommissioning decree modification file. It must include the justification of the time required to complete the decommissioning operations authorised by the Decree of 18 September 28. Its submission is planned for mid-2021. ASN will be attentive to the progress of the studies planned prior to submission of the file.

Alongside this, the year 2019 saw the stopping of a large part of the decommissioning and clean-out operations, the safeguarding and teardown of the worksites, in relation with the CEA's decommissioning and waste management strategy examined by ASN (see chapter 13).

ASN considers that the level of safety of BNI 49 undergoing decommissioning is satisfactory. The inspections of the facility confirmed the setting up of corrective measures further to the significant events in 2018 linked to the fire risk. They also confirmed the strong involvement of the licensee in the management of safety, particularly in the monitoring of worksites. In addition, the measures taken by the CEA for controlling detrimental effects were found to be satisfactory.

This being said, the monitoring of hazardous substances in the facility must be improved. Vigilance is also required with the proper characterisation of deviations and the tracking of the continuous improvements sheets.

Artificial Radionuclide Production Plant of CIS bio international

The UPRA constitutes BNI 29. It was commissioned in 1964 on the Saclay site by the CEA, which in 1990 created the CIS bio international subsidiary, the current licensee. In the early 2000's, 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, now forming the Curium group, which owns three production sites (in the United States, France, and the 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 2019, the role of BNI 29 was also to recover disused sealed sources which were used for radiotherapy and industrial irradiation. CIS bio international has made good progress with the removal of disused high-activity sealed sources that are stored in the facility. The group has moreover decided to stop its iodine-131-based productions on the Saclay site, which will significantly reduce the consequences of accident situations.

Assessment of the CEA Saclay site

ASN considers that the Basic Nuclear Installations (BNIs) of the Saclay centre are operated under satisfactory conditions of safety and observes that certain operations important to the protection of people and the environment have been completed. In August 2019, the The French Alternative Energies and Atomic Energy Commission (CEA) thus announced the end of the Ulysse reactor decommissioning operations. Removal of the irradiated fuel from the centre's reactors continued, contributing to the reduction in of the source term stored in the BNIs concerned.

Through its inspections, ASN has observed that the overall organisation in place for tracking discharges from the BNIs and monitoring the environment is satisfactory. The process for managing noteworthy BNI modifications is well documented, but recurrent schedule slippages are observed, delaying the implementation of physical modifications or updates of the operating baseline requirements.

ASN considers that the CEA must maintain its vigilance in the performance of the periodic checks and tests of its equipment, particular concerning compliance with deadlines and validation of the operations performed before the equipment is put back into service. It must also make sure of the operational availability of the means contributing to fire protection and the management of accident and emergency situations.

With regard to the emergency organisation and means, the CEA submitted an update of its On-site Emergency Plan (PUI) in the second quarter of 2019. Nevertheless, the CEA must ensure that the operational documents of the BNIs are updated without delay so that they correspond to the state of the facilities and check that the provisions set by ASN with regard to emergency situation preparedness and management are properly taken into account.

As in 2018, the CEA still has difficulties in fulfilling technical requirements within the deadlines set by ASN.

The decommissioning and waste recovery and packaging operations continue to fall behind schedule. ASN considers that the progress of the decommissioning projects is one of the major safety challenges for the shutdown installations and that the management of the waste from the decommissioning operations is crucial for the smooth running of the decommissioning programmes. The majority of the CEA Saclay centre BNIs are concerned, either directly or indirectly, by decommissioning or decommissioning preparation operations In view of the structural delays in the decommissioning preparation operations, ASN expects the CEA to make its implementation schedules for these operations more robust. ASN will be particularly vigilant in monitoring the progress of the decommissioning and waste retrieval and packaging projects, with the aim of ensuring control over the schedules.

Further to the Fukushima Daiichi NPP accident, ASN had initiated stress tests on the nuclear installations. More particularly, the emergency management means of the centres were examined for the Saclay centre. In 2016, ASN prescribed the creation of new emergency management means, notably the construction or reinforcement of "hardened safety core" emergency centres capable of withstanding extreme conditions. In view of the confirmed delays in the deployment of the new emergency management buildings, ASN gave the CEA formal notice in September 2019 to submit a file on the justification and sizing of its future emergency situation management premises before the end of 2019. In the letter accompanying its file, the CEA undertakes to submit a commissioning application for these premises in June 2020.

Broadly speaking, ASN considers that the safety of the facility improved in 2019. ASN notes in particular the efforts CIS bio international has made to makes its organisation and functioning more effective, and the culmination of large-scale projects and actions fostering safety.

The inspections have revealed an improvement in the management of the periodic checks and tests, in the monitoring of deviations and the identification of significant events, and more effective tracking of commitments, even if numerous schedule slippages are still observed. The organisation of radiation protection during work interventions is satisfactory, but greater rigour is nevertheless required in some them.

Further to the formal notice served in 2018 to comply with the requirements resulting from the preceding safety review, the efforts made by CIS bio international brought a satisfactory response to all these requirements. Two inspections in 2019 confirmed that these requirements had been met.

Numerous projects, studies and works undertaken by CIS bio international were finalised in 2019 or will be in early 2020. These projects help improve the safety of the facility. Broadly speaking, the time frames for completing the large-scale actions undertaken by CIS bio international –some of which are already underway for several years and are often difficult to implement– must be better controlled.

ASN nevertheless observes that there is considerable room for progress in several areas. The causes of the numerous significant events almost always include organisational and human deficiencies. Compliance with the requirements of the operating rules, the monitoring and management of activities must be improved, particularly as regards complying with the operating envelope and the management of liquid effluents. ASN's oversight reveals, with regard to safety, a lack of rigour and integration of experience feedback and highlights the need for a robust action plan relative to organisational and human factors.

To conclude, ASN expects CIS bio international to continue the ongoing improvement actions. Operating rigour, safety culture, consolidation of the workforce and skills, control of operations, the cross-disciplinary functioning of the organisation, compliance with the baseline requirements of the facility and control of the schedules are areas in which CIS bio international must particularly concentrate its improvement efforts.

THE CEA FONTENAY-AUX-ROSES SITE

Created in 1946 as the CEA's first research centre, the Fontenay-aux-Roses site is continuing its transition from nuclear activities towards research activities in living sciences.

The 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 1980s-1990s. BNI 166 is a facility for the characterisation, treatment, reconditioning and storage of legacy radioactive waste and waste from the decommissioning of BNI 165.

Broadly speaking, the CEA's decommissioning and waste management strategy has been examined by ASN, which stated its position on the so-defined priorities in May 2019 (see Notable events in the introduction to this report and chapter 13).

Procédé facility and Support facility

– CEA Centre

Decommissioning of these two facilities, Procédé and Support, which constitute BNI 165 and BNI 166 respectively, was authorised by two Decrees of 30 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 that the decommissioning plan would be modified. In June 2015, the CEA submitted an application to modify the prescribed deadlines for these decommissioning operations.

ASN deemed that the first versions of these decommissioning decree modification application files were not admissible. In accordance with the commitments made in 2017, the CEA submitted the revised versions of these files in 2018. The complementary studies announced in the files were submitted in the first quarter 2019.

In its examination of the periodic safety review reports received in 2017 and 2018, ASN identified that the CEA had to provide complementary information on the state of the soils, the decommissioning plan and the safety analysis report, particularly concerning the demonstration of control of the fire risks and seismic risks.

Assessment of the CEA Fontenay-aux-Roses site

On the basis of the inspections carried out in 2019, ASN finds that the monitoring of outside contractors is properly ensured on the CEA Fontenay-aux-Roses site and that the majority of the commitments and actions defined further to the inspections and significant events of the preceding years have been carried out.

However, there are weaknesses in the organisation and technical provisions for radiation protection within the BNIs of the Fontenay-aux-Roses site. ASN will monitor the deployment of the CEA's action plan to remedy the observed deviations. Furthermore, with regard to the fire risk, improvements are required in the control and monitoring of the fire loads.

Several significant events that occurred in 2019 highlighted problems of equipment ageing, in particular the malfunctioning of certain alarms that play a role in monitoring and maintaining the safety of the facilities.

In 2019, as in 2018, ASN observed slippages in the performance of the studies, in project scheduling and in the decommissioning operations schedule. ASN underlines in particular the delay in the projects for new equipment necessary for the decommissioning of the Fontenay-aux-Roses nuclear facilities. What ASN expects of the CEA is the implementation of decisive measures in 2020 to meet the deadlines for these various projects, especially those contributing to the reduction of the potential source term in the old facilities, which constitute priorities for safety.

Normandie region

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:

- Basic Nuclear Installations:
  - 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 Orano Cycle spent nuclear fuel reprocessing plant at La Hague,
  - the Andra Manche repository (CSM),
  - the National Large Heavy Ion Accelerator (Ganil) in Caen;

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- small-scale nuclear activities in the medical sector:
  - 8 external-beam radiotherapy departments (27 devices),
  - 1 proton therapy department,
  - 3 brachytherapy departments,
  - 12 nuclear medicine departments,
  - 50 centres using interventional procedures,
  - 70 computed tomography scanners,
  - some 2,100 medical and dental radiology devices;

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- small-scale nuclear activities in the veterinary, industrial and research sectors:
  - about 450 industrial and research centres, including 20 companies with an industrial radiography activity,
  - 5 particle accelerators, including 1 cyclotron,
  - 21 laboratories situated mainly in the universities of the region,
  - 5 companies using gamma ray densitometers,
  - about 260 veterinary surgeries or clinics practising diagnostic radiology, 1 equine research centre and 1 equine hospital centre;

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- activities linked to the transport of radioactive substances;
- ASN-approved laboratories and organisations:
  - 9 head-offices of laboratories approved for taking environmental radioactivity measurements,
  - 1 organisation approved for radiation protection controls.

In 2019, ASN carried out 200 inspections in Normandie, comprising 56 inspections in the Nuclear Power Plants (NPP) of Flamanville, Paluel and Penly, 14 inspections on the construction site of the Flamanville 3 EPR reactor, 72 inspections on fuel cycle facilities, research facilities and facilities undergoing decommissioning, 50 inspections in small-scale nuclear activities and 8 in the transport of radioactive substances.

In addition to this, 13 days of labour inspection were carried out on the NPP sites and the Flamanville 3 construction site.

In 2019, 1 significant event rated level 2 and 20 significant events rated level 1 on the INES scale were reported ASN. In addition, 2 events rated level 2 on the ASN-SFRO scale were reported by the heads of radiotherapy departments in the Normandie region.

ASN inspectors issued 2 violation reports in the exercise of their oversight duties.

Flamanville nuclear power plant

Operated by EDF and situated in the Manche *département* in the municipality of Flamanville, 25 km south-west of Cherbourg, the Flamanville NPP comprises two pressurised water reactors, each of 1,300 MWe commissioned in 1985 and 1986. Reactor 1 constitutes BNI 108 and reactor 2 BNI 109.

ASN considers that the performance of the Flamanville NPP in the areas of safety, radiation protection and environmental protection deteriorated in 2019 and is below the standard of the other EDF NPPs.

With regard to reactor operation and operational control, ASN considers that the site's performance has to be improved, particularly as regards control of the state and conformity of the facilities. The licensee must ensure that all the employees properly embrace the baseline requirements and improve the detection of deviations in the field.

With regard to the ten-yearly outage of reactor 2, ASN again considers that work preparation and monitoring of the maintenance operations must be improved. ASN still observes a large number of maintenance errors on equipment important to safety. Moreover, ASN considers that the licensee has not taken sufficient account of the lessons learned from the shutdown of reactor 1 for its first ten-yearly outage, particularly as concerns the preparation and performance of the primary cooling system hydrostatic test, the monitoring of outside contractors and management of foreign material exclusion from the systems.

Tightened monitoring

In 2019, ASN decided to place the Flamanville Nuclear Power Plant (NPP) under tightened monitoring further to the difficulties EDF has encountered with this NPP since mid-2018. Following the summoning of the NPP director, EDF submitted an action plan aiming to reinforce the control and monitoring of the operating activities. ASN will be particularly attentive to this action plan and will increase its oversight in 2020.

ASN considers that the performance of the NPP with regard to worker radiation protection is inadequate. Inappropriate operating conditions for workers have been observed several times during ASN inspections. The licensee also reported a large number of significant radiation protection events in 2019, including several cases of internal or external contamination. These events confirm the site's lack of proficiency in the fundamentals of radiation protection and the workers' lack of culture in this area.

With regard to environmental protection, ASN has observed that the licensee has an insufficient grasp of the waste management regulations. EDF must also improve its monitoring of the service providers who work in the area of environmental protection.

With regard to worker safety, ASN notes that several workplace accidents were caused by shortcomings in work preparation by EDF.

Paluel nuclear power plant

The Paluel NPP operated by EDF in the municipality of Paluel in the Seine-Maritime *département*, 30 km south-west of Dieppe, comprises four 1,300 MWe pressurised water reactors, commissioned between 1984 and 1986. Reactors 1, 2, 3 and 4 constitute BNIs 103, 104, 114 and 115 respectively.

The site accommodates one of the regional bases of the Nuclear Rapid Intervention Force (FARN) created by EDF in 2011 further to the Fukushima Daiichi NPP accident. Its role is to intervene in pre-accident or accident situations, on any nuclear power plant in France, by providing additional human resources and emergency equipment.

ASN considers that performance of the Paluel NPP with regard to nuclear safety, radiation protection and environmental protection is on the whole in line with the general assessment of EDF.

With regard to nuclear safety, ASN considers that the deviation management process implemented on the site is effective and that causes stemming from organisational and human factors are analysed in depth. The licensee must now focus on addressing the identified root causes, as a large number of significant events result from inappropriate responses by the workers, deficiencies in the knowledge of the baseline requirements, or operational documentation of sub-standard quality or readability.

As far as operation is concerned, ASN considers that the performance of the NPP has dropped slightly and it notes a lack of rigour in the operational control activities. On this subject, improvements are expected in the quality of the operational control documentation, in staff training, in activity preparation and in the monitoring of activities in the control room.

Performance concerning maintenance is satisfactory. However, at several inspections ASN has observed deficiencies in the performance of the conformity checks, chiefly concerning the ventilation system anchoring points. ASN therefore considers it necessary to continue to increase rigorousness in the preparation and checking of maintenance activities. The NPP must also improve the monitoring of work performed by outside contractors.

ASN considers that the NPP's performance in occupational radiation protection must be improved, particularly regarding compliance with the requirements for entering controlled areas and the radiation protection culture of the workers.

With regard to environmental protection, ASN considers that the licensee must tighten the monitoring of outside contractors, mainly at the wastewater treatment plant. ASN underlines the improvements the site has made in order to control discharges of gases that deplete the ozone layer.

In 2019, ASN revised the texts regulating water intakes and effluent discharges from the Paluel NPP through resolutions 2019-DC-0676 and 2019-DC-0677 of 9 July 2019.

With regard to labour inspection, the analysis of the fatal accident that occurred in 2019 reveals the need for far-reaching improvements in the coordination and implementation of worker protection measures.

Penly nuclear power plant

The Penly NPP operated by EDF in the Seine-Maritime *département* in the municipality of Penly, 15 km north-east of Dieppe, comprises two 1,300 MWe pressurised water reactors commissioned between 1990 and 1992. Reactor 1 constitutes BNI 136 and reactor 2 BNI 140.

ASN considers that the performance of the Penly NPP with regard to nuclear safety and radiation protection is, on the whole, in line with the general assessment of EDF plant performance. The environmental protection performance, however, is considered to be below the EDF plant average.

With regard to nuclear safety, ASN considers the performance of the NPP to be satisfactory. However, ASN still observes shortcomings in the licensee's organisation for managing deviations, with numerous findings not being adequately characterised or traced.

As far as maintenance is concerned, the performance of the NPP remains stable. Nonetheless, at the end of 2019 the licensee notified ASN of a significant event rated level 2 on the INES scale concerning faults on electric cell components. This event revealed deficiencies in the planning of maintenance operations and the management of reactor state changes. An inspection will be organised on these themes in 2020.

Lastly, ASN considers that particular attention must be paid to the preparation of operational control activities in order to improve the quality of the documentation supporting operation of the facilities and the rigour with which the instructions are applied.

With regard to radiation protection, the forward-looking personnel radiological exposure targets were met during the reactor 2 outage. However, there are disparities in the way the radiation risks are taken into account. The practices witnessed by inspectors during worksite inspections and the increasing number of significant radiation protection events still reflect a lack of rigour. ASN underlines the need for outside contractors to be better informed of the radiological risk.

In the area of environmental protection, ASN observes significant progress in the managements of gases that deplete the ozone layer. Shortcomings have nevertheless been noted in the grasp of the regulations concerning waste management. ASN does however underline the quality of operation of the treatment plant.

The inspections relating to worker safety reveal shortcomings in the prevention of chemical risks in the facilities in operation, in the prevention of electrical risks, and in work at height on the construction sites, particularly that of the ultimate backup diesel-generator sets.

Flamanville 3 EPR reactor construction worksite

Following issuing of the Creation Authorisation Decree 2007-534 of 10 April 2007 and the building permit, the Flamanville 3 EPR reactor has been under construction since September 2007.

The end of assembly and finishing activities continued in 2019, in view of carrying out the overall tests of the facility. Important start-up test phases have also taken place, with the performance of the hot tests, which enable the functioning of the nuclear steam supply system and the associated auxiliary systems to be tested under the nominal temperature and pressure conditions. ASN conducted several inspections focusing specifically on these operations, including one 3-day tightened inspection on site. ASN underlines the mobilisation of resources and the marked improvement in EDF's organisation for the start-up tests. EDF must nevertheless supplement the demonstration of representativeness of the tests performed with respect to the test procedures, in particular through better command of the instrumentation and control configuration and tests carried out on a temporarily modified installation. Improvements are also expected in the utilisation of the accrued experience feedback and the implementation of the resulting corrective actions.

ASN also inspected the organisation implemented by EDF for the quality review of the EPR reactor equipment. This review was requested by ASN in 2018 due to serious shortcomings in EDF's monitoring of outside contractors. ASN considers that EDF must substantially supplement its complementary inspections programme, particularly as regards equipment other than pressure equipment. Greater rigour is also required in the implementation of this programme. This review has nevertheless already disclosed a number of deviations that EDF must address appropriately.

EDF must also ensure that a strategy is applied for the conservation, maintenance and testing of the equipment and structures present on the worksite until the reactor is commissioned.

ASN inspected EDF's organisation for the protection of the environment, in particular for the integration of ASN resolutions 2018-DC-0639 and 2018-DC-0640 of 19 July 2018 relative to water intakes, effluent discharges and environmental monitoring and on the themes linked to the prevention of pollution, the control of non-radiological risks and the management of liquid containment. ASN notes numerous events concerning the environment during 2019 and considers that the way environmental risks are taken into account by the future licensee must be improved.

With regard to worker safety, ASN considers that the development of risks generated by the new activities, including the hot tests, was generally well managed by the existing organisation. Nevertheless, several serious workplace accidents occurred in 2019 as a result of breaches of basic rules.

Manche waste repository

The Manche waste repository (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 further waste in July 1994.

Examination of the periodic safety review guidance file had resulted in ASN formulating specific demands at the end of 2017, concerning the justification of the technical principles of deployment of the long-term cover, the CSM memory system and the updating of the impact study. In this context, ASN began the examination of the CSM periodic safety review file submitted by Andra in 2019.

ASN considers that the organisational set-up implemented for operating the facilities in 2019 is satisfactory. The licensee must however improve the the way the monitoring of outside contractors is organised in order to better identify those services that require monitoring and to clearly inform the contractors of the requirements relating to performance of the activities. It must also introduce robustness into deviation management, particularly with regard to meeting commitments and the associated deadlines. Lastly, the licensee must consolidate its integrated management system documents to ensure full consistency between the general operating rules and the various operating procedures.

National Large Heavy Ion Accelerator

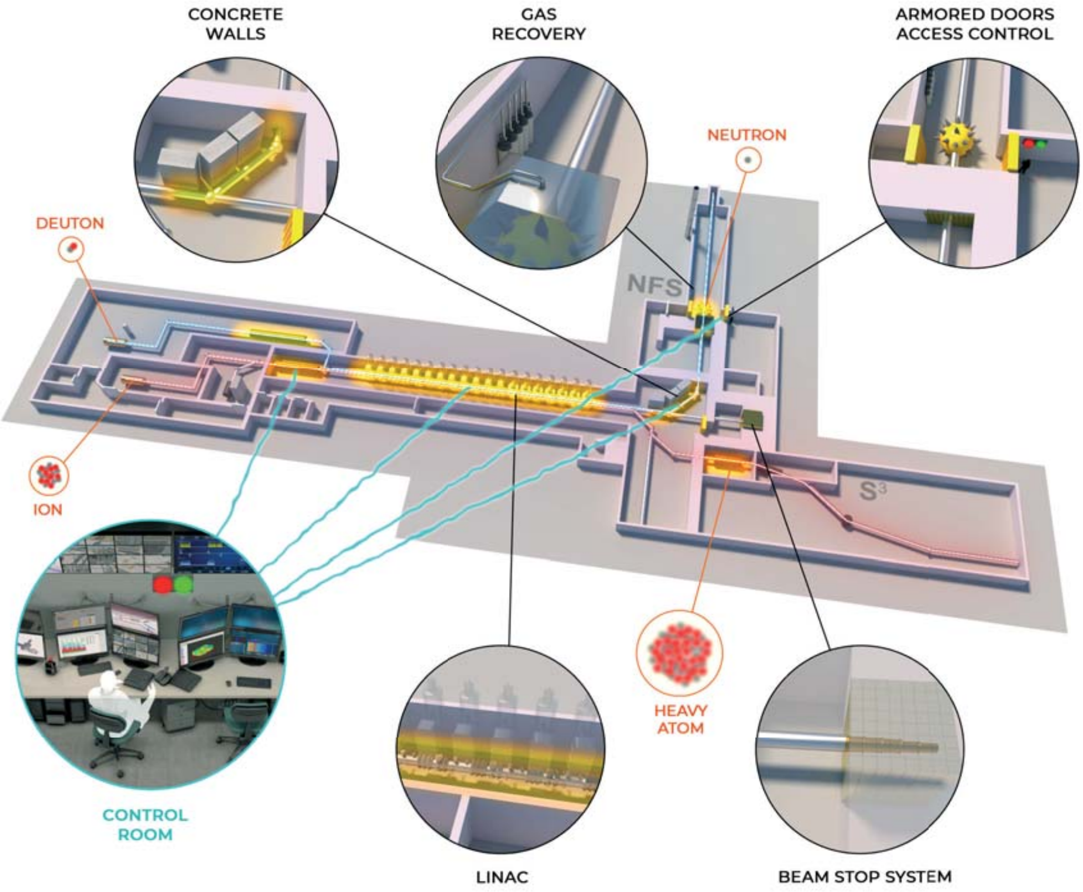
The National Large Heavy Ion Accelerator (Ganil) economic interest group was authorised in 1980 to create an ion accelerator in Caen (BNI 113). This research facility produces, accelerates and distributes ion beams with various energy levels to study the structure of the atom. The high-energy beams produce strong fields of ionising radiation, activating the materials in contact, which then emit radiation even after the beams have stopped. Irradiation is therefore the main risk presented by Ganil.

"Exotic nuclei" are nuclei which do not exist naturally on Earth. They are created artificially in Ganil for nuclear physics experiments on the origins and structure of matter. In order to be able to produce exotic nuclei, Ganil was authorised in 2012 to build phase 1 of the SPIRAL 2 project, whose commissioning was authorised by ASN in 2019.

In accordance with the requirements of resolution 2015-DC-0512 of 11 June 2015 relative to its first periodic safety review, Ganil continued its compliance work on the fire-detection and fire-fighting devices, the management of radioactive waste and containment of the facilities. After analysing the difficulties encountered, ASN authorised Ganil to push back the deadlines for the compliance work provided for by six of the ten prescriptions of this periodic safety review. ASN notes an improvement in the management of projects linked to safety and will remain attentive to the meeting of deadlines, as much for Ganil's commitments as for the requirements laid down by ASN.

ASN considers that the organisation defined and implemented for the operation of the facilities in 2019 must be improved. The licensee must more specifically supplement its safety analysis report and incorporate all the modifications induced by the commissioning of phase 1 of the SPIRAL 2 facility. Ganil must also pursue its efforts with the updating of its integrated management system in order to improve the integration of changes in the regulatory baseline, especially in the area of radiation protection. Lastly, improvements are also expected in the completeness and quality of the files submitted to ASN.

Phase 1 of the SPIRAL 2 extension



Through resolution 2019-DC-0675 of 27 June 2019, ASN authorised the commissioning of phase 1 of the SPIRAL 2 extension of the National Large Heavy Ion Accelerator (Ganil). This resolution marks the end of an examination that lasted 10 years!

Situated in Caen, Ganil is an Economic Interest Group (GIE) comprising the IN2P3 (National Institute of Nuclear and Particle Physics) of the French National Centre for Scientific Research (CNRS) and the Sciences of matter department of the CEA. This Basic Nuclear Installation (BNI 113) was built in 1980. The scientists it has hosted since its commissioning in 1983 study the nuclei of exotic atoms (atoms which do not exist on Earth in the natural state) created by the interaction between a target and a beam of ions, whether radioactive or not, produced by a series of particle accelerators.

After entry into service of the SPIRAL 1 extension in 2001 (SPIRAL in French stands for “first-generation system for on-line production of radioactive ions”) for the production of “light” exotic nuclei, Ganil applied to modify its facility in 2009 to install the SPIRAL2 extension in two phases in order to produce “heavy” radioactive ions.

In its first phase, SPIRAL 2 aims to give Ganil a new accelerator, the Linac, which will deliver, more specifically, very high intensity beams of heavy ions. The beam is then directed to the experiment rooms containing various experimentation devices: Neutrons For Science (NFS) and Super Separator Spectrometer (S3). The facility is also equipped with devices for stopping the beam, called “beam stops”. Their function is to stop the beam of particles during the adjustment phases or in the accident or incident situations.

This new extension will make it possible to explore the nuclei of atoms which are not accessible with the current Ganil equipment. Subsequently, phase 2 of SPIRAL 2 will, through a dedicated production building, allow the creation of ion beams that are among the most intense in the world. This phase shall be built later and will form the subject of a new authorisation application.

LA HAGUE SITE

The Orano site at La Hague is located on the north-west tip of the Cotentin peninsula, in the Manche *département*, 20 km west of Cherbourg and 6 km from Cap de La Hague. This site is situated about fifteen kilometres from the Channel Islands.

LA HAGUE ORANO CYCLE REPROCESSING PLANTS IN OPERATION

The La Hague plants for reprocessing fuel assemblies irradiated in the nuclear reactors are operated by Orano Cycle La Hague.

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 10 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 water intake by the site are defined by ASN resolutions 2015-DC-0535 and 2015-DC-0536 of 22 December 2015.

Operations carried out in the plants

The reprocessing plants comprise several industrial units, each intended for a particular operation. Consequently there are facilities for the reception and storage of spent fuel assemblies, for their shearing and dissolution, for the chemical separation of fission products, uranium and plutonium, for the purification of uranium and plutonium, for treating the effluents and for packaging the waste.

When the spent fuel assemblies arrive at the plants in their transport packaging, they are unloaded either "under water" in a pool, or dry in a sealed shielded cell. The fuel assemblies are first stored in pools to cool them down.

The fuel assemblies are then sheared and dissolved in nitric acid to separate the fragments of metal cladding from the spent nuclear fuel. The fragments of cladding, insoluble in nitric acid, are removed from the dissolver, rinsed in acid and then water, and transferred to a compacting and packaging unit.

The nitric acid solution containing the dissolved radioactive substances is then processed to extract the uranium and plutonium from it, leaving the fission products and the other transuranium elements.

After purification, the uranium is concentrated and stored as uranyl nitrate $UO_2(NO_3)_2$. It will then be converted into a solid compound (U_3O_8) called "reprocessed uranium" in the TU5 facility on the Tricastin site.

After purification and concentration, the plutonium is precipitated by oxalic acid, dried, calcined into plutonium oxide, packaged in sealed containers and stored. The plutonium is then used for the fabrication of MOX fuels in the Orano Cycle plant (Melox) on the Marcoule site.

The effluents and waste produced by the operation of the plants

The fission products and other transuranium elements resulting from reprocessing are concentrated, vitrified and packaged in standard vitrified waste packages (CSD-V). The fragments of metal cladding are compacted and packaged in standard compacted waste packages (CSD-C).

Furthermore, the reprocessing operations described in the previous paragraph involve chemical and mechanical processes which produce gaseous and liquid effluents and solid waste.

The solid waste is packaged on site by either compaction or encapsulation in cement. The solid radioactive waste resulting from the reprocessing of the spent fuel assemblies from the French reactors is, depending on its composition, either sent to the Aube repository (CSA) or stored on the Orano Cycle La Hague site until a definitive disposal solution is found (particularly the CSD-V et CSD-C packages).

In accordance with Article L. 542-2 of the Environment Code, the radioactive waste resulting from the reprocessing of spent fuel assemblies originating from foreign countries is sent back to the owners. However, it is impossible to physically separate the waste according to the fuels from which it originates. In order to guarantee an equitable distribution of the waste resulting from the reprocessing of the fuels of its various customers, the licensee has proposed an accounting system that tracks the entries into and exits from the La Hague plant. This system, called Exper system, was approved by the Order of 2 October 2008 of the Minister responsible for energy.

The gaseous effluents are released mainly when the fuel assemblies are sheared and during the dissolution process. These gaseous effluents are treated by washing in a gas treatment unit. The residual radioactive gases, particularly krypton and tritium, are checked before being discharged into the atmosphere.

The liquid effluents are treated and generally recycled. Some radionuclides, such as iodine and tritium, are channelled –after being checked– to the sea discharge outfall. This outfall, like the other outfalls of the site, is subject to discharge limits. The other effluents are routed to the site's packaging units (solid glass or bitumen matrix).

Management of the condition of the evaporation concentration containers

ASN continued its verification of implementation of the provisions of ASN resolution 2016-DC-0559 of 23 June 2016 relative to the fission product evaporators, issued further to the finding of a rate of corrosion of these equipment items exceeding that considered in their design.

ASN conducted a five-day tightened inspection focusing on the non-destructive tests performed by the licensee on the evaporators of the T2 facility during its maintenance outage. ASN considers that these inspections were prepared and carried out under satisfactory conditions. Nevertheless, the results show that the thickness of the T2 facility evaporator 4120-23, identified as being the most affected by the corrosion, is close to the minimum thickness. Before restarting the facility, the licensee undertook to continue to reduce the utilisation of this evaporator and to conduct another measurement campaign in 2020.

ASN will be particularly attentive to the monitoring of these evaporators until the new replacement evaporators are commissioned.

"New Fission Products Concentration" project (NCPF)

ASN continued its examination of the NCPF project relative to the commissioning of new fission product evaporator concentrators to replace the old ones, the introduction of which began in August 2019 and ended in November 2019 (see chapter 11). An inspection was carried out in October 2019 on the construction worksites of the buildings for these six new evaporators. The organisation for managing this worksite was found to be rigorous. Another ASN inspection on these worksites is scheduled in 2020.

The installations at La Hague

SHUT DOWN INSTALLATIONS UNDERGOING DECOMMISSIONING:

- **BNI 80 – Oxide High Activity facility (HAO):**
  - **HAO/North:** facility for "under water" unloading and storage of spent fuel elements,
  - **HAO/South:** Facility for shearing and dissolving spent fuel elements;
- **BNI 33 – UP2-400 plant, first reprocessing unit:**
  - **HA/DE:** Facility for separating uranium and plutonium from fission products,
  - **HAPF/SPF (1 to 3):** Facility for fission product concentration and storage,
  - **MAU:** Facility for separating uranium and plutonium, uranium purification and storage as uranyl nitrate,
  - **MAPu:** Facility for purification, conversion to oxide and initial packaging of plutonium oxide,
  - **LCC:** Central product quality control laboratory,
  - **ACR:** Resin conditioning facility;
- **BNI 38 – STE2 facility: Effluent collection and treatment and storage of precipitation sludge, and AT1 facility, prototype facility currently being decommissioned;**
- **BNI 47 – ELAN IIB facility, research installation currently being decommissioned.**

INSTALLATIONS IN OPERATION:

- **BNI 116 – UP3-A plant:**
  - **T0:** Facility for dry unloading of spent fuel elements,
  - **Pools D and E:** Pools for storing spent fuel elements,
  - **T1:** Facility for shearing fuel elements, dissolving and clarification of the resulting solutions,
  - **T2:** Facility for separating uranium, plutonium and fission products and concentrating/storing 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:** Fission product vitrification facility,
  - **BSI:** Plutonium oxide storage facility,
  - **BC:** Plant control room, reagent distribution facility and process control laboratories,
  - **ACC:** Hull and end-piece compaction facility,
  - **AD2:** Technological waste packaging facility,
  - **ADT:** Waste transit area,
  - **EDS:** Sold waste storage area,
  - **D/E EDS:** Solid waste storage/removal from storage,
  - **ECC:** Facilities for storage and retrieval of technological waste and packaged structures,
  - **E/EV South-East:** Vitrified residues storage facility,
  - **E/EV/LH and E/EV/LH 2:** Vitrified residues storage facility extensions;
- **BNI 117 – UP2-800 plant:**
  - **NPH:** Facility for "under water" unloading and storage of spent fuel elements in pool,
  - **Pool C:** Spent fuel element storage pool,
  - **R1:** Facility for shearing and dissolving fuel elements and clarification of the resulting solutions (including the URP: Plutonium Redissolution Facility),
  - **R2:** Facility for separating uranium, plutonium and fission products and concentrating the fission product solutions (including the UCD: centralised alpha waste conditioning unit),
  - **SPF (4, 5, 6):** Fission product storage facilities,
  - **R4:** Facility for purification, conversion to oxide and initial packaging of plutonium oxide,
  - **BST1:** Facility for secondary packaging and storage of plutonium oxide,
  - **R7:** Fission products vitrification facility,
  - **AML-AMEC:** Packaging reception and maintenance facility;
- **BNI 118 – STE3 facility: Effluent collection and treatment and storage of bituminised waste packages:**
  - **D/E EB:** Storage of alpha waste,
  - **MDS/B:** Mineralisation of solvent waste.

Extension of the standard compacted waste package (CSD-C) storages areas

In April 2017, Orano Cycle submitted a substantial modification authorisation application file with the aim of extending the CSD-C package storage areas. The public inquiry was held from 5 June to 8 July. ASN is continuing the examination of this file.

FINAL SHUTDOWN AND DECOMMISSIONING OPERATIONS

The former UP2-400 plant (BNI 33) was commissioned in 1966 and has been definitively shut down since 1 January 2004.

Final shutdown also concerns three BNIs associated with the UP2-400 plant: BNI 38 (STE2 installation and AT1 facility), BNI 47 (ELAN IIB facility) and BNI 80 (HAO facility).

In 2019, ASN finalised the examination of the periodic safety review files for BNIs 33, 38 and 47. ASN resolution 2019-DC-0673 governing the continuation of their decommissioning was published on 25 June 2019.

ASN continued its examination of the partial decommissioning authorisation applications for BNIs 33 and 38 submitted in April 2018. The schedule push-backs requested by the licensee lead to decommissioning completion deadlines in 2046 and 2043 instead of 2035, the current deadline for the two BNIs. In early 2020, Orano must supplement firstly the decommissioning file for BNI 33 regarding the elimination of interactions between the MAPu facility and the BST1 facility in the event of an earthquake by demolishing the upper storeys of the MAPu, and secondly its dissertation in response to the opinion of the Environmental Authority, before starting the public inquiry.

ASN notes that the schedule push-backs requested are significant and largely due to the delays in legacy waste retrieval and packaging. Consequently, ASN will continue to monitor the management of these projects in 2020.

LEGACY WASTE RETRIEVAL AND PACKAGING OPERATIONS

Unlike the direct on-line packaging of waste, as is done with the waste produced in the new UP2-800 and UP3-A plants at La Hague, the majority of the waste produced by the first UP2-400 plant was stored in bulk without final packaging. The operations to retrieve this waste are complex and necessitate deployment of substantial means. They present major safety and radiation exposure risks, which ASN monitors with particular attention.

The retrieval of the waste contained in the old storage facilities of the La Hague site is also a prerequisite for the decommissioning and clean-out of these storage facilities.

Retrieval and packaging of the STE2 sludges

The UP2-400 plant effluent treatment station, STE2, served to collect the effluents from the UP2-400 plant, treat them and store the precipitation sludges resulting from the treatment. The STE2 sludges are thus precipitates that fix the radiological activity contained in the effluents and they are stored in seven silos. A portion of the sludges has been encapsulated in bitumen and packaged in stainless steel drums in the STE3 facility. Following ASN's banning of bituminisation in 2008, Orano studied other packaging methods for the non-packaged or stored sludges.

The scenario for the retrieval and packaging of the STE2 sludges presented in 2010 was broken down into three steps:

- retrieval of the sludges stored in the silos of STE2 (BNI 38);
- transfer and treatment, initially envisaged by drying and compaction, in STE3 (BNI 118);
- packaging of the resulting pellets in "C5" packages for subsequent disposal in a deep geological repository.

ASN authorised the first phase of the work to retrieve the STE2 sludges in 2015 and the decree authorising the creation of the effluent treatment station STE3 was modified by the Decree of 29 January 2016, to allow the implementation of the STE2 sludge treatment process.

At the end of 2017 however, Orano Cycle informed ASN that the process chosen for treating the sludges in STE3 could lead to difficulties in equipment operation and maintenance. Orano Cycle proposed an alternative scenario using centrifugation and in August 2019 it submitted a Safety Options Dossier (DOS), which is however based on insufficiently substantiated hypotheses. An inspection held at the end of 2019 showed that the project was not sufficiently mature for ASN to be able to give an opinion on this DOS. The DOS must be revised, particularly in the fundamental options of the project concerning effluent treatment, discharges into the environment and control of the fire risk.

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 as from 1973, until the 1981 fire which forced the licensee to flood the waste. The leak-tightness of the silo thus filled with water is today ensured only by 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 sludges from the bottom of the silo;**
- **retrieval and packaging of the soils and rubble.**

Orano Cycle has built a retrieval unit above the pit containing the waste and a new building dedicated to the sorting and packaging operations. The first lowering of the gripper into the

The safety issues associated with silo 130

Silo 130 was designed and built in accordance with the safety requirements in effect in the 1960's. Today, the civil engineering structure of silo 130 is weakened by ageing and by a fire that occurred in 1981. Furthermore, part of the waste that was initially stored dry is now submerged in a large volume of water that served to extinguish the 1981 fire. The water is therefore in direct contact with the waste and can contribute to corrosion of the carbon steel liner, which at present is the only containment barrier.

One of the major risks therefore concerns the dispersion of radioactive substances into the environment (infiltration of 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 phenomena of radiolysis or corrosion (presence of water). These elements contribute to the risks of fire and explosion.

pit with waste pick-up took place on 24 June 2019 and filling of the first drum began at the end of 2019. ASN inspected the future licensee's preparation of the waste retrieval facilities in 2019 and considers that the organisation implemented is satisfactory. ASN notes recurrent difficulties when starting the retrieval operations. Orano Cycle must ensure that these difficulties are resolved rapidly in order to ensure waste retrieval in accordance with the requirements of resolution 2010-DC-0190 of 29 June 2010, amended in November 2019.

HAO silo and SOC (Organised Storage of Hulls)

The Oxide High Activity facility (HAO – BNI 80) ensured the first steps of the spent nuclear fuel reprocessing process: 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.

BNI 80 comprises:
- HAO North, spent fuel unloading and storage site;
- HAO South, where the shearing and dissolution operations were carried out;
- the "filtration" building, which accommodates the filtration system for the HAO South pool;
- the HAO silo, in which are stored the hulls and end-pieces (fragments of cladding and fuel end-pieces) in bulk, fines coming primarily from shearing, and resins and technological waste from the operation of the HAO facility between 1976 and 1997;
- the Organised Storage of Hulls (SOC), comprising three pools in which the drums containing the hulls and end-pieces are stored.

In 2019, the licensee continued the operations prior to retrieval of the waste from the HAO silo (notably the construction of the future waste retrieval unit) and started the tests important to safety.

The legacy fission product solutions stored in the SPF2 unit of the UP2-400 plant

For the packaging of the fission products from the reprocessing of the GCR reactor fuels and containing molybdenum in particular (PF UMo), the licensee has opted for cold crucible vitrification. The package thus produced is a standard package of vitrified UMo waste (CSDU). Orano Cycle continued the retrieval of these solutions in 2019 and encountered various unforeseen technical difficulties linked to the use of the cold crucible. ASN will be attentive to the completion of retrieval of these solutions, planned for 2020.

Legacy waste retrieval and packaging project deadlines

ASN has regulated all the legacy waste retrieval and packaging programmes on the La Hague site by requirements set out in resolution 2014-DC-0472 of 9 December 2014. This resolution defines the priorities with regard to the safety of waste retrieval and packaging operations and sets milestones for each of the programmes concerned.

The retrieval of this waste has fallen significantly behind the initial schedule and has continued to do so over the last few years. ASN has examined the deadline push-backs requested by Orano Cycle and their justifications; it considers that the delays must be accompanied by compensatory measures to reduce the risk to as low a level as possible, because the buildings in which this legacy waste is stored do not meet current safety standards. ASN thus considers that the waste retrieval and packaging projects must be managed in exemplary fashion and have robust reference frameworks that allow the implementation of rapid retrieval solutions in order to minimise the risks as early as possible. On this account, ASN considers that Orano Cycle must make effective improvements in the management of the retrieval projects for the legacy waste produced by the operation of the UP2-400 plant, particularly those concerning the sludges stored in the STE2 silos, the waste in the HAO silo and that in silo 130.

In 2019, ASN examined the requests to push back the deadlines for recovery of the legacy fission products solutions stored in the SPF2 unit, the waste from silo 130, from silo HAO and from the SOC pools. ASN has pushed back the deadline for completion of retrieval of the legacy fission product solutions stored in the SPF2 unit until the end of December 2002 by resolution 2019-DC-0665 of 9 April 2019. The new deadline for starting retrieval of the waste from silo 130 is set at 29 February 2020 by resolution 2019-DC-0682 of 12 November 2019. Lastly, ASN postponed to June 2022 the deadline for starting retrieval of the waste from the HAO silo and the SOC pools.

In view of the difficulties with the waste retrieval and conditioning projects, ASN has started an exploratory approach for monitoring the progress of the legacy waste retrieval and decommissioning projects on the La Hague site, which included a licensee self-assessment and an in-depth inspection at the end of 2019. ASN observes that the licensee has defined a satisfactory project management methodology, but progress is required in the actual management of these projects in order to meet the time lines.

Assessment of the La Hague site

ASN considers that the performance of the Orano Cycle La Hague site in 2019 is satisfactory in the areas of nuclear safety, radiation protection and environmental protection.

With regard to nuclear safety, ASN notes an improvement –to be consolidated– in the management of the periodic checks and tests resulting from the integration of the lessons learned from the significant events reported in the last few years. ASN has nevertheless observed several cases where the time intervals between checks have been exceeded because organisational deficiencies have affected their integration in the tracking tool.

The licensee must also significantly improve its organisation for managing risks involving hazardous substances. During several inspections, ASN has observed shortcomings in the prevention of major accidents involving hazardous substances and a lack of means to control the conformity of the site's Installations Classified for Protection of the Environment (ICPEs).

ASN considers that the licensee must continue the efforts made in the monitoring of outside contractors, notably by improving the monitoring plan preparation methodology and the formalising of the monitoring documents. ASN notes that the licensee has initiated a plan of action in this respect and will be attentive to the deployment of new practices in 2020.

ASN considers that the licensee's fire risk organisation is satisfactory. Orano Cycle must nevertheless ensure that the fire response times given in its nuclear safety case are in line with those observed during exercises. Furthermore, the licensee must improve the prioritising of the fire-fighting teams' interventions. In 2020, ASN will remain attentive to the consistency between the intervention actions to accomplish and the human resources mobilised on the site.

With regard to radiation protection, ASN notes that the organisation of the La Hague site and the results obtained are satisfactory, particularly with respect to dosimetry optimisation during work interventions. Random checks have nevertheless revealed delays on the performance of radiation protection technical controls, and insufficient rigour in the keeping of the entry registers for limited-stay areas and prohibited areas, and in tracking the mobile radiation monitors.

ASN considers that the licensee's environmental protection organisation is satisfactory. Orano Cycle must nevertheless increase the rigour of waste management in the facilities, particularly with regard to storage conditions and radiological checks.

With regard to the management of the decommissioning and legacy waste retrieval and packaging projects, ASN considers that the organisation and project management must undergo fundamental improvements in order to meet the deadlines for the commitments made by Orano and transcribed in ASN requirements or decrees. ASN notes positively the integration of the lessons learned from the silo 130 project with the aim of improving the performance of the tests important to the safety for the HAO silo project and control of the fire risks in the project to retrieve the legacy waste from silo 115. The efforts must however be increased and widened. Orano must take all appropriate measures to allocate the necessary resources, whether internal or external, over the medium and long term in order to guarantee the effectiveness of its project management. Furthermore, ASN will ensure that Orano provides rigorous justification for the changes in scenario and durations of the associated operations, and will be attentive to the rigour of project management.

Nouvelle-Aquitaine region

The Bordeaux division regulates nuclear safety, radiation protection and the transport of radioactive substances in the 12 *départements* of the Nouvelle-Aquitaine region.

THE INSTALLATIONS AND ACTIVITIES TO REGULATE COMPRISE:

- Basic Nuclear Installations:
  - the Blayais NPP (4 reactors of 900 MWe),
  - the Civaux NPP (2 reactors of 1,450 MWe);

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- small-scale nuclear activities in the medical sector:
  - 19 external-beam radiotherapy departments,
  - 6 brachytherapy departments,
  - 24 nuclear medicine departments,
  - 88 centres performing fluoroscopy-guided interventional procedures,
  - 89 computed tomography scanners,
  - some 6,000 medical and dental radiology devices;

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- small-scale nuclear activities in the veterinary, industrial and research sectors:
  - about 700 industrial and research centres, including 50 companies with an industrial radiography activity,
  - 1 cyclotron particle accelerator,
  - 67 laboratories situated mainly in the universities of the region,
  - about 500 veterinary surgeries or clinics practising diagnostic radiology;

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- activities linked to the transport of radioactive substances;
- ASN-approved laboratories and organisations:
  - 5 organisations approved for radiation protection controls,
  - 8 organisations approved for measuring radon,
  - 4 laboratories approved for taking environmental radioactivity measurements.

In 2019, ASN carried out 143 inspections in the Nouvelle-Aquitaine region, comprising 40 inspections in the Blayais and Civaux NPPs, 89 inspections in the small-scale nuclear activity sector, 7 inspections in the area of radioactive substance transport and 7 inspections of approved organisations and laboratories.

ASN also carried out 17 days of labour inspection at the Blayais NPP and 4.5 days at the Civaux NPP.

During 2019, four significant events rated level 1 on the INES scale were reported by the NPP licensees of Nouvelle-Aquitaine. In small-scale nuclear activities, one significant radiation protection event rated level 1 on the INES scale was reported to ASN. One event involving radiotherapy patients was rated level 2 on the ASN-SFRO scale.

In the exercise of their oversight duties, the ASN inspectors issued one violation report to a firm performing industrial radiography in bunkers.

Blayais nuclear power plant

Situated in the Gironde department, 50 km north of Bordeaux, the Blayais NPP is operated by EDF. This NPP comprises four 900 MWe pressurised water reactors. Reactors 1 and 2 constitute BNI 86 and reactors 3 and 4 BNI 110.

ASN considers that the performance of the Blayais NPP is in line with its general assessment of EDF performance for nuclear safety, and below it for radiation protection. The environmental protection performance, although comparable with the average for the nuclear fleet, must be improved.

As far as nuclear safety is concerned, ASN considers that the NPP is progressing in the area of maintenance and demonstrates proficiency in the work performed during the reactor outages. ASN does however still observe deficiencies in the quality of the operational documentation covering the preparation and performance of the activities. ASN considers that these deficiencies contribute to shortcomings in the following of procedures, which subsists in 2019 despite the implementation of an action plan on this subject. Deficiencies in monitoring in the control room, due in particular to the many demands made of the operators, have been noted in several significant events. Furthermore, in 2019 ASN observed a succession of events that could jeopardise the fuel cladding, which is the first radioactive substance containment barrier.

In the area of occupational radiation protection, ASN considers that the situation regarding various aspects related to the control of radiological cleanliness, the behaviour of the workers and the organisation of the worksites has deteriorated. In addition, ASN observes a lack of integration of the experience feedback over the year, illustrated in particular by a series of events during the last of the four reactor shutdowns in 2019.

As regards environmental protection, ASN considers that the licensee is being slow in providing lasting corrective solutions to the legacy pollution of the soils and groundwater detected in the last few years. It does however note that the investigations conducted by the site are moving forward. Furthermore, noncompliant non-radioactive liquid discharges occurred, linked to the difficulties the licensee is having with the upkeep of its wastewater networks.

With regard to labour inspection, ASN has monitored the conformity files of the heavy cranes, locally manufactured tooling and the ventilation of premises with specific pollution characteristics. The diagnostic and remediation times are deemed too long. In collaboration with the Regional Directorate for Enterprises, Competition, Consumption, Labour and Employment (Direccte), ASN has identified poor control of the asbestos risk. A verification of employee working times was also undertaken.

Civaux nuclear power plant

The Civaux NPP is operated by EDF in the Vienne *département*, 30 km south of Poitiers in the Nouvelle-Aquitaine region. It comprises two 1,450 MWe pressurised water reactors. Reactors 1 and 2 constitute BNIs 158 and 159 respectively. The site accommodates one of the regional bases of the Nuclear Rapid Intervention Force (FARN) created by EDF in 2011 further to the accident at the Fukushima Daiichi NPP in Japan. Its role is to intervene in pre-accident or accident situations, on any nuclear power plant in France, by providing additional human resources and emergency equipment.

ASN considers that the performance of the Civaux 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.

In the area of nuclear safety, with regard to the operating activities, ASN considers that the reactor control operations are on the whole conducted with rigour. Nevertheless, the licensee must remain attentive to the proper preparation and performance of delicate operational control actions when other activities carried out at the same time can necessitate the attention of the same operators. ASN considers that, on the whole, the licensee successfully accomplished the maintenance activities planned during the maintenance outage of reactor 2, the only outage in 2019. The licensee must further improve the quality of the maintenance operations in order to tackle under the best possible conditions the years to come, which will have higher outage and maintenance workloads, particularly with the ten-yearly outages which will be carried out in the context of the periodic safety review of the reactors.

Concerning worker radiation protection, ASN considers that the licensee has made progress in the implementation of prevention measures. ASN nevertheless considers that the site must improve the management of worker access to certain areas presenting a high level of exposure to ionising radiation.

In the area of environmental protection, ASN considers that the licensee must improve its strategy for managing an accidental discharge of hazardous substances in order to prevent their transfer into the environment. ASN's requirements have been prescribed by resolution 2019-DC-0666 of 18 April 2019. The material and organisational measures put in place by the licensee in this context shall be checked by ASN in 2020. ASN also considers that the licensee must improve the management of radioactive waste in its facilities.

With regard to labour inspection, specific investigations were conducted following the occurrence of workplace accidents, notably after accidental exposures to asbestos. ASN considers that the licensee took appropriate measures in response to the chemical risk in 2019, the lack of control of which had been underlined in inspections the year before.

Polluted sites and soils and mining sites

Pollution by radium-226 was revealed when earthworks were carried out on land belonging to the city of Bordeaux (wet docks sector). On a proposal from ASN, the Prefectoral Order of 1 June 2015 required the city of Bordeaux to carry out an in-depth study to characterise the origin and extent of the pollution and propose remediation solutions.

After analysing the information provided by the city of Bordeaux, ASN proposed to the Prefect of Gironde an order setting the perimeter and conditions of the intervention, the remediation objectives and the public information measures.

The order was signed on 14 June 2019 and the depollution work was carried out during the summer. During an inspection of the depollution worksite in July 2019, ASN verified compliance with the measures prescribed in the order concerning the conduct of the excavations and the removal of the contaminated rubble, and the regulatory requirements for the radiation protection of workers. ASN will decide in 2020, after an expert assessment by IRSN, whether the remediation objectives for the site have been achieved.

Occitanie region

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:

- Basic Nuclear Installations:
  - the Golfech NPP comprising 2 pressurised water reactors of 1,300 MWe,
  - the Melox "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,
  - the facility for storing Écrin waste on the Malvési site;

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- small-scale nuclear activities in the medical sector:
  - 14 external-beam radiotherapy departments,
  - 6 brachytherapy departments,
  - 22 nuclear medicine departments,
  - 97 centres performing fluoroscopy-guided interventional procedures,
  - 113 computed tomography scanners,
  - some 5,000 medical and dental radiology devices;

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- small-scale nuclear activities in the veterinary, industrial and research sectors:
  - about 800 industrial and research centres, including 4 cyclotron particle accelerators, 26 companies exercising an industrial radiography activity and 79 laboratories situated mainly in the universities of the region,
  - about 450 veterinary surgeries or clinics practising diagnostic radiology;

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- activities linked to the transport of radioactive substances;
- ASN-approved laboratories and organisations:
  - 3 laboratories approved for taking environmental radioactivity measurements,
  - 5 organisations approved for measuring radon,
  - 7 organisations approved for radiation protection controls.

In 2019, ASN carried out 115 inspections in the Occitanie region, comprising 50 inspections in BNIs, 47 inspections in small-scale nuclear activities, 8 in the transport of radioactive substances and 10 concerning organisations and laboratories approved by ASN.

ASN also carried out 7.5 days of labour inspection at the Golfech NPP.

During 2019, 1 significant event rated level 2 on the INES scale and 3 events rated level 1 were reported by nuclear installation licensees in Occitanie. In small-scale nuclear activities, 4 significant radiation protection events rated level 1 on the INES scale were reported to ASN.

In the exercise of their oversight duties, the ASN inspectors issued one violation report to a nuclear licensee and gave the Paul Sabatier University of Toulouse formal notice to remove its most intensely irradiating sources and nuclear waste within one year (see chapter 8).

Golfech nuclear power plant

The Golfech NPP operated by EDF is located in the Tarn-et-Garonne *département*, 40 km west of Montauban. This NPP comprises two 1,300 MWe pressurised water reactors. Reactor 1 constitutes BNI 135 and reactor 2 BNI 142.

ASN considers that the environmental protection performance of the Golfech NPP is in line with its general assessment of EDF performance, but that its radiation protection performance falls short of this general assessment. The nuclear safety performance, for its part, is significantly below ASN's general assessment for the nuclear fleet. ASN considers that enhancing nuclear safety performance must be a priority for the licensee; it will monitor this closely in 2020.

In the area of nuclear safety, the quality of operating actions continued to deteriorate in 2019. ASN conducted a week-long in-depth inspection which highlighted a systemic lack of rigour. ASN considers that improving performance in this area must be an absolute priority for the licensee. The lack of rigour was also observed in the area of maintenance. ASN also considers that the opinion of the independent safety organisation is not sufficiently taken into consideration by the NPP's senior management. The year 2019 was marked by the reporting of numerous significant safety events. Eight events occurred during the scheduled outage of reactor 2, one of which was rated level 2 on the INES scale.

With regard to worker radiation protection, ASN considers that control of the radiological cleanliness of potentially contaminated premises must be improved rapidly. Deficiencies were again observed in the preparation and performance of activities presenting high radiation exposure risks.

With regard to environmental protection ASN considers that the licensee must make progress in the prevention of environmental releases, particularly in the detection of hazardous substance leaks and the control of equipment contributing to the containment of these substances on site.

In the area of labour inspection, ASN conducted specific investigations further to workplace accidents or notable situations, which led, for example, to a request to verify the electrical installations. ASN kept tracks on the conformity files of the heavy cranes and the ventilation of premises with specific pollution characteristics. In collaboration with the Regional Directorate for Enterprises, Competition, Consumption, Labour and Employment (Direccte), ASN identified poor control of the asbestos risk.

MARCOULE PLATFORM

The Marcoule nuclear platform is situated to the west of Orange in the Gard *département*. Its six 6 civil installations are dedicated to research activities relating to the downstream part of the fuel cycle and the irradiation of materials, and to industrial activities concerning in particular the fabrication of mixed oxyde fuel (MOX), the processing of radioactive waste and the irradiation of materials. The majority of the site is occupied by defence nuclear installations.

CEA Marcoule centre

Created in 1955, the The French Alternative Energies and Atomic Energy Commission (CEA) Marcoule centre accommodates three civil installations: the Atalante laboratories (BNI 148), the Phénix NPP (BNI 71) and the Diadem storage facility (BNI 177).

Atalante facility – *CEA Centre*

The main purpose of the Atalante facility, created in the 1980s, is to conduct research and development concerning the recycling of nuclear fuels, the management of ultimate waste, the exploration of new concepts for fourth generation nuclear systems. Developments were made in 2017 to extend the research activities by accommodating the activities and equipment of the Lefca (Laboratory for Research and Fabrication of Advanced Nuclear Fuels), transferred from the CEA Cadarache centre.

In December 2016, the CEA submitted the facility's periodic safety review report to ASN. The conclusions of this report were examined by the Advisory Committee for Laboratories and Plants (GPU) on 19 June 2019. ASN considers that the performance of the periodic safety review of the facility and the resulting plan of action are relatively robust. The licensee must nevertheless improve its control of the fire risk.

ASN considers that the level of safety of Atalante is relatively satisfactory. The licensee must nevertheless make improvements in the performance of the periodic checks and tests, the monitoring of outside contractors and waste management. ASN moreover carried out an in-depth analysis of an event that occurred on 19 December 2018 which led to the shattering of a vial containing a radioactive liquid while being handled in a glove box. The event injured the person who was handling the vial. ASN asked the licensee to analyse the root causes of this incident, rated level 1 on the INES scale, focusing particular attention on the reagents that caused the explosion and the social, organisational and human factors behind the event. The premises concerned are padlocked pending the results of this analysis.

Phénix reactor – *CEA Centre*

The Phénix reactor is a demonstration fast breeder reactor cooled with liquid sodium. This reactor, with an electrical power rating of 250 MWe, was definitively shut down in 2009 and is currently being decommissioned.

The major decommissioning phases are regulated by Decree 2016-739 of 2 June 2016. ASN resolution 2016-DC-0564 of 7 July 2016 sets various decommissioning milestones and operations for the CEA.

In 2019, the licensee continued the actions to meet the ASN requirements and the commitments it made further to the periodic safety review.

ASN considers that the level of nuclear safety and radiation protection of the Phénix reactor is relatively satisfactory. Improvements are more particularly required in the management of the fire risk, the monitoring of outside contractors, and the analysis of the organisational causes of significant events. Removal of the irradiated fuels and dismantling of equipment continued in 2019 under generally satisfactory conditions of safety, but at a slower rate than planned as far as fuel removal is concerned, due to technical incidents. Construction of the NOAH facility, which will treat the sodium from Phénix and other CEA installations, progressed in 2019 and the first operating tests were carried out. The commissioning file for this facility is to be submitted in 2020.

Diadem facility – *CEA Centre*

The Diadem facility, currently under constructions, shall be dedicated to the storage of containers of radioactive waste emitting beta and gamma radiation, or waste rich in alpha emitters, pending construction of facilities for the disposal of long-lived waste, or low and intermediate-level short-lived wastes whose characteristics –especially the dose rate– means they cannot be accepted as-is by the Aube repository (CSA).

After partial suspension of the construction work (apart from civil engineering work) in 2018 for budgetary reasons, the majority of the work packages resumed their activity in January 2019. Submission of the commissioning file for this facility is planned in 2020.

ASN considers that worksite management is satisfactory. It underlines that this facility is to play a key role in the overall decommissioning and waste management strategy of the CEA, and that the CEA must consider the operations necessary for its commissioning to be a priority. It is to be noted that a request to modify the creation authorisation decree will be necessary in order to change the package closure technology with the aim of reducing the fire risk in the facility.

Assessment of the CEA Marcoule centre

ASN considers that the level of nuclear safety and radiation protection of the CEA Marcoule centre is relatively satisfactory. With regard to environmental protection, the licensee is deploying an action plan to bring the centre's piezometers into compliance with the Order of 11 September 2003.

ASN considers that the management of on-site transport operations at the Marcoule centre and the local emergency organisation are on the whole satisfactory.

In the context of the stress tests carried out further to the Fukushima Daiichi NPP accident, the CEA Marcoule centre in 2018 submitted an update of its file relative to the planned work to reinforce the centre's emergency management building against the tornado risk. The ongoing examination of this file will endeavour to assess the impact of these reinforcements on the seismic resistance of the buildings and the demonstration of habitability and accessibility of the premises in the different potential accident situations. At the joint request of ASN and Defence Nuclear Safety Authority (ASND), an expert assessment of the seismic site effects specific to the Marcoule site is being carried out.

Melox plant

Created in 1990 and operated by Orano Cycle, the Melox plant (BNI 151) produces MOX fuel which consists of a mix of uranium and plutonium oxides.

ASN considers that the level of nuclear safety and radiation protection of the Melox plant remains satisfactory.

The containment barriers, on which a large part of the safety case is based, are effective and robust.

The radiation exposure risks in the facility are addressed with rigour, and the licensee is continuing the work to improve dosimetry in the context of ageing facilities and the necessary optimisation of work stations. In 2019, the licensee deployed a major plan for preventive maintenance of equipment and increasing the reliability of the production facilities, which had a positive impact on the dosimetry in the medium term. In 2019, ASN also observed substantial research and development work on techniques for measuring and evaluating the dose at the lens of the eye and on lens-of-the-eye protection devices that are adapted to the facility, to take into account the lowering of the regulatory limit of exposure of the crystalline lens for workers to 20 mSv/year (millisieverts per year) as of 1 July 2023.

Prevention of the criticality risk in this facility is a major concern for the licensee and ASN, notably with the consideration of social, organisational and human factors in the operational aspects and in the maintenance operations.

With regard to integration of the lessons learned from the Fukushima Daiichi NPP accident, the improvements required by ASN are currently being implemented. Commissioning of the new emergency command post will take place later than initially planned due to technical and contractual difficulties with the prime contractor. On the basis of compensatory measures proposed by the licensee, ASN revised the commissioning deadline, pushing it back to September 2020 by ASN resolution 2019-DC0678 of 16 July 2019.

2019 was also marked by a failure to meet production targets in the Melox plant (see chapter 11).

Centraco plant

The Centraco plant (BNI 160), was created in 1996 and is operated by Cyclife France, a 100% 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 resulting from the plant's processes is then routed to Andra's Aube respository (CSA). 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; and
- storage areas.

ASN considers that the level of nuclear safety and radiation protection in the facility is on the whole satisfactory. The licensee must nevertheless comply with the provisions of ASN resolution 2017-DC-0592 of 13 June 2017 relative to the obligations of BNI licensees with regard to emergency situation preparedness and management and the content of the on-site emergency plan, and improve its in-service monitoring of pressure equipment.

In 2019, the licensee submitted a facility modification request to the competent administrations (ASN, the Minister responsible for nuclear safety and the Prefect of the Gard), with a view to widening the range of waste that can be treated by the facility. The examination of this request has revealed shortcomings concerning the nature of the waste treated and consideration of the flood risk, making it necessary to revise the project.

Gammatec ioniser

The Gammatec ioniser (BNI 170), is an industrial irradiator operated by the company Stéris since 2013. Gammatec treats products by ionisation (emission of gamma radiation) with the aim of sterilising them or improving their performance. The installation consists of an industrial bunker and an experimental bunker. Both bunkers contain sealed sources of cobalt-60 which provide the radiation necessary for the facility's activity.

ASN considers that the level of nuclear safety and radiation protection of Gammatec remained satisfactory in 2019. The licensee must nevertheless improve the management of the facility's radioactive sources and of emergency situations, as much with regard to safety as to the security of the sources.

Écrin facility

The Écrin facility (BNI 175), is situated within the Malvési plant operated by Orano Cycle in the municipality of Narbonne in the Aude *département*. The Malvési plant transforms the concentrates from the uranium mines into uranium tetrafluoride, which represents the first step in the fabrication of a uranium-based nuclear fuel (excluding extraction of the ore). The transformation process produces liquid effluents containing nitrated sludges loaded with natural uranium, which are decanted and evaporated in lagoons in the facility. The entire Malvesi plant is subject to the system governing Seveso high-threshold Installations Classified for Protection of the Environment.

The Écrin BNI is made up by the plant's two legacy sludge storage basins (B1 and B2), which stopped being used in the process in 2004 following failure of the basin B2 embankment. These two basins are classified as a BNI due to the presence of traces of artificial radionuclides resulting from the treatment of reprocessed uranium from the Marcoule site. The Écrin BNI was authorised by Decree of 20 July 2015 for the storage of radioactive waste for a period of 30 years with a volume of waste not exceeding 400,000 m^3 and total radiological activity of less than 120 TBq (terabecquerels).

Commissioning of the installation was authorised by ASN resolution 2018-DC-0645 of 12 October 2018, which enabled the licensee, in 2019, to start the work specified in the authorisation decree, such as the creation of a compartment to the south of basin B2, the end-purpose of which is to store materials coming from the emptying of basins B5 and B6. Once all this work is completed, a bituminous cover will be put in place over the BNI basins.

Furthermore, in the French National Radioactive Material and Waste Management Plan (PNGMDR), ASN asked Orano Cycle to study the various long-term disposal options for the waste contained in the Écrin facility. These studies are currently being examined.

ASN considers that the level of nuclear safety and environmental protection of the Écrin facility is satisfactory. It considers that the anomalies affecting the west embankment of basin B1 were addressed appropriately.

Pays de la Loire region

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:

- Basic Nuclear Installations:
  - the Ionisos irradiator in Sablé-sur-Sarthe,
  - the Ionisos irradiator in Pouzauges;

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- small-scale nuclear activities in the medical sector:
  - 7 external-beam radiotherapy departments,
  - 2 brachytherapy departments,
  - 11 nuclear medicine departments,
  - 39 centres performing fluoroscopy-guided interventional procedures,
  - 53 computed tomography scanners,
  - some 2,500 medical and dental radiology devices;

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- small-scale nuclear activities in the veterinary, industrial and research sectors:
  - 1 cyclotron,
  - 23 industrial radiography companies, including 7 gamma radiography contractors,
  - some 400 industrial and research equipment licenses;

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- activities linked to the transport of radioactive substances;
- ASN-approved laboratories and organisations:
  - 6 agencies approved for radiation protection controls,
  - 13 organisations approved for measuring radon,
  - 1 head-office of laboratories approved for environmental radioactivity measurements.

In 2019, ASN carried out 56 on-site inspections comprising 1 in the Ionisos facility in Pouzauges, 48 inspections in small-scale nuclear activities and 7 inspections in the transport of radioactive substances.

In 2019, one significant event was rated level 2 on the INES scale (exposure of a worker) and one rated level 1.

Ionisos irradiator

The company Ionisos operates two industrial ionisation installations, on the sites of Pouzauges (Vendée *département*) and Sablé-sur-Sarthe (Sarthe *département*). These installations, constituting BNI 146 and 154 respectively, use high-activity cobalt-60 sealed radioactive sources.

The gamma radiation emitted is used to sterilise, destroy pathogenic germs or reinforce (by cross-linking) the technical properties of certain polymers, by exposing the products to be ionised (single-use medical equipment, packaging, raw materials and finished productions for the pharmaceutical and cosmetic industries, packing films) for a pre-determined length of time.

The installation comprises a pool for underwater storage of the radioactive sources which is surmounted by a bunker in which the ionisation operations are performed, premises for storing the products before and after treatment, offices and technical rooms.

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 its examination of the periodic safety review reports of the two irradiators in 2019.

Polluted sites and soils and mining sites

ASN assists the Regional Directorates for the Environment, Planning and Housing (Dreal) regarding polluted sites and soils and mining sites. With regard to the sites in public areas where uranium-bearing mining waste rock was reused, the 10 Pays de la Loire areas concerned by the priority works have been treated (partial or complete removal of the mining waste rock). The Écarpière site (Loire-Atlantique *département*) also received materials radiologically contaminated by mine water from the old uranium-bearing mines in Bretagne.

Provence Alpes-Côte d'Azur region

The Marseille division regulates nuclear safety, radiation protection and the transport of radioactive substances in the 6 *départements* of the Provence-Alpes-Côte d'Azur region.

THE INSTALLATIONS AND ACTIVITIES TO REGULATE COMPRISE:

- Basic Nuclear Installations:
  - the CEA Cadarache research centre which counts 21 civil BNIs, including the Jules Horowitz Reactor currently under construction,
  - the ITER installation construction site, adjacent to the CEA Cadarache centre,
  - the Gammaster industrial ioniser;

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- small-scale nuclear activities in the medical sector:
  - 12 external-beam radiotherapy departments,
  - 4 brachytherapy departments,
  - 17 nuclear medicine departments,
  - 106 centres performing fluoroscopy-guided interventional procedures,
  - 106 computed tomography scanners,
  - some 8,200 medical and dental radiology devices;

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- small-scale nuclear activities in the veterinary, industrial and research sectors:
  - about 800 industrial and research centres, including 3 cyclotron particle accelerators and 21 companies with an industrial radiography activity,
  - about 300 veterinary surgeries or clinics practising diagnostic radiology;

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- activities linked to the transport of radioactive substances;
- ASN-approved laboratories and organisations:
  - 2 laboratories approved for taking environmental radioactivity measurements,
  - 8 organisations approved for measuring radon,
  - 5 organisations approved for radiation protection controls.

In 2019, ASN carried out 125 inspections in the PACA region, comprising 57 inspections in BNIs, 52 inspections in small-scale nuclear activities, 5 in the transport of radioactive substances and 11 concerning organisations and laboratories approved by ASN.

During 2019, three significant events rated level 1 on the INES scale were reported by nuclear installation licensees.

In small-scale nuclear activities, six significant events rated level 1 on the INES scale were reported to ASN.

In the exercise of their inspection duties, the ASN inspectors gave one BNI licensee formal notice to comply with the regulations concerning operating experience feedback and the designation of activities and equipment important to nuclear safety and their specified requirements.

CADARACHE SITE

CEA Cadarache centre

Created in 1959, the CEA Cadarache centre is situated in the municipality of Saint-Paul-lez-Durance in the Bouches-du-Rhône *département*, and covers a surface area of 1,600 hectares. This site focuses its activity primarily on nuclear energy and, as concerns its civil installations in operation, on research and development to support and optimise the existing reactors and the design of new-generation systems.

The following BNIs are located on the site:
- the Pégase-Cascad installation (BNI 22);
- the Cabri research reactor (BNI 24);
- the Rapsodie research reactor (BNI 25);
- the Solid Waste Treatment Station (STD - BNI 37-A);
- the Active Effluent Treatment Station (STE, BNI 37-B);
- the Plutonium Technology Facility (ATPu, INB 32);
- the Masurca research reactor (BNI 39);
- the ÉOLE research reactor (BNI 42);
- the enriched Uranium Processing Facilities (ATUe, BNI 52);
- the Central Fissile Material Warehouse (MCMF, BNI 53);
- the Chemical Purification Laboratory (LPC, BNI 54);
- the High-Activity Laboratory LECA-STAR (BNI 55);
- the solid radioactive waste storage area (BNI 56);
- the Phébus research reactor (BNI 92);
- the Minerve research reactor (BNI 95);
- the Laboratory for research and experimental fabrication of advanced nuclear fuels (Lefca, BNI 123);
- the Chicade laboratory (BNI 156);
- the Cedra storage facility (BNI 164);
- the Magenta storage warehouse (BNI 169);
- the Effluent advanced management and processing facility (Agate, BNI 171);
- the Jules Horowitz Reactor (RJH, BNI 172) under construction.

At the Cadarache centre, 10 installations are in final shutdown status, 10 are in operation and one is under construction. The CEA Cadarache centre operates numerous installations which vary in their nature and their safety implications. ASN has moreover started or is continuing the examination of the periodic safety review guidance files or the conclusion reports for 16 of the 21 installations: Pégase-Cascad, Cabri, Rapsodie, STE, ATPu, ÉOLE, ATUe, MCMF, LPC, LECA-STAR, the waste storage area, Phébus, Minerve, Chicade, Cedra and Magenta. When examining these reports, ASN is particularly attentive to the robustness of the proposed and deployed action plans. It ensures that the installations are in conformity with the applicable regulations and that the risks and adverse effects are effectively controlled.

Pégase-Cascad facility – *CEA Centre*

The Pégase reactor was commissioned on the Cadarache site in 1964 and was operated for about ten years. The French Alternative Energies and Atomic Energy Commission (CEA) was authorised by a Decree of 17 April 1980 to reuse the Pégase facility (BNI 22) for the storage of radioactive substances, in particular spent fuel elements in a pool.

This facility, which does not meet current safety requirements for storage facilities, has received no more radioactive substances for storage since 2008 and has removed a large part of its source term[1]. The decommissioning file for the facility, whose final shutdown is planned for the end of 2023, was submitted in 2019. Some specific removal-from-storage operations shall be subject to ASN authorisation.

The CEA is effectively significantly behind schedule in the Pégase removal-from-storage operations, initially prescribed in ASN resolution CODEP-CLG-2017-006524 of 10 February 2017. Technical difficulties led the CEA to request the modification of these prescriptions to set 2035 as the deadline for completion of the removal-from-storage operations in Pégase. ASN is currently examining this request.

The Cascad facility, authorised by a Decree of 4 September 1989 modifying the Pégase facility and operated since 1990, is dedicated to the dry storage of irradiated fuel in wells.

ASN's assessment of nuclear safety and radiation protection in the Pégase and Cascad facilities in 2019 finds them to be relatively satisfactory. The CEA must nevertheless improve the monitoring of the action plan established further to the last periodic safety review of the facility.

Cabri research reactor – *CEA Centre*

The Cabri reactor (BNI 24), created on 27 May 1964, was designed for conducting experimental programmes aiming to achieve a better understanding of the behaviour of nuclear fuel in the event of a reactivity accident. The reactor has been equipped with a pressurised water loop since 2006 in order to study the behaviour of the fuel at high combustion rates in accident situations of increasing reactivity in a pressurised water reactor. Since January 2018, the CEA has been conducting a programme of tests called "CIP" (Cabri International Program), which began in the early 2000's and necessitated substantial modification and safety upgrading work on the facility.

The year 2019 was devoted to the ten-yearly requalification of the reactor's pressurised water loop, in view of the next cycle of tests planned for 2020.

In 2019, ASN started the examination of a request to modify the creation authorisation decree for Cabri, submitted by the CEA with a view to having authorisation to irradiate electronic equipment in the Cabri reactor.

*1. The Potential Source Term (TSM is the French acronym for "*terme source mobilisable*") corresponds to the quantity of radioactive activity that could be involved in an incident or accident.*

ASN considers that the level of nuclear safety and radiation protection of the Cabri reactor is satisfactory.

Rapsodie research reactor – *CEA Centre*

The Rapsodie reactor (BNI 25) is the first sodium-cooled fast neutron reactor built in France. It operated from 1967 to 1978. A sealing defect in the reactor pressure vessel led to its final shutdown in 1983. Decommissioning operations were subsequently undertaken, but have been partially stopped further to a fatal accident in 1994 during the washing of 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 is contained. The reactor pool has been emptied, partially cleaned out and decommissioned and the waste containing sodium has been removed.

Examination of the decommissioning file of BNI 25, submitted by the licensee at the end of 2014 and supplemented in 2016, is in progress. The licensee is continuing the clean-out and decommissioning preparation work in parallel.

ASN considers that the level of safety of Rapsodie in 2019, particularly concerning waste management, is on the whole satisfactory. The licensee must nevertheless improve the monitoring of outside contractors and of the fire loads present in the facility.

Solid Waste Treatment Station – *CEA Centre*

BNI 37 of CEA Cadarache historically comprised the Effluent Treatment Station (STE) and the Waste Treatment Station (STD), grouped into a single installation. As the CEA wishes to ensure continued operation of the STD and proceed with the final shutdown of the STE, BNI 37 was divided into two BNIs: 37-A (STD) and 37-B (STE) by ASN resolutions CODEP-DRC-2015-027232 and CODEP-DRC-2015-027225 of 9 July 2015. These records were made further to the Orders of 9 June 2015 defining the perimeters of these two BNIs.

At present, the STD is the CEA's only civil BNI licensed for the packaging of ILW-LL (intermediate-level, long-lived) radioactive waste before it is stored in the Cedra facility (BNI 164) pending transfer to a deep geological repository. This situation makes the STD an indispensable part of the CEA's decommissioning and waste management strategy. The continued operation and long-term durability of the STD necessitates renovation work which was prescribed in 2016, at the end of its second periodic safety review, by ASN Chairman's resolution CODEP-CLG-2016-015866 of 18 April 2016. In the meantime, compensatory measures concerning more specifically the limiting of the quantities of radioactive substances in the facility and fire protection, are applied.

Following an event involving the falling of a package of moderately irradiating waste in the facility on 25 October 2017, which was not reported to ASN until July 2018 and led to an inspection, ASN gave the CEA formal notice through resolution CODEP-MRS-2019-011621 of 19 March 2019, to comply with the provisions of Articles 2.4.1 and 2.5.1 to 2.5.3 of the Order of 7 February 2012 respectively with regard to the preparation of operating experience feedback and the identification of activities important to protection for the operation of BNI 37-A. ASN also required the CEA, through resolution CODEP-MRS-2019-026031 of 23 July 2019, to submit to it:

- a review of the conditions of retrieval of the damaged package jammed in the well bottom;
- the guarantee that no damaged packages can have been stored in the Cedra facility;
- a regular report on the processes for detecting, examining and addressing all safety deviations in the facility and, where applicable, reporting them to ASN;
- a verification of compliance with the regulations concerning the use of subcontracting in BNI 37-A;
- an analysis of the root causes of this event, particularly regarding social, organisational and human factors;
- a third-party analysis of its organisation concerning the information and decision-making processes related to safety.

ASN conducted an inspection on 26 November 2019 to verify compliance with these requirements. ASN concluded that the CEA had taken proper account of the requirements of the compliance notice, subject to the provision of additional information concerning experience feedback on the use of a suction-cup pick-up system, which will be examined in 2020.

The CEA's action plan for improvement with regard to safety culture and operating rigour is found on the whole to be satisfactory. ASN expects a strong commitment from the CEA to take into account all the requirements of its resolutions, and the improvement actions stemming from its action plan, in order to improve the level of safety of BNI 37-A and the organisational processes at the CEA, in the short-term and lastingly, in order to ensure the rigour necessary for the operation of this type of BNI, which is pivotal to the CEA's decommissioning and waste management strategy.

ASN also continued the examination of the facility modification request submitted by the CEA with a view to improving the facility's resistance to external hazards. This ongoing examination has required ASN to make several additional information requests, more specifically to check the earthquake resistance of the renovated facility.

Active Effluents Treatment Station – *CEA Centre*

The STE (BNI 37-B) has been shut down since 1 January 2014. The CEA has requested the modification of a prescription in order to push back the deadline for submission of the decommissioning file for this facility, in view in of the complexity of the facility and the time required to characterise the soils and equipment before starting decommissioning. ASN is currently examining this postponement request.

ASN considers that the level of safety of BNI 37-B in 2019 is on the whole satisfactory. With regard to environmental protection, the results of the soil characterisation carried out for the preparation of the facility decommissioning file and the data resulting from the monitoring of discharges led the licensee in 2018 and 2019 to report several significant events to ASN relative to the presence of artificial radionuclides in the networks and in the stormwater coming from the facility. The treatment of these contaminations and stormwater management are covered by a CEA action plan, for which ASN has issued additional information requests.

Plutonium Technology Facility (ATPu) and Chemical Purification Laboratory (LPC)

– CEA Centre

The ATPu (BNI 32) produced plutonium-based fuel elements intended for fast neutron or experimental reactors as from 1967, then, from 1987 until 1997, for pressurised water reactors using mixed oxyde (MOX) fuel. The activities of the LPC (BNI 54) were associated with those of the ATPu: physical-chemical verifications and metallurgical examinations, treatment of effluents and contaminated waste. The two facilities were shut down in 2003 and are currently undergoing decommissioning.

Removal of the waste and materials from the facilities continued in 2019. The decommissioning of the cryogenic waste processing unit of the LPC, as well as certain legacy waste repackaging and removal operations, have fallen behind schedule.

ASN considers that the level of nuclear safety and radiation protection of the facilities in 2019 is on the whole satisfactory. Improvements are still required in the monitoring of the facility's periodic checks and tests.

Masurca research reactor *– CEA Centre*

The Masurca reactor (BNI 39), whose construction was authorised by a Decree of 14 December 1966, was intended for neutron studies, chiefly on the cores of fast neutron reactors, and the development of neutron measurement techniques. The reactor has been shut down since 2007.

The licensee is preparing the installation decommissioning file, which must be submitted before the end of December 2020, following the declaration of final shutdown of the installation on 31 December 2018. Decommissioning preparation work, such as asbestos removal from the premises, is in progress.

The situation of the Masurca reactor in terms of nuclear safety and radiation protection in 2019 is satisfactory on the whole.

ÉOLE and Minerve research reactors

– CEA Centre

The experimental ÉOLE and Minerve reactors are very-low-power (less than 1 kilowatt) critical mock-ups that were used for neutron studies, in particular to evaluate the absorption of gamma rays or neutrons by materials.

The ÉOLE reactor (BNI 42), whose construction was authorised by a Decree of 23 June 1965, was intended primarily for neutron studies of moderated arrays, in particular those of pressurised water reactors and boiling water reactors. The Minerve reactor (BNI 95), whose transfer from the Fontenay-aux-Roses studies centre to the Cadarache studies centre was authorised by a Decree of 21 September 1977, is situated in the same hall as the ÉOLE reactor. Teaching and research activities were carried out on these mock-ups until their final shutdown on 31 December 2017.

ASN continued the examination of the decommissioning files for these reactors in 2019. Pending decommissioning, operations in preparation for decommissioning, such as the removal of radioactive and hazardous substances, took place in 2019.

ASN considers that the level of nuclear safety and radiation protection of the ÉOLE and Minerve reactors in 2019 is on the whole satisfactory. ASN has nevertheless observed a drift in the schedule of certain decommissioning preparation operations, even though the licensee had given its commitment. In 2019, the licensee reported one significant event relative to the control of criticality.

The enriched Uranium Processing Facilities (ATUe) *– CEA Centre*

From 1963 to 1995, the ATUe (BNI 52) converted UF_6 (uranium hexafluoride) from the enrichment plants into sinterable oxide, and ensured the chemical reprocessing of waste from the manufacture of fuel elements. Decommissioning of this facility was authorised by Decree in February 2006.

The licensee is seriously behind schedule in these decommissioning operations, mainly due to the poor assessment of the radiological condition of the installation prior to the first decommissioning operations. On this account, in 2010 the licensee requested a modification to its decree to take account of the actual radiological condition of the installation, which led to several additional information requests. A new file must be submitted to provide clarifications on the characterisation of the final state and the planned steps to validate the in-depth clean-out of the facility. The only activities authorised today in the facility are the clean-out of the soils and the maintenance operations governed by periodic and regulatory checks.

The level of nuclear safety and radiation protection of the ATUe facilities in 2019 is on the whole satisfactory.

Central Fissile Material Warehouse (MCMF)

– CEA Centre

Created in 1968, the MCMF (BNI 53) was a warehouse for storing enriched uranium and plutonium until its final shutdown and the removal of all its nuclear materials on 31 December 2017. The licensee submitted its decommissioning file in November 2018, and ASN is currently examining it. The decommissioning preparation operations, notably the chemical and radiological characterisations of the facility, continued in 2019.

High-activity laboratory LECA-STAR
– CEA Centre

The Active Fuel Examination Laboratory (LECA-BNI 55) and the Treatment, Clean-out and Reconditioning Station (STAR) –an extension of LECA, constitute expert assessment tools used by the CEA for the analysis of spent fuels. Commissioned in 1964, the LECA laboratory enables the 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 old, it was partially reinforced in the early 2010's to ensure its earthquake resistance.

Commissioned in 1999, the STAR facility is an extension of the LECA laboratory, designed for the stabilisation and reconditioning of spent fuel.

The CEA gave ASN the periodic safety review reports for the LECA facility in June 2014 and for STAR in February 2018. With regard to the LECA facility, ASN submitted a draft resolution on continued operation for consultation by the public and the licensee at the end of 2019, which makes continued operation conditional on conducting work to improve control of the risks associated with earthquakes, fire, lightning and flooding, while at the same time limiting the potential source term of the facility in an accident situation.

Furthermore, as the LECA's resistance to the "safe shutdown earthquake" potential is not guaranteed today, the CEA proposed a strategy to ASN in 2019 to ensure the durability of this facility. ASN is currently examining this strategy.

ASN considers that the level of nuclear safety and radiation protection of BNI 55 in 2019 is on the whole satisfactory. ASN nevertheless remains vigilant with regard to the consideration of social, organisational and human factors in the operation of the facility.

Solid radioactive waste storage area
– CEA Centre

BNI 56, declared in January 1968 for the disposal of waste, is used for storing legacy solid radioactive waste from the Cadarache centre. It comprises 3 pools, 6 pits, 5 trenches and hangars, which contain in particular intermediate-level long-lived waste (ILW-LL) from the operation or decommissioning of CEA installations.

Major legacy waste retrieval and packaging work continued in 2019, including the finalisation of the operations to retrieve low-level waste (LLW) from the cells of the F3 pit and measurement of the drums of bulk waste in the H4 hangar. ASN also continued examining the facility decommissioning file which was submitted in 2018, and asked the CEA for substantial amounts of additional information.

ASN considers that the level of nuclear safety and radiation protection of BNI 56 has progressed markedly over the last few years and has reached a satisfactory level. With regard to environmental protection, given the operating background and the radiological contamination of certain zones of the facility, ASN has asked the CEA to produce an action plan to ensure compliance with the stormwater management procedures in order to prevent the facility from causing any off-site pollution. In 2019, the CEA started taking steps to improve its stormwater management system, but further measures are still required.

Furthermore, BNI 56 is one of the priorities identified by the CEA in its new decommissioning and waste management strategy (see chapter 13). ASN will therefore be attentive to the progress of the actions aiming to reduce as far as possible the risks and adverse effects that the facility presents for the environment.

Phébus research reactor *– CEA Centre*

The Phébus reactor (BNI 92) is a pool experimental reactor with a power rating of 38 megawatt thermal (MWth) (megawatt thermal) which functioned from 1978 to 2007. Phébus was designed for the study of serious accidents affecting light water reactors and for defining operating procedures to prevent core melt-down or to mitigate its consequences.

The licensee submitted its decommissioning file to ASN in February 2018, and it is currently being examined, jointly with its periodic safety review report submitted in 2017. Removal of the spent fuel from the reactor, which was one of the priorities of the decommissioning preparation operations, was completed in January 2019.

ASN considers that the nuclear safety and radiation protection of the Phébus installation for 2019 is on the whole satisfactory. It notes an improvement in the monitoring of outside contractors.

Laboratory for research and experimental fabrication of advanced nuclear fuels (Lefca) *– CEA Centre*

Commissioned in 1983, the Lefca (BNI 123) was a laboratory designed for conducting studies on plutonium, uranium, actinides and their compounds, which carried out studies aimed at understanding the behaviour of these materials in the reactor and in the various stages of the fuel cycle. In 2018, the Lefca finalised the transfer of part of its research and development equipment to the Atalante laboratories (BNI 148) of Marcoule.

The CEA sent the final shutdown declaration for the facility in April 2019 and submission of its decommissioning file is planned for 2021.

The electrical renovation work planned for after the last periodic safety review of the facility, further to which technical requirements were issued by ASN in resolution CODEP-CLG-2018-034301 of 5 July 2018 governing the continued operation of the facility, was carried out in 2019.

ASN considers that the level of nuclear safety and radiation protection of the facility is relatively satisfactory. Improvements are required in the monitoring of outside contractors and control of the fire risk.

Chicade laboratory – *CEA Centre*

Since 1993, the Chicade facility (BNI 156) has been conducting research and development work on low and intermediate-level objects and waste, chiefly involving:

- 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 expert assessment and inspection of waste packages packaged by the waste producers.

ASN considers that the level of nuclear safety and radiation protection of Chicade is on the whole satisfactory. With regard to environmental protection, the CEA has undertaken to review the impact study of its facility to take into account the gaseous discharges of tritium which were not provided for in its baseline requirements, and to submit a request to modify the facility creation decree once the ongoing examination of the facility's periodic safety review file is completed.

Cedra storage facility – *CEA Centre*

Since 2006, the Cedra facility (BNI 164) processes intermediate-level long-lived waste (ILW-LL) pending the creation of appropriate disposal routes. The CEA forecasts that this facility will be filled to capacity by 2027. The studies concerning a project to double the storage capacity should start in 2020.

The CEA sent ASN the periodic safety review report for the facility in November 2017, and ASN is currently examining it. The licensee has been asked for additional information concerning the conformity check of the facility's baseline requirements and the external hazards.

ASN considers that the level of nuclear safety and radiation protection of Cedra is on the whole satisfactory. ASN remains particularly attentive to compliance with the requirements of resolution CODEP-MRS-2019-026031 of 23 July 2019 relative to the incoming inspections and examination of the packages from BNI 37-A which are stored in the facility.

Magenta storage warehouse – *CEA Centre*

The Magenta facility (BNI 169), which replaces the MCMF currently being decommissioned, has been dedicated since 2011 to the storage of non-irradiated fissile material and the non-destructive characterisation of the nuclear materials received.

In 2019, the examination of the commissioning authorisation application for the glove boxes, submitted in 2018, led to a refusal decision on account of the shortcomings in the supporting file, particularly regarding the prevention of criticality risks and the exhaustiveness of the list of items important to control of the fire risk in these glove boxes.

ASN considers that the level of nuclear safety and radiation protection of the facility is relatively satisfactory. The CEA must nevertheless improve operating rigour, in particular regarding compliance with radiation protection requirements and the formal tracking of modifications. In view of the personnel changes, particular attention must be given to maintaining skills.

Effluent advanced management and processing facility (Agate) – *CEA Centre*

The Agate facility (BNI 171), commissioned in 2014 to replace BNI 37-B which is now shut down, uses an evaporation process to concentrate radioactive liquid effluents containing mainly beta- and gamma-emitting radionuclides.

The regulatory operations for the ten-yearly requalification of the evaporator, which a nuclear pressure equipment item, were completed in early 2019, after the licensee had met with difficulties in 2018 through the unexpected discovery of deposits on the internal surfaces of the tank. Evaporation operations resumed in September 2019.

ASN considers that the level of nuclear safety, radiation protection and environmental protection in the Agate facility is on the whole satisfactory.

Jules Horowitz Reactor project – *CEA Centre*

The Jules Horowitz Reactor (RJH-BNI 172), under construction since 2009, is a pressurised-water research reactor designed to study the behaviour of materials under irradiation and of power reactor fuels. It will also allow the production of artificial radionuclides for nuclear medicine. Its power is limited to 100 MWth.

The year 2019, which saw the continuation of the facility construction work, was marked by the completion of installation of the reactor pool lining and the start of assembly of the reactor pile block elements, which will continue until 2021. In addition, the three primary/secondary heat exchangers were introduced into the dedicated bunker of the reactor building in the second half of 2019. The lining of the pools and channels of the nuclear auxiliaries building is currently being installed. The off-site manufacture of large equipment items, which includes the reflector, is still in progress.

ASN considers that the nuclear safety requirements are taken properly into account in the construction of the facility and that the CEA's management of the construction worksite is satisfactory. Deviations are managed with rigour and efficiency.

Delays in construction and a third-party review of its project led the CEA to make a request to push back the commissioning deadline by 9 years with respect to the initial deadline of October 2019, a request which was authorised by a Decree of 10 October 2019 after receiving a favourable opinion from ASN, which considered in particular that the elements essential for the protection of people and the environment were not modified and that the CEA was implementing a procedure guaranteeing proper conservation of the equipment already installed or waiting to be installed on site. ASN will be attentive to the CEA's implementation of measures to maintain its technical skills for operating the reactor.

ITER

The International Thermonuclear Experimental Reactor installation (ITER-BNI 174), under construction on the Cadarache site since 2010 and adjacent to the CEA facilities, will be a fusion experimental reactor used for the scientific and technical demonstration of the control of thermonuclear fusion energy obtained by magnetic confinement of a deuterium-tritium plasma during long-duration experiments with a significant power level (500 MW developed for 400 seconds). 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.

The inspections of ITER Organisation –the nuclear licensee of the facility– conducted by ASN on the Cadarache site and in South Korea on the manufacturing site of some of the sectors of the vacuum chamber, conclude that the safety requirements are taken into account in a generally satisfactory manner by the entire chain of outside contractors, as from the facility design stage.

Assessment of the CEA Cadarache centre

ASN considers that the level of nuclear safety of the CEA Cadarache centre in 2019 is on the whole satisfactory. It does nevertheless note persistent disparities between the facilities of the centre.

ASN considers that the BNIs are operated satisfactorily on the whole, especially the control of the condition of the equipment, compliance with the operating baseline requirements and, more generally, the radiation protection measures taken by the senior management of the centre. Improvements are however expected in waste management and the control of fire risks.

Nuclear safety management is on the whole satisfactory, but, as in 2018, ASN considers that the sharing of experience feedback and good practices between facilities must be improved, as must the management of deviations. Moreover, despite a noted improvement in 2019, the licensee's monitoring of outside contractors and subcontractors shows contrasts; the activities carried out under contracts concerning the centre must be monitored with the same rigour as those carried out under contracts concerning the BNIs.

ASN considers that the organisation in place for the periodic safety reviews of the facilities in on the whole satisfactory. The extent to which the results of studies are taken on board or the human resources allocated to performing them seem nevertheless to vary from one BNI to another. ASN will be attentive to the application of the BNI periodic safety review action plans, particularly with regard to carrying out the work identified in the reviews.

ASN considers that the CEA ensures the on-site transport of radioactive substances at the Cadarache centre in a satisfactory manner. Improvements have been made in the centre's baseline requirements with regard to organization and support to the BNIs, particularly as concerns the maintenance of packages and vehicles.

With regard to emergency situation management, the CEA has initiated a plan of action to meet the requirements of ASN resolution 2017-DC-0592 of 13 June 2017. The main improvements achieved or under way concern the emergency management agreements signed with the outside organisations, the emergency exercises, the instruction and training of the personnel involved in emergency management and learning lessons from experience feedback.

With regard to the lessons learned from the Fukushima Daiichi NPP accident, in 2019 ASN authorised, in view of the compensatory measures put in place by the CEA, postponement of the construction of emergency situation management premises that are robust to extreme hazards until October 2023, given the CEA's project management difficulties.

ASN and ASND have made a position statement on the CEA's decommissioning and waste management strategy. This strategy leads to changes in the projects for facility renovation and the construction of new facilities for the CEA Cadarache centre, in favour of certain priority decommissioning work projects. ASN will nevertheless make sure that the CEA keeps the in-service facilities at the right operating level, while at the same time ensuring the progress of the priority decommissioning and legacy waste retrieval and packaging projects.

ASN considers that the radiation protection situation of the CEA centre is satisfactory.

Lastly, ASN observes that the level of environmental protection is relatively satisfactory. With regard to discharge management, the licensee has proposed an action plan to improve the management of stormwater in certain old BNIs (BNI 37-B and BNI 56 in particular) to comply with the requirements of the Order of 7 February 2012 and ASN resolution 2013-DC-0360 of 16 July 2013. ASN has asked that the plan be supplemented. With regard to monitoring of the environment, improvements are required in the representativeness of the measurement samples and the consideration of metrological uncertainties in the utilisation of the data. Furthermore, the laboratory performing the sample analyses for the non-radiological parameters must comply with standard 17025 in order to be able to continue its activity.

ASN is maintaining its focus on the quality of execution of this complex project and expects greater rigour in the assessment of the radiation protection issues. In effect, following ASN's discovery in December 2018 of the noncompliance with a defined requirement concerning the minimum thickness of a concrete wall, ASN and the licensee had technical discussions concerning the assessment of the radiological mappings in the facility. ASN considers that the licensee, at this stage, has not provided elements that can attest to its full control of radiation protection in the facility, even though the construction of the buildings is well advanced.

Gammaster ioniser

Since 2008, the company Stéris has been operating an industrial irradiator called Gammaster situated in the municipality of Marseille. Gammaster treats products by ionisation (emission of gamma radiation) with the aim of sanitising, sterilising or improving the performance of materials. The facility is made up of an industrial bunker and houses sealed sources of cobalt-60 which provide the radiation necessary for its activity.

ASN considers that the level of nuclear safety and radiation protection of Gammetec remained satisfactory in 2019. The licensee must nevertheless make progress in the area of emergency situation management, as much with regard to safety as to the security of the sources.

The examination of the periodic safety review report for the facility continued and culminated in 2019 in the publication of ASN Chairman's resolution CODEP-MRS-2019-048140 of 5 December 2019 governing the continued operation of the facility. Alongside this, ASN has also set requirements relative to the limits and methods of effluent management, water consumption and monitoring the environment of the facility through ASN Chairman's resolutions CODEP-MRS-2019-048718 and CODEP-MRS-2019-048719 of 11 December 2019.

01.

NUCLEAR ACTIVITIES: IONISING RADIATION AND HEALTH AND ENVIRONMENTAL RISKS

CHAPTER 01

Nuclear activities: ionising radiation and health and environmental risks

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 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 (...)*".

These nuclear activities include those carried out in Basic Nuclear Installations (BNIs) 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 2.

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. The state of knowledge of the hazards and risks associated with ionising radiation

Ionising radiation is defined as being capable producing ions –of 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 (external to the organism) or endogenous (resulting from cellular metabolism).

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

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

Cells can also repair the damage thus caused, although imperfectly or incorrectly. Of the damage that persists, that to DNA is of a particular nature because residual anomalies in the chromosomes 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 which appears after a variable lapse of time (5 to 20 years after exposure).

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 leukaemia, bronchopulmonary cancers (owing to radon inhalation) and jawbone sarcomas. Outside the professional area, the monitoring for more than 60 years of a cohort[1] of about 85,000 people irradiated at Hiroshima and Nagasaki (Japan) has allowed the morbidity and mortality due to cancer following exposure to ionising radiation to be regularly assessed and the dose-effects relationships –which form the basis of current regulations– to be described. 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 (Ukraine) 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 (Japan) 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 (produced by chance) or random effects.

The internationally established public health objectives related to radiation protection aim to prevent the appearance of deterministic

1. Cohort: group of individuals considered together and participating in a statistical study of the circumstances of occurrence of diseases.

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.

1.2 Assessment of the risks associated with ionising radiation

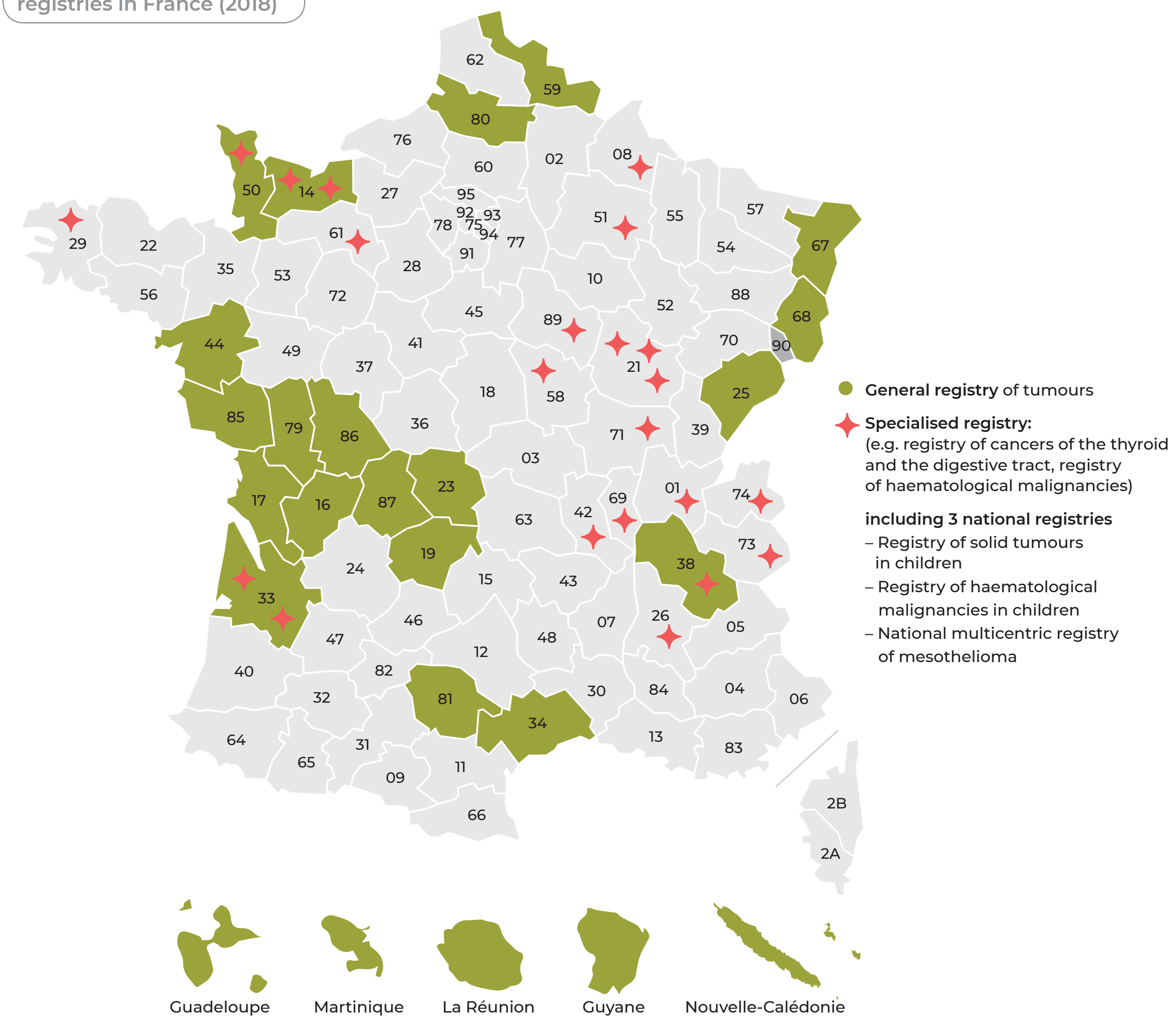
The monitoring of cancer epidemiology in France is based on disease registries, on the monitoring of causes of death and also, more recently, on the utilisation of data from the Medicalised Programme for Information Systems (PMSI) of healthcare facilities and the Long-Term Disease (LTD) notifications. The registries are structures that provide "*a continuous and exhaustive collection of nominative data concerning one or more health events in a geographically defined population, for purposes of research and public health, managed by a team with the appropriate skills*". At present there are 32 cancer registries in France. Some are "general registers", concerning all types of cancer and covering one *département*[2] or more; others are "specialised registers", focusing on a particular type of cancer. Their geographical perimeter can vary (town, *département*, region, or even nationwide). Of the three national registers, one concerns pleural mesothelioma, primarily in the context of exposure to asbestos fibres, while the other two cover all the cancerous pathologies in the child and adolescent up to 18 years of age (source: INCa).

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 rate of incidence in the different cancer locations, or to identify clusters of cases.

Some registers, depending on the quality of their population database and their age, are used in numerous studies exploring cancer risk factors (including environmental risks). However, the registers do not necessarily cover the areas close to nuclear installations.

Epidemiological investigation is complementary to monitoring. Its purpose 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

The various cancer registries in France (2018)



2. *Administrative region headed by a Prefect.*

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, as is the case in particular with low exposure levels of a few tens of millisieverts (mSv), 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 radiation protection of populations exposed to low doses of ionising radiation (nuclear industry workers, medical personnel, medical exposure for diagnostic purposes, etc.).

When there are no data on the impact of low doses on the occurrence of a cancer, estimates are provided by making linear no-threshold extrapolations of the observed effects described for high doses. These models give estimations of the risks run during exposure to low doses of ionising radiation, which nevertheless remain scientifically controversial. Studies on very large populations are currently underway to develop these models.

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 ICRP publication 103).

The evaluation of the risk of lung cancer due to radon[(3)] 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 (becquerels per cubic metre)– 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 radon constitutes the second-highest risk factor in lung cancer, coming far behind tobacco. Furthermore, for given levels of exposure to radon, the risk of lung cancer is much higher in smokers: three quarters of the deaths by lung cancer that can be attributed to radon reportedly occur in smokers.

In metropolitan France, about 12 million people spread over some 7,000 municipalities are potentially exposed to high radon concentrations. According to the national Public Health Agency (ARS - 2018), an estimated 4,000 new cases of lung cancer are caused by radon in metropolitan France each year, far behind the number due to tobacco (nearly 69,000). 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 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 Basic Nuclear Installations (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 according to age, the existence of signatures (specific mutations of DNA) that could be observed in radiation-induced cancers and certain non-cancerous diseases observed after radiotherapy.

The recommendations of the International Commission on Radiological Protection (ICRP)

The ICRP, which published new recommendations for the calculation of effective and equivalent doses (publication 103) in 2007, is gradually updating the values of the effective dose coefficients for internal and external exposure. Its publication 137 (2017), entitled "*Occupational intakes of radionuclides – Part 3*", concerns fourteen radionuclides, including radon.

The doses delivered by radon and its progeny depend on many parameters (variability of exposure situations, individuals, etc.).

The preceding dose coefficients recommended by the ICRP (publication 65 – 1993) for exposure to radon and its progeny were based on an epidemiological approach. ICRP publication 115 (2010) updated the risk of lung cancer associated with radon exposure on the basis of new epidemiological studies. The ICRP had concluded that the risk of death from lung cancer in adults having been chronically exposed to low concentrations of radon was nearly two times higher than that estimated on the basis of the knowledge available in 1993.

The dose coefficients for radon taken from ICRP publication 137 (2017) are based on a dosimetric approach, in the same way as for the other radionuclides. For an equal given level of exposure to radon and its progeny, they lead to a significant increase in the annual effective dose received by workers exposed to radon (nearly two times higher).

In view of these developments and pending the updating of the regulations[(*)] to revise the dose coefficients applicable for radon and its progeny, ASN has called upon the Advisory Committee for Radiation Protection in Industrial and Research Applications of Ionising Radiation and for the Environment (GPRADE) to identify the difficulties that could arise from application of the new ICRP coefficients (publication 137 - 2017). The GPRADE report is expected in 2020.

**Order of 1 September 2003 defining the methods for calculating effective doses and equivalent doses resulting from human exposure to ionising radiation.*

3. Radon is a natural radioactive gas, a progeny product of uranium and thorium, an emitter of alpha particles and has been classified as a known human pulmonary carcinogen by the International Agency for Research on Cancer (IARC) since 1987.

1.3.1 Radiosensitivity

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

Furthermore, 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. Thanks to the lowering of detection thresholds, recent methods of immunofluorescence of molecular targets for signalling and repairing DNA damage enable the effects of ionising radiation at low doses to be better documented. 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.

Progress in research and the confirmation of clinical results should allow the optimum conditions for monitoring individual radiosensitivity in patients to be rapidly defined.

Under the work of the European research group on low doses (MELODI, Multidisciplinary European Low Dose Initiative), two review documents were published in 2019, addressing the clinical and epidemiological aspects of the individual response to ionising radiation, and the available screening tests and their robustness, respectively.

Furthermore, the ICRP working group (TG111) dedicated to this subject is preparing, on the basis of acquired knowledge, radiation protection recommendations that it plans publishing in 2020.

The individual response to ionising radiation is thus gradually being recognised as an important subject of research and application in radiobiology and radiation protection, while at the same raising ethical and societal questions.

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.

Radiography room in the Léon Bourgeois clinic (Paris) in 1916

• 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[4]. 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 industry 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.

• 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 have been 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. 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).

4. The radioactive dose rate determines the absorbed dose (energy absorbed by the material per unit mass and time). It is measured in Gray per second (Gy/s) in the International System of Units (SI). It is used in physics and in radiation protection.

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.

It is known that in the first stages of carcinogenesis (process of cancer formation) 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 100 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 ageing and to carcinogenesis.

Consequently, in a multi-risk approach to carcinogenesis, can we still talk about radiation-induced cancers? Yes we can, given the quantity of epidemiological data which indicate that cancer frequency increases when the dose increases, with the other main risk factors taken into account. However, the radiation-induced event can also in certain cases be the only event responsible (radiation-induced cancers in children).

Highlighting a radiological 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, but has not been demonstrated to date.

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 nSv/h (nanosieverts per hour) 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 Institute of Radiation Protection and Nuclear Safety (IRSN) in 2015, the average dose per individual would be about 0.32 mSv/year (millisieverts per year). The average concentration of potassium-40 in the organism represents about 55 Bq/kg (becquerels per kilogram) body mass, resulting in an average effective dose of about 0.18 mSv/year.

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

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 *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. In 2011, IRSN published a map of France considering the radon exhalation potential of the ground, based on data from the French Geological and Mining Research Office. Based on this, a more fine-grained classification, by municipality, was published through the Ministerial Order of 27 June 2018 (see search engine by municipality and mapping accessible on *asn.fr* and *irsn.fr*).

Ultimately, the new obligation placed on radon detector analysis laboratories to communicate the dosimeter results to IRSN should enhance knowledge of radon exposure in France (see the 3rd National Plan 2016-2019 for Radon Risk Management, published in January 2017 and accessible on *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/h and that resulting from the neutronic component at 3.6 nSv/h.

Radon exhalation potential in metropolitan France (source: IRSN)

— Bounds of 31 priority *départements* for radon monitoring
▪ Areas of the potential for radon exhalation

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/year, whereas it could exceed 1.1 mSv/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/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

Nuclear activities are highly diverse, covering any activity relating to the preparation or utilisation of radioactive substances or ionising radiation. 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. BNIs are defined in Article L. 593-2 of the Environment Code:

1° nuclear reactors;

2° facilities, corresponding to characteristics defined by Decree of the Council of State, for the preparation, enrichment, fabrication, treatment or storage of nuclear fuels, or for the treatment, storage or disposal of radioactive waste;

3° installations containing radioactive or fissile substances and meeting characteristics defined by Decree of the Council of State;

4° particle accelerators meeting characteristics defined by Decree of the Council of State;

5° deep geological repositories for radioactive waste mentioned in Article L. 542-10-1 of the Environment Code.

The installations and facilities are subject to the BNI System, governed by Chapters III and VI of Title IX of Book V of the Environment Code and their implementing texts.

The list of BNIs as at 31 December 2019 figures in an appendix to this report.

• Risk 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, risk prevention, medical monitoring of workers, including those from outside contractors, etc.).

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. More particularly, discharges of liquid and gaseous effluents, whether radioactive or not, are strictly limited (see chapter 3).

2.2.2 Transport of radioactive substances

When transporting radioactive substances, the main risks are those of internal or external exposure, of criticality, and 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 is 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 and fluoroscopy-guided interventional practices), 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.

2.2.4 Radioactive waste management

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

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

Finally, management of radioactive waste must be determined prior to any creation of new activities or modification of existing activities in order to:

- ensure the availability of processing channels for the various categories of waste likely to be produced, from the front-end phase (production of waste and packaging) to the back-end phase (storage, transport and disposal);
- optimise the waste disposal routes.

2.2.5 Management of contaminated sites

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

Depending on the current or future uses of the site, decontamination objectives must be set. 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.

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 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 in these activities:

- 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. As of June 2018, these activities are subject to the same rules as the Installations Classified for Protection of the Environment.

3. Monitoring exposure to ionising radiation

Given the difficulty in attributing a cancer solely to the ionising radiation risk factor, "risk monitoring" to prevent cancers in the population 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 per person per year (see Diagram 1), 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.

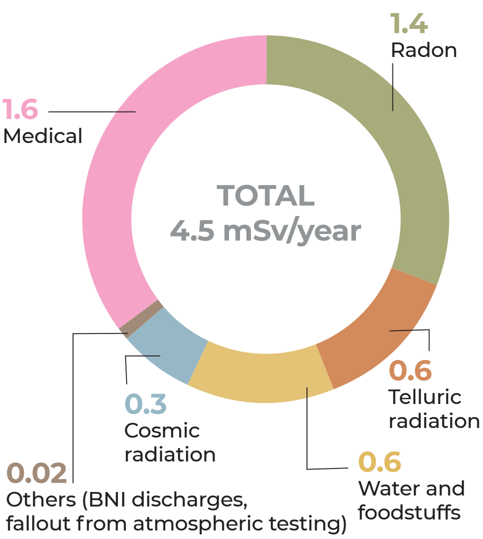
3.1 Doses received by workers

3.1.1 Monitoring the exposure of persons working in nuclear facilities

The system for monitoring the external exposure of persons liable to be exposed to ionising radiation, working in BNIs or in small-scale nuclear facilities, has been in place for several decades. This system is based primarily on the mandatory wearing of passive dosimeters for workers liable to be exposed and enables compliance with the regulatory limits applicable to workers to be checked. These limits concern the total exposure (since 2003, the annual limit expressed in terms of effective

DIAGRAM 1

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



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

Source: IRSN 2015.

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 "References" heading on *asn.fr*).

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 sub-contractor companies. They are grouped together in Ionizing Radiation Exposure Monitoring Information System (Siseri) managed by IRSN and are published annually.

The results of worker exposure to ionising radiation presented below are taken from the IRSN 2018 assessment of occupational exposure to ionising radiation in France. From the methodological aspect, the IRSN assessment for 2017 introduced a significant change. This is because in the preceding years the assessment was produced exclusively by aggregating the annual summaries requested of the dosimetry organisations. As in 2017, the 2018 assessment of external exposure was obtained exclusively from the data on individual monitoring of the external exposure of workers recorded in Siseri. Consequently, the 2018 and 2017 results are not directly comparable with those published in the preceding reports. Nevertheless, for comparison purposes, the results for 2015 and 2016 have been retroactively reassessed applying the new methodological approach (see Table 3).

Tables 1 and 2 present, per area of activity and for the year 2018, a breakdown of the populations monitored, the collective dose (the collective dose is the sum of the individual doses received by a given group of persons) 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 (61%), accounts for only 17% of the collective dose; on the other hand, the nuclear industry, which represents just 24% of the headcount, accounts for 75% of the collective dose. The industrial sector, which represents 4.3% of the headcount, accounts for 4.7% of the collective dose.

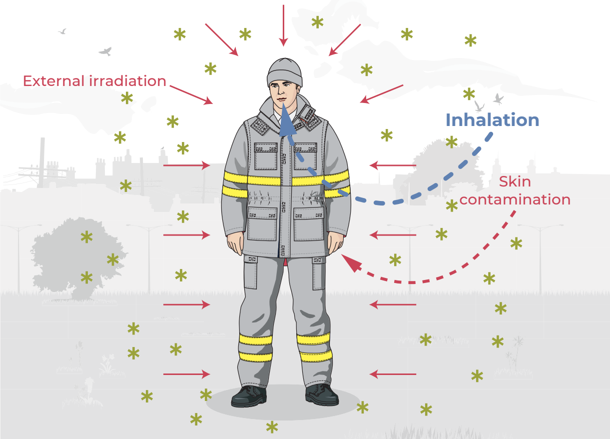
Table 3 shows that the total number of workers monitored by external passive dosimetry has increased by about 1% per year since 2015 (1.5% between 2017 and 2018).

In 2018, the collective dose reached 55.24 man-Sv, a value that is slightly higher (3.2%) than in 2017, whereas the average dose increased by 11%. These increases are primarily linked to the increase in the amount of maintenance work in the nuclear sector.

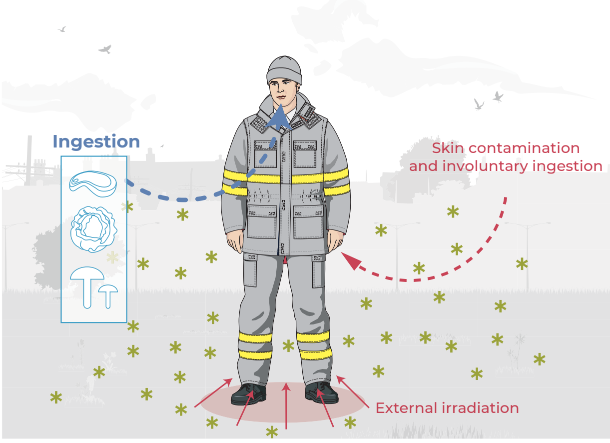
In 2018, 10 cases exceeding the regulatory effective dose limit of 20 mSv were registered (see Diagram 2). Eight of them concerned professionals in the medical sector, while the other 2 concerned workers in the non-nuclear industry sector. It should nevertheless be noted that out of these 10 cases of exceeding the effective dose limit, 8 were kept by default as there was no feedback from the occupational physician on the conclusions of the inquiry.

With regard to the dosimetry of the extremities (fingers and wrist), 27,627 workers were monitored in 2018 (i.e. 8% of the total number of persons monitored). Out of all the persons monitored, there were three cases where the regulatory equivalent dose limit at the extremities of 500 mSv was exceeded, all in the medical sector (2 in interventional radiology with a maximum recorded value of 754 mSv and 1 in nuclear medicine).

Sources and routes of exposure to ionising radiation



External irradiation
Internal contamination by inhalation of radioactive substances
Skin contamination



External irradiation
Internal contamination through ingestion of contaminated foodstuffs
Skin contamination and involuntary ingestion

Furthermore, 3,492 workers were subject to monitoring of lens of the eye exposure. This represents an increase in monitoring of nearly 40% compared with 2017. This significant increase is linked to the arrival on the market of several new dosimeters suited to this type of measurement. Four workers received an equivalent dose exceeding 20 mSv. The maximum recorded dose is 53.4 mSv and concerns the radiology sector. This value should be compared with the new regulatory dose limit for the lens of the eye: cumulative value of 100 mSv over 5 years, without exceeding 50 mSv in a given year (20 mSv/year as from 2023).

To conclude, as in the preceding years, the results of dosimetric monitoring of worker external exposure in 2018 published by IRSN in September 2019 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). Although there is an increase in the number of cases where the regulatory limit values are exceeded (10 cases exceeding the annual limit of 20 mSv), they remain the exception. 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.

3.1.2 Worker exposure to Technologically Enhanced Naturally Occurring Radiation and to radon of geological origin

Occupational exposure to Technologically Enhanced Naturally Occurring Radiation (TENOR) is the result either of the ingestion of dust from materials 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 studies carried out in France from 2005 until their publication by ASN in January 2010, along with the more recent studies, 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 2018.

With regard to exposure to radon of geological origin, the results from monitoring the exposure of workers to radon have not yet been exhaustively recorded in Siseri. Consequently, not all the companies whose premises have a radon activity concentration in the air that makes individual monitoring necessary are included in the IRSN 2018 report published in September 2019.

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 1 July 2014, the date of entry into effect of the Order of 17 July 2013 relative to the medical and dosimetric monitoring card for workers exposed to ionising radiation, the Sievert system for calculating the cosmic radiation doses received by flight crews during a flight (*sievert-system.org*) –system put in place by the General Directorate for Civil Aviation (DGAC), IRSN, the Paris Observatory and the French Institute for Polar Research Paul-Émile Victor– has been changed. It is IRSN that calculates the individual doses with 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.

As at 31 December 2018, SievertPN had sent Siseri all the flight crew doses for 13 airlines having subscribed to the system, giving a total of 23,356 flight crew members monitored by this system. In 2018, 19% of the individual annual doses were below 1 mSv and 80% of the individual annual doses were between 1 mSv and 5 mSv. The maximum permitted individual annual dose is 5.9 mSv.

3.2 Doses received by the population

3.2.1 Exposure of 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 3).

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/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. An estimation of the doses from BNIs is presented in Table 4 which shows, for each site and per year, the estimated effective doses received by the most exposed reference population groups.

There are no known estimates for nuclear activities other than BNIs 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, 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/year (IRSN, 2015). With regard to the fall-out in France from the Fukushima Daiichi accident, 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).

Results of dosimetry monitoring of worker external exposure to ionising radiation (natural radioactivity excluded) in 2018

(Source: Occupational exposure to ionising radiation in France – IRSN results, September 2019)

- Total population monitored: 365,980 workers
- Monitored population for whom the annual effective dose remained below the detection threshold: 296,515 workers, or more than 81%
- Monitored population for whom the annual effective dose remained below the detection threshold: 56,581 workers, or about 15.5%
- Monitored population for whom the annual effective dose remained between 1 mSv and 20 mSv: 12,874 workers, or more than 3.5%:
- Monitored population for whom the annual effective dose exceeded 20 mSv: 10 workers
- Monitored population for whom the equivalent dose to the extremities exceeded 500 mSv: 3 workers
- Collective dose (sum of individual annual effective doses): 55.24 man-SvAverage annual individual effective dose in the population which recorded a dose higher than the detection threshold: 0.80 mSv

Results of internal exposure monitoring (natural radioactivity excluded) in 2018

- Number of routine examinations carried out: 262,900 (of which 0.4% were considered positive)
- Population for which a dose estimation was made: 415 workers
- Number of special monitoring examinations or verifications performed: 11,978 (of which 14% were above the detection threshold)
- Population having recorded a committed effective dose exceeding 1 mSv: 4 workers

Results of cosmic radiation exposure monitoring in 2018 (civil aviation)

- Collective dose for 23,356 flight crew members: 48.7 man-Sv
- Average annual individual effective dose: 2.1 mSv

Results of monitoring of exposure to natural radionuclides of the uranium and thorium decay chains in 2018

- External exposure:
  - collective dose for 601 workers: 85.2 man-mSv
  - Average annual individual effective dose in the population which recorded a dose higher than the detection threshold: 0.26 mSv
- Internal exposure:
  - collective dose for 372 workers: 150.1 man-mSv
  - Average annual individual effective dose in the population which recorded a dose higher than the detection threshold: 0.63 mSv

TABLE 1

Monitoring of external exposure of workers in the civil nuclear field (year 2018)

	NUMBER OF PERSONS MONITORED	COLLECTIVE DOSE (man.Sv(*))	INDIVIDUAL DOSE > 20 mSv
Reactors and energy production (EDF)	24,626	6.01	0
Fuel cycle; decommissioning	12,680	3.34	0
Transport	739	0.08	0
Logistics and maintenance (contractors)	30,315	27.74	0
Effluents, waste	689	0.09	0
Others	6,716	1.07	0
Total civil nuclear	75,765	38.33	0

(Source: Occupational exposure to ionising radiation in France – IRSN results, September 2019)
* 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 2018)

	NUMBER OF PERSONS MONITORED	COLLECTIVE DOSE (man.Sv(*))	INDIVIDUAL DOSE > 20 mSv
Medicine	162,564	7.74	7
Dental	39,220	1.49	1
Veterinary	20,091	0.33	0
Industry	15,772	2.57	2
Research and education	12,414	0.32	0
Total small-scale nuclear activities	250,061	12.45	10

(Source: Occupational exposure to ionising radiation in France – IRSN results, September 2019)
* Man.Sv: Unit of quantity of collective dose.

TABLE 3

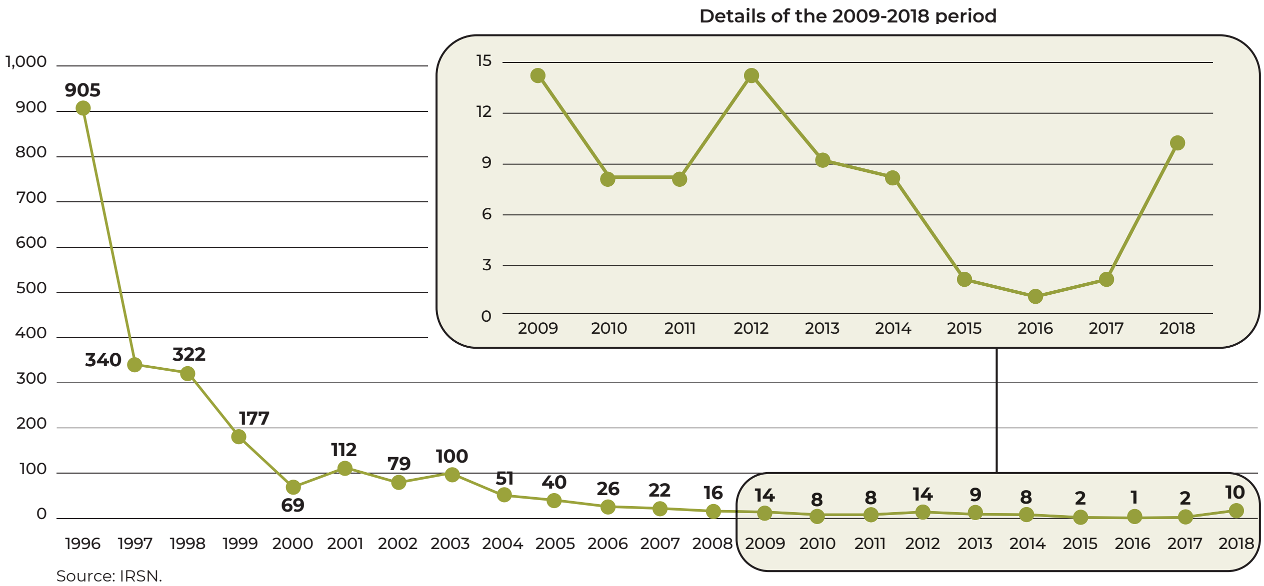
Development of number of persons monitored in all sectors and of the collective dose from 2015 to 2018(*)

YEAR	NUMBER OF PERSONS MONITORED	COLLECTIVE DOSE (man.Sv)	AVERAGE INDIVIDUAL DOSE (mSv)
2015	352,641	65.61	0.76
2016	357,527	66.71	0.73
2017	360,694	53.52	0.72
2018	365,980	55.24	0.80

(Source: Occupational exposure to ionising radiation in France – IRSN results, September 2019)
* For comparison purposes, the results for 2015 and 2016 have been retroactively reas-sessed applying the new methodological approach.

DIAGRAM 2

Evolution of number of workers monitored, with an annual effective dose in excess of 20 mSv from 1996 to 2018



Source: IRSN.

Since 2019, measurement of the radon content of tap water and bottled water has been compulsory. To assist the introduction of this new provision, an instruction was drawn up in consultation with ASN and issued in 2018 to the Regional Health Agencies by the General Directorate for Health (ASN opinion 2018-AV-0302 of 6 March 2018 on the radon management procedures in the sanitary control of water intended for human consumption).

• Exposure due to radon

In France, the regulations relative to management of the radon risk, put in place in the early 2000's for certain buildings open to the public, were extended to certain work places in 2008. In 2016, radon was introduced into the indoor air quality policy.

Transposition of Council Directive 2013/59/Euratom of 5 December 2013 laying down Basic Safety Standards for protection against the dangers arising from exposure to ionising radiation led to the amending of the provisions applicable to radon since 1 July 2018. A reference level of 300 Bq/m^3 has been introduced. It is applicable to all situations, which enables the health risk associated with radon to be managed with an all-inclusive approach. The regulations have been extended with provisions concerning the three main sectors:

- With regard to the general public, a significant improvement has been introduced: radon is now included in the information to be provided to buyers and tenants of real estate situated in areas where the radon potential could be the highest.
- In workplaces, the regulations have been extended to cover professional activities exercised on ground floor levels and in certain specific workplaces. Whatever the radon potential zone in which the workplace is situated, radon must be considered in the risk assessment. A radon measurement can be carried out in this context if necessary. If there is a risk of reaching or exceeding the reference level of 300 Bq/m^3, the employer must take action to reduce the radon activity concentration. If the action turns out to be ineffective, the employer must identify potential "radon zones", then implement radiation protection measures, if necessary according to the level of exposure of the workers.
- In some buildings open to the public, the radon management methods have been adjusted, more specifically with the addition of facilities accommodating children under 6 years of age and an obligation to inform the public by displaying the radon measurement results. The type of action to be taken if the reference level of 300 Bq/m^3 is exceeded is graded according to the measurement results[(5)]: simple corrective actions for radon concentrations between 300 and 1,000 Bq/m^3, expert assessment and remediation work if the corrective actions do not reduce the radon concentration to below the reference level or if the measurement results equal 1,000 Bq/m^3 or higher.

On the basis of the results communicated by the ASN-accredited organisations for the 2018/2019 campaign, the majority of the screenings was carried out in educational institutions and healthcare and medical-social institutions (51% and 48% of screenings respectively). The radon activity concentration is lower than the reference level of 300 Bq/m^3 in 64% of educational institutions and 82% of the healthcare and medical-social institutions screened (see Diagram 3).

On the basis of the data collected in some one hundred buildings open to the public, one third of the radon activity concentration inspections carried out by the ASN-accredited organizations confirmed that the radon activity concentration had been brought below the 300 Bq/m^3 level after carrying out radon remediation work.

• Results of the 3rd national radon action plan (2016-2019) and broad lines of the 4th plan (2020-2024)

The 3rd radon action plan covered the 2016-2019 period. Although its implementation was strongly impacted by the transposition of Council Directive 2013/59/Euratom of 5 December 2013 (in 2016 for the legislative part and in 2018 and 2019 for the regulatory part), the majority of the actions concerned are either completed or in progress. The results reveal the following main points:

- A radon risk map[(6)] defined on the more precise scale of the municipality, and now including the overseas territories, was published in June 2018. It constitutes a tool common to all the management strategies, based on the division of the territory into three radon potential zones.
- The deployment of numerous communication campaigns on the radon risk and on the new regulatory provisions introduced into French law since 1 July 2018. More particularly, the local awareness raising operations for the public continued and information sessions were organised at national and local level for the various stakeholders: managers of buildings open to the public, risk prevention specialists, building trade professionals, organisations approved by ASN for measuring radon activity concentration.
- The gradual defining of good practices regarding prevention methods for new buildings and radon concentration reduction methods in existing buildings. This was made possible by capitalising on examples of constructions and works, experience feedback from building professionals and the publication of French and foreign studies.
- The development of training courses for building professionals, as radon is now included in broader subjects, such as indoor air quality and energy renovation.

• 4th radon plan (2020-2024)

The 4th radon plan (2020-2024) ties in with the 4th national health environment plan which will now coordinate all the sectorial plans concerning health or the environment. The three axes of the 2016-2019 plan are maintained: informing the audiences, enhancing knowledge and improving integration of the management of the radon in buildings. In particular, informing and raising awareness of the radon risk remain major subjects of the plan, due to insufficient knowledge of this risk not only on the part of the general public, but also the players in the regulated sectors. A specific communication campaign shall target smokers, because they constitute the population the most at risk of developing lung cancer linked to cumulative exposure to radon and tobacco. Various studies will continue in order to improve knowledge of the impact of radon on health, but also of the exposure of the French population: factors influencing the radon content of the soil, the contribution of construction materials. The good practices in prevention and reduction of the radon concentration in buildings shall be synthesised and disseminated. Indicators have been put in place to track the progress of the various actions and estimate their impacts for the people concerned.

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 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

5. Order of 26 February 2019 relative to the methods of managing radon in certain buildings open to the public and dissemination of information to the people frequenting these buildings.
6. Order of 27 June 2018 delimiting the radon potential zones on French territory.

TABLE 4

Radiological impact of BNIs since 2013 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)

LICENSEES/SITE	REFERENCE GROUP MOST EXPOSED IN 2018	DISTANCE TO SITE IN KM	ESTIMATION OF RECEIVED DOSES, IN mSv [(a)] (the values calculated by the licensee are rounded up to the next higher unit)					
			2013	2014	2015	2016	2017	2018
Andra / CSA	Multi-activity group Ville-aux-Bois	1.7	1.10^{-6}	2.10^{-6}	2.10^{-6}	2.10^{-6}	2.10^{-6}	3.10^{-7}
Andra / Manche repository	Hameau de La Fosse	2.5	3.10^{-4}	3.10^{-4}	2.10^{-4}	2.10^{-4}	2.10^{-4}	2.10^{-4}
Framatome Romans	Ferme Riffard	0.2	5.10^{-4}	3.10^{-4}	3.10^{-4}	3.10^{-4}	2.10^{-5}	2.10^{-5}
Orano Cycle / La Hague	Digulleville	2.8	2.10^{-2}	2.10^{-2}	2.10^{-2}	2.10^{-2}	2.10^{-2}	2.10^{-2}
Orano / Tricastin (Areva NC, Comurhex, Eurodif, Socatri, SET)	Les Girardes	1.2	3.10^{-4}	3.10^{-4}	3.10^{-4}	2.10^{-4}	2.10^{-4}	9.10^{-5}
CEA / Cadarache [(b)]	Saint-Paul-lez-Durance	5	2.10^{-3}	2.10^{-3}	1.10^{-3}	$<2.10^{-3}$	$<2.10^{-3}$	$<3.10^{-3}$
CEA / Fontenay-aux-Roses [(b)]	Achères	30	3.10^{-5}	1.10^{-4}	2.10^{-4}	$<2.10^{-4}$	$<2.10^{-4}$	$<2.10^{-4}$
CEA / Grenoble [(c)]	-	-	5.10^{-9}	[(c)]	[(c)]	[(c)]	[(c)]	[(c)]
CEA / Marcoule [(b)] (Atalante, Centraco, Phénix, Melox, CIS bio)	Codolet	2	2.10^{-4}	2.10^{-3}	2.10^{-5}	$<2.10^{-3}$	$<2.10^{-3}$	$<2.10^{-3}$
CEA / Saclay [(b)]	Le Christ de Saclay	1	2.10^{-3}	2.10^{-3}	2.10^{-3}	$<2.10^{-3}$	$<2.10^{-3}$	$<2.10^{-3}$
EDF / Belleville-sur-Loire	Beaulieu-sur-Loire	1.8	7.10^{-4}	4.10^{-4}	5.10^{-4}	4.10^{-4}	3.10^{-4}	4.10^{-4}
EDF / Blayais	Braud et Saint-Louis	2.5	2.10^{-3}	6.10^{-4}	5.10^{-4}	5.10^{-4}	4.10^{-4}	5.10^{-4}
EDF / Bugey	Vernas	1.8	4.10^{-4}	2.10^{-4}	2.10^{-4}	9.10^{-5}	2.10^{-4}	2.10^{-4}
EDF / Cattenom	Koenigsmacker	4.8	5.10^{-3}	8.10^{-3}	7.10^{-3}	9.10^{-3}	8.10^{-3}	9.10^{-3}
EDF / Chinon	La Chapelle-sur-Loire	1.6	3.10^{-4}	2.10^{-4}	2.10^{-4}	2.10^{-4}	2.10^{-4}	2.10^{-4}
EDF / Chooz	Chooz	1.5	2.10^{-3}	7.10^{-4}	6.10^{-4}	6.10^{-4}	4.10^{-4}	5.10^{-4}
EDF / Civaux	Valdivienne	1.9	2.10^{-3}	8.10^{-4}	9.10^{-4}	2.10^{-3}	8.10^{-4}	8.10^{-4}
EDF / Creys-Malville	Creys-Mépieu	0.95	2.10^{-4}	2.10^{-4}	2.10^{-6}	3.10^{-4}	1.10^{-4}	2.10^{-5}
EDF / Cruas-Meysse	Savasse	2.4	4.10^{-4}	2.10^{-4}	2.10^{-4}	2.10^{-4}	4.10^{-4}	3.10^{-3}
EDF / Dampierre-en-Burly	Lion-en-Sulias	1.6	9.10^{-4}	4.10^{-4}	5.10^{-4}	5.10^{-4}	5.10^{-4}	5.10^{-4}
EDF / Fessenheim	Rheinwartenhaus	1.3	1.10^{-4}	4.10^{-5}	4.10^{-5}	3.10^{-5}	2.10^{-5}	5.10^{-5}
EDF / Flamanville	Flamanville	0.8	7.10^{-4}	5.10^{-4}	2.10^{-4}	2.10^{-4}	2.10^{-4}	2.10^{-4}
EDF / Golfech	Valence	3.4	6.10^{-4}	2.10^{-4}	3.10^{-4}	3.10^{-4}	2.10^{-4}	2.10^{-4}
EDF / Gravelines	Grand-Fort-Philippe	2.5	6.10^{-4}	8.10^{-4}	4.10^{-4}	4.10^{-4}	5.10^{-4}	8.10^{-4}
EDF / Nogent-sur-Seine	Saint-Nicolas-la-Chapelle	2.3	1.10^{-3}	5.10^{-4}	4.10^{-4}	7.10^{-4}	5.10^{-4}	5.10^{-4}
EDF / Paluel	Paluel	1.1	9.10^{-4}	9.10^{-4}	4.10^{-4}	3.10^{-4}	3.10^{-4}	4.10^{-4}
EDF / Penly	Berneval-le-Grand	3.1	7.10^{-4}	4.10^{-4}	4.10^{-4}	4.10^{-4}	5.10^{-4}	5.10^{-4}
EDF / Saint-Alban	Saint-Maurice-l'Exil	1.7	4.10^{-4}	2.10^{-4}	2.10^{-4}	3.10^{-4}	2.10^{-4}	2.10^{-4}
EDF / Saint-Laurent-des-Eaux	Lestiou	1.7	2.10^{-4}	2.10^{-4}	1.10^{-4}	1.10^{-4}	1.10^{-4}	1.10^{-4}
EDF / Tricastin	Bollène	1.3	5.10^{-4}	2.10^{-4}	2.10^{-4}	2.10^{-4}	2.10^{-4}	2.10^{-4}
Ganil / Caen	IUT	0.6	$<2.10^{-3}$	$<2.10^{-3}$	$<2.10^{-3}$	$<2.10^{-3}$	8.10^{-3}	8.10^{-3}
ILL / Grenoble	Fontaine (gaseous discharges) and Saint-Égrève (liquids)	1 et 1.4	2.10^{-4}	3.10^{-4}	2.10^{-4}	2.10^{-4}	5.10^{-5}	2.10^{-5}

(a) For installations operated by EDF, 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 the 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) As the site has no longer had radioactive discharges since 2014, the radiological impact caused by radioactive discharges has been nil since 2014.

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. It is the contribution of computed tomography to the effective collective dose that 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 the most 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.

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 120,000 children born between 2000 and 2015, IRSN reports (2015 report) that in 2015, 31.3% of the children in the sample were exposed to ionising radiation for diagnostic purposes (up by 2% compared with 2010). The average effective dose is estimated at 0.43 mSv and the median at 0.02 mSv (down for the average but equivalent for the median value). A large age-related disparity is noted: below 1 year of age the median value is 0.55 mSv (highest value) and between 6-10 years, the median value equals 0.012 mSv (lowest median value).

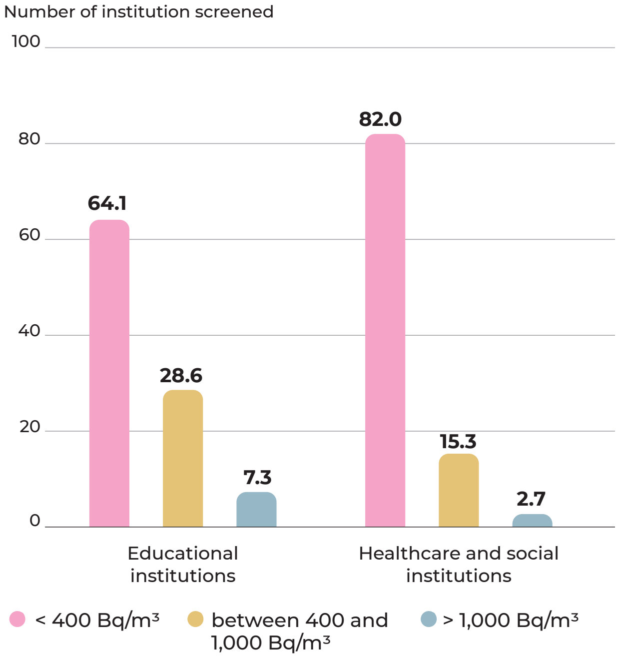
The substantial uncertainties in these studies with regard to the average effective dose values per type of procedure must nevertheless be taken into account, which justifies the need for progress in estimating doses in the next exposure study of the general population.

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 a final effective dose value of several tens of millisieverts; at this level of exposure, certain epidemiological surveys have revealed the occurrence of radiation-induced cancers.

Controlling the doses of ionising radiation delivered to persons during a medical examination remains a priority for ASN. A second plan of action was published in July 2018. This plan extends the first one (2011-2017), drawn up in collaboration with the stakeholders (institutional and professional). A new IRSN assessment of how doses delivered to patients are evolving is expected in 2020.

DIAGRAM 3

Distribution of radon activity concentrations by type of building open to the public screened (in%), 2018/2019 campaign



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 is 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 (GPRADE) adopted an opinion in September 2015. The draft guide is to be submitted to ASN in the first quarter of 2020.

ASN regional divisions playing a front-of-stage role in the prevention of the radon risk in the regions

The year 2019 was marked by the implementation of regulatory provisions aiming to better protect the public and workers against the radon risk (see point 3.2.2). ASN thus contributed, with the public administration departments –Dreal, Regional Health Agency (ARS), Direccte– and the partner organisations (Cerema, trade associations, local authorities, etc.), to raising the awareness of elected officials, building trade professionals, employers, managers of buildings open to the public and the general public to these changes.

On 1 July 2020, each building open to the public must be able to provide ASN with the reports on the radon measurements carried out in the building.

In the Auvergne-Rhône-Alpes region, the Lyon division inspected the Departmental Council of the Puy de Dôme, which is responsible for state-run junior secondary schools (*collèges*), and the services of the Regional Council, which is responsible for state-run senior secondary schools (*lycées*). These inspections verified the way in which these authorities manage the radon risk in these schools. The findings of these inspections have led ASN to maintain inspections of regional authorities in 2020.

In 2019, the Lyon division also inspected the *Grands Thermes de la Bourboule*, a thermal spa faced with a high radon concentration. The inspectors also inspected a penal institution following repeated reports from the employees.

In 2020, the Lyon division plans measures to raise elected officials' awareness of their obligations with regard to information and prevention.

The inspections carried out in Bourgogne-Franche-Comté in 2019 in medical or industrial facilities situated in municipalities with a significant radon potential also provided the opportunity to explain the regulatory obligations of the managers of buildings open to the public and those of employers. Within the framework of the Franco-Swiss JURADBAT project, a website now offers the public, the regional authorities and building trade professionals general and regulatory information, practical and technical guidance sheets, interactive maps of radon measurements in Switzerland and Franche-Comté, as well as training modules.

The Regional Council and the Urban Community of Besançon were also inspected. All the secondary schools have undergone initial screening which has been renewed at the required frequencies. The secondary schools presenting a radon concentration exceeding the reference level have been identified and corrective or remediation measures have been initiated. In some cases however, it is necessary to perform an expert assessment of the buildings to obtain appropriate work recommendations.

In the Pays de la Loire region, where the *départements* (apart from Sarthe) have between 65% and 80% of their municipalities situated in zones of significant radon potential, the Nantes division organised jointly with the ARS, Dreal and Cerama, two "Radon mornings" in the Mayenne *département* and in the municipality of Lion d'Angers (Maine-et-Loire *département*). Some 80 representatives of local authorities, schools, healthcare and social institutions, associations and design offices took part in each event. Both events presented the new regulatory obligations applicable in buildings open to the public, in the workplace and in private homes (informing house buyers and tenants) to encourage the local authorities to conduct campaigns to measure radon in private homes and to raise radon awareness in the general public. The Nantes division also funded several actions promoted by associations or Local Centres for Environmental Initiatives (CPIEs), notably campaigns of voluntary measurement of radon in homes and assisting people faced with high radon concentrations. ASN also carried out, jointly with the ARS or in its presence, inspections of the Regional Council and the Departmental Councils (Mayenne, Maine-et-Loire, Loire-Atlantique, Vendée) in order to verify the launching of the radon measurement campaigns in junior and senior secondary schools). Likewise, an inspection of the Departmental Council of Ille-et-Vilaine in Bretagne was also carried out with the ARS. These six inspections revealed considerable disparities in the integration of the new radon monitoring requirements in secondary schools.

In the Grand Est region, in collaboration with the ARS and ATMO Grand Est (an approved air quality monitoring association), two information meetings for local elected officials were held on 19 June in Rouffach (Bas-Rhin *département*) and on 20 June in Andlau (Haut-Rhin *département*). The targeted municipalities are effectively situated on a granitic fault in the foothills of the Vosges, most of which are classified as significant radon potential zones. Alongside this, the alert given by the inhabitants of the former coal-mining municipality of Ottange (Moselle *département*) in 2016 with regard to a supposed abnormally high incidence of cancers in this municipality mobilised the State services, carrying on the work of 2018. Several meetings were thus coordinated by the Sub-Prefect of Thionville: an inter-service meeting on 8 July and a public meeting on 20 September 2019. At the end of the latter meeting, it was indicated that nearly 95% of the measurements taken during the winter campaign of 2019 are below 300 Bq/m^3 and none exceeded 1,000 Bq/m^3. Another radon measurement campaign will be carried out in winter 2020.

In Normandie, in collaboration with the State services, ASN also organised two information days on the radon risk intended for the mayors of the municipalities at risk, held on 11 June in Vire (Calvados *département*) and 12 June in Cherbourg-Octeville (Manche *département*).

Lastly, in Occitanie, ASN was informed by the ARS on 5 April 2019 of a school in the municipality of Aumont-Aubrac (Lozère *département*) where the reference level of 300 Bq/m^3 was significantly exceeded. The pupils and personnel were evacuated from the school. The school immediately contracted an ASN-approved organisation to conduct an expert assessment of the building, diagnose the routes of radon entry into the buildings and recommend works to bring the school into compliance. The school had work carried out to seal the building and install a ventilation system, then had further radon measurements taken, which led to the authorisation for pupils and staff to re-enter the school. The school shall be subject to further radon measurements.

TABLE 5

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

IMAGING METHOD	PROCEDURES		TOTAL COLLECTIVE EFFECTIVE DOSE: 102,198 Sv
	NUMBER	%	%
Conventional radiology (dentistry excluded)	44,175,500	54.0	17.7
Dental radiology	27,616,000	33.8	0.2
Computed tomography	8,484,000	10.4	71.2
Diagnostic interventional radiology	377,000	0.5	3.1
Nuclear medicine	1,103,000	1.3	7.8
Total	81,755,500	100.0	100.0

Source: IRSN 2014.

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

In France, exposure for medical purposes represents the primary source of artificial exposure of the public to ionising radiation. This exposure is rising, mainly owing to the increasing number of computed tomography examinations. Imaging examinations have proven their benefits for both diagnosis and treatment. The issue at stake however is to avoid examinations that are not really necessary or that offer no real benefit for the patients and the results of which could be obtained by other available, non-irradiating techniques.

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.

ASN's second action plan, published in July 2018, aims at continuing to promote a culture of radiation protection in medical professionals with the reinforcing of skills and the harmonising of practices in an updated regulatory framework. The actions target several areas: increasing accountability and awareness in the medical professionals, training, new practices and techniques, and the equipment. They hinge on 7 themes:

Enhancing accountability, awareness, quality

Theme 1. Heighten the awareness of physicians making referrals for examinations and provide updated guides to good practices in examination referral in order to improve the individual justification of medical imaging procedures.

Theme 2. Detail the roles of all the health professionals involved in the procedure justification process and dose optimisation.

Theme 3. Put in place analyses of professional practices (clinical audits) relating to the justification of procedures and dose optimisation.

Theme 4. Adapt and reinforce the legal and economic framework relative to the justification of medical radiological imaging procedures and dose optimisation.

Training

Theme 5. Put in place a system of initial and continuous training of medical professionals in the radiation protection of persons exposed for medical purposes.

New practices and techniques

Theme 6. Put in place a new system for accompanying the implementation of new procedures and new techniques "involving risks".

Equipment

Theme 7. Enable the professionals to have the most suitable equipment for performing the "justified" procedures and optimising doses.

Two ASN resolutions were published under this plan in 2019: resolution 2019-DC-0660 of 15 January 2019 setting the quality assurance requirements for medical imaging procedures that use ionising radiation and resolution 2019-DC-0669 of 11 June 2019 which amends resolution 2017-DC-0585 of 14 March 2017 relative to the continuous training of medical professionals in the radiation protection of people exposed to ionising radiation for medical purposes.

Lastly, to coincide with the International day of radiology on 8 November 2019, on the initiative of the European association Heads of European Radiological protection Competent Authorities (HERCA), a campaign was launched in 19 European countries to make health professionals more aware of the appropriate use of medical imaging examinations. This event provided ASN with the opportunity to publish a census of French institutional and associative initiatives fostering the justification and the relevance of imaging examinations using ionising radiation, divided into three broad categories: recommendations for health professionals, guidance documents for communicating with patients, and awareness-raising campaigns.

The notion of justification effectively converges with the notion of relevance. The aim of justifying each examination is to ensure that the patient derives benefit from the examination that outweighs the risks inherent to exposure to ionising radiation. The medical notion of relevance means endeavouring to perform "the right procedure for the right patient at the right time", taking into account the benefit-risk trade-off.

02.

THE PRINCIPLES OF NUCLEAR SAFETY AND RADIATION PROTECTION AND THE REGULATION AND OVERSIGHT STAKEHOLDERS

CHAPTER 02

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

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 of 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, Labour Code and Public Health Code);
- at the European level, rules defined by Directives establishing a community framework for the safety of nuclear facilities and for the responsible and safe management of spent fuel and radioactive waste;
- at an international level, ten fundamental safety principles defined by IAEA (see box below and chapter 6, point 3.1) implemented by the Convention on Nuclear Safety (see chapter 6 point 4.1), establishing 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.

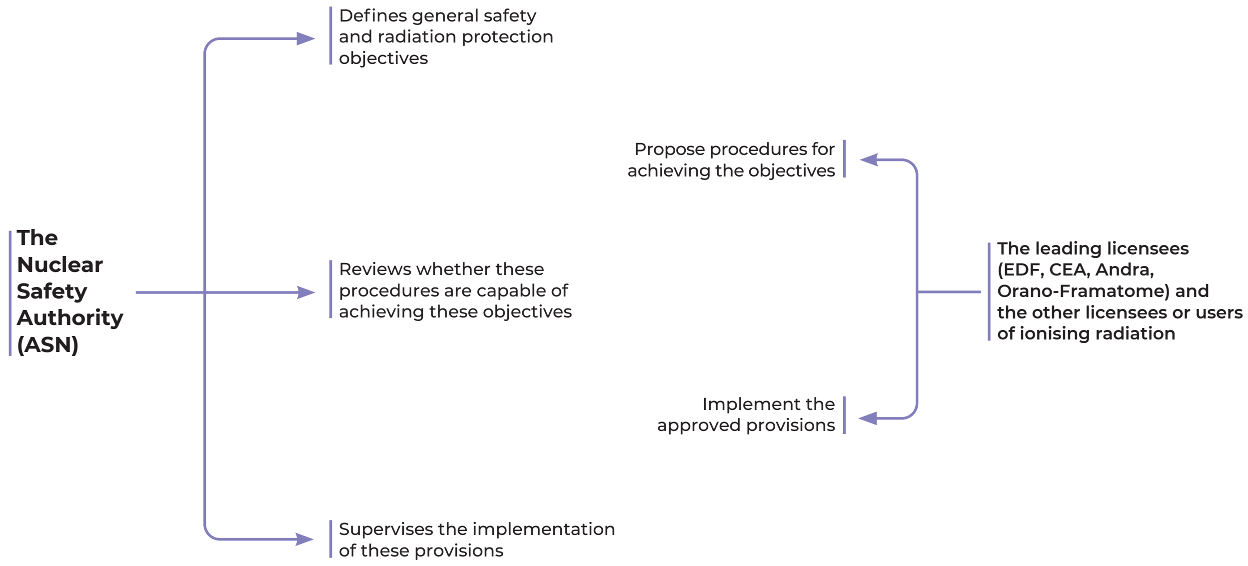
1.1.2 "Polluter-pays" principle

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*".

Responsibility of licensees and responsibility of ASN



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

1.1.4 Public participation principle

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

The justification principle, 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 Optimisation principle

The optimisation principle, 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[1] (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 monitoring 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 Limitation principle

The limitation principle, 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 purposes or for the purposes of research as mentioned in 1° of Article L. 1121-1*".

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.

1. The ALARA (As Low As Reasonably Achievable) principle appeared for the first time in Publication 26 from the International Commission on Radiological Protection (ICRP) in 1977. It was the result of a process of reflection on the principle of optimising radiological protection. Over the past 30 years, the acceptance and implementation of the ALARA principle has developed significantly in Europe, with strong backing from the European Commission, leading in 1991 to the creation of a European ALARA network.

The fundamental safety principles

The IAEA defines the following ten principles in its "Fundamental principles of safety" publication, IAEA Safety Standards Series – No. 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.**

Exceeding these limits leads to an abnormal situation and one which may eventually lead 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 Prevention principle

To anticipate any environmental damage, the prevention principle, 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), reporting to the Director General of the IAEA, as that complete range 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.

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

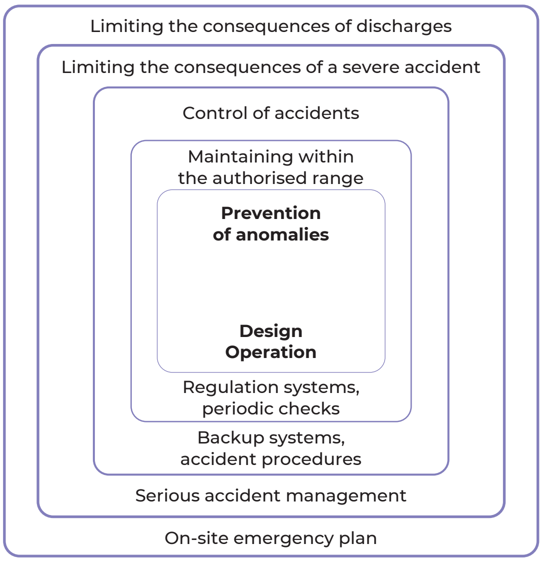
Regulation and governing systems must be designed, installed and operated such that the installation is kept within an operating range that is far below the safety limits. For example, if the temperature in a system increases, a cooling system starts up before the temperature reaches the authorised limit. 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 it is postulated that in

The 5 levels of "Defence in Depth"



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 brought 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 10).

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 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 (OEF)

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). The 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, the second goal is to share the resulting knowledge on the basis of the date of detection and recording of the anomaly, the lessons learned from it and how it was rectified. The 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.

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

1.2.6 Social, Organisational and Human Factors

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

The contribution of humans and organisations to safety, radiation protection and environmental protection is decisive in the design, 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, to detect and correct errors, to rectify degraded situations and to counter certain difficulties involved in the application of procedures.

ASN defines 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 these workers constantly need to adapt how they work in order 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 13 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 7 February 2012, setting the general rules for BNIs, requires that licensees 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 oversight of nuclear safety in France is compliant with the requirements of 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 Contracting Party "*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.*" and "*... shall take the appropriate steps to ensure an effective separation between the functions of the regulatory body and those of any other body or organization concerned with the promotion or utilization of nuclear energy*". These provisions were confirmed by European Council Directive 2009/71/Euratom of 25 June 2009 concerning Nuclear Safety, the provisions of which were in turn reinforced by the amending Directive of 8 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 13 June 2006, on Transparency and Security in the Nuclear field (TSN Act) and Programme Act 2006-739 of 28 June 2006, on the sustainable management of radioactive materials and waste.

In 2015, Parliament adopted Act 2015-992 of 17 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.

Pursuant to the provisions of the Environment Code, ASN regularly reports on its activity to Parliament, notably to the Parliamentary Office for the Evaluation of Scientific and Technological Choices (OPECST) 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 5.

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.

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.

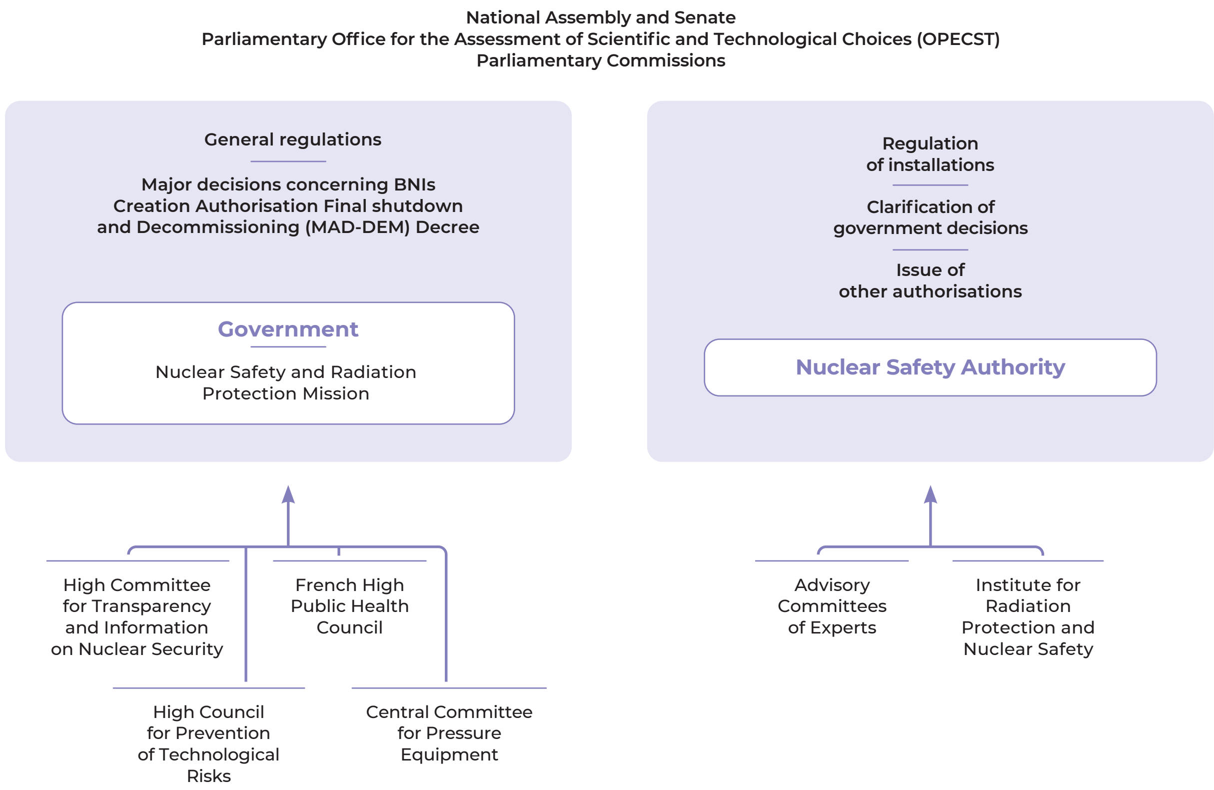
• The Nuclear Safety and Radiation Protection Mission
The Nuclear Safety and Radiation Protection Mission (MSNR), within the General Directorate for Risk Prevention at the Ministry for Ecological and Solidarity-Based Transition, is in particular tasked –in collaboration with ASN– with proposing Government 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 Defence and Security High Official (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 to discuss these matters.

Regulation of nuclear safety and radiation protection in France



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 intervene in the various procedures. 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 to transparency within its fields of competence.

ASN is governed by a Commission comprising five commissioners, including the ASN Chairman. They are appointed for a 6-year term. Three are appointed by the President of the Republic and one by the President of each Parliamentary assembly. ASN comprises departments placed under the authority of its Chairman.

For the purposes of technical analysis and assessment, it more particularly draws on the services of IRSN and the Advisory Committees of Experts (GPE).

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 regulations 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 *Journal Officiel* (*Official Gazette*).

• 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 *Bulletin Officiel* (*Official Bulletin*) on its website (*asn.fr*).

• 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, radiation protection inspectors and inspectors carrying out labour inspectorate duties.

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 10 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.

Administrative fines are imposed by the sanctions commission in order to comply with the principle of separation between the investigation, charging and sentencing functions instituted in French law and in international conventions on the right to a fair trial. Chapter 3 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 4 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 6 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 5 of this report describes ASN actions in this field.

• Definition of orientations and oversight of research
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 above-mentioned Ordinance of 10 February 2016 comprises provisions giving ASN competence to ensure that public research is tailored to the needs of nuclear safety and radiation protection (Article L. 592-31-1 of the Environment Code).

On the basis of the work done by the Scientific Committee (see point 2.5.3.), ASN has issued three opinions since April 2012. The third opinion dated 4 May 2018 required that research topics be taken further in the fields of external natural hazards, the fire risk in BNIs, nuclear fuel cladding materials for PWR reactors, the health impact of ionising radiation and the socio-economic consequences of a nuclear accident.

ASN released information relating to the publication of this third opinion *via* letters sent out in 2019 to fifty or so recipients nationwide (licensees, administrations, public research organisations). ASN thus established numerous contacts with public research organisations active in fields directly linked to those areas which it felt needed to be reinforced. These ASN exchanges with public research organisations and with the State's administrative departments in charge of national research strategy are continuing so that ASN can inform these players of the research fields it considers to be priorities for improving nuclear safety and radiation protection. ASN's opinions on research and ASN's actions in terms of orientation are also being disseminated internationally. Contacts have been made with several European safety regulators involved in research and ASN's research opinions will be disseminated internationally in 2020.

The Fukushima accident highlighted the need for more research in the field of nuclear safety and radiation protection. A Call for Projects (AAP) in these fields 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 AAP, which led to 23 projects being carried out between 2013 and 2018. Final seminars took place for some projects at the end of 2019 and others are scheduled during the course of 2020.

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 *Bulletin Officiel* (*Official Bulletin*).

In 2019, the ASN Commission met 72 times. It issued 25 opinions and 24 decisions.

• ASN head office departments

The ASN head office departments comprise an Executive Committee, an Office of Administration, a Management and Expertise Office, an Oversight Support Office and nine departments covering specific themes.

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

The role of the departments is 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 took charge of oversight of the security of radioactive sources. The DTS comprises two Branches: "Transport Monitoring" and "Radiation Protection and Sources", plus a "Source Security" section.
- The Waste, Research Facilities and Fuel Cycle Department (DRC) is responsible for monitoring nuclear fuel cycle facilities, research facilities, nuclear installations being decommissioned, contaminated sites and radioactive waste management. It takes part in monitoring the Meuse/Haute-Marne underground research laboratory and the research facilities covered by international conventions, such as the European Organisation for Nuclear Research (CERN) or the ITER reactor project. The DRC comprises five Offices: "Radioactive Waste Management", "Monitoring of Laboratories-Plants-Decommissioning and Research Facilities", "Monitoring of Fuel Cycle Facilities", "Management of Reactor Decommissioning and the Cycle Front-end" and "Management of Cycle Back-end Decommissioning 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. The DEU comprises two Offices: "Safety and Preparedness for Emergency Situations" and "Environment and Prevention of Detrimental Effects".
- The Legal Affairs Department (DAJ) provides consulting, analysis and assessment and assistance services on legal matters. It assists the various departments and the regional divisions with drafting ASN standards and analyses the consequences of new texts and new reforms on ASN's actions. It takes part in drawing up ASN's enforcement and sanctions doctrine. It defends ASN's interests before administrative and judicial courts, jointly with the entities concerned. It takes part in the legal training of staff and in coordinating regulations steering committees.
- The Information, Communication and Digital Usages Department (DIN) implements the ASN information and communication policy in the fields of 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. It is responsible for the IT infrastructure, for overseeing the digital transformation and the development of digital services for the parties concerned and the ASN audiences. The DIN comprises

The Commission

From left to right: **Bernard Doroszczuk, Philippe Chaumet-Riffaud, Lydie Évrard, Sylvie Cadet-Mercier and Jean-Luc Lachaume**

The Executive Committee

From left to right: **Daniel Delalande, Bastien Poubeau, Olivier Gupta, Christophe Quintin, Anne-Cécile Rigail and Julien Collet**

two offices: "Communication and Information" and "IT and Digital Usages".

- 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, HERCA –Heads of European Radiation Control Authorities) or cooperative groups under multilateral State-based initiatives (e.g.: NSSG –Nuclear Safety and Security Working Group, under the G7).
- 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 implementing the ASN budget policy and ensures optimised use of its financial resources. The SG comprises three offices: "Human Resources", "Budget and Finance", "Logistics and Real Estate".
- The Management and Expertise Office (MEA) provides ASN with 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 consists of six staff in charge of expert appraisals, research, quality and relations with IRSN. The MEA is in charge of overseeing the research network and the quality network at ASN.
- The Oversight Support Office (MSC) ensures that the inspections carried out by ASN are pertinent, harmonised, effective and in-line with ASN's values. For this purpose, it more particularly coordinates the processes involved in drawing up and monitoring the ASN inspection programme implemented by its departments and the approved organisations.

• 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/she is placed at the disposal of ASN to fulfil this role. 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, as applicable, the defence zone Prefect, and supervise the operations carried out to ensure the safety of the facility on the site. In order to prepare these situations, they take part in drawing up the emergency plans drafted by the Prefects and in periodic emergency exercises.

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

The members of the Management Committee

From left to right: **Julien Husse, Christophe Kassiotis, Carole Rousse, Fabien Féron, Céline Acharian, Brigitte Rouède, Olivier Rivière, Rémy Catteau, Corinne Silvestri, Olivia Lahaye and Adeline Clos (not in photo: Luc Chanial)**

The regional division heads

From left to right and from bottom to top: **Rémy Zmyslony, Marc Champion, Émilie Jambu, Aubert Le Brozec, Pierre Bois, Vincent Bogard and Adrien Manchon (not in photo: Hermine Durand, Caroline Coutout, Jean-Michel Férat and Alexandre Houlé)**

2.3.3 Operation

• Human resources

As at 31 December 2019, the total ASN workforce stood at 521, divided between the head office departments (288 staff members), the regional divisions (230 staff members) and various international organisations (3 staff members).

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

ASN utilises a diversified hiring policy with the aim of ensuring that there are sufficient numbers of the qualified and complementary human resources needed for performing its duties.

• 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 ASN personnel skills 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 11 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 match between the skills acquired –both within and outside ASN– and 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 31 December 2019, ASN employed 321 nuclear safety or radiation protection inspectors holding at least one clearance, or nearly 61% of the 521 ASN staff.

In 2019, nearly 3,800 days of training were provided to ASN staff through 230 sessions forming part of 133 different courses.

A Training Committee was set up in 2019 with the role of defining the training recommendations with respect to teaching procedures and tools and their adaptation to the new strategic objectives set out in the multi-year strategic plan.

• Social dialogue

As a State administration, ASN has three social dialogue bodies:
- the Social Dialogue Committee (SDC), with competence for all questions concerning the organisation and working of the departments, workforce and budget aspects;
- the Joint Consultative Commission (CCP) with competence for all individual or collective questions concerning ASN's tenured contract staff;
- the Health, Safety and Working Conditions Committee (CHSCT) with competence for all questions concerning the occupational health and safety of ASN staff.

These three bodies allow wide-ranging and regular internal discussions on all subjects affecting its organisation, its operations and the working environment of its personnel.

During the course of 2019, the ASN SDC met on three occasions to discuss various subjects: the new IT charter, the implementation of preliminary administrative inquiries, the social audit, the training audit, badging-in to a workstation, or budget execution. The SDC was also consulted on transfer of the Steering Committee responsible for Post-Accident Management (Codirpa) file from the DIS to the DEU, transfer of approved organisations monitoring from the MSC to the DIS, but also the reorganisation of departments such as the DIN or MEA. The SDC meetings were also an opportunity to review arrangements such as home-working or the reorganisation of cross-disciplinary functions.

For its part, the CHSCT focused on ensuring that the occupational health and safety aspects are considered in the above-mentioned major programmes. It met on three occasions in 2019.

The debates and discussions with the personnel representatives also covered the following topics:
- the actions supported by the CHSCT, notably the fight against sexist behaviour and violence in the workplace;

The regional representatives

From left to right: **Annick Bonneville, Jérôme Goellner, Alice-Anne Médard, Jean-Pierre Lestoille, Corinne Tourasse, Hervé Vanlaer, Laurent Tapadinhas, Christophe Chassande and Olivier Morzelle (not in photo: Françoise Noars)**

- annual audit of the general health, safety and working conditions situation at ASN;
- coordination of the network of prevention assistants and occupational health and safety training;
- the occupational health/safety inspector's visit to the head office premises;
- visits by the CHSCT delegation to head office (DRC and DTS).

In consultation with the members of the CHSCT and with the assistance of the network of prevention assistants, the administration also continued its actions to improve the prevention of occupational risks and updated the consolidated Occupational Risks Assessment Document (DUERP).

For its part, the Joint Consultative Commission, with competence for contractual staff, met twice in 2019. The debates primarily concerned the processes for increasing the salaries of ASN tenured staff and their career development and mobility projects.

It should be noted that regarding the actions decided on by the CCP, and for the second consecutive year, the administration organised a meeting in September 2019, bringing together all the ASN contractual staff.

• 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 29 December 2011 on strengthening the safety of drugs and health products) and Articles R. 1451-1 and following of the Public Health Code: the 4 July 2012 decision by the ASN Chairman applies the DPI requirements to the members of the Commission, the Management Committee and the Advisory Committee for Radiation Protection for Medical and Forensic Applications of Ionising Radiation (GPMED). Until mid-July 2017, the DPI were posted on the ASN website. The DPI are henceforth declared on the single remote-declaration site. There are 63 of them.
- Declarations of interests and assets to the High Authority for Transparency in Public Life (HATVP) derived from Act 2013-907 of 11 October 2013 on Transparency in Public Life: the members of the Commission submit their declarations on the HATVP website. The same applies to the Director General, the Deputy Director Generals, the Secretary General since 15 February 2017 (modification of the Act of 13 October 2013 by Act 2016-1691 of 9 December 2016 extending the declaration obligations to the persons occupying these functions).
- "Civil service" declaration of interests introduced by Act 2016-483 of 20 April 2016 into Article 25 of Act 83-634 of 13 July 1983 and governed by Decree 2016-1967 of 28 December 2016 (see 2-3° for ASN):
- Management by the ASN Director General of his financial instruments in conditions which preclude all right of review on his part, pursuant to Article 25 quater of the 13 July 1983 Act and Decree 2017-547 of 13 April 2017: the ASN DG submitted substantiating data to the HATVP before 2 November 2017.

In a decision dated 6 November 2017, the ASN Chairman appointed Henri Legrand as the professional ethics coordinator pursuant to Article 28 bis of the 13 July 1983 Act and Decree 2017-519 of 10 April 2017. He had played a major role in setting up the ASN professional ethics framework. Following his passing away, the Chairman will shortly be appointing a new coordinator.

Procedures for collecting internal ethics alerts from ASN personnel, pursuant to Act 2016-1691 of 9 December 2016 and Decree 2017-564 of 19 April 2017 were also put into place.

ASN has also modified its internal regulations. These now comprise two appendices: the first contains provisions regarding the professional ethics of the commissioners and staff, while the second contains provisions concerning external analysis and assessment performed at the request of ASN, for example by the Advisory Committees (see below).

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 21 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 23 April 2019, ASN considers that the creation of a single budget programme specifically for the regulation and oversight of safety and radiation protection is the current priority in order to:
- on the one hand, make all the efforts made by the State on behalf of the regulation and oversight of nuclear safety and radiation protection more legible and more visible both to Parliament and to the public, at a time when the importance of the nuclear sector in energy policy is being reaffirmed;
- on the other, enable ASN to improve how it controls and optimises the resource devoted to the technical expert assessments it orders, as is done abroad in the nuclear field and in France with regard to industrial risks.

• ASN management tools

ASN's management tools are more specifically evaluated during peer review missions (IAEA Integrated Regulatory Review Service –IRRS), devoted to analysis of the French system of oversight of nuclear safety and radiation protection (see box p. 131).

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.

"Nuclear safety" inspector training programme, Pressurised Water Reactor (PWR), Laboratories, Plants, Decommissioning and Waste (LUDD) and cross-disciplinary qualification

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
- Nuclear Pressure Equipment
- 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

The PSP for the 2018-2020 period, available on *asn.fr*, 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 oversight;
- promote the French and European safety approaches on the international stage.

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 actions 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 oversight.

The HCTISN's activities in 2019 are described in chapter 5.

2.4.2 The High Council for Public Health

The High Council for Public Health (HCSP), created by Act 2004-806 of 9 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 27 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 28 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 pressure equipment 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.

ASN international audits (IRRS missions)

IAEA's Integrated Regulatory Review Service (IRRS) missions are designed to improve and reinforce the efficiency of national nuclear regulatory frameworks, while recognising the ultimate responsibility of each State to ensure safety in this field. These missions take account of regulatory, technical and strategic aspects, make comparisons with IAEA Safety Standards and, as applicable, take account of best practices observed in other countries.

These audits are in response to the European Nuclear Safety Directive which requires a peer review mission every ten years.

Record of missions in France

2006: ASN hosted the first IRRS (Integrated Regulatory Review Service) mission concerning all the activities of a safety regulator.

2009: IRRS follow-up mission.

2014: new review mission extended to include management of security/safety interfaces.

2017: follow-up mission in October to assess the steps taken following the review carried out at the end of 2014, with the following findings and recommendations:

- implementation of measures to address 14 of the 16 recommendations;
- achievement of significant progress in improving its management system;
- drafting of general policy principles including safety culture aspects in training, self-evaluation and management;
- achievement of efficiency gains across all activities;
- need to continue improving 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, plus 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 *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 it was the first safety regulator to have hosted two full IRRS missions, including the follow-up missions. It is also closely involved in the review teams carrying out missions in other countries, as was the case in Germany and the United Kingdom in 2019.

2.4.4 The Local Information Committees and the National Association of Local Information Committees and Commissions (Anccli)

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 Council of the département, comprise various categories of members: representatives of *département* 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 13 June 2006 and by Articles R. 125-50 *et seq.* of the Environment Code. It was reinforced by the 2015 TECV Act.

The duties and activities of the CLIs are described in chapter 5.

The roles of the Anccli are to represent the CLIs in dealings with the national and European authorities and to provide assistance to the commissions with regard to questions of common interest.

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 Institute of Radiation Protection and Nuclear Safety (IRSN)

IRSN was created by Act 2001-398 of 9 May 2001 setting up a French environmental health safety agency and by Decree 2002-254 of 22 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 of the TECV Act and Decree 2016-283 of 10 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 31 December 2019, IRSN's overall workforce stood at 1,700 employees, of which 427 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.

• TECV Act
This 17 August 2015 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.

2.5.2 Advisory Committees of Experts

To prepare its decisions and resolutions, ASN draws on the opinions and recommendations of eight Advisory Committees of Experts (GPE), with competence for waste, decommissioning, NPE, reactors, transport, laboratories and plants, medical radiation protection, radiation protection in industry and the environment, respectively. A distinction is made between the expert assessment requested from IRSN (see point 2.5.1) and that requested from the GPEs.

At ASN's request, the GPEs issue an opinion on certain technical dossiers with particularly high potential consequences prior to decisions being taken.

ASN renews the composition of the Advisory Committees every 4 years. They are broken down according to their areas of expertise:
- the Advisory Committee for Decommissioning (GPDEM) created in October 2018;
- the Advisory Committee for Nuclear Reactors (GPR) renewed in October 2018;
- the Advisory Committee for Laboratories and Plants (GPU) renewed in October 2018;
- the Advisory Committee for Waste (GPD) renewed in October 2018;

TABLE 1

Advisory Committee meetings and visits in 2019

GPE	MAIN TOPIC	DATE
GPR	**Examination of the dossier for the 4th periodic safety review of the 900 MWe reactors** • Meeting on accident studies • Meeting on internal and external hazards • Meeting on severe accidents (all plant series concerned) • Meeting on probabilistic safety assessments	30 and 31 January 20 and 21 February 27 and 28 March 11 and 12 July
GPR (GPESPN)	Examination of the orientations dossier for the 4th periodic safety review of the 1,300 MWe reactors	22 May
GPR	Examination of the dossier on OEF from operation of EDF's nuclear power reactors and foreign reactors for the period 2015-2017	5 June
GPESPN	Examination of the dossier presenting the EDF approach for handling the deviations affecting the EPR reactor main secondary system steam line welds	9 April and 6 June
GPESPN	Examination of the dossier on the in-service strength of the austenitic-ferritic stainless steel cast elbow assemblies on the main primary system of 900 MWe reactors, except for those of the Fessenheim NPP, up to 20 years after their 4th ten-yearly outage	23 May
GPESPN	Examination of the dossier on the updating of the regulation reference files for the continued operation of the 900 MWe reactors beyond their 4th ten-yearly outage	8 October
GPESPN	Examination of the dossier on the in-service strength of the pressure vessels of the 900 MWe reactors for the 10-year period following their 4th ten-yearly outage	15 October
GPESPN	Information meeting on the segregated channel heads	16 October
GPD	Information meeting (*Cigéo* news, review of the PNGMDR and of the work done by the LLW-LL working group)	5 July
GPD (ESK)	Meeting with the ESK and visit to the Andra underground laboratory	11 and 12 September
GPU	Examination of the dossier for the periodic safety review of BNI 148 (Atalante)	19 June
GPU	Examination of the dossier for the periodic safety review of BNI 117 (follow-up to meetings held in November 2018)	2 and 3 July
GPMED-GPRADE	Joint meeting concerning the orientations determined for the "*Radiation protection advisor*" Order and referral concerning the updating of the national guide on "*Medical intervention in a nuclear or radiological event*"	12 February
GPMED	Examination of proposed recommendations for "*improved radiation protection in fluoroscopy-guided interventional procedures in operating theatres*"	28 May
GPMED	Examination of recommendations for "*improved radiation protection in fluoroscopy-guided interventional procedures in operating theatres*" and risk assessment approach	1 October
GPRADE	Presentation of the recommendations of the working group on occupational exposure to radon, the risk assessment approach and the presentation of regulatory subjects	16 September
GPDEM	Examination of the final shutdown/decommissioning (MAD/DEM) file and periodic safety review of CEA BNI 72 in Saclay	19 February
GPDEM	Information meeting on regulations	21 June

- the Advisory Committee for Transport (GPT) renewed in October 2018;
- the Advisory Committee for Nuclear Pressure Equipment (GPESPN) renewed in October 2018;
- the Advisory Committee for the radiation protection of workers and the public for industrial and research applications, as well as for ionising radiation of natural origin and in the environment (GPRADE) renewed in December 2016;
- the Advisory Committee for the radiation protection of health professionals, the public and patients for medical and forensic applications of ionising radiation (GPMED) renewed in December 2016.

For most of the subjects covered, the GPEs examine the reports produced by IRSN, by an expert working group or by one of the ASN departments. The representatives of the ASN departments or external structures which carried out the expert assessment prior to a GPE meeting, present their conclusions to the group. Following each consultation, the GPE consulted can send the ASN Director General a written opinion, plus recommendations where necessary. The contents of the dossier are made available to the members of the GPEs so that they can reach an informed and independent conclusion. This independent perspective is of use for the decision-making process.

In addition to being consulted on the dossiers submitted by a licensee, the Advisory Committees act as guarantor of nuclear safety and radiation protection doctrine and contribute to its development. They can be invited to take part in the debate on changes to regulations, or on a general nuclear safety or radiation protection topic.

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.

As an expert assessment body, the members of the Advisory Committees are required to abide by the provisions of the external expert assessment charter produced at the request of ASN and contained in Appendix 2 to the ASN internal regulations. Each member of an Advisory Committee draws up a Declaration of Interest (which is made public in the particular case of the GPMED which deals with health products questions, in accordance with the health expert assessment Charter of 21 May 2013 as set out in Article L. 1452-2 of the Public Health Code).

New internal regulations common to the eight GPEs was approved in 2019. The provisions to prevent conflicts of interest have been reinforced. More specifically, an organisation was defined for identifying ties and conflicts of interest and for dealing with them in an appropriate manner.

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 "Decommissioning" (GPDEM)
Chaired by Michèle Viala since 12 November 2019, following the death of the former chairman of the Advisory Committee, Henri Legrand, the GPDEM comprises 33 experts appointed for their competence in the field of BNI decommissioning. The GPDEM met twice in 2019, including one information meeting on the regulations.

• Advisory Committee for Waste (GPD)
The GPD is chaired by Pierre Bérest and comprises 38 experts appointed for their competence in the nuclear, geological and mining fields. It held one information meeting in 2019. A visit to Andra's underground laboratory in Meuse/Haute-Marne was organised in September 2019 on the occasion of a meeting with the ESK, the German counterpart of the GPD.

• Advisory Committee for Nuclear Pressure Equipment (GPESPN)
Since 2009, the GPESPN has replaced the Standing Nuclear Section (SPN) of the Central Committee for Pressure Equipment (CCAP). This latter was replaced as of 28 December 2016 by a standing sub-committee of the CSPRT (see point 2.4.3). The GPESPN has been chaired by Matthieu Schuler since 6 October 2018 and comprises 29 experts appointed for their competence in the field of pressure equipment. In 2019, it held six plenary sessions, including two information meetings. The meeting to examine the EDF dossier on the handling of the EPR reactor main secondary system steam line weld anomalies was opened to the public.

• 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. In 2019, it held three plenary meetings, one of which was organised jointly with the GPRADE. The GPMED experts were also invited to attend a session of the GPRADE. A call for candidates will be issued during the course of 2020, in preparation for the renewal of the Committee scheduled for December 2020.

• 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 31 experts appointed for their competence in the fields of radiation protection of workers (other than health professionals) and the public, for industrial and research applications using ionising radiation and for exposure to ionising radiation of natural origin, and protection of the environment. In 2019, it held two plenary meetings, one of which was organised jointly with the GPMED. The GPRADE experts were also invited to attend a session of the GPMED. A call for candidates will be issued during the course of 2020, in preparation for the renewal of the Committee scheduled for December 2020.

A new ASN Advisory Committee: The Advisory Committee for decommissioning

The ASN Advisory Committee for Decommissioning (GPDEM) was created by ASN resolution 2018-046422 of 30 October 2018. By creating this new GPE, ASN's aim was to address the need for expert assessment to analyse the decommissioning dossiers from the BNI licensees. At present, more than one quarter of the BNIs (35 out of 125) are shutdown or being dismantled.

ASN observes numerous delays in the decommissioning projects. There would appear to be a number of reasons for this: technical and organisational difficulties, human and financial resources allocated, etc. However, since 2015, the TECV Act has stipulated "*decommissioning as rapidly as possible*" after shutdown of the facility.

One of the specific features of assessing the decommissioning dossiers is that the safety issues in these facilities differ from those of the facilities in service. These issues concern the waste recovery and dismantling operations themselves, which are sometimes complex and which sometimes require the workers to intervene in close proximity to hazardous substances, but also the speed at which they progress. The time associated with reduction of the source term is a significant component in the safety of these facilities, which frequently do not meet current safety standards. The robustness of the strategy and the ability of the licensee to carry out its project on-time are therefore important factors in the safety of the facilities being decommissioned.

The analysis of these dossiers thus requires expertise appropriate to the specific features and the competence of the experts making up the GPDEM reflect this need. For example, some members of the GPDEM have specific project management skills.

Owing to their composition and their skills, the Advisory Committees can offer the critical perspective needed for the drafting of their opinions, in order to inform the decisions taken by ASN on the regulatory dossiers submitted to it on the occasion of the major milestones in the life of the BNIs (creation, commissioning, decommissioning). Their opinion is drafted on the basis of technical debates and the judgement of their experts regarding the organisations and processes of the licensees. In their debates, the Advisory Committees can draw on the IRSN opinion presented during specific sessions in the ASN premises (lasting one or more days).

In February 2019, the GPDEM met for the first time to examine the periodic safety review conclusions report and the decommissioning dossier for BNI 72 – Solid Waste Management Zone (ZGDS) in CEA's Saclay centre. In 2020, the GPDEM will examine the dossiers for the Phébus test reactor (BNI 92) in the CEA Cadarache centre, and EDF's EL4-D heavy water reactor in the Brennilis NPP (BNI 162).

- **Advisory Committee for Nuclear Reactors (GPR)**
The GPR is chaired by Philippe Saint Raymond and comprises 36 experts appointed for their competence in the field of nuclear reactors. In 2019, it held six plenary meetings, including four dealing with the 4th periodic safety review of the 900 MWe reactors. The meeting concerning the orientations of the 4th periodic safety review of the 1,300 MWe reactors was opened to members of the GPESPN.

- **Advisory Committee for Transport (GPT)**
The GPT is chaired by Jérôme Joly and comprises 25 experts appointed for their competence in the field of transport. It held no meetings in 2019.

- **Advisory Committee for Laboratories and Plants (GPU)**
The GPU is chaired by Alain Dorison and comprises 32 experts appointed for their competence in the field of laboratories and plants concerned by radioactive substances. In 2019, it held two plenary meetings and visited two BNIs before holding an examination session.

2.5.3 Scientific Committee

ASN calls 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 decision dated 6 November 2018, the ASN Commission appointed the nine members of the Scientific Committee for four years, on the basis of their expertise notably in the fields of research, radiation protection and nuclear safety. Under the Chairmanship of Michel Schwarz, former scientific director of IRSN, the Committee comprises Benoît De Boeck, Jean-Marc Cavedon, Edward Lazo, Catherine Luccioni, Antoine Masson, Jean-Claude Micaelli, Christelle Roy and Marc Vannerem. After the kick-off meeting held in November 2018, the Scientific Committee met twice, in May and November 2019.

2.5.4 The ASN's other technical support organisations

To diversify its expertise and benefit from other particular skills, ASN committed credits of €0.12 million in 2019.

In 2019, ASN more particularly continued or initiated collaborations with a group of several organisations approved for NPE, 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 Material and Waste Management Plan

Article L. 542-1-2 of the Environment Code requires the drafting of a 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 drafting 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 working group is presented in greater detail in chapter 14.

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

Pursuant to an Interministerial Directive of 7 April 2005 on the action of the public authorities in the case of an event leading to a radiological emergency situation, ASN, together with the ministerial departments concerned, is tasked 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. This Committee, headed by ASN, has representatives from the ministerial departments concerned, the health agencies, associations, the CLIs, and IRSN.

The work of the Codirpa is presented in greater detail in chapter 4.

2.6.3 The Committee for the Analysis of New Techniques and Practices using Ionising Radiation

The Committee for the Analysis of New Techniques and Practices using Ionising Radiation (Canpri) was created on 8 July 2019.

It is chaired by ASN, comprises 16 experts appointed by ASN, representing their learned societies, and representatives of the French health institutions. This committee met once on 27 August 2019.

2.6.4 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, as well as guidelines for studies to be taken to shed light on subjects for which there is a shortage of data or lack of clarity.

ASN also heads the national committee in charge of monitoring the National Plan for the management of the radon risk. In 2019, the Committee more specifically worked on producing the summary of the 3rd plan (2016-2019) and on preparing for the 4th radon plan for the period 2020-2024. The Committee met five times in 2019 (see chapter 1). Within the framework of this plan, ASN has since 2018 been heading a WG in charge of coordinating communication measures regarding management of radon risks.

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 1 May 2012. The ANSM, a public body reporting to the Ministry of Health, has taken up the duties of the French Health Products Safety Agency (Afssaps) and has been given 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 (*ansm.sante.fr*). The ASN-ANSM convention was renewed on 27 June 2017.

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 (*has-sante.fr*).An ASN-HAS agreement, signed on 4 December 2008, was renewed on 15 December 2015. An ASN-HAS action plan is appended to this agreement and is regularly updated.

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 (*e-cancer.fr*). Regular discussions take place between INCa and ASN.

2.8 The safety regulators: an international comparison

The Table below describes the status and activities of the safety regulators. In terms of status, most of these regulatory authorities are Government or independent agencies. With regard to their activities, most of them regulate and oversee the complete spectrum of nuclear activities, including in terms of protection against malicious acts (except for France with regard to malicious acts).

TABLE 2

Competencies of the main regulatory Authorities(*) for civil nuclear activities

COUNTRY/ REGULATORY AUTHORITY	STATUS			ACTIVITIES						
	ADMINIS-TRATION	GOVERN-MENT AGENCY	INDE-PENDENT AGENCY	SAFETY OF CIVIL INSTALLA-TIONS	RADIATION PROTECTION			SECURITY (PROTECTION AGAINST MALICIOUS ACTS)		TRANS-PORT SAFETY
					LARGE NUCLEAR FACILITIES	OUTSIDE BNIs	PATIENTS	SOURCES	NUCLEAR MATERIALS	
Europe										
Germany/BMUB + *Länder*	■			■	■	■	■	■	■	■
Belgium/AFCN		■		■	■	■	■	■	■	■
Spain/CSN			■	■	■	■	■	■	■	■
Finland/STÜK		■		■	■	■	■	■	■	■
France/ASN			■	■	■	■	■	■(**)		■
United Kingdom/ ONR		■		■	■			■	■	■
Sweden/SSM		■		■	■	■	■	■	■	■
Switzerland/ENSI			■	■	■				■	■
Other Countries										
Canada/CNSC			■	■	■	■	■	■	■	■
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.
*** Responsibility for source security was given to ASN by the Ordinance of 10 February 2016. This provision came into force on 1 July 2017.
** National transports only.

TABLE 3

Breakdown of licensee contributions

LICENSEE	AMOUNT FOR 2019 (millions of euros)			
	BNI TAX	ADDITIONAL TAXES WASTE AND DISPOSAL	SPECIAL ANDRA CONTRIBUTION	CONTRIBUTION ON BEHALF OF IRSN
EDF	544.78	96.67	115.92	48.42
Orano-Framatome	16.66	6.20	7.44	6.29
CEA	4.78	18.34	25.30	6.92
Andra	5.41	3.30	-	0.40
Others	3.16	1.67	-	0.71
Total	574.79	126.18	148.66	62.74(*)

* The amount allocated to IRSN is capped at €62.5 M.

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 the 2019 Budget Act, the ASN budget (action 9 of programme 181 "Risk prevention") amounted to €63.97 million in payment credits (CP). It included €46.44 million for personnel expenses and €17.53 million in CP for operating credits for ASN head office and its 11 regional divisions, and intervention credits. The ASN's budget is divided among five different public policy programmes:
- action 9 "Regulation and oversight of nuclear safety and radiation protection" of programme 181 "Risk prevention" covers the ASN workforce and personnel credits, as well as the operating, investment and intervention spending incurred for the performance of its duties;
- in addition, a certain number of operating costs (of head office and the regional divisions) are included in the support programmes of the economic and financial ministries (programme 218), the Ministry for Ecological and Solidarity-based Transition (programme 217) and the General Secretariat of the Government (programme 333 –"Shared resources and decentralised administrations"). ASN's assets on these various programmes, whether in terms of actions carried out for ASN or of credits, cannot be precisely identified owing to the overall, shared nature of these programmes;
- finally, pursuant to the provisions of Article L. 592-14 of the Environment Code, "*ASN is consulted by the Government regarding the share of the State subsidy to IRSN corresponding to the technical support mission performed by this Institute on behalf of ASN*". These ASN support credits are part of action 11 "Research in the field of risks" of programme 190 "Research in the fields of sustainable energy, development and mobility".

The total IRSN budget for 2019 amounted for its part to €233.3 million, of which €83.4 million were devoted to the provision of technical support for ASN. IRSN credits for providing ASN with technical support come in part (€41.15 million) from programme 190 (see above). The rest (€42.25 million) is covered by a contribution from the nuclear licensees. This contribution was put into place by the budget amendment Act of 29 December 2010.

In total, in 2019, the State's budget for transparency and the regulation of nuclear safety and radiation protection in France amounted to €297.42 million.

As a point of comparison, the amount of taxes collected by ASN in 2019 amounted to €849.63 million:
- €574.79 million from BNI taxes (paid into the State's general budget);
- €126.18 million from additional "support", "disposal" and "research" taxes (allocated to various establishments, including Andra, municipalities and Public Interest Groupings –GIP);
- €148.66 million from the special contribution for the management of radioactive waste (allocated to Andra).

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.

BNI tax, additional "research", "support" and "disposal" taxes, 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 30 December 1999). The revenue generated by this tax, the amount of which is set yearly by Parliament, came to €574.79 million in 2019. The proceeds go to the central State budget.

In addition, for certain BNIs, said Act 99-1172 of 30 December 1999 also creates three additional taxes, known as "research", "support" and "disposal", respectively. 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 €126.18 million in 2019, of which €3.30 million were paid in 2019 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 29 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 €148.66 million in 2019.

Finally, Article 96 of Act 2010-1658 of 29 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 €62.7 million in 2019.

4. Outlook

The legitimacy of ASN's decisions is built on a foundation of principles implemented with rigour, competence, transparency and independence. This implementation is based first of all on efficient internal operations. In 2020, ASN will thus continue to deploy actions decided on under the 2018-2020 multi-year strategic plan and aim for a graded and efficient approach to its regulation and oversight, improved coordination of technical instructions and consolidation of its actions in the field. In concrete terms, this for example means closer ties between the "licensing" and "inspection" processes, notably to target the inspections on the most critical moments in the life of the facility, deploying new methods for inspection of reactor outages, or giving priority this year to the inspection programme for management of the fire risk on nuclear reactors.

Moreover, in 2020, ASN will be informing the Government of the means needed for regulation and oversight, after re-examining its needs, more specifically in the light of the steps already taken to reinforce its efficiency, the decisions taken regarding energy policy and those taken concerning new facilities. As an additional guarantee of efficiency, ASN will continue to ask for a single budget programme devoted to the regulation and oversight of nuclear safety and radiation protection.

Finally, ASN will continue to involve the stakeholders in the decision-making process, as early on in the process as possible, while maintaining its own independence. In 2020, this will for example be the case with the consultation on improving the safety of the 1,300 MWe nuclear reactors, or the continued support for the Anccli or the Local Information Committees.

TABLE 4

Budget structure of the credits allocated to transparency and the regulation of nuclear safety and radiation protection in France

MISSION	PROGRAMME	ACTION	NATURE	BUDGET RESOURCES				REVENUE
				INITIAL BUDGET ACT 2019 AE (€M)	INITIAL BUDGET ACT 2019 CP (€M)	BUDGET BILL 2020 AE (€M)	BUDGET BILL 2020 CP (€M)	BNI TAX 2019 (€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)	46.44	46.44	47.67	47.67	
			Operating and intervention spending	12.53	17.53	12.65	17.65	
			Total	58.97	63.97	60.32	65.32	
		Action 1: Prevention of technological risks and pollution	Operation (evaluation) of the HCTISN (High Committee for Transparency and Information on Nuclear Security)	0.15	0.15	0.15	0.15	
			Sub-total	59.12	64.12	60.47	65.47	
Ministerial mission **Oversight of Government actions**	**Programme 217:** Management and coordination of policies for ecology, energy and sustainable development and the sea **Programme 333:** Resources shared by decentralised administrations	-	Operation of ASN's 11 regional divisions (real estate, etc.)	The credits allocated to ASN for these various programmes cannot be identified owing to the overall, shared nature of these programmes				574.79
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					
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):** French Institute for Radiation Protection and Nuclear Safety	IRSN technical support activities for ASN	41.15	41.15	41.15	41.15	
		Sub-action 11-2 (3 others areas): French Institute for Radiation Protection and Nuclear Safety	-	129.65	129.65	129.65	129.65	
Annual contribution on behalf of IRSN instituted by Article 96 of budget amendment Act 2010-1658 of 29 December 2010 dedicated to IRSN's activities (apart from technical support for ASN)			-	20.25	20.25	20.58	20.58	
Annual contribution on behalf of IRSN instituted by Article 96 of budget amendment Act 2010-1658 of 29 December 2010 dedicated to IRSN's activities in support of ASN			-	42.25	42.25	41.87	41.87	
			Sub-total	233.30	233.30	233.25	233.25	574.79
Grand Total (excluding IRSN and programmes 217, 218 and 333)				**142.52**	**147.52**	**143.49**	**148.49**	**574.79**
ASN Grand Total (excluding programmes 217, 218 and 333) and IRSN				**292.42**	**297.42**	**293.72**	**298.72**	

03.

REGULATION OF NUCLEAR ACTIVITIES AND EXPOSURE TO IONISING RADIATION

CHAPTER 3

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 linked to ionising radiation for humans and the environment, the State regulates nuclear activities, a task it has entrusted to ASN. With the aim of ensuring greater administrative efficiency, ASN has also been entrusted with the oversight of regulation concerning the environment and Pressure Equipment (PE) in Basic Nuclear Installations (BNIs).

Control and regulation of nuclear activities is a fundamental responsibility of ASN. Its primary goal is to ensure that a party responsible for a nuclear activity effectively assumes its obligations. ASN has a vision of control and regulation encompassing material, organisational and human aspects. Following safety and radiation protection assessments in each activity sector, the ASN implements its oversight action by issuing resolutions, binding requirements, inspection follow-up letters, plus penalties as applicable.

The oversight priorities are defined with regard to the risks inherent in the activities, the behaviour of those responsible for the activities and the means they deploy to control them. In the priority areas, ASN must reinforce its oversight. Conversely, for lower-risk areas, ASN must be able to explicitly scale-back its regulation and oversight.

1. Verifying that the licensee assumes its responsibilities

1.1 The principles of ASN's oversight duties

ASN's oversight aims primarily to ensure that those responsible for an activity effectively assume their obligations and comply with the requirements of the regulations concerning nuclear safety and radiation protection, in order to protect persons and the environment from radioactivity-related risks.

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.

ASN applies the principle of proportionality when determining its actions, so that the scope, conditions and extent of its regulatory action are 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).

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 Basic Nuclear Installations (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 subcontractors 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 oversees the entities and laboratories that it approves in order to take part in the inspections and oversight of nuclear safety and radiation protection. ASN is responsible for labour inspectorate duties in the nuclear power plants (see chapter 10).

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. It follows a continuous improvement approach to its regulation and oversight practices in order to consolidate the effectiveness and quality of its actions. ASN uses the Operating Experience Feedback (OEF) from more than forty years of nuclear activity oversight and the exchange of best practices with its foreign counterparts.

The licensee is the key player in the regulation of its activities.

ASN regulates nuclear activities by various means:
- inspection, generally on-site, or in an inspected department, or at 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;
- 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 entities and laboratories taking part in radioactivity measurements and radiation protection inspections, as well as qualification of entities for pressure equipment monitoring;
- presence in the field, also frequently outside actual inspections;
- consultation with the professional organisations (trades unions, professional orders, learned societies, etc.).

The performance of certain inspections by organisations and laboratories offering the necessary guarantees, as validated by ASN approval or qualification, contributes to the oversight of nuclear activities.

2.1 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.

• 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 BNIs, as well as the transport of radioactive substances– which are adopted with a view to preventing accidents or limiting their effects". This notion includes the measures taken to optimise waste and effluent management.

The safety of nuclear installations is based on the implementation of 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 8 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 10 February 2016 implementing the Energy Transition for Green Growth Act 2015-992 of 17 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.

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,

TABLE 1
Methods of ASN regulation of the various radiation protection players

	EXAMINATION/AUTHORISATION	INSPECTION	OPENNESS AND COOPERATION
Users of ionising radiation sources	• Examination of the application files required by the Public Health Code (Articles R. 1333-1 and seq.). • Pre-commissioning inspection, mainly in the medical field. • Receipt of notification, registration or issue of authorisation (Article R. 1333-8).	• Radiation protection inspection (Article L. 1333-29 of the Public Health Code).	• Jointly with the professional organisations, drafting of guides of good practices for users of ionising radiation.
Organisations approved for radiation protection checks	• Examination of approval application files for performance of inspections required by Article R. 1333-172 of the Public Health 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 checks.

non-destructive testing, maintenance work, disposition of nonconformities affecting these systems and periodic post-maintenance testing.

ASN also assesses the compliance of the most important new NPE with the requirements of the regulations. 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 9).

• 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.

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 checks and inspections on these users.

The methods of regulating the radiation protection players are presented in Table 1. They were updated with the June 2018 publication of the Decrees transposing European Directive 2013/59/Euratom of 5 December 2013 setting the Basic Standards for Health Protection against the dangers arising from exposure to ionising radiation.

• Regulating the application of Labour Law in the Nuclear Power Plants
ASN carries out labour inspectorate duties on the 58 reactors in operation –distributed among the 19 Nuclear Power Plants (NPPs)–, the Flamanville EPR reactor and the eight reactors being decommissioned. 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.

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.

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 designed to deal with these issues. The action of the ASN labour inspectors –19 staff, 11 of whom are in charge of the sites, representing 6.4 Full-Time Equivalent (FTE) and 2 for the labour inspectorate mission– has been reinforced in the field since 2019, 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 Committees on Safety and Working Conditions (CIESCT), as well as regular discussions with the social partners.

2.2 Internal checks performed by the licensees

2.2.1 BNI licensee internal oversight

In 2017, ASN issued a resolution (2017-DC-0616 of 30 November 2017) which specifies the criteria for distinguishing the significant modifications requiring ASN authorisation from those simply requiring notification. It also defines the requirements applicable to the management of significant modifications, more particularly the internal checks procedures to be implemented by the licensees.

ASN checks correct application of the provisions stipulated by this resolution.

2.2.2 Internal monitoring of radiation protection by the users of ionising radiation sources

The provisions of Articles R. 4451-40 to R. 4451-51 of the Labour Code effect an in-depth reorganisation of the procedures for the performance of technical inspections, now referred to as "verifications". They harmonise the relevant requirements with those applicable to other risks, notably the electrical risks (Article R. 4226-14), or more generally for work equipment (Article R. 4323-22), making the measures to be taken proportionate to the nature and scale of the risk. During the lifetime of the work equipment or the facilities, these verifications take the form of initial verifications (by an accredited organisation) repeated if necessary, and periodic verifications –by the Radiation Protection Advisor (RPA). The Order set out in Article R. 4451-51, which is to be published in 2020, will notably determine the work equipment or work equipment category and the type of radioactive sources for which the employer is required to conduct an initial verification and, as applicable, to repeat it and the procedures and conditions for the performance of these verifications.

2.3 ASN approval of organisations and laboratories

ASN can draw on the results of inspections performed by the independent organisations and laboratories that it approves and whose actions it monitors.

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. The list of organisations and laboratories is available on *asn.fr*.

ASN thus approves organisations so that they can perform the technical inspections or verifications required by the regulations in the fields within its scope of competence:
• radiation protection verifications;
• 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

TABLE 2

Number of radiation protection inspections performed in 2018 by organisations approved for radiation protection inspections

	MEDICAL	VETERINARY	RESEARCH / TEACHING	INDUSTRY OUTSIDE BNIs	BNI	TOTAL
Sealed sources	2,655	17	3,261	13,447	12,662	32,042
Unsealed sources	515	10	2,474	1,082	7,100	11,181
Mobile electrical generators of ionising radiation	3,592	361	44	911	6	4,914
Fixed electrical generators of ionising radiation	8,836	1,257	734	7,092	178	18,097
Particle accelerators	463	5	151	126	31	776
Dental	3,288	-	-	-	-	3,288
Total	19,349	1,650	6,664	22,658	19,977	70,298

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 2018, the Organisations Approved for Radiation Protection inspections (OARP) carried out 70,298 inspections, for which the breakdown per type of source and per field is given in Table 2.

The reports of the verifications 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 mandatory verifications 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. ASN thus approves laboratories to monitor radioactivity in the environment (see point 4.3).

The updated list of approvals issued by ASN is available on *asn.fr*.

Further to the opinion of the Interministerial Commission on the Carriage of Dangerous Goods (CITMD), ASN also approves:
- the training organisations for drivers of vehicles carrying radioactive materials; two organisations have been approved. A renewal was issued in 2019;
- the organisations responsible for certifying the conformity of packagings designed to contain 0.1 kilogramme or more of UF_6 (uranium hexafluoride);
- the organisations responsible for type approval of tank containers and swap tanks intended for the carriage of class 7 dangerous goods;
- the organisations responsible for the initial and periodic inspections of tanks intended for the carriage of class 7 dangerous goods.

Two organisations are approved for the qualification of tank-containers and for certification of the conformity of uranium hexafluoride packagings. One organisation was renewed in 2019.

As at 31 December 2019, the following are approved by ASN:
- 37 organisations tasked with radiation protection checks; 3 approvals or approval renewals were delivered in 2019;
- 79 organisations tasked with measuring radon activity concentration in buildings. Eleven of these organisations can also carry out measurements in cavities and underground structures, while ten are approved to identify sources and means of radon ingress into buildings. In 2019, ASN issued 48 new approvals or approval renewals;
- 4 organisations tasked with NPE inspections;
- 3 organisations qualified for 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;
- 64 laboratories for environmental radioactivity measurements covering 880 approvals, of which 361 are approvals or approval renewals delivered during 2019.

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; it is based on sampling and focuses on the subjects with the highest potential consequences.

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;
- 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 activities (work, transport operation, etc.). 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 number of similar installations, following a predetermined template.

Labour inspectorate work in the NPPs entails various types of interventions[1], which more particularly involve:
- checking application of the Labour Code by EDF and outside contractors in the NPPs (verification operations that include inspections);
- participation in meetings of the Health, Safety and Working Conditions Commissions (CSSCT), created as of 2020 for EDF, of Social and Economics Committees (CSE) and CIESCT (EPR construction site);
- conducting inquiries on request, following complaints or based on information, following which the inspectors may take decisions as specified by the labour regulations, such as cessation of the works or the obligation to have the work equipment verified by an approved organisation.

ASN sends the licensee an inspection follow-up letter, published on *asn.fr*, 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.

Any non-compliance found during the inspection can lead to administrative or criminal penalties (see point 6.2).

Some inspections are carried out with the support of an IRSN representative specialised in the facility checked or the topic of the inspection.

Artificial intelligence system for nuclear inspection and assessment (Siance)

As part of its multi-year strategic Plan, ASN initiated work on the digital transformation of nuclear safety inspection. Siance is one of the projects involved in this.

The purpose of the project is to take advantage of the data generated by ASN inspections on nuclear sites, contained in nearly 22,000 letters of an average of six pages. By means of an artificial intelligence method, the goal is to exploit a mine of text information that a human would not be able to analyse, given the technical richness of the content of the letters.

In 2018, ASN won the first call for expressions of interest issued by the Interministerial Directorate for Digital Affairs (DINUM) and the Interministerial Directorate for Public Transformation (DITP). In 2019, it thus received the support of experts from the digital world and a budget to develop an algorithm using artificial intelligence. This support concerned both technical and organisational aspects. The goal is to exploit the content of these letters in real time.

This project should help improve ASN's inspection policy, in other words lead to greater efficiency with inspections being focused on actions which produce the greatest benefits for safety as well as for the protection of people and the environment.

The project took place over 5 months in Agile(*) mode. Assimilating the content of the letters demanded significant resources: nearly 4,000 letters were annotated by 300 ASN inspectors from 11 regional divisions and 5 technical departments. The initial results from the algorithm are promising and show that the annotation work is already bearing fruit. A user-friendly human-machine interface will be developed.

At an organisational level, the project was built around a cross-disciplinary team which required mobilisation of both inspectors and senior management from the departments and regional divisions. Development of the tool will continue and it will be operational in 2020.

** The Agile mode (or method) recommends that short-term targets be set, with the project being divided into several sub-projects. Once the target is reached, one moves onto the next one until the final goal is achieved. This approach is more flexible. Because it is impossible to predict and anticipate everything, it leaves room for contingencies and changes.*

1. *The intervention is the unit representative of the activity traditionally used by the labour inspectorate.*

TABLE 3

Breakdown of inspectors per inspection domain (as at 31 December 2019)

INSPECTOR CATEGORIES	DEPARTMENTS	DIVISIONS	TOTAL
Nuclear safety inspector (BNI)	117	121	238
of which nuclear safety inspectors for transport	*16*	*49*	*65*
Radiation protection inspector	40	108	148
Labour inspector	2	11	13
Number of inspectors all domains	145	176	321

TABLE 4

Number of inspection days per field

BASIC NUCLEAR INSTALLATION (BNI) (EXCLUDING PRESSURE EQUIPMENT)	PRESSURE EQUIPMENT	TRANSPORT OF RADIOACTIVE SUBSTANCES	SMALL-SCALE NUCLEAR ACTIVITIES	APPROVED ORGANISATIONS AND LABORATORIES	TOTAL
2,019	264	141	1,641	209	4,274

• ASN inspectors

ASN has inspectors designated and accredited by its Chairman, in accordance with the conditions defined by Decree 2007-831 of 11 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 (Dreal), ANSM, Regional Health Agencies (ARS), etc. It also proposes organising joint inspections with these authorities concerning the activities within their joint field of competence;
- by encouraging its staff to take part in inspections on subjects in different regions and domains, notably to ensure the uniformity of its practices. Each ASN inspector in a particular region takes part in at least one inspection performed in a different region.

Table 3 presents the headcount of inspectors, which stood at 321 on 31 December 2019. 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 55% of the ASN inspectors. The 145 inspectors assigned to the departments take part in ASN inspections within their field of competence; they represent 45% of the inspector headcount and carried out 16% of inspections in 2019, with most of their work being the examination of files.

As previously mentioned, ASN continuously improves the efficiency of its oversight by targeting and adopting a graded approach to its inspections according to the scale of the implications for the protection of persons and the environment.

In 2019, the ASN inspectors carried out a total of 1,817 inspections, representing 4,274 inspection days in the field, broken down as shown in Table 4. The inspection work carried out by the ASN inspectors is not adequately reflected simply by the number of inspections performed and the number of inspection days (a day spent on an inspection by one inspector represents 1 inspector.day).

• 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 3.1). 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 online at *asn.fr*.

Moreover, for each in-depth inspection, ASN publishes an information notice on *asn.fr*.

3.1.3 Inspection of Basic Nuclear Installations (BNIs) and Pressure Equipment (PE)

In 2019, 2,283 inspector.days were devoted to inspecting BNIs and PE, broken down into 755 inspections, about 21% of which were unannounced.

This inspection work is broken down into 1,199 inspector.days in the NPPs (349 inspections), 820 inspector.days in the other BNIs (301 inspections), in other words mainly fuel cycle facilities, research facilities and installations being decommissioned, along with 264 for PE (105 inspections).

Two in-depth inspections were performed in 2019:
- in the Golfech NPP on the topic "safety management and organisation" and in particular the fields of Organisational and Human Factors (OHF), Operating Experience Feedback (OEF), the drafting of and compliance with the operating documentation, maintenance and normal operation;
- in the Fessenheim NPP, on the topic of preparation for decommissioning operations.

The ASN labour inspectors also carried out 577 interventions during the 225 inspection days in the NPPs.

The topical breakdown of these inspections is presented in Graph 1.

3.1.4 Inspection of radioactive substances transport

141 inspector.days were devoted by ASN to inspecting transport activities, comprising 92 inspections, of which 41% were unannounced; their breakdown into topics is illustrated in Graph 2.

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 2019, 1,641 inspector.days were devoted to inspections in small-scale nuclear activities, broken down into 854 inspections, of which 13% were unannounced. This inspection work was more particularly divided among the medical, industrial and research and veterinary sectors.

The breakdown of small-scale nuclear sector inspections according to the various activity categories is described in Graphs 3 and 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;
- supervisory checks, which are usually unannounced, to ensure that the organisation's staff work in satisfactory conditions.

In 2019, 209 inspector.days were devoted to inspecting approved organisations and laboratories, comprising 116 inspections, of which 40% were unannounced.

3.1.7 Checks on exposure to Radon and Naturally Occurring Radioactive Materials (NORM)

ASN also checks radiation protection in premises where the exposure of persons to naturally occurring radiation may be reinforced owing to the underlying geological context (radon in buildings open to the public).

• Monitoring exposure to radon
Article R. 1333-33 of the Public Health Code states that the activity concentration of radon in buildings open to the public is measured either by IRSN, or by organisations approved by ASN. These measurements are to be taken between 15 September of a given year and 30 April of the following year.

Article R. 4451-44 of the Labour Code requires that the initial checks on the radon activityconcentration, whenever required, are carried out by accredited organisations or by organisations approved by ASN.

The number of approved organisations, depending on the type of measurement, is given in Table 5.

• Monitoring natural radioactivity in water intended for human consumption
Monitoring the natural radioactivity in water intended for human consumption is the role of the Regional Health Agencies. The procedures for these checks take account of the recommendations issued by ASN and are taken up in the DGS Circular of 13 June 2007.

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

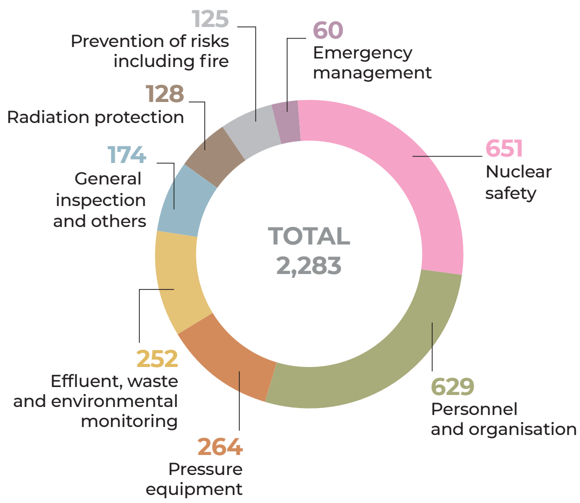
Reviewing the supporting documents produced by the licensees and the technical meetings organised with them are one of the forms of control carried out by ASN.

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 certain dossiers, ASN asks the competent Advisory Committee of Experts (GPE) for its opinion. 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 chapter 2.

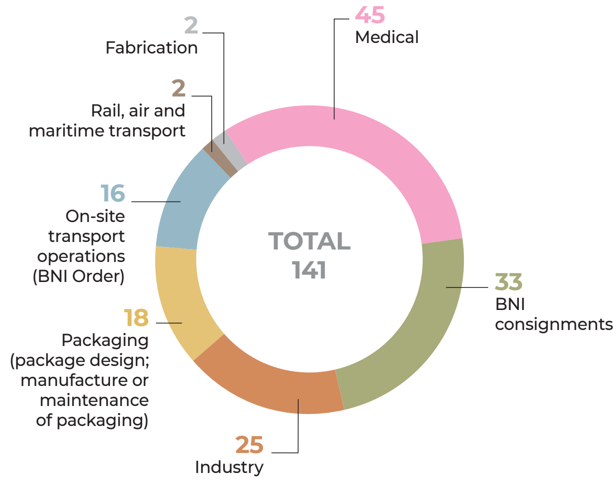
GRAPH 1

Breakdown of inspection days in the BNIs by topic in 2019(*)



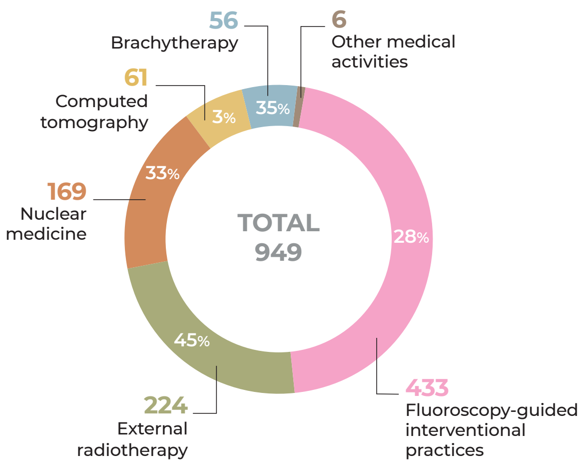
GRAPH 2

Breakdown of inspection days in the transport of radioactive substances by topic in 2019(*)



GRAPH 3

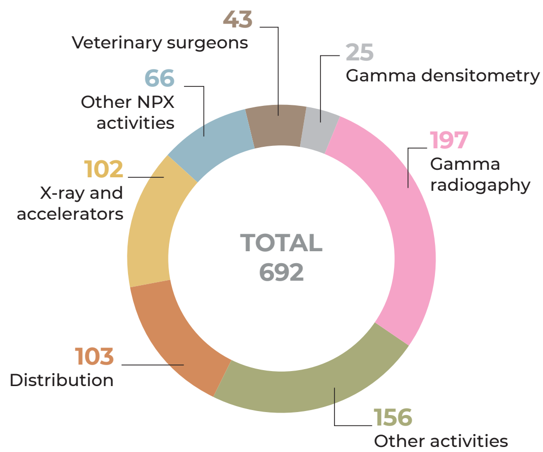
Breakdown of inspection days in the medical field by nature of activity in 2019(*)



% = percentage of the pool inspected

GRAPH 4

Breakdown of inspection days in small-scale nuclear industrial and veterinary activities by nature of activity in 2019(*)



* Inspection day figures rounded off.

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 (PWR). 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.

• The other files submitted by BNI licensees

A large number of dossiers concern specific topics such as fire protection, fuel management in PWRs, relations with the outside contractors, etc.

The licensee therefore periodically provides activity reports as well as summaries of water intake, liquid and gaseous discharges and waste produced.

TABLE 5

Number of organisations approved for measuring radon levels(*)

	NUMBER OF APPROVED ORGANISATIONS (AS AT 31/12/2019)
Level 1 option A(**)	78
Level 1 option B(***)	10
Level 2(****)	9

* IRSN is also competent for the measurement of radon (R. 1333-36 of the Public Health Code).
** Workplaces and premises open to the public for all building types.
*** Workplaces, cavities and underground structures (except buildings).
**** Represents complementary investigations.

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 verifications carried out under the responsibility of the facilities and the periodic checks required by the regulations, ASN carries out its own controls when examining the applications.

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 20 September 1994; Article 9v of the Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management of 5 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 10 August 1984 already required the adoption of such a system.

Based on thirty years of experience, ASN felt that it would be useful to transpose this approach, 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:
- Guide of 21 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 7 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 describes procedures for the notification of events relating to the transport of radioactive substances (see chapter 9). This guide has been applicable since 1 July 2017.

These guides can be consulted on the ASN website, *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. For example, the nuclear licensees detect and analyse several hundred anomalies every year, for each EDF reactor.

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 7 February 2012 (Article 2.6.4), the Public Health Code (Articles L. 1333-13, R. 1333-21 and R. 1333-22), the Labour Code (Article R. 4451-74) and the regulatory texts applicable to the transport of radioactive substances (for instance, the European 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 ensure that other parties responsible for similar activities benefit from experience feedback about the event.

The purpose of this system is not to identify or penalise any individual person or party.

Moreover, the number and rating on the International Nuclear and Radiological Event Scale (INES 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.

TABLE 6

Rating of significant events on the INES scale between 2014 and 2019

		2014	2015	2016	2017	2018	2019
Basic Nuclear Installations (BNIs)	Level 0	872	848	847	949	989	1,057
	Level 1	99	89	101	87	103	112
	Level 2	0	1	0	4	0	3
	Level 3 and +	0	0	0	0	0	0
	Total BNI	**971**	**938**	**948**	**1,040**	**1,092**	**1,172**
Small-scale nuclear activities (medical and industry)	Level 0	157	126	111	144	143	142
	Level 1	34	25	30	36	22	35
	Level 2	4	2	0	3	0	2
	Level 3 and +	0	0	0	0	0	0
	Total NPx	**195**	**153**	**141**	**183**	**165**	**179**
Transport of radioactive substances	Level 0	60	56	59	64	88	85
	Level 1	3	9	5	2	3	4
	Level 2	0	1	0	0	0	0
	Level 3 and +	0	0	0	0	0	0
	Total TSR	**63**	**66**	**64**	**66**	**91**	**89**
	Total	**1,229**	**1,157**	**1,153**	**1,289**	**1,348**	**1,439**

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, as applicable, 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 report 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. 4451-35 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 drafting 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.

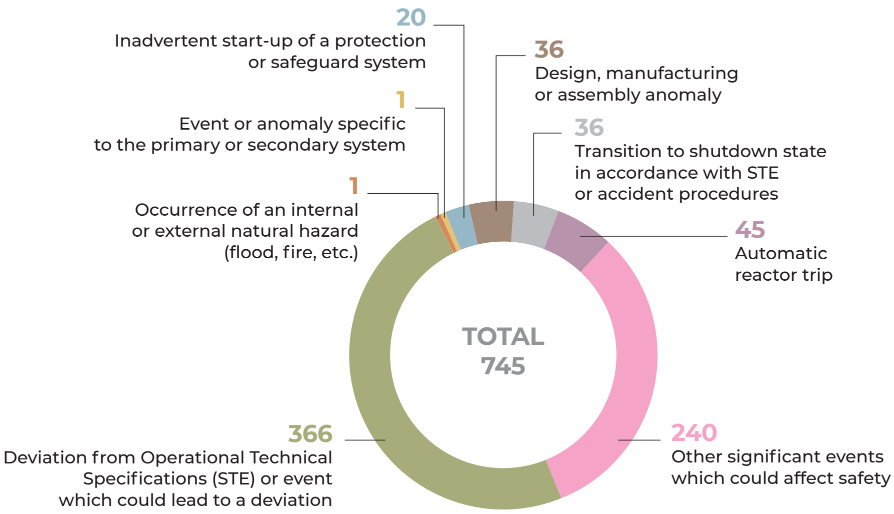
The ASN review focuses on compliance with the applicable rules for detecting and notifying significant events, the immediate technical, organisational or human measures taken by the licensee to maintain or bring the installation into a safe condition, and the pertinence of the submitted analysis.

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.

OEF comprises the events which occur in France and abroad in nuclear facilities or in those presenting non-radiological hazards, if it is pertinent to take them into account in order to reinforce nuclear safety or radiation protection.

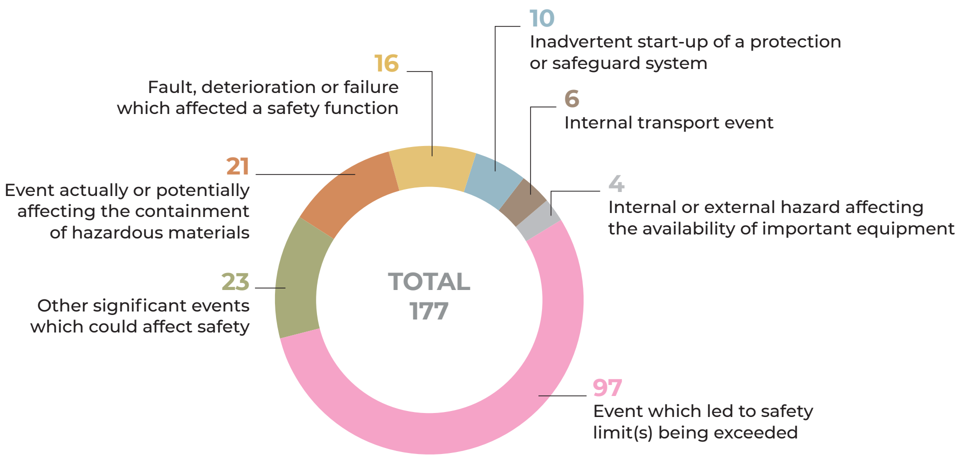
GRAPH 5

Events involving safety in NPPs, notified in 2019



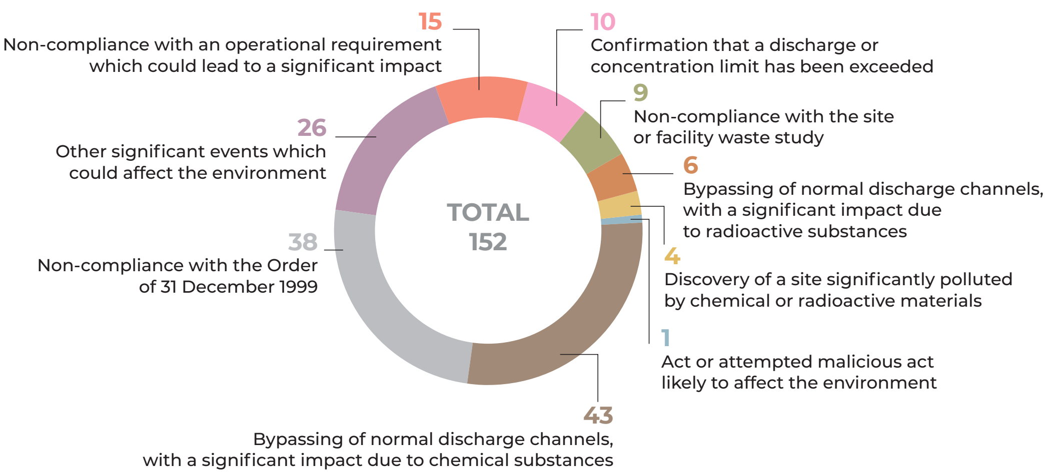
GRAPH 6

Events involving safety in BNIs other than NPPs notified in 2019



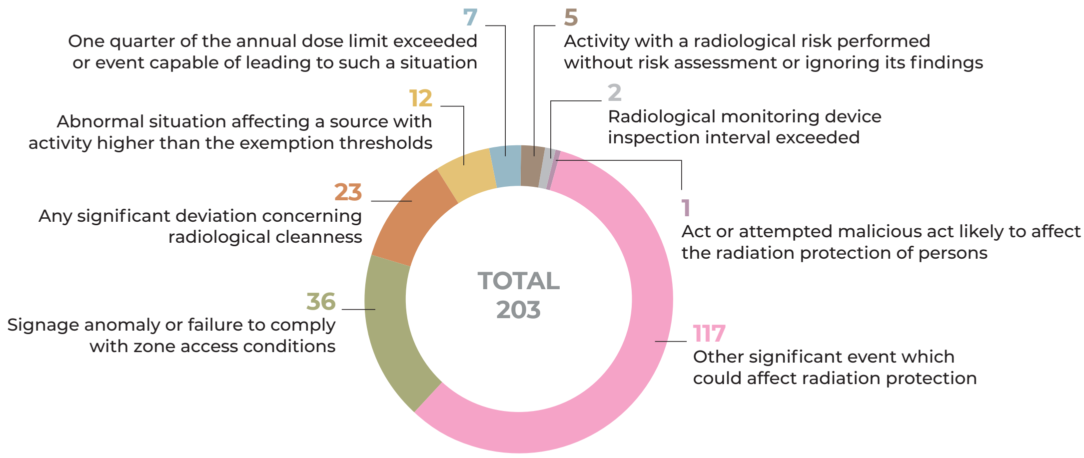
GRAPH 7

Significant environment-related events in BNIs notified in 2019



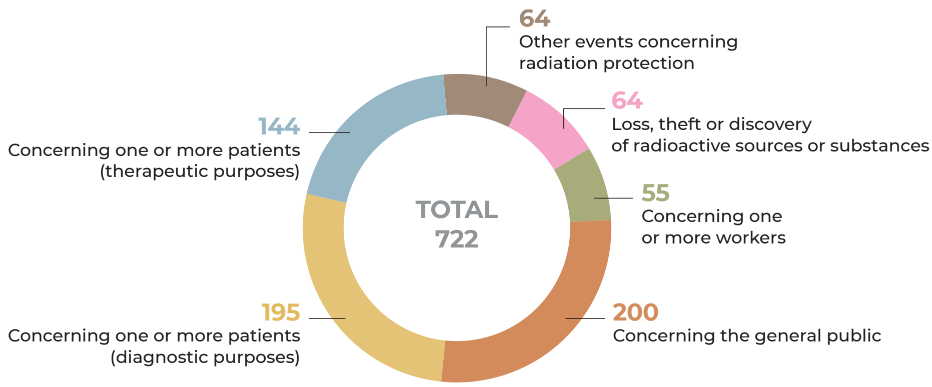
GRAPH 8

Events involving radiation protection in BNIs notified in 2019



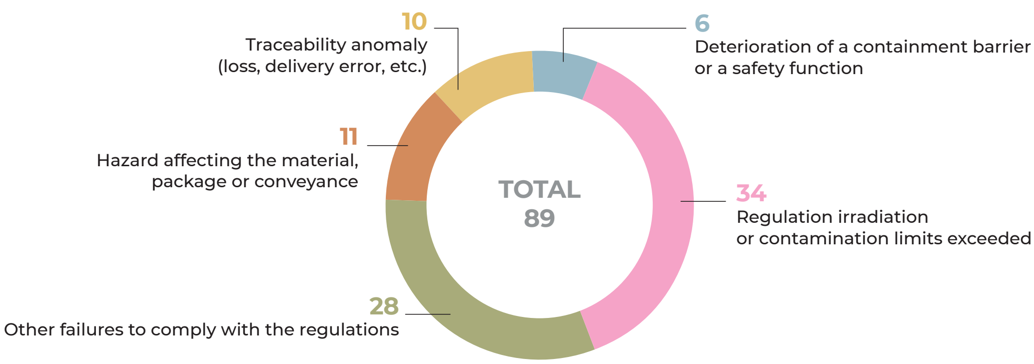
GRAPH 9

Events involving radiation protection (other than BNIs and RMT) notified in 2019



GRAPH 10

Events involving the transport of radioactive substances notified in 2019



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 6 November 2007 on technical inquiries into accidents or incidents concerning a nuclear activity specifies the procedure to be followed. It is based on practices defined for the other inquiry commissions and takes account of aspects specific to ASN, notably its independence, its own roles, its ability to impose binding requirements or sanctions.

3.3.4 Statistical summary of events

In 2019, 2,088 significant events were reported to ASN:
- 1,277 significant events concerning nuclear safety, radiation protection, the environment and on-site transportation of dangerous goods within BNIs, of which 1,172 were rated on the INES scale (1,057 level 0 events, 112 level 1 events and 3 level 2 events). Of these events, 29 significant events were categorised as "generic" –concerning several reactors, of which 4 were of level 1 on the INES scale and 1 of level 2 on the INES scale;
- 89 significant events concerning the transport of radioactive substances on the public highway, including 4 level 1 events on the INES scale;
- 722 significant events concerning radiation protection in small-scale nuclear activities, including 179 rated on the INES scale (35 were level 1 events and 2 level 2).

In 2019, 5 events were rated level 2 on the INES scale:
- Three BNI-related events: the first concerned defective electrical components rendering the emergency systems on the Penly NPP unavailable. The second concerned non-compliance with the general operating rules when draining the primary system on the Golfech NPP. The last was a "generic event" affecting the NPPs of Saint-Laurent-des-Eaux, Civaux, Paluel and Gravelines and concerned a risk of damage of the emergency diesel generating set lines owing to their potential contact with civil engineering structures in the event of an earthquake (see box in chapter 10). It should also be noted that the results of additional investigations carried out by EDF in response to requests from ASN following anomalies involving a lack of seismic resistance on the auxiliary systems of the emergency diesel generating set led EDF in 2019 to broaden the scope of an event notified in 2017 and reclassify this event as level 2 on the INES scale for the reactors of the Bugey NPP and the Fessenheim NPP.
- Two events in the field of small-scale nuclear activities: the first concerned a worker performing climatic and energy engineering maintenance work on sites carrying out nuclear activities and who, during the course of the work, received an effective dose in excess of the regulation limit value defined by the Labour Code. The second concerned a member of a nuclear medicine unit who on a single occasion exceeded the ionising radiation occupational exposure limit value defined by the Labour Code.

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. The INES scale does not apply to significant events affecting patients and the rating on the ASN-SFRO scale[2] of significant events affecting one or more radiotherapy patients is explained in chapter 7.

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 2019, 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 practices and professional information guides.

In 2019, ASN published two "avoiding accidents" sheets with the aim of sharing its OEF analyses.

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.

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 *asn.fr*:
- its resolutions and decisions;
- 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.

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

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 7 February 2012 and ASN resolution 2013-DC-0360 of 16 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 6 April 2017, ASN defined the conditions for water intake and consumption, effluent discharge and environmental monitoring applicable more specifically to PWRs. This resolution was approved by the Minister for Ecological and Solidarity-based Transition in an Order of 14 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 ASN 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 measurements taken by the licensee laboratories is maintained over time.

• The inspections carried out by ASN

Through dedicated inspections, ASN ensures that the licensees actually comply with the regulations binding on them with regard to the management of discharges and the environmental and health impact of their facilities. Every year, it carries out about 90 inspections of this type, split into three topics:
- prevention of pollution and management of detrimental effects;
- water intake and effluent discharge, monitoring of discharges and the environment;
- waste management.

Each of these topics covers both radiological and non-radiological aspects.

Every year, ASN carries out 10 to 20 inspections with sampling and measurement. They are generally unannounced and are run with the support of specialist, independent laboratories appointed by ASN. Effluent and environmental samples are taken for radiological and chemical analyses. Finally, every year, ASN carries out several reinforced inspections which aim to check the organisation put into place by the licensee to protect the environment; the scope of the inspection is then broadened to cover all of the above-mentioned topics. Within this context, simulations such as exercises to test the organisation implemented for pollution management can be carried out.

• 2016-2021 Micro-pollutants Plan

The 2016-2021 Micro-pollutant Plan[3] 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 meets 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 the NPPs, the campaigns to search for hazardous substances in water concluded that close monitoring of copper and zinc discharges was required. Under the Micro-pollutants Plan, the ASN action initiated in 2017 comprises 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 substances.

To allow a revision of the emission limits for copper and zinc, among other things, ASN has since the end of 2018 been carrying out work to revise the resolutions regulating water discharge and intake for the NPPs of Dampierre-en-Burly and Belleville-sur-Loire.

• Accounting of BNI discharges

The rules for accounting of discharges, both radioactive and chemical, are set in the general regulations by amended ASN resolution 2013-DC-0360 of 16 July 2013 relative to control of the detrimental effects and the impact of BNIs on health and the environment. These rules were set so as to guarantee that the discharge values accounted by the licensees, notably those taken into account in the impact calculations, will in no case be under-estimated.

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.

Operating Experience Feedback (OEF)

Following the fire which broke out on 26 September 2019 in the Lubrizol plant in Rouen, ASN asked the BNI licensees to learn the relevant lessons from this accident. ASN will be stepping up the number of inspections on the topic of managing non-radiological risks in BNIs in 2020 and the subsequent years. ASN will also be taking part in the work to be done to learn the lessons from the management of the event.

3. A micro-pollutant can be defined as an undesirable substance detectable in the environment at very low concentrations. 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.

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 opposite) are considered to be at the decision threshold level.

For discharges of chemical substances with an emission limit value set by an ASN requirement, 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 29 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 (GPRADE), for industrial and research applications of ionising radiation and the environment. ASN consulted the stakeholders in 2017 on this subject. The report from the working group and a circular letter intended for the professionals concerned were published on the ASN website on 14 June 2019.

In the small-scale industrial nuclear sector, few plants discharge effluents apart from cyclotrons (see chapter 8). The discharge permits stipulate requirements for the discharges 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 16 July 2013 concerning control of detrimental effects and the impact of BNIs 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. 1333-11 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. The doses received must remain below this limit.

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 and are detailed in the facility's impact assessment. During its assessment, ASN devotes efforts to verifying that these models are conservative, in order to ensure that the impact assessments are not 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 used in the impact assessment and to monitor changes in the radioactivity level in the various compartments of the environment around the facilities (see point 4.1.1).

The doses from BNIs for a given year are estimated on the basis of the actual discharges from each installation accounted for the year in question. This assessment takes account of discharges from the identified outlets (stack, river or sea discharge pipe), the diffuse emissions not channelled to the outlets (for example tank vent) and the sources of radiological exposure to ionising radiation present in the installation.

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.

The Table entitled "Radiological impact of BNIs since 2012" in chapter 1 presents an assessment of the doses due to BNIs calculated by the licensees for the most exposed reference groups.

For each of the nuclear sites presented, the radiological impact remains far below, or at most represents about 1% of the limit for the public, this limit being 1 mSv/year (millisievert 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 European Commission has carried out the following verification 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;
- the CEA site at Cadarache in 2011;
- the environmental radioactivity monitoring facilities in the Paris area in 2016;
- the La Hague reprocessing plant in 2018.

4.2 Environmental monitoring

4.2.1 The French National Network for Environmental Radioactivity Monitoring (RNM)

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 10 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 Local Information Committees (CLIs).

The French National Network for Environmental Radioactivity Monitoring (RNM) brings all these players together. Its primary aim is to collect and make available to the public all the regulatory environmental measurements taken on French territory, by means of a dedicated website (*mesure-radioactivite.fr*). The quality of these measurements is guaranteed by subjecting the measuring laboratories to an approval procedure (see point 4.3).

The guidelines of the RNM are decided by a network steering committee made up of representatives from all the stakeholders in the network: ministerial departments, regional health agencies, representatives of nuclear licensee or association laboratories, members of the CLIs, of IRSN, of ASN, etc.

4.2.2 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 16 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.

This environmental monitoring:
- contributes to understanding the radiological and radio-ecological state of the facility's environment through measurements of parameters and substances regulated in the requirements, in the various environmental compartments (air, water, soil) as well as in the biotopes and food-chain (milk, plants, etc.): a datum is determined before the facility is created and monitoring the environment throughout the lifetime of the facility enables any changes in this datum to be followed;
- 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.

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).

4.2.3 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 regulation monitoring of the environment of BNIs is tailored to each type of facility, depending on whether it is a nuclear power reactor, a plant, a research facility, a waste disposal facility, and so on. The minimum provisions of this monitoring are defined by the amended Order of 7 February 2012 setting the general rules for BNIs and by the above-mentioned modified resolution of 16 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 7 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.

4.2.4 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 kilometres 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 published in the RNM and in accordance with the provisions of ASN resolution 2008-DC-0099 of 29 April 2008, as amended, IRSN regularly publishes a *Detailed summary of the radioactive state of the French environment*. The third edition of this report was published at the end of 2018 and covers the period 2015-2017. In addition to this report, IRSN also produces regional radiological findings to provide more precise information about a given area.

4.3 Laboratories approved by ASN to guarantee measurement quality

Articles R. 1333-25 and R. 1333-26 of the Public Health Code require the creation of a French National Network for Environmental Radioactivity Monitoring (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 29 April 2008 amended.

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 4.2.1).

The approvals cover all environmental matrices for which regulatory oversight is imposed on the licensees: water, soil or sediment, 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 29 April 2008 amended.

In total, an approval covers about fifty measurements, for which there are as many Inter-laboratory Comparison Tests (ILT). These tests are organised by IRSN in a 5-year cycle, which corresponds to the maximum approval validity period.

In order to produce operating experience feedback from the interlaboratory comparison tests organised by IRSN, since they were set up in 2003, ASN and IRSN decided to organise a joint seminar in 2020 bringing together all the environmental monitoring stakeholders (laboratories of nuclear facility licensees, public institutions, universities, private, association or foreign players, etc.).

4.3.1 Laboratory approval procedure

The above-mentioned ASN resolution 2008-DC-0099 of 29 April 2008, as 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 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.

Environmental monitoring and limitation of radioactive discharges from nuclear facilities: the example of tritium

Tritium discharges from nuclear facilities require ministerial authorisation (creation decree) supplemented by ASN requirements concerning the conditions in which discharges are possible. Their direct and indirect effects on health and the environment are evaluated by the licensee in the facility's impact assessment. Discharges into the natural environment and their effects must be as low as possible through the licensee's use of the best available technologies. The discharge limit values for each facility are set by ASN resolutions.

Following the June 2019 publication by the Association for the Control of Radioactivity in the West (ACRO) of a report showing an unusual tritium value (310 Bq/L –becquerels per litre) measured in a sample taken from the Loire river at Saumur in January 2019, ASN conducted various investigations, together with IRSN, in order to identify the cause of this unusual value. It notably reviewed all the discharge notification registers transmitted monthly by the licensees, carried out an unannounced reactive inspection on the Chinon NPP, made contact with the Defence Nuclear Safety Authority (ASND) in charge of oversight of the defence BNIs and questioned industrial firms authorised to possess tritium sources. So far, these actions have been unable to identify the origin of the above-mentioned unusual value measured. ASN recalled that this isolated and unusual concentration had no consequences for people or the environment. As a comparison, the guideline value for drinking water recommended by the World Health Organisation (WHO) is 10,000 Bq/L.

So that the investigations can continue, ASN and IRSN decided to initiate a measurements campaign in the area concerned in 2020, involving the various stakeholders.

ASN kept the public informed and in particular published two information notices on its website in June and October 2019.

Further information will be released during the course of 2020, when the measurement campaign is launched.

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.

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 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 (*mesure-radioactivite.fr*). Up to 70 laboratories sign up for each test, including a number of laboratories from other countries.

The approval commission defined the evaluation criteria used for analysis of the ILTs. When the result obtained in an ILT by a laboratory is not conclusive enough, ASN may, on the advice of the approval commission, issue an approval for a trial period of one to two years for example, or make issue of the approval dependent on the provision of additional data, or even the participation in a further corroborating test.

In 2019, IRSN organised six ILTs. Since 2003, 82 ILTs have been carried out, covering 58 types of approval. The most numerous approved laboratories (55) are in the field of monitoring of radioactivity in water. About thirty to forty laboratories are approved for measurement of biological matrices (fauna, flora, milk), atmospheric dust, air, or ambient gamma dosimetry. 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 2019, ASN issued 361 approvals or approval renewals. As at 1 January 2020, the total number of approved laboratories stood at 64, which represents 880 approvals of all types currently valid.

The detailed list of approved laboratories and their scope of technical competence is available on *asn.fr*.

TABLE 7

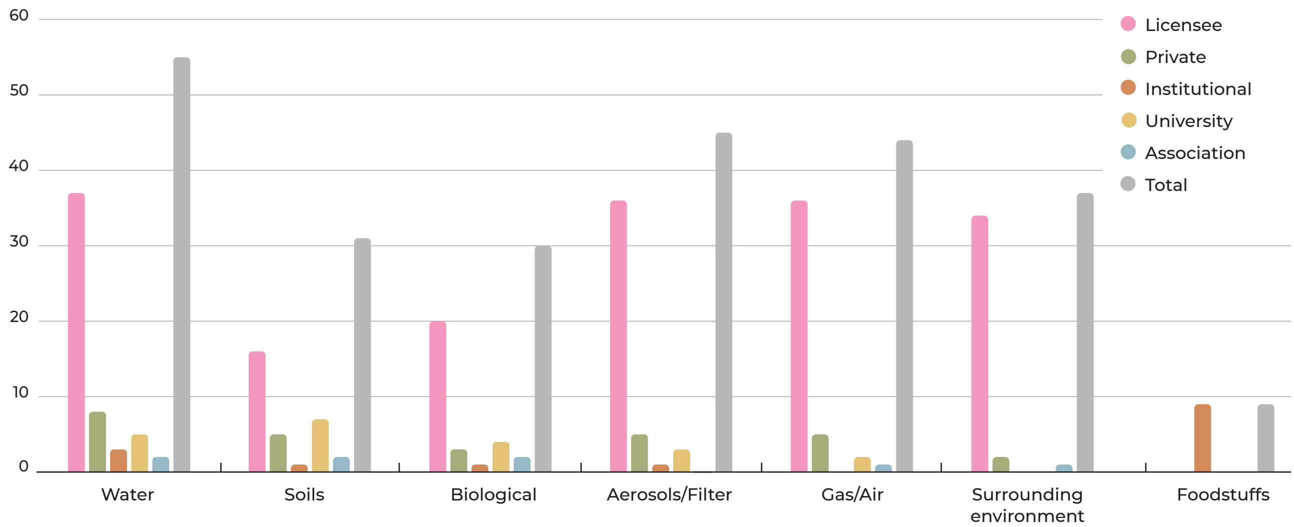
Example of radiological monitoring of the environment around BNIs

ENVIRONMENT MONITORED OR TYPE OF INSPECTION	CATTENOM NUCLEAR POWER PLANT (RESOLUTION 2014-DC-0415 OF 16 JANUARY 2014)	ORANO PLANT AT LA HAGUE (ASN RESOLUTION 2015-DC-0535 OF 22 DECEMBER 2015)
Air at ground level	• 4 stations continuously sampling atmospheric dust on a fixed filter, with daily measurements of the total β activity (βG) – γ spectrometry if βG > 2 mBq/m³ – Monthly γ spectrometry on grouped filters per station • 1 continuous sampling station downwind of the prevailing winds, with weekly measurement of atmospheric ^{3}H	• 5 stations continuously sampling atmospheric dust on a fixed filter, with daily measurements of the total α activity (αG) and total β activity (βG) – γ spectrometry if αG or βG > 1 mBq/m³ – 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 ^{3}H • 5 continuous sampling stations with bi-monthly measurement of atmospheric ^{14}C • 5 continuous measurement stations for ^{85}Kr activity in the air
Ambient γ radiation	• Continuous measurement with recording: – 4 detectors at 1 km – 10 detectors on the site boundary – 4 detectors at 5 km	• 5 detectors with continuous measurement and recording • 11 detectors with continuous measurement at the site fencing
Rain	• 1 continuous sampling station under the prevailing winds with bi-monthly measurement of βG and ^{3}H	– 2 continuous sampling stations including one under the prevailing winds with weekly measurement of αG, βG and ^{3}H – γ spectrometry if significant αG or βG
Liquid discharge receiving environment	• Sampling from the river upstream of the discharge point and in the good mixing area for each discharge – Measurement of βG, potassium (K)* and ^{3}H • Continuous sampling in the river at the good mixing point – ^{3}H measurement (average daily mixture) • Annual sampling in aquatic sediments, fauna and flora upstream and downstream of the discharge point with γ spectrometry, free ^{3}H measurement, and, on fish, organically bound ^{14}C and ^{3}H • Periodic sampling from a stream and in the dam adjoining the site with measurements of βG, K, ^{3}H	• Daily seawater samples from 2 points on the coast, with daily measurements (γ spectrometry, ^{3}H) at one of these points and for each of the 2 points, α and γ spectrometry and βG, K, ^{3}H and ^{90}Sr measurements • Quarterly seawater samples at 3 points offshore with γ spectrometry and βG, K, ^{3}H measurements • Quarterly samples of beach sand, seaweed and limpets at 13 points with γ spectrometry + ^{14}C measurements and α spectrometry for the seaweed and limpets at 6 points • Sampling of fish, crustaceans, shellfish and molluscs in 3 coastal zones of the Cotentin with α and γ spectrometry and ^{14}C measurement • Quarterly sampling of offshore marine sediments at 8 points with α and γ spectrometry and ^{90}Sr measurement • Weekly to six-monthly samples of water from 19 streams around the site, with αG, βG, K and ^{3}H 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 ^{3}H measurement
Groundwater	• Monthly sampling at 4 points, bi-monthly at 1 point and quarterly at 4 points with βg, K and ^{3}H measurement	• 5 sampling points (monthly check) with αG, βG, K and ^{3}H measurement
Water for consumption	• Annual sampling of water intended for human consumption, with βG, K and ^{3}H measurements	• Periodic sampling of water intended for human consumption at 15 points, with αG, βG, K and ^{3}H 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, ^{3}H and ^{14}C measurements	• Monthly grass sampling at 5 points and quarterly at 5 other points with γ spectrometry and ^{3}H and ^{14}C measurements, – Annual α spectrometry at each point • Annual campaign for the main agricultural crops, with α and γ spectrometry, ^{3}H, ^{14}C and ^{90}Sr measurements
Milk	• 2 sampling points, situated 0 to 10 km from the facility, including one under the prevailing winds, with monthly γ spectrometry, quarterly ^{14}C measurement and annual ^{90}Sr and ^{3}H measurement	• 5 sampling points (monthly check) with γ spectrometry, K, ^{3}H, ^{14}C and ^{90}Sr measurement

αG = α total; βG = β total
* Measurements of total concentration of potassium and by spectrometry for 40K.

GRAPH 11

Breakdown of the number of approved laboratories for a given environmental matrix as at 1 January 2020



5. Inspections concerning fraud and processing of reported cases

5.1 Managing, monitoring and control of fraud

Since 2015, several cases of irregularities that could be considered to be falsifications have been brought to light at known manufacturers, suppliers or organisations who have been working for many years on behalf of the French nuclear industry. Confirmed cases of counterfeit or falsification have also been encountered in a number of other countries in recent years. The term of irregularity is employed by ASN to cover any intentional modification, alteration or omission of certain information or data. An irregularity detected by ASN can be dealt with by a judge in a case of criminal fraud.

The number of confirmed or suspected cases only represents a very small proportion of the nuclear activities, but these cases show that neither the robustness of the monitoring and inspection chain, for which the manufacturers, suppliers and licensees have prime responsibility, nor the high level of quality required in the nuclear industry, have been able to totally rule out the risk of counterfeit, fraud and falsification. Not all of these cases were detected by the licensee's monitoring process, which must now be more adequately tailored to the prevention, detection, analysis and processing of cases of fraud.

In 2016, ASN began to look at adapting BNI inspection methods in an irregularity context. In so doing, it questioned other oversight administrations, its foreign counterparts and the licensees with regard to their practices, in order to learn the pertinent lessons. This particular risk led to changes in the ASN oversight methods, but it continues to be dealt with using the existing procedures. In 2019, ASN hired two staff from administrations regularly faced with these problems: the gendarmerie and national police force. These two persons are tasked with developing actions already in progress, notably with regard to inspections. They also give ASN the benefit of their experience in proposing different approaches, notably with regard to the possible enforcement measures and relations with the Public Prosecutors' Offices.

In 2018, ASN also reminded the BNI licensees and the main manufacturers of nuclear equipment that an irregularity is a deviation as defined by the BNI Order. The requirements of the BNI Order therefore apply to the prevention, detection and processing of cases that can be considered to be fraud. More generally, the regulatory requirements concerning the safety and protection of persons against the risks related to ionising radiation also apply. For example, applying a signature to certify that an activity has been correctly carried out, whereas in reality it was not, could, depending on the circumstance, be a breach of the rules of organisation, technical inspection of activities, skills management, etc.

In 2019, ASN carried out 25 inspections devoted in part or in full to the search for irregularities. Two inspections were carried out in the EDF and Orano head office departments, with the goal of examining how these groups have incorporated prevention of the risk of fraud into their buying policies and the state of progress of the handling of certain confirmed cases of fraud they have identified. The other inspections took place on the nuclear sites: the inspectors were able to identify suspicious cases compromising the performance of important activities: inspection sheets filled out before these inspections were actually carried out, failure to carry out these inspections, signature by a checker on a date when they were apparently absent, and so on. These cases are first of all dealt with as deviations from the regulatory requirements. They are also the subject of discussions with the site management and the head office departments of the licensees, so that they can be addressed as a priority. Depending on the potential implications of the deviation, a report or notification is sent to the Public Prosecutor's Office. One report and three notifications were sent in 2019.

In order to improve practices, ASN shares its experience feedback:
- with the licensee. For example, it participated in a day of debates organised by EDF;
- with its foreign counterparts. ASN notably takes part in the working groups of the Nuclear Energy Agency and the Multinational Design Evaluation Programme (MDEP) for new reactors, which held discussions on this subject. ASN is coordinating action to produce a model for rapid information between safety regulators when irregularities occurring abroad are discovered in a country.

Particular cases of irregularity are mentioned in point 2.2.2 of chapter 10.

5.2 Processing of reported cases

At the end of November 2018, ASN set up a portal to enable anyone wishing to notify it of irregularities potentially affecting the protection of persons and the environment (whistle-blower) to do so.

By means of a system of pseudonyms for the notifications received, ASN guarantees the confidentiality of anyone sending it a notification. Only a request from a judicial authority could override this confidentiality, something which has not yet happened. It is however preferable for the person sending in the notification to leave their contact details so that ASN can:
- acknowledge receipt of the notification;
- contact them if clarification is required;
- inform them if action has been taken following their notification.

As at 31 December 2019, 62 notifications had been sent to ASN: half *via* the notification portal, the others by other means of transmission (13 notifications by mail, 10 by direct contact with the geographically competent ASN division, etc.). The notifications received vary in terms of the field concerned, whether a BNI or small-scale nuclear facility, and in their content. Some are also forwarded by ASN to other administrations when it is not competent to deal with them. This could for example be the case of information concerning the security of a BNI, which is the responsibility of the High Defence and Security Official.

Twelve notifications have been verified during the course of inspections. The follow-up measures are managed within the same framework as the routine inspections.

For eight notifications, ASN recontacted the authors of the notification in order to obtain clarification.

Fourteen notifications were received anonymously: two of them, even if their content was taken into account in the overall monitoring actions, did not lead to targeted actions, as they were too vague and their anonymous authors could not be contacted. In addition, ASN was unable to inform the authors of the anonymous notifications of the action taken.

6. Identifying and penalising deviations

ASN implements enforcement measures, making it possible to oblige a licensee or party responsible for an activity to restore compliance with the regulations, along with penalties.

6.1 Fairness and consistency in the decisions regarding enforcement and sanction measures

In certain situations in which the actions of the licensee or party responsible for a nuclear activity fail 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 resort to enforcement measures and impose the penalties provided for by law. The principles of ASN actions in this respect are:
- actions 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 actions 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 regarding the party responsible for a nuclear activity or a licensee, more particularly:
- the inspector's observations;
- the official letter from the ASN departments (inspection follow-up letter);
- formal notice from ASN to regularise the 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.

6.2 An appropriate policy of enforcement and sanctions

When ASN observes non-compliance with the legislative and regulatory provisions applicable to radiation protection (provisions of the Public Health Code and the Labour Code), enforcement measures or sanctions may be taken against the licensees or parties responsible for a nuclear activity, after an exchange of views –in accordance with the right of defence– and prior formal notice.

In the event of failure to comply with the applicable provisions and requirements, the law (Environment Code and Public Health 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 carried out without consulting the licensee or 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 operation of the facility or of the transport operation until conformity is restored, or suspension of the activity until complete performance of the conditions imposed and the adoption of interim measures at the expense 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 licensee or 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 are proportionate to the gravity of the infringements observed. The administrative fine falls within the competence of the ASN Sanctions Committee.

TABLE 8

Number of infringement reports transmitted by the ASN inspectors between 2014 and 2019

	2014	2015	2016	2017	2018	2019
Report excluding labour inspection in the nuclear power plants	15	14	7	13	14	8
Labour inspection report in the nuclear power plants	9	3	1	5	2	4

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;
- 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 authorisation, non-compliance with the provisions of ASN resolutions or decisions, or irregular management of radioactive waste.

Any infringements observed are written up in reports by the nuclear safety and radiation protection 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 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.

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.

Class-5 penalties (fines) are stipulated in the field of nuclear safety for infringements mentioned in Article R. 596-16 of the Environment Code, as well as in the field of radiation protection by Decree 2018-434 of 4 June 2018 constituting various nuclear provisions (Article R. 1337-14-2 to 5 of the Public Health Code), notably with regard to non-compliance with the requirements for notification of a significant event, the administrative system (transmission of the title application file, compliance with general requirements, information concerning changes to the Radiation Protection Advisor).

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.

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.

6.3 2019 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 NPE, labour inspectors and radiation protection inspectors) transmitted twelve infringement reports to the public prosecutor's offices, two of which concerned labour inspections in the NPPs.

ASN served formal notice to BNI licensees and nuclear activity managers on five occasions. Table 8 shows the number of reports issued by the ASN inspectors since 2014.

7. Outlook

In 2020, ASN will continue to develop its oversight actions and aim to acquire greater knowledge of practices by field operators, notably through a greater number of inspections, comprising interviews.

ASN will also be reinforcing its inspection presence by deploying changes to its NPP inspection method during reactor outage phases (see box in chapter 10 "ASN oversight of reactor outages").

The development of digital tools to help the inspectors, which demanded considerable man-hours in 2019, will be continuing, notably with the Siance project (see box point 3).

ASN will continue to experiment with different inspection practices, partly implemented by other French or foreign inspection organisations.

Finally, in 2020, ASN will even more closely examine the irregularities that can be considered to be fraud, and the implementation of detection, processing and prevention measures by those in charge of nuclear activities or taking part in the subcontracting chain will need to be effective.

04.

RADIOLOGICAL EMERGENCY AND POST-ACCIDENT SITUATIONS

Radiological emergency and post-accident situations

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 substances;**
- **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, at the request of the Prime Minister, ASN also set up a Steering Committee for the Management of the Post-Accident Phase (Codirpa) so that, following on from the management of a radiological emergency, preparations can be made for the post-accident phase. This Committee proposed aspects of doctrine to the Government for the emergency phase exit, transitional and long-term periods, published in November 2012.

Since then, the Codirpa has been giving thought to new aspects of doctrine based notably on the lessons learned from the accident which struck the Fukushima NPP in Japan in March 2011 and the national exercises carried out on this subject. This work has led to new proposals for the population protection zoning strategy, in order to set up a system that is simpler and more operational.

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.

a) Major Nuclear or Radiological Accident National Response Plan

ASN took part in drafting the Major Nuclear or Radiological Accident National Response Plan (PNRANRM), which was published by the Government in February 2014. The Plan incorporates the lessons learned from the Fukushima accident and the post-accident doctrine drawn up by the Codirpa in 2012. It specifies the national organisation in the event of a nuclear accident, the strategy to be applied and the main actions 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 and it is now in the completion phase.

b) Off-site Emergency Plans

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. 741-18 et seq. of the Domestic Security Code, "*to protect the populations, property and the environment, and*

New types of inspections in the field of emergency management in 2019

During inspections on the topic "Emergency organisation and resources", ASN explored new inspection methods in 2019.

In order to test the alert chain and the activation of a licensee's entire emergency response organisation, ASN simultaneously inspected the head office departments of the Alternative energies and Atomic Energy Commission (CEA), national emergency response organisation managers and the CEA Marcoule site where an incident was simulated. By activating an emergency exercise simulating an airplane crash on the Marcoule site, followed by a fire in the ATALANTE facility, the team of inspectors present on the Marcoule site was able to observe the first actions taken by the management on-call team and then activation of the local emergency centre. At the same time, activation of the emergency response organisation at CEA's head office departments was observed by the team of inspectors present on the CEA national site in Saclay. This simultaneous inspection exercise was the first of its kind and produced a wealth of information.

In September 2019, ASN carried out an inspection in the Dampierre-en-Burly NPP on the topic of emergency organisation and resources, more specifically concerning the regional service of the Nuclear Rapid Intervention Force(*) (FARN). This was the first inspection of the EDF FARN by ASN.

The inspection entailed spot checks to ensure that the regional organisation and resources of the FARN enabling it to carry out its duty of supporting a site affected by an accident were both pertinent and operational, with regard to preparedness and the emergency management phase. This inspection more particularly comprised a simulation exercise involving the departure by a FARN convoy to a site affected by an accident in another region, following a request from the EDF national emergency response organisation.

This inspection was followed by the observation of a large-scale FARN intervention exercise on the Golfech NPP, as part of the national training of the FARN teams, during which large numbers of mobile resources were deployed (helicopter, barge, site machinery, etc.).

** The FARN is a national emergency system involving specialised crews and equipment for intervening on a site affected by an accident within less than 24 hours.*

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.

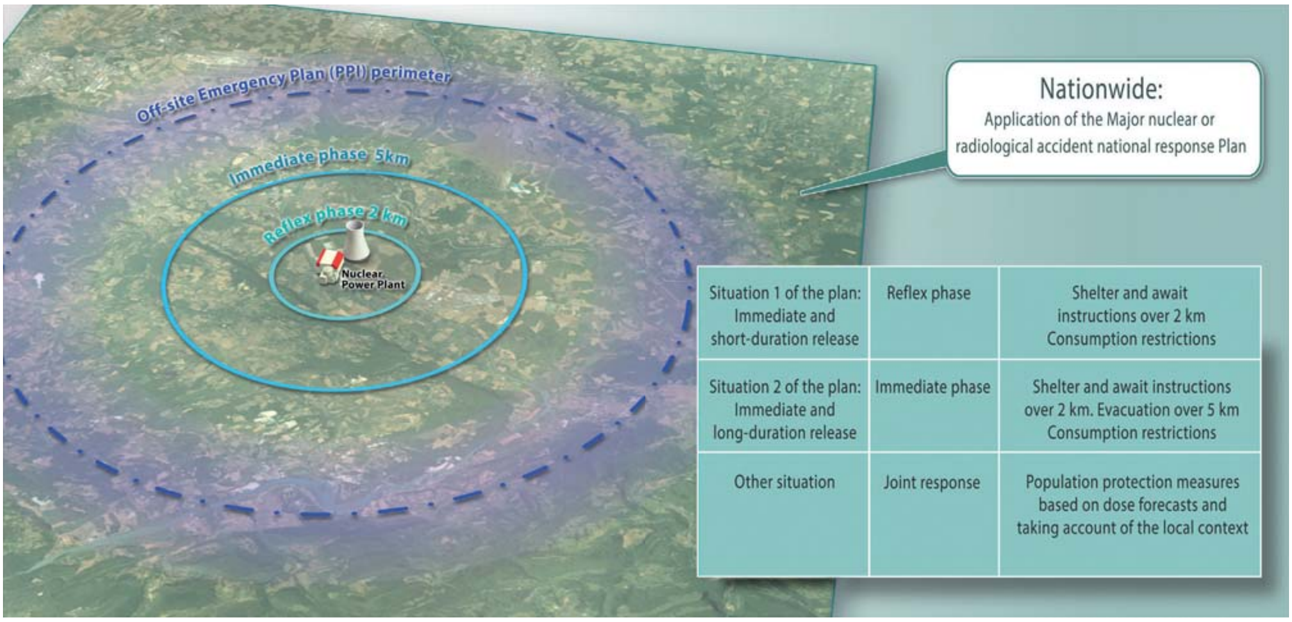
The PPI specifies the initial actions to be taken to protect the general public, the roles of the various services concerned, the systems for giving the alert, and the human and material resources likely to be engaged in order to protect the general public.

The PPI falls within the framework of the Disaster and Emergency Response Organisation (Orsec) 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. ASN assists the Prefect, who is responsible for the drafting and approval of the PPI, by analysing the various aspects with its technical support organisation, IRSN, including those concerning the nature and scale of the radiological consequences of an accident.

The PPI currently make it possible to plan the public authorities' response in the first hours of the accident in order to protect the population living within a 20 km radius around the affected reactor. This distance was increased from 10 to 20 km following the Ministry of the Interior's publication on 3 October 2016 of

DIAGRAM 1

Major nuclear or radiological accident national response plan



an Instruction concerning the response to a major nuclear or radiological accident –"*Changes in national doctrine for drafting or modifying 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 5 km 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.

c) On-site Emergency Plan

As part of the BNI commissioning authorisation procedures, ASN examines and approves the On-site Emergency Plans (PUI) and their updates (Article R. 593-31 of the Environment Code).

The PUI, prepared by the licensee, is designed to restore the plant to a controlled and stable condition and mitigate the consequences of an event. It defines the organisational actions and the resources to be implemented on the site. It also comprises arrangements for informing the public authorities rapidly. The obligations of the licensee relative to the preparation for and management of emergency situations are defined in Title VII of the Order of 7 February 2012 setting the general rules for BNIs. The associated provisions were stipulated in ASN resolution 2017-DC-0592 of 13 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 28 August 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.

ASN examines and approves the management plans for events linked to the transport of radioactive substances drawn up by the stakeholders in the transport of such substances pursuant to the international regulations for the carriage of dangerous goods. These plans describe the steps to be taken, depending on the nature and scale of the foreseeable hazards, in order to avoid damage or, as necessary, mitigate the effects. 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 PNRANRM 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 the parties concerned, ASN drafted Circular DGSNR/DHOS/DDSC No. 2005/1390 of 23 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 7 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, the 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 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 plant accident that occurred in Toulouse in 2001. Act 2006-686 of 13 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 (ICPE) 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 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" zone, determined by the Circular of 10 March 2000 revising the PPIs for BNIs, the pertinence of which was confirmed by the instruction of 3 October 2016. In this "reflex" zone, 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 17 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.

1.2 The emergency situation stakeholders

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 13 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 7 April 2005 on the action of the public authorities in the case of an event leading to a radiological emergency situation (see Diagram 1 above).

Thus, at the national level, ASN is actively involved in interministerial work on nuclear emergency management.

The Fukushima accident showed that it was necessary to improve preparation for the occurrence of an accident involving cumulative failures (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.

1.2.1 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, it calls on assessments by IRSN and can at any time ask the licensee to perform any assessments and take any actions it deems necessary.
- 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. ASN assists the Prefect with 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 that the steps taken between *départements* are consistent 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 relaying the information and heightening population awareness, more particularly during iodine tablet distribution campaigns.

1.2.2 National response organisation

In a radiological emergency situation, each Ministry –together with the decentralised State services– is responsible for preparing for and executing national level measures within its 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).

1.3 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.

1.3.1 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 the media.
- 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.

Administering stable iodine tablets is a means of saturating the thyroid gland and protecting against the carcinogenic effects of radioactive iodines.

The Circular of 27 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.

This Circular requires that as the party responsible for the safety of its facilities, the licensee finances the public information campaigns within the perimeter of the PPI and carries out permanent preventive distribution of the stable iodine tablets, free of charge, through the network of pharmacies.

The national campaign of iodine tablets distribution to the populations within the zone covered by the PPIs between 10 and 20 km around the NPPs, was launched in September 2019 (see Notable Events at the beginning of the report).

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 - Eprus). 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 11 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 PNRANRM.

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).

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:
- An evacuation zone, defined according to the ambient radioactivity (external exposure) within which the residents must be evacuated for a variable period of time.
- A zone, including the first zone, within which action is required to reduce both the exposure of the populations to ambient radioactivity and the consumption of contaminated food, to a level that is as low as reasonably achievable (for example a ban

on consumption of produce from the garden, restriction on access to wooded areas, ventilation and cleaning of homes, etc.).
- A last zone, which is more extensive than the first two and which is concerned more with the economic management of the area, within which specific surveillance of foodstuffs and agricultural produce will be implemented.

1.3.2 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.

The Circular of 18 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 2 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 aegis of the General Secretariat for Defence and National Security (SGDSN), a new version of this guide taking account of changes to certain practices, is currently under preparation.

1.4 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 30 October 1968, amended, concerning Civil Liability in the field of nuclear energy. France has also ratified the protocols signed on 12 February 2004, reinforcing the Paris Convention of 29 July 1960 and the Brussels Convention of 31 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 17 August 2015 on Energy Transition for Green Growth (TECV Act). An Order of 19 August 2016 sets the list of sites with more limited risks which benefit from a reduced liability amount.

As part of its ongoing analysis of the management of the post-accident phase, the Steering Committee for the Management of the Post-Accident Phase (Codirpa), set up by ASN in 2005 at the request of the Prime Minister, concentrated on learning the lessons from the post-accident management employed in Japan after the Fukushima disaster, but also the experience feedback from emergency exercises.

Following this work, the Codirpa recommended a number of changes to post-accident doctrine, which ASN transmitted to the Prime Minister in November 2019. The main one is simplification of the post-accident zoning, constituting the basis for the population protection measures:
- To protect the population from the risk of external exposure, the population evacuation perimeter (uninhabitable zone) would be maintained, on the basis of an annual effective dose value of 20 mSv/year for the first year, due to external exposure alone. The consumption and sale of foodstuffs produced locally would be prohibited within this zone.
- To limit exposure of the population to the risk of contamination through consumption, a non-consumption perimeter for fresh local produce is proposed. First of all, this perimeter would be defined from the largest of the population protection perimeters (sheltering, ingestion of iodine, etc.) determined during the emergency phase. It would then be refined using environmental contamination measurements and the available models.
- With regard to the sale of local produce, the Codirpa proposes adopting a regional approach per agricultural production and livestock sector, based on the maximum allowable radioactive contamination levels defined by the European authorities for the sale of foodstuffs.

In addition, to meet the request for support for initiatives to transfer aspects of the doctrine to the regional level, the Codirpa set up a working group involving numerous associations (including the Anccli), IRSN but also representatives of national and decentralised administrations. The work done led to:
- the creation of an Anccli/ASN/IRSN website raising post-accident awareness (*https://post-accident-nucleaire.fr*). This site enables elected officials, health professionals, associations, education personnel and economic players to access documents and information of use for preparing or managing life in a region contaminated by a nuclear accident;
- the publication of a practical guide intended for the inhabitants of a region contaminated by a nuclear accident;
- frequently asked questions/answers drawn up with and for health professionals on subjects concerning health and everyday life.

This initial information work will be continued over the long term, and the post-accident awareness-raising website will be enhanced in the future with Codirpa producing information to support and assist the post-accident stakeholders.

2. ASN's role in an emergency and post-accident situation

2.1 The four key duties of ASN

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 coordinated 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 1986 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 (International Atomic Energy Agency (IAEA) and European Union) and to the countries affected by the possible consequences on their own territory, jointly with the Ministry for Foreign Affairs.

2.2 Organisation in the event of a major accident

The ASN emergency response organisation set up to deal with a major accident more specifically comprises:
- the participation of ASN staff in the various units of the CIC;
- the creation of a national Emergency Centre in Montrouge organised around an emergency director and various specialised units:
  - an "information management and coordination" unit, in charge of supporting the emergency director;
  - a logistics unit;
  - a "safety" unit in charge of understanding and assessing the ongoing event;
  - a "protection of persons, the environment and property" unit, notably in charge of proposing population protection actions;
  - an "internal and external communication" unit;
  - an "international relations" unit;
  - a "forward planning" unit.

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 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 2019, the national Emergency Centre was activated 9 times, for 8 national exercises, 3 of which concerned a national defence nuclear installation, jointly with the Defence Nuclear Safety Authority[1] (ASND), plus one real situation.

For instance, on 11 November 2019 at 12h, following the earthquake which struck the Rhone valley, the on-call team was mobilised in the Montrouge Emergency Centre to check the condition of the installations with the licensees of the nuclear facilities in the region, provide its expertise to the State services and answer queries from the media.

During exercises, or in the event of a real emergency, ASN is supported by a team of analysts working in IRSN's Technical Emergency Centre.

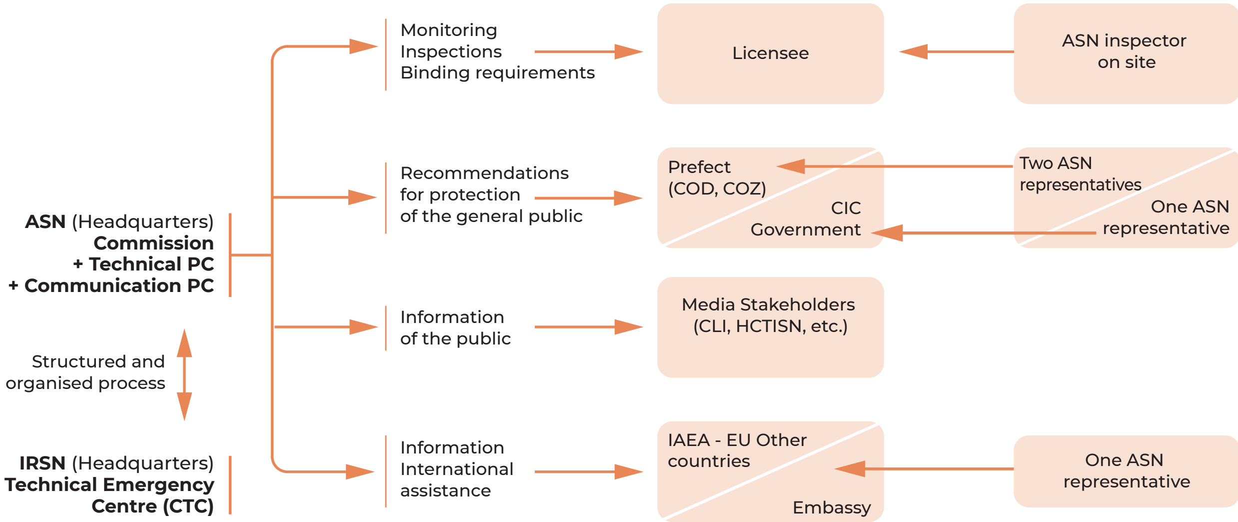
ASN's alert system allows mobilisation of its Emergency Centre staff and those of the IRSN. This automatic system sends an alert signal to the staff equipped with appropriate reception devices, as soon as it is remotely triggered by the BNI licensee originating the alert. It also sends the alert to the staff of the SGDSN, the General Directorate for Civil Security and Emergency Management (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.

A radiological emergency toll-free telephone number (**0 800 804 135**) enables ASN to receive calls reporting events 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 provided during the call is transmitted to the on-call team. Depending on the severity of the event, ASN may activate its Montrouge Emergency

1. Defence Nuclear Safety Authority (ASND), in charge of regulation and oversight of nuclear safety and radiation protection for defence-related activities and facilities, more particularly those operated by CEA.

DIAGRAM 2

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

Centre by triggering the alert system. 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.

Since 2018, an on-call duty system reinforces the robustness and the mobilisation and intervention reactivity of the ASN staff.

Diagram 2 above 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 below 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.

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, contribute to civil protection;
- to build on emergency situation management knowledge and experience.

These exercises, which are scheduled by an annual interministerial review, involve the licensee, the Ministries, the offices of the Prefects 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 2019, concerning BNIs and the transport of radioactive substances. This programme, announced to the Prefects in the Interministerial Instruction of 20 December 2018, took account of the lessons

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

learned from the Fukushima NPP accident and the emergency exercises performed in 2018.

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 below describes the key characteristics of the national exercises conducted in 2019.

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 the transport of radioactive substances, would seem to be a fair compromise between the training of individuals and the time needed to effect changes to organisations.

In 2019, 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 2018.

Certain exercises were thus extended by a day devoted to training the response crews (fire brigade, police, etc.), 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, three exercises run by the ASND were organised during the course of 2019, 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 the two Authorities on 5 July 2017.

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.

TABLE 2

National civil nuclear and radiological emergency exercises conducted in 2019

NUCLEAR SITE	DATE OF THE EXERCISE	MAIN CHARACTERISTICS
RMT CEA / NCT (Yonne *département* - 89)	10 January	Unusual players: carrier NCT and consignor CEA First implementation of the new emergency response organisation Simulated media pressure
Bugey EDF nuclear power plant (Ain *département* - 01)	23 and 24 January	Mid-day shift change
Belleville-sur-Loire EDF nuclear power plant (Cher *département* - 18)	3 and 4 April	Initial activation of the emergency centre by on-call team, then reinforcements after one hour Simulated media pressure
CEA Valduc facility (Côte d'Or *département* - 21)	5 and 6 June	Interfacing with ASND Initial activation by on-call team, then reinforcements after one hour Simulated media pressure
CEA Bruyères le Châtel facility (Essonne *département*- 91)	25 and 26 September	Interfacing with ASND Initial activation by on-call team, then reinforcements after one hour Simulated media pressure
Orano Tricastin site with implications for the Tricastin NPP (Drôme *département* - 26 and Vaucluse *département* - 84)	15 and 16 October	Consequences for 2 BNIs with 2 different licensees Participation by the Commission Internal communications Simulated media pressure
RMT EDF / TNI (Puy-de-Dôme *département* - 63)	14 November	Initial activation by on-call team, then reinforcements after one hour Simulated media pressure
Toulon naval base (Var *département* - 83)	13 December	Interfacing with ASND Initial activation by on-call team, then reinforcements after one hour

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 consequences in the form of maps: the tool called Criter developed by IRSN gives a representation of the results of environmental radioactivity measurements.

4. Outlook

In 2019, ASN contributed to the French system for the response to a major nuclear or radiological accident *via* a range of actions:
- participation in the national emergency exercises;
- 24/7 response by an on-call team to the various requests from Ministries, licensees, etc.;
- inspections of the various licensees on the topic of organisation and emergency management;
- coordination of the work done by the Codirpa.

During exercises held in 2019, in accordance with the goals set, ASN took part in tests of the new PPI doctrine applicable around the NPPs, in particular immediate evacuation within a radius of 5 km. ASN also observed improvements on various points, notably the transmission of the alert and coordination between ASN and ASND in the case of events in defence facilities. However, progress is still required in the circulation and transmission of information, at a time of modernisation of digital data interchange capabilities. ASN will be focusing more particularly on these points during the exercises in 2020.

With regard to the on-call system set up at ASN in January 2018, the documentation and procedures are proving to be effective, even if work is still required to take account of experience feedback.

The inspections were also notably able to check the implementation by the licensees of the "Emergency" resolution issued in 2017, for which the final deadlines are in 2021. ASN will monitor these final actions in 2020.

Lastly, the work of the Codirpa over the period 2014-2019 led to proposed changes to aspects of doctrine published in 2012. The Major Nuclear or Radiological Accident National Response Plan will be updated on the basis of the Government's decision concerning the incorporation of the proposed changes, notably concerning post-accident zoning.

In addition, under a new mandate from the Prime Minister, the Codirpa will be required to work in new areas, including adaptation of post-accident doctrine for nuclear or radiological accidents outside NPPs (transport accidents, LUDD (Laboratories, Plants, Waste, Decommissioning)).

Finally, the Lubrizol accident revealed differences in how chemical and radiological risks are addressed in the management of population protection actions. In 2020, ASN will aim to learn all relevant lessons from this accident and will assist in any work that could be initiated by other administrations on this topic.


05.

INFORMING THE PUBLIC AND OTHER AUDIENCES

CHAPTER 5

Informing the public and other audiences

At ASN, the French Nuclear Safety Authority, informing the public and other audiences is the centre of its activities. The Acts of 2006 on Transparency and Security in the Nuclear Field and 2015 on Energy Transition for Green Growth 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 (BNIs) 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. After each inspection, ASN publishes an "inspection follow-up letter" which sets out its findings and the recommendations for the licensee: nearly 23,000 follow-up letters can thus be consulted online. It also publishes notices, guides and reports intended for the professionals and accessible to the public.

ASN promotes the involvement of civil society and considers it very important that the citizens should contribute to the maintaining of nuclear safety and radiation protection: it consults, for example, 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 it endeavours to render even the most technical issues understandable.

In 2019, to promote informing of the general public, ASN was involved in many events in the regions. It played an active part in the consultation on the 4th periodic safety review of the 900 MWe Nuclear Power Plants (NPPs) and in the information and stable iodine tablet distribution campaign over a widened perimeter around the NPPs. It participated in all the meetings for public debate on the French National Radioactive Material and Waste Management Plan (PNGMDR) organised by the French National Public Debate Commission (CNDP) to answer the public's questions concerning nuclear safety and radiation protection.

1. Developing relations between ASN and the public

1.1 Raising awareness in the public at large and developing a radiation protection culture among citizens

ASN works to ensure that citizens have reliable information on the nuclear risk and that they develop the right radiation protection reflexes in all circumstances. It fosters, for example, a prevention activity against the risks of exposure of medical personnel and patients in medical activities involving radioactive sources. 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.

1.1.1 The website *asn.fr*

With more than 85,000 visits per month on average, the *asn.fr* website is at the heart of the system for informing the various audiences. It posts the majority of draft opinions and resolutions for consultation. The website is also a reference source of information for the more informed audiences: expert citizens, members of environmental associations and professionals.

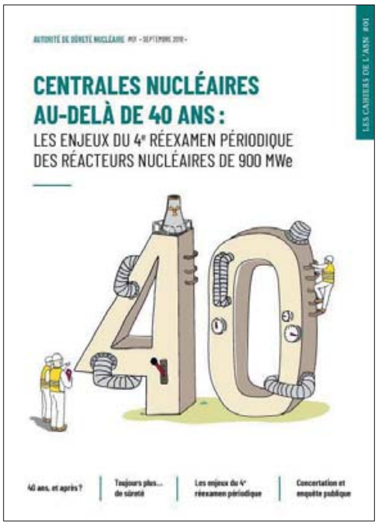
To satisfy the needs for explanations inherent to a wide audience, the publication formats are varied and meet new expectations, particularly on the social networks. New educational content is also regularly put online.

ASN takes care to translate into English the majority of the information notices, press releases, publications and content concerning major issues. These English translations support ASN's work in large international organisations and foster a concerted global 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 5,000 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 *asn.fr*.

In all, more than 4 million pages of the site were viewed in 2019.

On another note, further to the irregularities discovered at the Creusot Forge plant in 2016, ASN has stepped up the fraud prevention and detection measures in the nuclear sector. These measures include a readily accessible reporting system: the website *asn.fr* provides a secured form for submitting reports, guaranteeing the pro tection of whistle-blowers and the confidential treatment of the information received.



The *Les Cahiers de l'ASN booklet* #1: Nuclear power plants beyond 40 years

1.1.2 The social networks

The website content, which can be consulted on smartphones or tablets, is also shared on the main social media (primarily Twitter, Facebook and LinkedIn). The news feeds of the ASN social media accounts convey the main position statements. 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 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 to the audiences, including when several players are involved.

ASN news is followed and passed on by more than 10,000 subscribers on Twitter, nearly 15,500 on LinkedIn and nearly 4,000 on Facebook.

1.1.3 The ASN/IRSN exhibition

As part of their duty to inform the public, ASN and the Institute for Radiation Protection and Nuclear Safety (IRSN) have created educational content 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.

This content exists in several forms at present: an exhibition of some 80 display boards plus educational leaflets. These vectors are designed to provide information on radioactivity –whether natural or artificial, its uses, its implications and its effects on humans and the environment. Requests for information concerning this popularised content, the booklets and the exhibition are to be made to *info@asn.fr*.

In 2018 and 2019, the content of the ASN-IRSN exhibition was updated and referenced online to make it readily accessible and reusable. A specific website shall be provided for the public in 2020.

Information and iodine tablet distribution campaigns

Every seven years or so, an information and iodine tablet distribution campaign targets the populations living in the vicinity of Nuclear Power Plants (NPPs) over the entire zone covered by the Off-site Emergency Plans (PPIs)(*) (see chapter 4 point 1.1.1 b). Over and beyond the distribution of stable iodine tablets, the aim is to develop citizen awareness of the nuclear risk and knowledge of the means to protect themselves against it.

2019 saw the start of an information and iodine table distribution campaign in the areas situated between 10 and 20 km from nuclear installations following the recent extension of the radius of the PPIs from 10 to 20 km. It is complementary to the 2016-2017 campaign which concerned residents in the 0-10 km zone. Conducted by the Ministry of the Interior, it involves health professionals, education stakeholders, elected officials, Local Information Committee (CLI) members, IRSN, EDF, etc. ASN, on the strength of its experience, assists the Ministry of the Interior in this procedure. The campaign must continue in 2020 in order to achieve the best possible coverage of the populations concerned.

Iodine tablet collection from pharmacies had reached about 25% by late February 2020. This result is down compared with the preceding campaign (2016), even though the same media were used to inform the population (postal mail, press relations, social networks, toll-free phone number, website); it may be explained by the fact that this type of operation is completely new in these areas, with the recent extension of the radius from 10 to 20 km. In effect, stable iodine tablets

have been distributed in the 0-10 km zone since 1997, but only since September 2019 in the 10-20 km zone.

ASN considers that development of the radiation protection culture of the population living in the 10-20 km zone is a major area for progress for all the stakeholders, and without waiting for the next distribution campaign (2023).

ASN is in favour of sending tablets by post to the people who have not collected them from pharmacies, as was done during the previous campaigns in the 0-10 km zone.

** PPI: French acronym meaning "Off-site Emergency Plan": a local plan put in place by the Prefect to manage the consequences on the neighbouring population of an accident occurring on a site presenting risks.*

The subjects at the core of media attention

A number of subjects received particular attention from the media and the public opinion in 2019, such as the Flamanville European Pressurised Reactor (EPR) construction site, the 4th periodic safety review of the 900 MWe reactors (and that of reactor 1 of the Tricastin NPP in particular), the prospect of the final shutdown of the Fessenheim NPP, or the detection of an abnormal level of tritium in the Loire river. Questions relating to decommissioning, to the ageing of the NPPs, or to the consequences of the earthquake of 11 November 2019 in the Rhône Valley are regularly broached by the French and foreign media. The journalists moreover remain extremely attentive to the question of the anomalies in nuclear equipment welds announced by EDF in 2018-2019. The anomalies in the Flamanville EPR reactor penetration welds were the subject of numerous interactions with the press. Requests also concerned the optimisation of doses in the medical sector, exposure to radon, and the iodine table distribution campaign around the NPPs.

1.1.4 The ASN Information Centre

Any citizen can address requests for information to ASN, either online (at the address *info@asn.fr*), by letter or by telephone. Each year, the online Information Centre responds 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 make known the regulations, to raise professionals' awareness of the responsibilities and the implications of nuclear safety and radiation protection, and lastly to encourage the reporting of significant events.

1.2.1 Making known the regulations and enhancing the radiation protection culture

ASN considers that having clear regulations based on the best safety standards is an important factor for improving the safety of BNIs. Over the last few years it has thus undertaken a major overhaul of the technical and general regulations applicable to BNIs, while always being attentive to the clarity and completeness of the information delivered to the professionals concerning these regulations. The same goes for radiation protection of workers and patients in the medical and industry sectors: ASN makes guides, practical sheets and reference manuals available to all the professionals.

• The *Contrôle* magazine and the *Les cahiers de l'ASN* booklets
Considered a reference by informed audiences, *Contrôle* magazine was published quarterly for more than 20 years until the end of 2016 (more than 200 issues). The last 100 issues of *Contrôle* magazine can still be consulted on *asn.fr*. A *Cahier de l'ASN* booklet provides popularised information on the implications and processes of the 4th periodic safety review of the 900 MWe nuclear reactors.

• *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 lessons learned from significant events. ASN updates existing guides or publishes new ones each year. In 2019, ASN published English versions of Guides No. 27 "*Stowage of Radioactive Packages, Materials or Objects for Transportation*" and No. 34 "*Implementation of the Regulatory Requirements Applicable to On-Site Transport Operations*".

• A section for the professionals on *asn.fr*
Professionals can find all the regulatory texts and forms concerning their area of activity, along with the sheets and results by sector, etc., in a specific section. The professionals are directed to the teleservices platform for their online formalities where necessary.

1.2.2 A platform to facilitate online procedures

Submitting notifications and license applications to ASN: month after month, the regulatory procedures are gradually being transformed into online services accessible *via* the *teleservices.asn.fr* portal. ASN thus aims to facilitate administrative procedures for the professionals to promote the culture of safety and radiation protection. Consequently, since May 2017, all significant radiation protection events are reported online, guaranteeing that all the stakeholders are informed immediately. More than 1,500 significant events have been reported online since this teleservice was created.

1.2.3 A bulletin and regular meetings to share good practices

The bulletin *Patient safety –Paving the way for progress* was created in March 2011 to keep radiotherapy professionals informed of the lessons learned from significant radiation protection events. Since July 2019 it alternates between subjects devoted to radiotherapy, diagnostic medical imaging (conventional, computed tomography scanning and nuclear medicine) and fluoroscopy guided interventional practices. Produced by multidisciplinary working groups coordinated by ASN, the bulletin offers a thematic presentation of the good practices of medical departments and the recommendations developed by the learned societies of the discipline concerned and the health and radiation protection institutions.

Two issues were published in 2019 on "Experience Feedback in other Countries" (April) and "Making Proper Use of Computed Tomography Scanner Functions" (July).

The "Avoiding accidents" sheets present ASN's analysis of the significant events reported in the industrial sector: identified deficiencies and good practices to adopt. The first two issues were published in 2019 on "Gamma radiography and concomitant activities" (May) and "Uncontrolled discharges into groundwater" (September).

ASN regularly participates in the congresses of the medical and radiation protection sector. In 2019, ASN attended the French Radiology Days (JFR) and the congresses of the French Association of Radiographers (AFPPE) and the French Radiation Protection Society (SFRP). At these events it presented the new quality assurance obligations in medical imaging and conducted radiation protection awareness-raising through talks on the regulatory changes and on the "theatre of errors" for interventional radiology. ASN also participated in the congress of the European Public Health Associations (EUPHA), where it presented its actions relating to medical activities, radon and emergency and post-accident management.

ASN was also behind the initiative of national and regional thematic professional seminars (three professional seminars held in Lyon, Nancy and Lille, were organised by the ASN regional divisions in 2019). These events provide the opportunity to interchange with specialised audiences, to enhance knowledge of the regulations and guide to regulatory provisions, to present the results of inspections and to share the analysis of significant radiation protection events.

1.3 ASN and the media

ASN maintains regular relations with the regional, national and foreign media throughout the year. Each year, the ASN spokespersons respond to more than 600 press requests, including from foreign media, and give some twenty local and national press conferences. The majority of the press requests concern local questions specific to a facility. Some concern more general issues, such as radioactive waste management, decommissioning, the conditions of continued reactor operation, and safety improvements. ASN also maintains relations with the medical press on the subjects of patient and medical personnel radiation protection.

At the time of the publication of its annual *Report on the situation of nuclear safety and radiation protection in France*, ASN meets regional press journalists. In 2019, 15 regional conferences were held between the end of May and mid-September. ASN was thus able to reply directly to about one hundred media representatives, resulting in wide dissemination of the information (more than 160 articles). At these meetings, the ASN regional divisions report on ASN's assessment of the safety of the facilities in the regions. The current radiation protection issues of the regions are addressed, whether they concern the medical and industrial sectors, sites contaminated by radioactive substances, population exposure to radon, former mining sites, etc.

1.4 ASN's relations with elected officials and institutional bodies

Each year, ASN presents its annual *Report on the situation of nuclear safety and radiation protection in France* 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 also submitted to the President of the Republic, to the Government and to Parliament. It is 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, etc.

Each year, ASN is called to about ten hearings before Parliament concerning its activities and subjects relating to nuclear safety and radiation protection, and with regard to the budget bill. ASN also maintains regular contact with the national and local elected officials, advising and assisting them at their request.

In July 2019, ASN attended a hearing, organised by the OPECST, of the parties concerned by the problem of anomalies in the welds of the Main Steam System (VVP) of the Flamanville EPR reactor. The ASN regional divisions responded to the requests of the Departmental Councils or the CESER[1] on subjects relating to nuclear safety and radiation protection (ageing of the nuclear fleet, management of radioactive waste, etc.).

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. ASN thus regularly participates in working groups on communication and informing the various audiences, coordinated by the International Atomic Energy Agency (IAEA), and in cooperation missions funded by the European Commission (see chapter 6). Each year, ASN receives foreign delegations to discuss best practices.

In 2019, ASN contributed to the "Workshop on Stakeholder Involvement: Risk Communication", an international seminar organized by the Nuclear Energy Agency (NEA), and shared its experience on the questions of transparency, communicating with the general public and emergency communication, with its Moroccan counterpart. ASN also took part in the conference organised by the Canadian nuclear regulator on the conditions fostering public confidence in the nuclear regulator, held in the sidelines of the general conference of the IAEA held in September.

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[2]. In order to prepare for this, ASN staff receive specific training and take part in emergency exercises. Each year, about ten emergency exercises are held, with simulated media pressure from journalists designed to test ASN's responsiveness to the media, as well as the consistency and quality of the messages put across by the various players, both nationally and locally (see chapter 4).

1. *Regional Economic Social and Environmental Council.*
2. *Pursuant to the provisions of Article L. 592-32 of the Environment Code.*

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 relative to 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[3]. ASN has published recommendations for the drafting of these reports in a guide published in 2010 (ASN Guide No. 3). The reports are often presented at CLI meetings (see point 2.3.4).

• Access to information in the possession of the licensees

Since the Transparency and Security in the Nuclear Field Act of June 2006, or TSN ACT, came into force, the nuclear field has a 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 reduce 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.

• The Commission for Access to Administrative Documents

If a licensee refuses to communicate a document, the requesting party can refer the issue to the Commission for Access to Administrative Documents (CADA), an independent administrative Authority. If the opinion of the CADA is not followed, the dispute may be taken before the administrative jurisdiction which will rule on whether or not the information in question can be communicated.

ASN is particularly attentive to the application of this right to information, in compliance with the protection of interests provided for in law (security, business confidentiality, etc.).

2.2 Information given to people living in the vicinity of Basic Nuclear Installations

The Act relative to Energy Transition for Green Growth, or TECV Act, has instituted an obligation to regularly inform the people 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 Consultation of the public on draft opinions, guides and 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. This provision is applicable to a large proportion of the resolutions issued by ASN or decisions in which it participates by formulating opinions (draft decrees and orders issued by the Government in particular).

In 2019, 91 draft resolutions, opinions and guides were thus subject to public consultation.

2.3.1 Public consultation on draft ASN regulations

Article L. 123-19-1 of the Environment Code provides for a procedure of consultation of the public *via* the Internet on draft resolutions other than individual resolutions 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.

ASN's regulations relating to radiation protection are also submitted to public participation if they concern activities involving significant discharges into the environment, producing a significant quantity of waste, causing significant nuisance for the neighbourhood or representing a risk for the people living nearby 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 draft guides and draft opinions.

Five consultations held in 2019 concerned draft ASN regulations.

2.3.2 Public consultation on draft individual resolutions

The individual resolutions[4] relating to 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 applications form the subject of a Public inquiry[5]. The file that undergoes the public inquiry contains the impact analysis and the risk control analysis, among other things. The latter provides a clearly understandable inventory of the risks that the projected installation represents and an analysis of the measures taken to prevent these risks. This analysis also includes a non-technical summary intended to facilitate the general public's understanding of the information it contains.

Since 2017, the public inquiry files can be consulted[6] online throughout the duration of the inquiry, and are provided in printed format in one or more predetermined places as soon as the public inquiry opens. The preliminary safety report (a more technical document) is not included in the public inquiry file

3. *See Article L. 121-15 of the Environment Code.*
4. *Individual resolution: resolution that applies to a licensee for a given installation.*
5. *In application of the provisions of Article L.123-12 of the Environment Code.*
6. *See: www.asn.fr/Reglementer/La-reglementation/Le-regime-juridique-des-installations-nucleaires-de-base/Les-autorisations-de-creation-et-de-mise-en-service-d-une-installation.*

First-hand news of the CLIs

In 2019, the CLIs were regularly called upon to participate in or co-organise consultation meetings under national schemes: they addressed issues pertaining to the ageing of the NPPs as part of the consultation on the 4th periodic safety reviews of the 900 MWe NPPs. They participated in the debate on the management of radioactive waste within the framework of the public debate on the French National Radioactive Material and Waste Management Plan (PNGMDR). In addition to this, they acted as local relays of the national information and iodine table distribution campaign over the 10-20 km perimeter (see below).

Initiatives praised by ASN: two inter-CLI meetings (InterCLI of the Val de Loire, InterCLI of the South-East) were organised in 2019, in an approach based on collective reflection, sharing knowledge and know-how, and sharing resources.

Consultations, what they involve

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.

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 *asn.fr*.

A synthesis of the remarks received, indicating how they were taken into account and a document setting out the reasons for the regulation are published on *asn.fr* at the latest on the date of publication of the regulation.

but can be consulted throughout the inquiry period under the conditions set by the order governing the inquiry.

A public inquiry was conducted for the Bugey site in 2019.

• **Disclosure of drafts on *asn.fr***
The individual resolutions that are not subject to public inquiry and are likely to have a significant effect on the environment (such as BNI modification projects or operating conditions that could cause a significant increase in water intakes or discharges) are subject to an Internet consultation. In this context, the licensee's file is made available to the public on *asn.fr*.

During 2019, 28 consultations concerned draft individual resolutions relating to BNIs and 51 concerned small-scale nuclear activities.

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 contribute, 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.

Digital technologies and citizen participation practices are bringing ASN to change the public consultation framework to ensure effective participation of the public in the decision-making process.

2.4 The actors in the area of information

2.4.1 The High Committee for Transparency and Information on Nuclear Security

The High Committee for Transparency and Information on Nuclear Security (HCTISN), created by the TSN Act, is a body that informs, discusses and debates on nuclear activities, their safety and their impact on human health and the environment. It can also deal with any issue concerning the accessibility of nuclear security information and propose any measures such as to guarantee or improve transparency.

The HCTISN develops opinions and makes them public. It organises four plenary meetings per year, at which major topical subjects are presented and discussed: all the presentations can be consulted online at *hctisn.fr*. The ASN Chairman is a member of the High Committee; ASN sits on the board of the HCTISN in an advisory capacity, takes part in its various working groups and regularly provides information on the subjects on plenary session agendas.

In 2019, with the assistance of ASN, IRSN, EDF and the National Association of Local Information Committees and Commissions (Anccli), the HCTISN set up the consultation on the continued operation of the 900 MWe reactors. This consultation formed the subject of a report made public in September 2019, and all the documents relating to said consultation are accessible on *concertation.suretenucleaire.fr*.

2.4.2 Institute of Radiation Protection and Nuclear Safety

IRSN implements a policy of information and communication that is consistent with the objectives agreement signed with the Government.

The TECV Act obliges IRSN to publish the opinions it gives to the authorities who referred matters to it. Thus since March 2016,

The functional framework of the Local Information Committees and the Site Monitoring Committees

The Local Information Committees (CLIs), whose creation is incumbent upon the President of the Departmental Council, comprise various categories of members: representatives of *département* General Councils, of the municipal councils or of the deliberative assemblies of the groups of communities and the Regional Councils concerned, members of Parliament elected in the *département*, representatives of environmental protection associations or of economic interests and representatives of employee trade union 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. All Basic Nuclear Installation (BNI) sites have a CLI, except for the Ionisos facility in Dagneux in the Ain *département*.

The CLIs are funded by the regional authorities, and by ASN which devotes about €1.25 million per year to the financial support of the CLIs and their national federation, Anccli. Within the framework of its reflections on the financing of the oversight of nuclear safety and radiation protection, ASN regularly suggests to the Government the application of the provision of the TSN Act of 13 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.

With regard to former nuclear sites, research laboratories and waste treatment sites, Site Monitoring Commissions (CSS) are gradually replacing the Local Information and Monitoring Committees (CLIS) in application of the Decree of 7 February 2012[*]. Providing frameworks for discussion and information concerning the actions of the licensees of the targeted installations, they promote the informing of the public. They are, for example, kept informed of the incidents and accidents affecting the installations –and even of installation creation, extension or modification projects.

ASN is invited to the meetings of the monitoring committees for defence sites and former mining sites.

** In application of Article L. 125-2-1 of the Environment Code.*

IRSN publishes twice monthly on its website all the opinions it issues at the request of ASN. These opinions are the synthesis of the expert assessment carried out by IRSN in response to ASN's request. On subjects of concern that prompt questions on the part of the public or the public actors, ASN and IRSN ensure that their statements are properly coordinated in order to guarantee coherent, clear and consistent information.

Alongside this, each year IRSN makes public the results of its research and development programs, with the exception of those concerning National Defence.

In the context of a referral from ASN and with ASN consent, IRSN can request the participation of informed audiences, neighbourhood residents, or even the public at large. The IRSN in this case provides them with information that is complete and understandable, and in return notes their subjects of concern and their questions in order to integrate them in the expert assessment work carried out for ASN.

2.4.3 The Local Information or Monitoring Committees

The CLIs often have a general mandate of monitoring, informing and consultation with regard to nuclear safety and radiation protection. They analyse the impacts on people and the environment of the nuclear activities of the installations of the nuclear sites around which they have been set up[7].

ASN considers that the smooth functioning of the CLIs contributes to safety and it maintains a meaningful dialogue with them. It is attentive to ensuring that the CLIs are as fully informed as possible, including by attending their public meetings.

In partnership with Anccli, ASN fosters the networking of the CLI special advisors and gives the CLIs the necessary tools and assistance for them to provide reliable information to "layman" audiences. ASN assisted the CLIs at their request, with inspectors helping them on technical issues and communication supervisors on questions of dissemination of information. The ASN-IRSN exhibition was made available to the CLIs whenever requested.

The ASN inspectors can also give the CLI representatives the opportunity to take part in inspections[8]. They motivate the BNI licensees to facilitate CLI access to files of the procedures in which their opinion will be required, and encourage involving the CLIs in the preparation of emergency exercises.

In the same spirit, ASN considers that the development of a diversified range of expertise in the nuclear field is essential to enable the CLIs to base their opinions on expert assessments other than those carried out for the licensee or ASN itself.

- **The CLIs and informing the various audiences**

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. ASN promotes exchanges of good practices in order to make these public meetings moments of worthwhile discussion and opportunities to contribute to having a well-informed population

The majority of the 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 a local authority).

7. The operating framework for the CLIs is defined by Articles L. 125-17 to L. 125-33 of the Environment Code and by Decree 2008-251 of 12 March 2008 relative to the CLIs for the BNIs, and by Decree 2019-190 of 14 March 2019 codifying the provisions applicable to BNIs, the transport of radioactive substances and transparency in the nuclear field.

8. In the current situation, only the ASN inspectors and the experts accompanying them 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.

In 2019, the CLI conference –the annual meeting of Local Information Committees (CLIs) organised by ASN in partnership with Anccli–reported on the CLIs' initiatives and questionings. The scaling up of the monitoring and information missions, with the widening of the perimeter of the off-site emergency plans, remains a major focus of the CLIs. The roles of the CLIs as trusted intermediaries on nuclear issues in the regions and the part they play in the preparation of emergency exercises or their vigilance on environmental issues, have been subjects of rich debates.

2.4.4 National Association of Local Information Committees and Commissions

Article L. 125-32 of the Environment Code provides for the constitution of a federation of CLIs and the Decree of 12 March 2008 details the missions of this federation. Anccli brings together the 34 French CLIs and the 34 committees put in place for the defence-related installations. 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.).

- **Partnership with ASN**

Anccli interchanges with ASN very regularly and participates in several of its permanent or occasional working groups. Anccli fosters the enhancing of the technical competence of CLI members by organising thematic seminars with IRSN in the context of its expert assessment work carried out for ASN. Anccli, with ASN and IRSN, maintains a technical dialogue on the high-stake issues and takes part in the public consultations on nuclear questions. Each year, in collaboration with Anccli, ASN organises the national CLI Conference which is attended by more than 250 people and represents a day of experience-sharing and collective reflection on the issues common to the CLIs.

- **The activity of Anccli**

Anccli runs the network of CLIs that it represents. By ensuring a regular watch and issuing clarifications and information that can be readily understood by the general public, Anccli helps give the CLIs the means to fulfil their duties of informing the various audiences. Attentive to the concerns of the CLIs and in relation with diverse sources of expertise, Anccli conducts national reflections on nuclear safety issues and widely passes on the results of this work (Anccli positions) to the national and European bodies and to local elected officials and CLI audiences.

06.

INTERNATIONAL RELATIONS

International relations

Through a range of bilateral, European and multilateral cooperation frameworks, which it develops or in which it participates, ASN aims to encourage the adoption of ambitious international requirements, to promote French positions and doctrines which could contribute to this and draws on the best practices from around the world to advance nuclear safety and radiation protection.

This approach to sharing, harmonising and improving knowledge and practices also includes cooperation regarding significant nuclear events and accidents (Chernobyl, Fukushima).

These actions as a whole are based on the legislative provisions of the Environment Code. They more particularly state that, within its scope of competence, ASN proposes France's positions on international negotiations to the Government and represents 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 the three main circles of cooperation.

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 the European level, the regulatory context has changed since 2009 with the adoption, updating and implementation of three European Directives concerning the fields of nuclear safety (Council Directive 2009/71/Euratom of 25 June 2009 establishing a community framework for the nuclear safety of nuclear facilities, modified in 2014), waste legislation (Council Directive 2011/70/Euratom of 19 July 2011 establishing a community framework for the responsible and safe management of spent fuel and radioactive waste) and radiation protection (Council Directive 2013/59/Euratom of 5 December 2013 setting Basic Standards for Health Protection against the dangers resulting 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 building this legal framework for nuclear safety, the European Commission is supported by European Nuclear Safety Regulators Group (ENSREG), which brings together experts from the European Commission and the member countries of the European Union[1].

The safety regulators, more specifically at European level, have also set up voluntary associations such as Western European Nuclear Regulators Association (WENRA), Heads of the European Radiological protection Competent Authorities (HERCA) and European Association of Competent Authorities (EACA), which provide the regulators and the European Commission with technical support, alongside the technical support organisations.

At the multilateral level, cooperation is continuing, more specifically within the framework of the International Atomic Energy Agency (AIEA), an agency of the United Nations (UN) founded in 1957, and the Nuclear Energy Agency (NEA) of the Organisation for Economic Cooperation and Development (OECD) created in 1958. These two agencies are the two most important intergovernmental 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 the European Directives for Nuclear Safety in June 2009, then the management of spent fuel and wastes in July 2011. This institution also took part in the process to revise the Nuclear Safety Directive proposed by the European Commission in 2013, following on from the assessment and analysis of the Fukushima NPP accident. Each safety regulator then provided technical insight for its government in charge of negotiations in Brussels, until its revision on 8 July 2014.

WENRA was created in 1999 and is an association whose members are the heads of the safety regulators of the European countries with electricity generating reactors. Other countries take part in the WENRA activities as observers or associate members. WENRA's actions are 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 to harmonise national practices.

1. The national delegations are split equally between heads of safety regulators and representatives from the Ministries for the Environment or Energy.

1.2 Cooperation in the fields of nuclear safety and radiation protection outside Europe

ASN's goal is for nuclear safety and radiation protection best practices and regulations to be shared outside Europe.

Within the framework of IAEA, ASN thus plays an active part in the work of the Commission on Safety Standards (CSS). This Commission draws up international standards for the safety of nuclear installations, waste management, radioactive substance transport and radiation protection. These standards, which are not legally binding, constitute an international benchmark, including in Europe where they are reviewed and supplemented by the work of WENRA. They also constitute the documentary baseline for the international audits headed by IAEA. These notably include the safety regulator audits (IRRS, Integrated Regulatory Review Service), the ARTEMIS missions to audit national radioactive waste, spent fuel and decommissioning management programmes and the audit missions to NPPs in operation (Osart, Operational Safety Review Team).

ASN also contributes actively to the MDEP (Multinational Design Evaluation Programme), launched in 2006 by ASN and the United States Nuclear Regulatory Commission (NRC). This programme, which currently comprises 16 safety regulators, aims to share the experience and approaches of the nuclear safety regulators in the field of the regulatory evaluation of new reactor models, with a view to ensuring progress and harmonisation.

In the field of radiation protection, ASN monitors the progress of the work done by the various international bodies, such as that of the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) or that of the International Commission on Radiological Protection (ICRP). ASN considers that through their publications, these entities contribute to improved understanding of exposure to ionising radiation and of health effects. These organisations issue recommendations helping to improve the protection of the exposed persons, whether patients in the medical sector or specific categories of workers.

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 instituting the European Atomic Energy Community (EURATOM) was signed on 25 March 1957 and constitutes primary law in the field, allowing the harmonised development of a strict regime of oversight for nuclear safety and security and radiation protection. The European Union (EU) Court of Justice, considering 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 The European Euratom Directive on the Safety of Nuclear Facilities

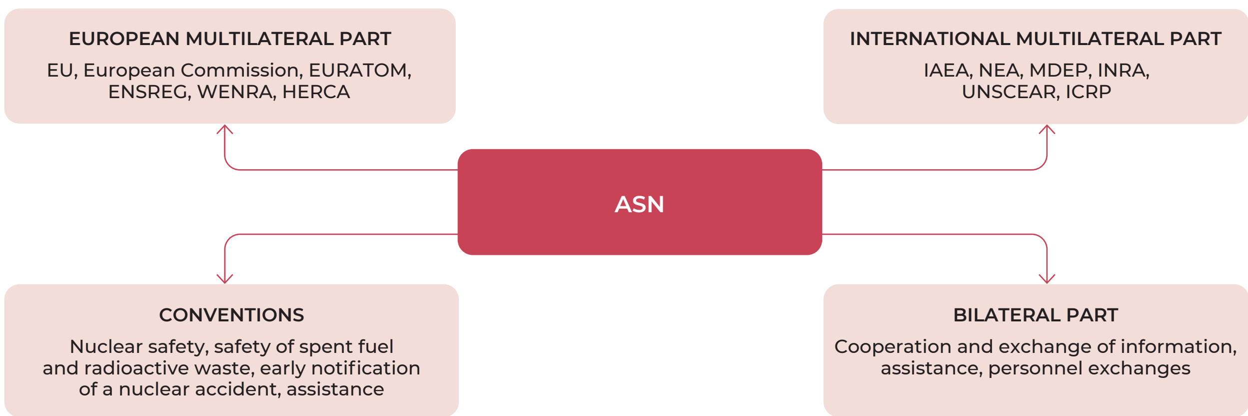
The Council 2009/71/Euratom Directive of 25 June 2009 aims to establish a Community framework to ensure nuclear safety within the European Atomic Energy Community and to encourage the Member States to guarantee a high level of nuclear safety (see "Regulation" on *asn.fr*).

It makes provision for increased powers and independence of the national safety regulators, sets an ambitious safety objective for the entire EU (based on the baseline safety requirements produced by WENRA) and establishes a European system of peer reviews on safety topics. It also establishes national periodic safety reassessments 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 17 August 2015 (TECV Act) and Ordinance 2016-128 of 10 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.

ASN action on the international stage



2.3 The European Euratom Directive on the Management of Spent Fuel and Radioactive Waste

On 19 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 contributes to reinforcing safety within the EU, by making the Member States more accountable for the management of their spent fuels and their radioactive waste.

This Directive is legally binding and covers all the aspects of spent fuel and radioactive waste management, from production through to long-term disposal. It reiterates the prime responsibility of the producers and the ultimate responsibility of each Member State to ensure the management of the waste produced on its territory, making sure that the necessary measures are taken to guarantee a high level of safety and to protect workers and the general public against the dangers of ionising radiation.

It clearly defines the obligations regarding the safe management of spent fuel and radioactive waste and requires that each Member State adopt a legal framework for safety issues, making provision for the creation of:
- a competent regulatory authority with a status that guarantees its independence from the waste producers;
- authorisation procedures involving authorisation requests examined on the basis of the safety cases required from the licensees.

The Directive regulates the drafting of the national spent fuel and radioactive waste management policies to be implemented by each Member State. More specifically, it requires each Member State to establish a legislative and regulatory framework designed to set up national programmes for the management of spent fuel and radioactive waste.

The Directive also contains provisions concerning transparency and participation of the public, the financial resources for management of spent fuel and radioactive waste, training, as well as obligations for self-assessment and regular peer reviews. These aspects constitute major advances in reinforcing the safety and accountability of spent fuel and radioactive waste management in the EU. The TECV Act and the Ordinance of 10 February 2016 have ensured the transposition of the provisions of the Directive.

2.4 The European Euratom Directive on Radiation Protection "Basic Standards"

Directive 2013/59/Euratom of 5 December 2013 on the Radiation Protection Basic Safety Standards, known as the "BSS" Directive, is wide-ranging: its requirements apply to justification, optimisation, dose limitation, regulatory oversight, preparedness for and response to emergency situations, training and other related fields –for example radon, NORM (Naturally Occurring Radioactive Materials) and construction materials. The HERCA association has issued numerous positions on these requirements (can be consulted on *herca.org*) to help the Member States with the transposition of this Directive. However, despite the clear coordination efforts made upstream, the transposition work, completed in 2018 in France, has not resulted in total harmonisation of the national requirements. HERCA will now focus its work on implementing this Directive, some aspects of which, such as justification, the graded approach to regulation or the preparedness for a response to emergency situations, are proving to be technically complex.

2.5 The European Nuclear Safety Regulators Group (ENSREG)

ENSREG 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.

ENSREG organised the first thematic peer review, as stipulated in the 2014 Safety Directive, on management of the ageing of nuclear power or research reactors of 1 megawatt (MW) or more. Each of the 19 participating countries first of all drafted a national report, which was then examined in 2018 by experts appointed by the Member States. This examination led to the drafting of a report on the generic results and a report on the specific results per country. All of these reports were adopted in an ENSREG plenary session and published on the ENSREG website at the end of 2018. On this basis, each participant produced a national action plan which was submitted in September 2019 and is also available on the ENSREG websites. The national report and the national action plan for France are also available on the ASN website, in both French and English.

2.6 The EURATOM Treaty European working groups

ASN experts also participate in the work of the EURATOM Treaty committees and working groups:
- group of experts specified in Article 31 (Basic Radiation Protection Standards);
- group of experts specified in Article 35 (verification and monitoring of radioactivity in the environment);
- group of experts specified in Article 36 (information concerning the monitoring of radioactivity in the environment);
- group of experts specified in Article 37 (notifications relative to radioactive effluent discharges).

2.7 The European Community Urgent Radiological Information Exchange system (ECURIE)

The European Community Urgent Radiological Information Exchange system (ECURIE) is one of the rapid action systems set up by the European Commission, which has an information exchange network for receiving and triggering an alert and thus for rapidly circulating information within the EU in the event of a radioactive emergency or major nuclear accident.

This system was set up in 1987 by a decision of the Council of the EU dated 14 December 1987 more specifically in the wake of the Chernobyl accident in 1986. This decision came into force on 21 March 1988 and was ratified by all the Member States of the European Union and a certain number of third-party countries, such as Switzerland and accession candidate countries such as Turkey.

2.8 The Western European Nuclear Regulators' Association (WENRA)

WENRA continues to develop a joint approach to nuclear safety and its regulation, more notably within the EU. WENRA comprises 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 on Waste and Decommissioning (WGWD).

The ASN Director General, Olivier Gupta, elected Chairman of the WENRA association

Olivier Gupta, Director General of ASN, has been elected Chair of WENRA (Western European Nuclear Regulators' Association) by his European peers. Involved in the work of this association since the early 2000's, Olivier Gupta chaired the WENRA working group responsible for harmonising reactor safety from 2007 to 2011. This group notably produced the post-Fukushima stress test specifications.

Under his chairmanship, ASN aims to reinforce the unique international character of WENRA, which notably relies on informal discussions and strong commitment by each of its members to harmonise safety requirements.

The challenges associated with the ASN mandate will be to implement the new strategy adopted by WENRA, more specifically:

- **continued development and updating of the "reference levels", with a broadened view of safety, notably taking account of the interfaces between safety and security;**
- **development, beyond the "reference levels", of new tools to harmonise the positions of the nuclear safety regulators on high-stakes issues;**
- **opening up of WENRA to non-European nuclear countries (Canada, Japan) with the status of associate member, as was the case with Russia at WENRA's last plenary meeting of the year.**

In each of these areas, the groups defined "reference levels" for each technical topic, based on the most recent standards from IAEA and on the strictest approaches adopted in the EU.

In 2019, WENRA held two plenary meetings: in April in Budapest and in October in Basel. These meetings notably led to:

- approval of WENRA's 10 strategic goals, as well as of its missions for the period 2019-2023, defined on the basis of the global civil nuclear outlook;
- the adoption of a report concerning the nuclear security-safety interface;
- an examination of the proposed topics which could be the subject of the next thematic peer review scheduled for 2023 under the European Directive on the Safety of Nuclear Facilities;
- approval of a report concerning the practical elimination of severe accident scenarios applied to the design of new reactors.

In addition, at its final plenary meeting of the year, WENRA elected Olivier Gupta, ASN Director General, as the new Chairman of the association for the next three years, in place of Hans Wanner, Director General of ENSI, the Swiss nuclear safety regulator.

2.9 The association of the Heads of European Radiological Protection Competent Authorities (HERCA)

HERCA was created in 2007 at the initiative of ASN in order to organise close consultation between these authorities and to advance harmonisation and regulation in the field of radiation protection. It now comprises 58 Authorities, 32 of which come from European countries. ASN is responsible for the technical secretariat.

Six working groups are currently working on the following themes:

- practices and sources in the research and industrial fields;
- medical applications of ionising radiation;
- preparedness for and management of emergency situations;
- veterinary applications;
- natural radiation sources;
- education and training.

HERCA is preparing a strategy document for the period 2020-2025, with its main focus being reinforced cooperation between the radiation protection competent authorities. This first of all requires improved (joint) knowledge of the various national approaches, in order to be in a position to harmonise the regulatory approaches. In 2020, HERCA will be more particularly involved in analysing ICRP documents concerning changes to radiation protection standards in order to identify areas warranting specific attention for changes to the regulations.

2.10 The European Commission's assistance programmes under the INSC

In 1991, the European Commission launched the "nuclear safety" part of the TACIS programme[2] 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 EU 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:

- help improve the operational safety of the existing reactors;
- financially support the improvement measures that can be taken in the short term on the less safe reactors;
- improve the organisation of safety oversight by identifying the responsibilities of the various entities involved and reinforcing the role and the competences of the national nuclear safety authorities.

Owing to the European budgetary restrictions, Regulation 237/2014/Euratom of the European Parliament and Council of 13 December 2013 revised the budget envelope (€225.3 million)

Meeting of the HERCA Council in Rome – October 2019

2. *TACIS:Technical Assistance to the Commonwealth of Independent States (European Union programme to provide aid to the countries of the former USSR).*

associated with the INSC instrument for the period from 1 January 2014 to 31 December 2020.

Moreover, Regulation 236/2014/EU of the European Parliament and Council dated 11 March 2014, laid out common rules and procedures for the implementation of the EU's instruments for financing external actions. The objectives of the new INSC regulation include the goal of:
- supporting the promotion and implementation of the strictest nuclear safety and radiation protection standards in nuclear facilities and for radiology practices in third-party countries;
- supporting the drafting and implementation of responsible strategies for the ultimate disposal of spent fuel, for waste management, for decommissioning of facilities and for clean-out of former nuclear sites.

These instruments are supplemented by other international technical assistance programmes that respond to resolutions taken by the G8 or by IAEA to improve nuclear safety in third-party countries and which are financed by contributions from donor countries and from the EU.

The tangible assistance actually provided by ASN *via* the INSC mainly took the form of aid for the nuclear safety Authorities. In 2019, ASN thus took part in regulatory assistance projects for China, Vietnam and Turkey.

3. International multilateral relations

3.1 The International Atomic Energy Agency (IAEA)

IAEA is a UN organisation based in Vienna. It comprises 170 Member States. 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 with developing and promoting applications of radioactivity, and nuclear energy in particular, on the one hand, and the safety and security of nuclear facilities and nuclear activities, on the other.

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 accident, IAEA is focusing its work on the following fields:
- **The revision and consolidation of the Safety Standards** describing the safety principles and practices that the vast majority of Member States uses as the basis for their national regulations.
  This activity is supervised by the IAEA's Commission on Safety Standards (CSS), set up in 1996. The CSS comprises 24 highest level representatives from the safety regulators, appointed for four years. The CSS coordinates the work of five committees tasked with drafting documents in their respective fields: NUSSC (Nuclear Safety Standards Committee) for the safety of facilities, RASSC (Radiation Safety Standards Committee) for radiation protection, TRANSSC (Transport Safety Standards Committee) for the safety of radioactive materials transport, WASSC (Waste Safety Standards Committee) for the safe management of radioactive waste and EPReSC (Emergency Preparedness and Response Standards Committee) for preparedness and coordination in a radiological emergency situation. Represented by ASN, France is present on each of these committees, which meet twice every year. Representatives of the various French organisations concerned also take part in the technical groups which draft these documents. The CSS held its 45th and 46th meetings in 2019. As the mandate of the national representatives on the CSS expires at the end of 2019, new members will be appointed in 2020 for a four-year term. A specific committee for security, the Nuclear Security Guidance Committee (NSGC) was created, along with an interface designed to improve the analysis of the interaction between safety and security. 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 peer review missions** organised at the request of the IAEA Member States to reinforce their effectiveness, such as the IRRS (Integrated Regulatory Review Service) and Operational Safety Review Team (Osart) missions, which use the IAEA Safety Standards as their baseline references.

• The IRRS missions

The IRRS missions are devoted to analysing all aspects of the framework governing nuclear safety and the activity of a safety regulator. ASN is in favour of holding these peer reviews on a regular basis, with widespread dissemination of their results. It should be noted that, pursuant to the provisions of the 2009/71/Euratom Directive amended in 2014, the Member States of the EU are already subject to periodic and mandatory peer reviews of their general nuclear safety and radiation protection oversight organisation. A follow-up mission organised 24 months after the original mission checks whether the recommendations and suggestions issued by the team of experts have actually been put into practice.

In 2019, ASN contributed to several IRRS missions, in Norway, Canada, Germany and the United Kingdom respectively.

• The Osart missions

The Osart missions are carried out by a team of experts from licensees in a third-party country, over a period of two to three weeks, to examine the safety organisation in NPPs in operation. A follow-up mission organised 18 months after the original mission checks whether the recommendations and suggestions issued by the team of experts have actually been put into practice.

In 2019, one mission took place in Civaux, two follow-up missions took place in Bugey and Golfech, and one pre-Osart mission in Flamanville.

• The regional training and assistance missions

ASN responds to 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.

In addition and still under the supervision of IAEA, ASN also participates in the RCF (Regulatory Cooperation Forum). This forum, created in 2010, aims to establish contacts between the safety regulators of countries adopting nuclear energy for the first time and the safety regulators of the leading nuclear countries, in order to identify their needs and coordinate the support to be provided, while ensuring that the fundamental principles of nuclear safety are met (independence of the regulator, appropriate legal and regulatory framework, and so on). In 2019, in addition to a close examination of the situation of the regulatory authorities in Bangladesh, Belorussia, Ghana, Morocco, Poland and Vietnam, the RCF reinforced its cooperation with the EU (INSC) and with "regional" forums such as Arab Network of Nuclear Regulators (ANNuR), Forum of Nuclear Regulatory Bodies in Africa (FNRBA) and Asian Nuclear Safety Network (ANSN).

• Harmonisation of communication tools
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 representatives of the member countries on the use of the International Nuclear and Radiological Event Scale (INES) and its updates. In this respect it was closely involved in the work to revise the INES scale manual recently published by IAEA, it having been last updated about ten years ago. In addition to the updates to take account of advances in scientific knowledge, this revision also includes guidelines for communication in how to use the scale as well on how to apply it in a crisis.

Generally speaking, ASN is closely involved in the various actions carried out by IAEA, providing significant support for certain initiatives, notably those which were developed following the Fukushima accident.

• Management of nuclear and radiological emergency situations
ASN takes part in IAEA's work to improve notification and information exchanges in radiological emergency situations.

On this subject, ASN takes part in the exercises prepared and regularly organised by IAEA to test the operational provisions of 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, called "Convention Exercices" or "ConvEx exercises". These exercises, which are more specifically designed to enable all the participants –both Member States and IAEA– to acquire practical experience and understand the procedures involved in preparing and running these interventions, are of three types:
- the ConvEx-1 exercises, more specifically designed to test the emergency lines of communication established with the points of contact in the Member States;
- the ConvEx-2 exercises, designed to test particular aspects of the international framework for the preparation and performance of emergency interventions and the assessment and prognosis provisions and tools for emergency situations;
- the ConvEx-3 exercises, aimed at assessing the emergency intervention provisions and the resources in place to deal with a severe emergency for several days.

In 2019, ASN took part in one ConvEx-2 type exercise.

ASN also takes part in defining international assistance strategy, requirements and means and in developing the RANET network (Response Assistance Network).

In addition to the four traditional committees which draft its safety standards, IAEA created a new committee in 2015 called EPReSC[3], to deal with emergency situations. ASN represents France at meetings of this committee.

3.2 The Nuclear Energy Agency (NEA) of the OECD

Created in 1958, the Nuclear Energy Agency (NEA) today comprises 33 member countries from among the most industrially developed states. Its main goal is to help the member countries to maintain and expand the scientific, technological and legal bases essential to the safe, environmentally-friendly and economical use of nuclear energy.

Within the NEA, ASN is more particularly involved in the work of the Committee on Nuclear Regulatory Activities (CNRA). It also takes part in the Committee on Radiological Protection and Public Health (CRPPH), the Radioactive Waste Management Committee (RWMC), the Committee on Decommissioning of Nuclear installations and Legacy Management (CDLM) as well as several working groups of the Committee on the Safety of Nuclear Installations (CSNI).

The various NEA committees coordinate working groups of experts from the member countries. Within the CNRA, ASN contributes to the working groups on inspection practices, acquired operating experience, the regulation of new reactors, safety culture, codes and standards, as well as public communication by safety regulators.

3.3 The Multinational Design Evaluation Programme (MDEP) for new reactor models

The Multinational Design Evaluation Programme (MDEP) is an association of safety regulators created in 2006, which aims to share the experience and approaches in the field of the regulatory evaluation of new reactor models, with a view to ensuring progress and harmonisation. The key goal of this programme is to contribute to the harmonisation and implementation of safety standards.

• Programme members
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), *Rostechnadzor* (Russian Federation), SSM (Sweden), STUK (Finland), TAEK (Turkey).

• Organisation
The broad outlines of the work done within the MDEP are defined by a strategy committee and implemented by a technical steering committee, which has been chaired by an ASN deputy Director General since 2014. The work is carried out by working groups for the main nuclear reactor designs currently under construction around the world: the Framatome EPR, the AP-1000 from the American Westinghouse, the APR-1400 from the Korean Kepco, the Russian VVER and the Chinese HPR-1000 (Hualong). A transverse working group concerns the inspection of nuclear component suppliers (VICWG, Vendor Inspection Cooperation Working Group).

Each of the groups dedicated to a particular reactor design brings together the safety regulators of the countries building or envisaging the construction of reactors of this type. The EPR group in which ASN participates includes authorities from the United Kingdom, Finland, China, India and Sweden.

• Activities in 2019
In 2019, discussions continued within the EPR group concerning the activities of the safety regulators regarding the reactor commissioning authorisation application and the technical problems encountered. The group is gradually entering a phase to finalise its works, coinciding with the end of the MDEP's mandate in 2022. International cooperation is expected to continue in the field of EPR reactor operations within a new framework yet to be set up between the safety regulators concerned.

3.4 The International Nuclear Regulators' Association (INRA)

The International Nuclear Regulators' Association (INRA) comprises the regulators of Canada, France, Germany, Japan, South Korea, Spain, Sweden, the United Kingdom and the United States. This association is a forum for regular and informal discussions concerning topical matters in these various countries

3. EPReSC: Emergency Preparedness and Response Standards Committee.

and the positions adopted on common 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). In 2019, in addition to discussions on nuclear safety, the work of this association notably highlighted the major issue of anticipating the training of experts in order to ensure the renewal of regulator personnel.

3.5 The United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR)

The UNSCEAR was created in 1955 and compiles all scientific data on radiation sources and the risks associated with this radiation for the environment and human health. This activity is supervised by the annual meeting of the national representations of the Member States, comprising international experts.

3.6 The International Commission on Radiological Protection (ICRP)

The International Commission on Radiological Protection (ICRP) is a non-governmental organisation 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 analyses the results of the research work carried out around the world and examines the work of other international organisations, such as in particular that of UNSCEAR. It Issues general recommendations on the protection rules to be adopted and the exposure levels to be adhered to. It was received by ASN on 16 September 2019 as part of its work on updating the recommendations.

4. International conventions

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).

4.1 The Convention on Nuclear Safety

The Convention on Nuclear Safety (CSN) is one of the results of international discussions initiated in 1992 in order to contribute to maintaining a high level of nuclear safety worldwide.

The Convention sets a certain number of nuclear safety objectives and defines the measures which aim to achieve them. France signed it on 20 September 1994 and approved it on 13 September 1995. The Convention on Nuclear Safety entered into force on 24 October 1996 and, on 19 August 2019, it had 88 contracting parties.

The objectives of the Convention are to attain 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.

In 2015, the contracting parties to the convention, taking account of the lessons learned from the Fukushima NPP accident, adopted the Vienna Declaration on nuclear safety. This Declaration, which extensively incorporates the principles of the European Directive on the Safety of Nuclear Facilities, sets precise and ambitious safety objectives aiming to prevent nuclear accidents worldwide and to mitigate the radiological consequences if one were to occur.

The Convention makes provision for review meetings by the contracting parties every three years, to develop cooperation and the exchange of experience.

In France, ASN acts as the Competent Authority for the CSN It coordinates the preparation for the review meetings, in close collaboration with the entities concerned. ASN also devotes considerable resources to participation in the review meetings, so that it is present at the various presentations and discussions.

The 8th review meeting of the contracting parties to the Convention will be held from 23 March to 3 April 2020 at the IAEA headquarters in Vienna.

Several months before the review meeting is held, each contracting party submits a national report describing how it is meeting its obligations under the convention. The French report was submitted in August 2019 and is available on the IAEA and ASN websites. Ahead of the 2020 review meeting, ASN is involved in the review of the national reports from the contracting countries.

4.2 The Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management

The Joint Convention is the counterpart to the Convention on Nuclear Safety for the management of spent fuel and radioactive waste from civil nuclear activities. France signed it on 29 September 1997 and it entered into force on 18 June 2001. This convention had 82 contracting parties at the end of 2019.

The drafting of the French national report for the 7th review meeting, which will be held in May-June 2021 at the IAEA headquarters in Vienna, began in December 2019. French and English versions of the French report will be made public on 27 October 2020 on the IAEA and ASN websites.

4.3 The convention on Early Notification of a Nuclear Accident

The Convention on Early Notification of a Nuclear Accident entered into force on 28 October 1986, six months after the Chernobyl accident and had 124 contracting parties on 31 December 2019.

The contracting parties undertake to inform the international community as rapidly as possible of any accident leading to the uncontrolled release of radioactive substances into the environment and liable to affect a neighbouring State. For this purpose, IAEA proposes a tool to the Member States for notification and assistance in the event of a radiological emergency. ASN made an active contribution to the production of this tool, the Unified System for Information Exchange in Incidents and Emergencies (USIE), which is present in ASN's emergency centre and is tested on the occasion of each exercise.

The Interministerial Directive of 30 May 2005 specifies the conditions of application of this text in France and mandates 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 pertinent information about the situation, in particular to border countries, so that they can 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.

4.4 The Convention on Assistance in the Event of a Nuclear Accident or Radiological Emergency

The Convention on Assistance in the event of a Nuclear Accident or Radiological Emergency entered into force on 26 February 1987 and, on 31 December 2019, had 119 contracting parties.

Its aim is to facilitate cooperation between countries should one of them be affected by an accident having radiological consequences. This Convention has already been activated on several occasions as a result of irradiation accidents caused by abandoned radioactive sources. More specifically, France's specialised medical services have already provided treatment for the victims of such accidents.

4.5 Other conventions related to nuclear safety and radiation protection

Other international conventions, whose scope of application does not lie within the remit of ASN, can have links with nuclear safety.

This is specifically the case with the Convention on the Physical Protection of Nuclear Material, which aims to reinforce protection against malicious acts and the misuse of nuclear material. This Convention entered into force on 8 February 1987 and, in 2019, had 159 contracting parties. An amendment to this convention, which entered into force in 2016, was ratified by 121 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.) and identify topics warranting more in-depth examination in the light of their safety implications or the context.

Moreover, maintaining bilateral relations with neighbouring and other European countries is one of ASN's priorities.

ASN's bilateral relations addressed numerous topics in 2019, notably the construction of new reactors, the safety of the reactors in service and the fuel cycle installations, management of emergency situations and cross-inspections.

In addition to its bilateral relations, ASN for the first time in 2019 brought together the nuclear safety and radiation protection regulators of Germany, Belgium, France, Luxembourg and Switzerland for a transboundary seminar. This seminar offered a broader forum for discussion of several topics covered during the various bilateral meetings. The topics selected for this first exercise were cross-inspections, stakeholder consultations, maintaining skills currency within the regulators and, finally, preparedness for emergency situations in a transboundary context (see box on next page).

5.1 Bilateral cooperation between ASN and its foreign counterparts

Germany

The Franco-German Commission (DFK) was created as an inter-governmental body and involves several competent authorities at both national and Prefect levels. With regard to ASN, it involves both the head office departments and the Strasbourg regional division. In addition to the Commission's plenary meetings, two working groups meet regularly, one to address the safety of nuclear power plants in border areas, the other the management of emergency situations.

From 11 to 12 June 2019, a plenary meeting of the Franco-German commission was held in Lyon. In the light of the context, the Commission decided to reinforce discussions on topics concerning decommissioning and waste within the NPPs working group.

Two cross-inspections were also organised, on **25 November** in Philippsburg, Germany, on the subject of decommissioning, and on **12 December** in France, at the Fessenheim NPP, on the topic of the environment.

Belgium

ASN cooperates on all subject within its field of competence with its counterpart the Belgian *Agence fédérale de Contrôle nucléaire* (AFCN). This leads to cooperation both nationally and locally, with certain of the ASN regional divisions. The Franco-Belgian steering committee met on **18 June 2019** in Montrouge.

A number of cross-inspections were organised:
- The Lyon division and AFCN carried out an inspection on the Orano TN international site in Villefranche-sur-Saône, concerning manufacturing of radioactive substance transport packagings for use in Belgium.
- AFCN and the Lille division took part in inspections in Belgium on industrial sources of radiation and the commissioning of radiotherapy and nuclear medicine facilities, and in France on the commissioning of nuclear medical facilities.
- On **24 September** at Nogent-sur-Seine, the Châlons-en-Champagne division and AFCN carried out an inspection of effluent discharges and the monitoring of discharges into the environment and, on **7 November**, an inspection on the management of waste from the decommissioning of the Chooz A NPP.

Canada

On **1 and 2 July 2019**, the Canadian Nuclear Safety Commission (CNSC) and ASN met at the ASN headquarters to discuss their respective national and regulatory topical matters (reinforced implementation of a graded approach, post-accident management, welds on the main steam letdown lines of the Flamanville EPR reactor, modular reactor projects in Canada, fuel cycle consistency in France, etc.). The discussions revealed that there were areas of cooperation to be developed, notably in inspector training and qualification.

On **2 July**, ASN accompanied its counterpart for a technical visit to the installations of the National Radioactive Waste Management Agency (Andra) on the site of the Bure Laboratory.

In the margins of the IAEA General Conference held in Vienna, Austria, **from 16 to 20 September 2019**, Bernard Doroszczuk, the ASN Chairman and his counterpart at the CNSC, Rumina Velshi, signed the MoU for cooperation and exchange between the two authorities, renewed for a further period of five years.

China

In 2019, discussions with the Chinese safety regulator, the National Nuclear Safety Administration (NNSA) took place mainly within the framework of multilateral projects and meetings, apart from those covered by the INSC instrument. They concerned the start-up tests on the EPR built in Taishan and the oversight of equipment manufacturing.

Spain

On 24 October 2019, a bilateral meeting was held in Madrid between ASN and its Spanish counterpart, the *Consejo de Securidad Nuclear* (CSN). The discussions concerned the maintenance of nuclear power reactors, the management of high-level waste and the handling of radiation protection events. This cooperation will continue, more particularly with the organisation of cross-inspections to compare the oversight of the NPPs in operation and with discussions on small-scale nuclear activities and issues concerning the management of high-level waste.

United States

From 12 to 14 March 2019, ASN took part in the 31st conference of the United States Nuclear Regulatory Commission (US NRC) in Washington. Each year, this conference is an opportunity for the NRC to present the regulation and oversight issues associated with its activities to American and foreign nuclear industry stakeholders.

On 14 March 2019, the 10th bilateral meeting between ASN and its counterpart NRC was held in Washington. During this meeting, the two Directors General, Margaret Doane and Olivier Gupta, discussed their respective national and regulatory topical matters, notably the anomalies affecting the welds on the main steam letdown lines of the Flamanville EPR reactor, ongoing public information and participation actions in France in 2019, NRC experience in terms of licensing modular reactors and new cooperation actions (inspection practices, data analysis and digital transformation, drug and alcohol screening tests in nuclear facilities). They also signed the Memorandum of Understanding for secondment of an NRC staff member to ASN in 2019.

In addition, discussions between the two regulators **in 2019** also covered:
- management of emergency situations with the secondment of an ASN expert **in March**, to observe an emergency exercise at the NRC's emergency centre and, **in October**, with the visit by an NRC expert to observe an emergency exercise at ASN's emergency centre;
- "environmental" aspects, with the participation of two NRC inspectors, **in June**, as observers during an ASN "environment" inspection on the Flamanville site.

ASN also held discussions with the US Department of Energy (US DoE) on the management of decommissioning and post-operational clean-out projects for some of its nuclear facilities (the Hanford site in particular).

Finland

From 30 September to 2 October 2019, a technical meeting was held between ASN and the Finnish safety regulator (STUK) at ASN headquarters, followed by a visit to the Flamanville EPR construction site, for discussions on the progress of the EPR projects In the two countries. The discussions primarily concerned topical technical subjects regarding the construction sites.

In December 2019, an ASN delegation went to Helsinki for a bilateral meeting with STUK. The two regulators discussed their respective national and regulatory topical matters and the challenges of the coming years. These discussions were followed by a visit to the Olkiluoto EPR and the Onkalo geological disposal project.

Japan

On 3 and 4 September 2019, a delegation from the NRA (Japanese Safety Regulator) visited ASN headquarters for discussions on

ASN organises its first transboundary seminar

A regional transboundary seminar bringing together the nuclear safety and radiation protection authorities from Germany, Belgium, France, Luxembourg and Switzerland, was held on 28 and 29 November 2019 in the ASN premises in Montrouge. ASN was the initiator of this seminar, after observing that a number of the topics covered during the various bilateral meetings and common to the five countries would benefit from broader and more in-depth discussions in order to share experiences and best practices.

The five delegations discussed their views of the issues, their experience and their practices in terms of cross inspections, stakeholder consultations, maintaining skills currency within the authorities and, finally, preparedness for emergency situations in a transboundary context.

Four successive workshops thus enabled prospects for collaboration between the countries to be identified, so that each one could aim to adopt the best practices, adapting them to its national context, and thus reinforce the consistency of action in parallel with the bilateral exchanges.

The participants recognised the value of these exchanges and the benefits of a "regional" format conducive to an enhanced sharing of experience. They confirmed their desire to take these exchanges further and restated the importance of maintaining a high level of dialogue, both bilateral and multilateral, with the format being adapted to the particular topic to be covered.

topical subjects, notably the distribution of iodine tablets and the decommissioning of fast neutron reactors. Several site visits were made over the course of the following days –Thermonuclear Experimental Reactor (ITER) installation under construction, LECA-STAR laboratory at CEA Cadarache and the Phénix reactor currently being decommissioned.

From 21 to 25 October 2019, the Lyon regional division welcomed a delegation of NRA inspectors to address post-Fukushima and 4th periodic safety review subjects, with a visit to the EDF NPPs of Bugey and Tricastin, as well as the Orano Philippe Coste and Georges Besse 2 plants.

ASN also received a large number of Japanese delegations in Paris and in the regions, under technical or university exchanges.

In early **September 2019**, a trilateral technical meeting of Japanese, British and French specialists from the respective safety regulators was held on the subject of the decommissioning of fuel cycle facilities.

Luxembourg

The Franco-Luxembourg joint commission on nuclear safety held its 16th meeting on **4 April 2019** in Luxembourg. The Commission consists of the national and Prefect level competent authorities and the Ministries of Foreign Affairs. It discussed recent developments in the two countries on the subjects of nuclear safety and radiation protection, including the 2018 results from the Cattenom NPP, implementation of the TECV Act, regulatory changes and the transposition of the Basic Safety Standards Directive (see point 2.5), the periodic safety reviews of the French NPPs and preparedness for and management of emergency situations.

Norway

On 4 April 2019, ASN made a presentation to the Norwegian safety regulator (DSA) of French regulatory aspects concerning decommissioning, along with the French doctrine of decommissioning as rapidly as possible after shutdown of the facilities. ASN then accompanied the regulator to the Saclay site of the Commission for Alternative Energies and Atomic Energy (CEA), where they visited the "solid waste management zone" (ZGDS) currently undergoing decommissioning and the Osiris reactor, which is being prepared for decommissioning following its final shutdown in 2015.

These visits gave the Norwegian regulator a tangible and practical illustration of some of the problems associated with the various steps in decommissioning: more specifically, the DSA stated that it was particularly interested in the development of tools for waste retrieval and packaging.

Signing of the MoU on cooperation and the exchange of information between ASN and CCSN – Bernard Doroszczuk, ASN Chairman and Rumina Velshi, his CCSN counterpart, at IAEA – September 2019

ASN delegation on the spent fuel disposal site at -450m (Finland) – December 2019

United Kingdom

In **February 2019**, a delegation from ASN and the Defence Nuclear Safety Authority (ASND) went to Sellafield and met the decommissioning heads at the ONR, while ASN also met the government agency in charge of decommissioning nuclear facilities, the Nuclear Decommissioning Authority (NDA). These discussions continued in **June** with a visit by the ONR to the La Hague reprocessing facilities, which included an inspection. Finally, an ONR delegation was able to take part in an exercise by EDF's nuclear rapid intervention force on the Le Blayais NPP in **November**.

Russia

Under the terms of the bilateral cooperation with the Russian safety regulator (*Rostechnadzor*), a fuel cycle facilities safety workshop was held in Moscow on **27 May 2019**. The ASN delegation held discussions with the Russian specialists from *Rostechnadzor* and its technical support organisation, SEC-NRS, on subjects related to the oversight and licensing of fuel cycle facilities and decommissioning. The meeting was followed over the course of the next few days by visits to facilities on the sites of the "mining and chemical combinat" and the "electrochemical plant" in the Krasnoyarsk region of Siberia. This was the third workshop of this type on the topic of fuel cycle facilities since 2017. Large amounts of information about the facilities and Russian oversight practices were collected. Owing to the similarity between the French and Russian nuclear landscapes, *Rostechnadzor* remains a major ASN partner and the two parties agree on the importance of this type of cooperation.

Sweden

The annual meeting between ASN and its Swedish counterpart, SSM, was held at ASN headquarters on **18 October 2019**. The Swedish delegation was headed by the new Director General of SSM, Ms Nina Cromnier, appointed in June 2019. The two authorities discussed their respective national and regulatory topical matters: management of decommissioning (including final shutdown of PWR reactors), periodic safety review beyond 40 years, new zoning rules and distribution of iodine around the facilities, deep geological disposal of ultimate nuclear waste, technical meetings and cross inspections. This meeting was also an opportunity for in-depth discussions on the physical phenomena involved in the clogging of nuclear reactor sumps.

Finally, the agreement between ASN and SSM signed in 2018 was confirmed: its roadmap was extended for a further year.

06

Switzerland

The Franco-Swiss intergovernmental Commission, which involves several competent national authorities at the national and Prefect level, met at the Strasbourg division on **27 and 28 May 2019**. With regard to ASN, this Commission involves both the head office departments and the ASN Lyon and Strasbourg regional divisions.

On 25 and 26 April 2019, the annual Franco-Swiss meeting of the Nuclear Emergency Experts Group (GECN) was held to look at the problems of preparedness for and responses to emergency situations arising from facilities located close to the Franco-Swiss border.

On 4 June 2019 the annual tripartite meeting was held at the European Organization for Nuclear Research (CERN), an internal organisation with facilities in both France and Switzerland. In addition, under the terms of its cooperation agreement with the Swiss Federal Office of Public Health (OFSP) the Lyon regional division carried out two joint inspections of the CERN with the OFSP, one on fire safety, the other on radiological optimisation of works during the second long shutdown of the accelerators complex.

5.2 ASN bilateral assistance actions

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 (ICSN) and international (RCF). The purpose of this cooperation is to enable the beneficiary countries to acquire the safety culture and transparency that is essential for a national system of nuclear safety and radiation protection oversight. Nuclear safety oversight must be based on national competence and ASN consequently only provides support for the establishment of an adequate national framework, ensuring that the national safety regulator it advises retains 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 requires a minimum of fifteen years before a nuclear power reactor can begin to operate 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 skills in terms of safety, safety culture and oversight as well as in radiological emergency management. In 2019, ASN invested in three ICSN projects on behalf of China, Vietnam and Turkey.

China

In 2019, ASN continued its mission with the Chinese Authority, National Nuclear Safety Administration (NNSA) and its technical support organisation, Nuclear Safety Center (NSC), by coordinating the second ICSN cooperation programme with China, which started in February 2017, for a period of three years.

The closing meeting of this project took place in Beijing in **December 2019** and enabled ASN to present NNSA and NSC with the main recommendations of the mission with regard to radioactive waste management, decommissioning, preparedness for emergency situations, the transport of radioactive substances, fuel reprocessing, seismic evaluation and the development of Research and Development skills in the field of nuclear safety.

Vietnam

In 2019, ASN completed its assistance mission for Vietnam to develop the safety, safety culture and oversight capabilities of the Vietnamese nuclear regulator, Vietnam Agency for Radiation and Nuclear Safety (VARANS). This three-year assistance project started in May 2016 and ended in May 2019. The final meeting to present the results took place in Hanoi on **4 April 2019**.

ASN is also involved in assistance to Vietnam within the framework of the RCF.

Turkey

In 2019, ASN continued to coordinate the management of the first assistance programme to Turkey under the INSC, in order to develop the capabilities of the nuclear safety regulator (TAEK) in the fields of probabilistic and deterministic safety assessments, inspections on construction and the manufacture of nuclear components and integrated safety management. This assistance project, which started in January 2018, is scheduled to last for three years.

5.3 Personnel exchanges between ASN and its foreign counterparts

Understanding the working and practices of foreign nuclear safety and radiation protection regulators enables pertinent lessons to be learned for the working of ASN and the training of its personnel. One of the means used to achieve this is to develop personnel exchanges, which can take various forms:
- very short duration actions (a few days) enabling ASN's counterparts to observe inspections or nuclear and radiological emergency exercises, as was for example the case in 2019 with Germany, Belgium, the United Kingdom and Switzerland;
- short duration missions (two weeks to six months) to study a precise technical topic;
- long-duration exchanges (one to three years) for immersion in the activities and workings of the nuclear safety regulator and in-depth discussions on subjects of common interest. This type of exchange must whenever possible be reciprocal. Since 8 January 2018, an ASN staff member has been seconded to the United States Nuclear Regulatory Commission (NRC) for a period of three years while, since mid-May 2019, an NRC staff member has been working at the ASN Waste, Research Facilities and Fuel Cycle Facilities department for a period of one year. In addition, since 1 January 2019, an ASN senior inspector has been seconded to the British regulator (ONR).

6. Outlook

At the international level, 2019 was a productive year for ASN. Through the relationship it has established within a variety of frameworks, ASN was able to compare its practices, discuss common issues, confirm new important subjects and identify new areas of cooperation with its foreign counterparts.

In 2020, it will be continuing its bilateral relations with countries from Europe, from Asia (Japan, China, South Korea) and the North-American continent (United States and Canada). In this context, it will focus on identifying the most pertinent subjects to be dealt with in this type of exchange, such as the decommissioning of legacy facilities or those which are about to shut down, or the conditions for radioactive waste management, subjects on which some countries have very real experience.

At the European level, ASN (whose Director General will be chairing WENRA) will pay particularly close attention to the correct implementation of the association's new strategy, notably with the aim of enhancing the harmonisation of regulatory practices and approaches. ASN will also focus on the satisfactory coordination between the European Commission, ENSREG and WENRA, in particular at a time when preparations will be starting for the next periodic peer review required by the Nuclear Safety Directive. In 2020, HERCA will be taking a strategic look at the consolidation of its goals, in order to provide an optimal response to the current challenges of radiation protection.

Finally, at an international level, 2020 will be an important year for ASN, notably with the 8th review meeting of the contracting parties to the Convention on Nuclear Safety and preparations for the 7th review meeting of the contracting parties to the Joint Convention on the Safety of Spent fuel Management and on the Safety of Radioactive Waste Management, scheduled for 2021.

07.

MEDICAL USES OF IONISING RADIATION

CHAPTER 07

Medical uses of ionising radiation

For 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).

1. Nuclear-based medical activities

1.1 The different activity categories

The nuclear-based therapeutic medical activities, particularly those dedicated to the treatment of cancer, include external-beam radiotherapy, brachytherapy and internal targeted radiotherapy[1].

The nuclear-based diagnostic medical activities include computed tomography, conventional radiology, dental radiology and diagnostic nuclear medicine.

Interventional practices using ionising radiation (fluoroscopy-guided interventional practices) group together different techniques used primarily for invasive medical or surgical procedures for diagnostic, preventive and/or therapeutic purposes.

These different activities and the techniques used are presented in sections 2 to 7.

1.2 Exposure situations in the medical sector

1.2.1 Exposure of health professionals

The risks for health professionals arising from the use of ionising radiation are firstly the risks of external exposure generated by the medical devices (devices containing radioactive sources, X-ray generators or particle accelerators) or by sealed and unsealed sources –particularly after administering RadioPharmaceutical Drugs (RPDs)[2]. When using unsealed sources, the risk of contamination must also be taken into consideration in the risk assessment (in nuclear medicine and in the biology laboratory).

According to the data collected in 2018 by the Institute for Radiation Protection and Nuclear Safety (IRSN), 221,875 people working in the areas of medical and veterinary activities were subject to dosimetric monitoring of their exposure. The average annual dose is 0.3 mSv (millisievert). This dose is stable with respect to 2017. Radiology activities (radiodiagnosis and interventional radiology) represent the largest proportion (40%) of exposed medical personnel and the lowest average annual dose with 0.2 mSv. Nuclear medicine represents 3% of the headcount but the average annual whole-body dose in nuclear medicine personnel is 0.8 mSv. 15,922 medical personnel (7%) were subject to dosimetry of the extremities. The average dose to the extremities is 6.22 mSv, which is stable with respect to 2017.

1.2.2 Exposure of patients

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 tumoral 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 in medical imaging remains a priority for ASN which, following on from the first plan initiated in 2011, published a new opinion on 24 July 2018, along with a second plan, in order to continue promoting a culture of radiation protection with the professionals (see chapter 1).

1.2.3 Exposure of the public

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 nuclear medicine treatment or examination, involving in particular radionuclides such as iodine-131, or brachytherapy using iodine-125;
- the specific professional categories likely to be exposed to effluents or wastes produced by nuclear medicine departments.

The available data on the impact of these discharges on the public (persons outside the health care institution) lead to estimated doses of a few tens of microsieverts per year for the most exposed persons, notably persons working in sewage networks and wastewater treatment plants (IRSN studies, 2005 and 2014).

1. Internal Targeted Radiotherapy (ITR) aims to administer a RadioPharmaceutical Drug (RPD) emitting ionising radiation which will deliver a high dose to a target organ for curative or remedial purposes.

2. An RPD (RadioPharmaceutical Drug) is a drug containing one or more radionuclides. RPDs can be used for diagnostic (scintigraphy) or therapeutic (internal targeted radiotherapy) purposes.

1.2.4 The environmental impact

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 of large towns occasionally reveal the presence of artificial radionuclides used in nuclear medicine (e.g. iodine-131) exceeding the measurement thresholds.

However, no trace of these radionuclides has been measured in water intended for human consumption (see chapter 1).

1.2.5 Significant radiation protection events

Significant Radiation protection Events (ESR) have been reported to ASN since 2007. These notifications provide professionals with increasingly valuable experience feedback, helping to improve radiation protection in the medical field. In 2019, ASN published two *Patient safety* bulletins entitled "Experience Feedback in other Countries" (April) and "Making Proper Use of Computed Tomography Scanner Functions", and an experience feedback sheet "Mapping the sensitive functions and alarms of computed tomography scanners". The latter two documents were produced further to the occurrence of an exposure incident during a computed tomography examination in 2018 and have been widely disseminated in France and Europe. In addition to this, the incident notices are published on *asn.fr*.

Since July 2015, radiotherapy departments can report significant radiation protection events on line. This on-line notification 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.

In 2019, the number of ESRs in the medical field reported to ASN totalled 617 (Graph 1), a figure that has been above 500 since 2012, with the exception of 2016. This overall stability in the total number of reported events with respect to 2018 concerns all the activities. The drop in the number significant events reported in radiotherapy has stabilised and the figure is equivalent to that of 2018.

Graphs 2, 3 and 4 illustrate the distribution of the number of ESRs in 2019 by activity category, how they have evolved since 2010, and the distribution of events by area of exposure (impact on the environment, exposure of the public, exposure of patients, exposure of medical workers), and by activity category concerned.

The reported events originate mainly from computed tomography (30%), radiotherapy (24%) and nuclear medicine (24%) departments.

Furthermore, the events chiefly concern exposure of patients (59%) and foetuses in pregnant women unaware of their pregnancy (31%), as in 2018.

In the light of the events reported to ASN in 2019, the most significant findings from the radiation protection aspect are:

- for the medical professionals: 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 the patients:
  - fluoroscopy-guided interventional practices, with deterministic effects observed in some patients having undergone long and complex procedures;
  - radiotherapy, with overdoses linked in particular to target errors and wrong-side errors;
  - nuclear medicine, with radiopharmaceutical drug administration errors;
- for the public and the environment: nuclear medicine, with losses of sources, leaks from radioactive effluent pipes and containment structures.

Detailed information per category is provided in sections 2 to 6.

1.2.6 The risks and the oversight priorities

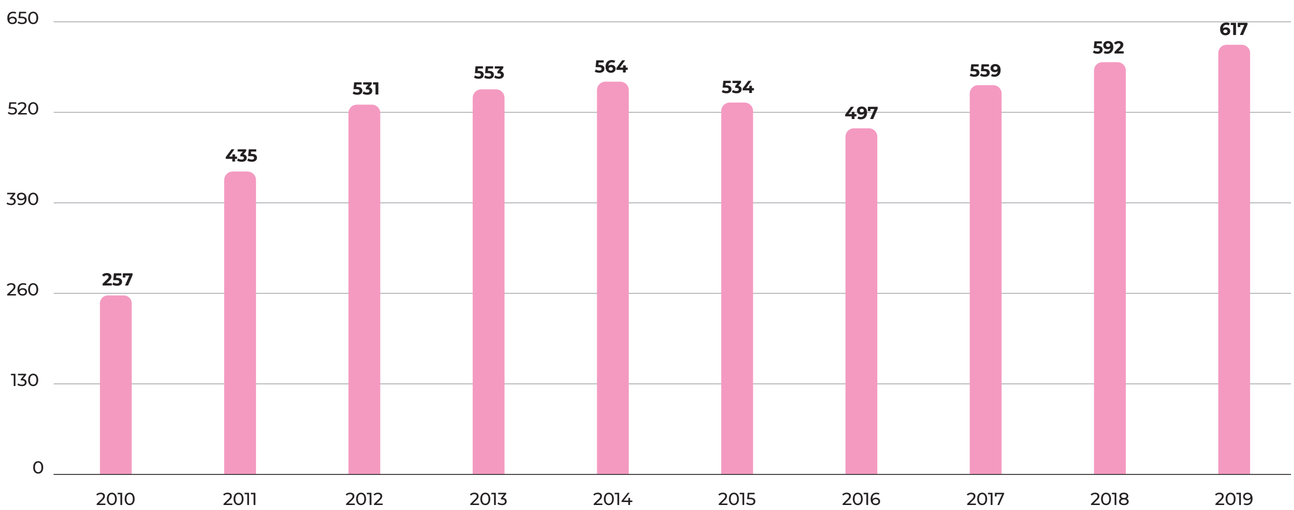
In order to establish its oversight priorities, ASN has classified the nuclear-based medical activities according to the risks for the patients, the personnel, the public and the environment. This classification takes particular account of the doses delivered or administered to the patients, the conditions of use of ionising radiation sources by the medical professionals, the possible impact on the environment, the significant events reported to ASN and the radiation protection situation in the institutions exercising these activities.

On the basis of this classification, ASN considers that its oversight must focus in priority on external-beam radiotherapy, brachytherapy, nuclear medicine and fluoroscopy-guided interventional practices.

07

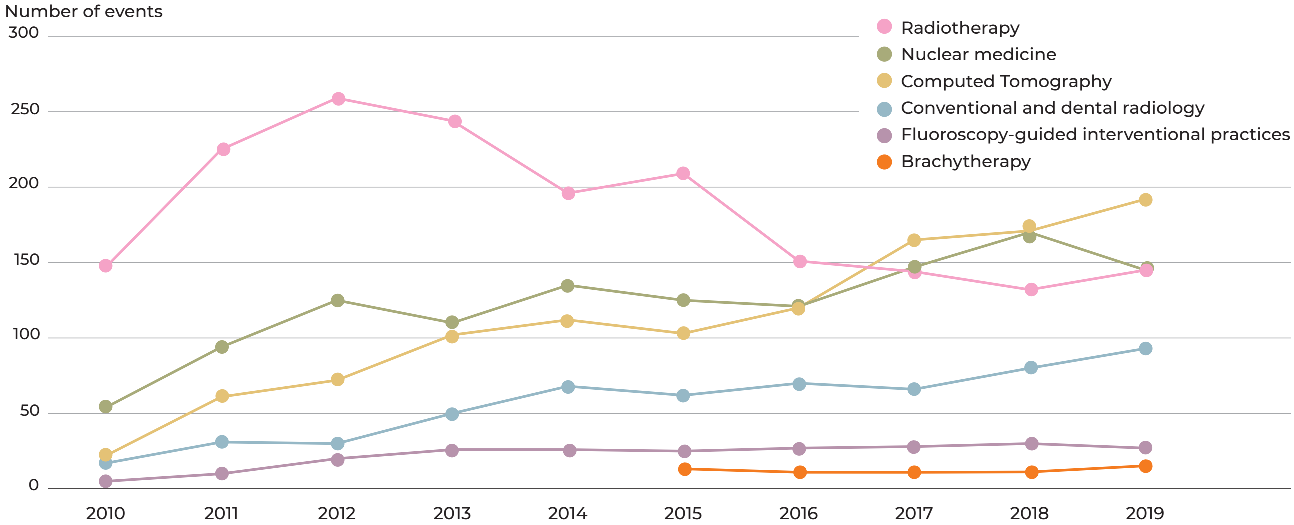
GRAPH 1

Trends in the number of annual ESR notifications from 2010 to 2019



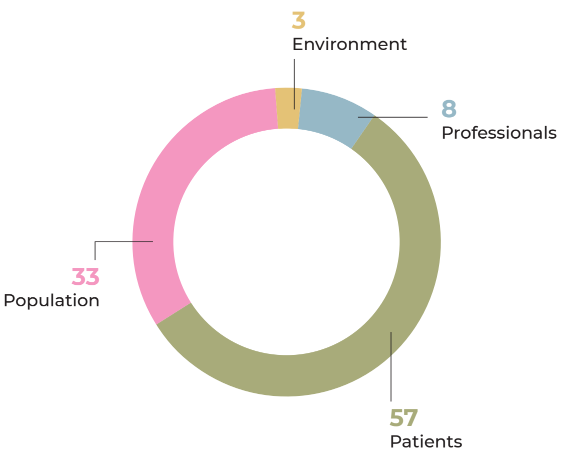
GRAPH 2

Number of ESRs per activity category during the period 2010-2019



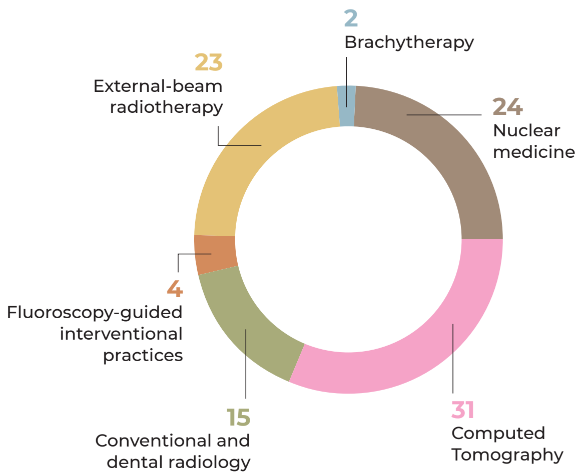
GRAPH 3

Breakdown of ESRs per area of exposure in 2019 (%)



GRAPH 4

Breakdown of ESRs per activity category concerned in 2019 (%)



As from 2018, ASN began implementing a new inspection strategy in the medical field based on systematic verifications of the regulatory provisions concerning radiation protection of the workers, the patients and the public. These verifications concern a limited number of inspection points, combined with indicators for conducting regional and national assessments. This approach is supplemented by deeper investigations focusing on specific themes defined on an annual or multi-year time frame.

The radiation protection situation in the medical environment has been assessed essentially on the basis of the indicators associated with the control points.

1.3 Regulations

1.3.1 General regulations

Protection of the personnel working in facilities that use ionising radiation for medical purposes is governed by the provisions of the Labour Code (Articles R. 4451-1 to R. 4451-135 of the Labour Code).

In order to protect the public and the workers, the facilities that use medical devices emitting ionising radiation must also satisfy the technical rules defined in the ASN decisions (see points 4 to 7).

TABLE 1

Nuclear-based medical activities: the main risks

ACTIVITIES	PATIENTS	MEDICAL PROFESSIONALS	PUBLIC AND ENVIRONMENT
External-beam radiotherapy	3	1	1
Brachytherapy	2	2	2
Internal targeted radiotherapy	3	2	3
Fluoroscopy-guided interventional practices	2 to 3 depending on the procedures	2 to 3 depending on the procedures	1
Diagnostic nuclear medicine	1 to 2 depending on the procedures	2 to 3 depending on the procedures	2
Computed Tomography	2	1	1
Fluoroscopy-guided procedures on remote-controlled table in radiology department	1	1	1
Conventional radiology	1	1	1
Dental radiology	1	1	1

1: no risk or low risk – 2: moderate risk – 3: high risk

1.3.2 Medical devices and radiopharmaceuticals

Medical devices emitting ionising radiation (electrical devices and particle accelerators), used in nuclear-based medical activities must meet the essential requirements defined in the Public Health Code (Articles 5211-12 to R 5211-24). The CE marking, which certifies conformity with these essential requirements, is mandatory. Further to technological developments, the Order of 15 March 2010 laying down the essential requirements applicable to medical devices has been modified to reinforce the provisions concerning the display of the dose during imaging procedures.

The RadioPharmaceutical Drugs (RPDs) used in nuclear medicine are covered by a Marketing Authorisation (MA) delivered by French Health Products Safety Agency (ANSM) or by the European Medicines Agency (EMA). Pending delivery of an MA, they can be granted a Temporary Authorisation for Use (ATU) –the French version of compassionate use– which can be for named patients or cohorts.

The monitoring of sources (radioactive sources including RPDs, devices emitting ionising radiation, particle accelerators) is subject to specific rules figuring in the Public Health Code (Articles R. 1333-152 to R. 1333-164).

1.3.3 Radiation protection of patients

Justification and optimisation – The protection of patients undergoing medical imaging examinations or therapeutic procedures using ionising radiation is regulated by specific provisions of the Public Health Code (Articles R. 1333-45 to R. 1333-80). However, contrary to the other applications of ionising radiation, the principle of dose limitation does not apply to patients because of the need to adapt –for each individual patient– the delivered dose according to the therapeutic objective or to obtain an image of adequate quality to make the diagnosis.

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*.

Through a decision subject to approval by Ministerial Order, ASN undertook as of 2017 to update and supplement the regulatory framework with specific provisions regarding optimisation, quality assurance, training and qualification.

1.3.4 Administrative procedures

Decree 2018-434 of 4 June 2018 introducing various nuclear-related provisions has brought the clarifications necessary for the implementation of the new system of procedures applicable in small-scale nuclear activities in application of Article L. 1333-7 of the Public Health Code: a third system baptised "registration" (it is a "simplified" licensing system) may be put in place in addition to the notification and licensing systems that exist for certain activities.

In view of the risks (Table 1), ASN has adopted the following changes:
- The existing list of medical activities subject to notification has been maintained by ASN resolution 2018-DC-0649 of 18 October 2018[3], conventional radiology and dental radiology continue to be covered by the notification system.
- The preparation of the conditions of application of the new registration system in the medical sector progressed well in 2019. It should be applied in computed tomography and to fluoroscopy-guided interventional practices involving radiation exposure risks (in the meantime, these practices remain subject to simple notification).
- The licensing system shall be maintained for external-beam radiotherapy, brachytherapy and diagnostic and therapeutic nuclear medicine.

3. ASN resolution 2018-DC-0649 of 18 October 2018 defining, in application of 2° of Article R. 1333-109 and Article R. 1333-110 of the Public Health Code, the list of nuclear activities subject to the notification system and the information that must be indicated in these notifications.

TABLE 2

Regulatory work in progress in the area of patient radiation protection

	EXISTING TEXT	WORK IN PROGRESS
Quality assurance in radiotherapy	Resolution 2008-DC-0103 of 1 July 2008	Updating planned in 2020
Quality assurance in medical imaging	Resolution of 15 January 2019 approved by Order of 8 February 2019	
Diagnostic reference level	Resolution of 18 April 2019 approved on 23 May 2019	
Continuous training of health professionals in the protection of persons exposed to ionising radiation for medical purposes	Resolution 2017-DC-0585 of 14 March 2017 amended by resolution of 11 June 2019 approved on 27 September 2019	
Qualifications of physicians involved in the exercise of nuclear-based medical activities	Resolution 2011-DC-0238 of 23 August 2011	Updating planned in 2020

2. External-beam radiotherapy

2.1 Description of the techniques

Alongside surgery and chemotherapy, radiotherapy is one of the key techniques employed to treat cancerous tumours. Some 200,000 patients[4] are treated each year, representing nearly 4.2 million irradiation sessions. Radiotherapy uses ionising radiation to destroy malignant cells (and non-malignant cells in a small number of cases). The ionising radiation necessary for the treatments is produced by an electric generator or emitted by radionuclides in sealed sources. We thus have 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 as close as possible to the area to treat.

According to the information gathered from the French National Radiotherapy Observatory (source: INCa, 2018), the radiotherapy facilities comprise 530 particle accelerators in 174 radiotherapy centres subject to an ASN license. ASN issued 95 licenses in 2019. The majority of these cases concerned the updating of an existing license.

This observatory had 818 radiotherapists on record in 2018.

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 MV (megavolts) or electrons with an energy level of between 4 and 25 MeV (megaelectronvolts) and delivering dose-rates that can vary from 2 to 6 Gy/min (grays per minute). It should be noted that some latest-generation linear accelerators can deliver much higher dose rates, of up to 25 Gy/min (in the case of photon beams).

2.1.1 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 French Society for Radiation Oncology (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.

2.1.2 Intensity-Modulated (conformal) Radiotherapy (IMRT)

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® –Volumetric Modulated Arc Therapy, RapidArc®) depending on the manufacturer, is achieved using conventional isocentric linear accelerators equipped with this technological option.

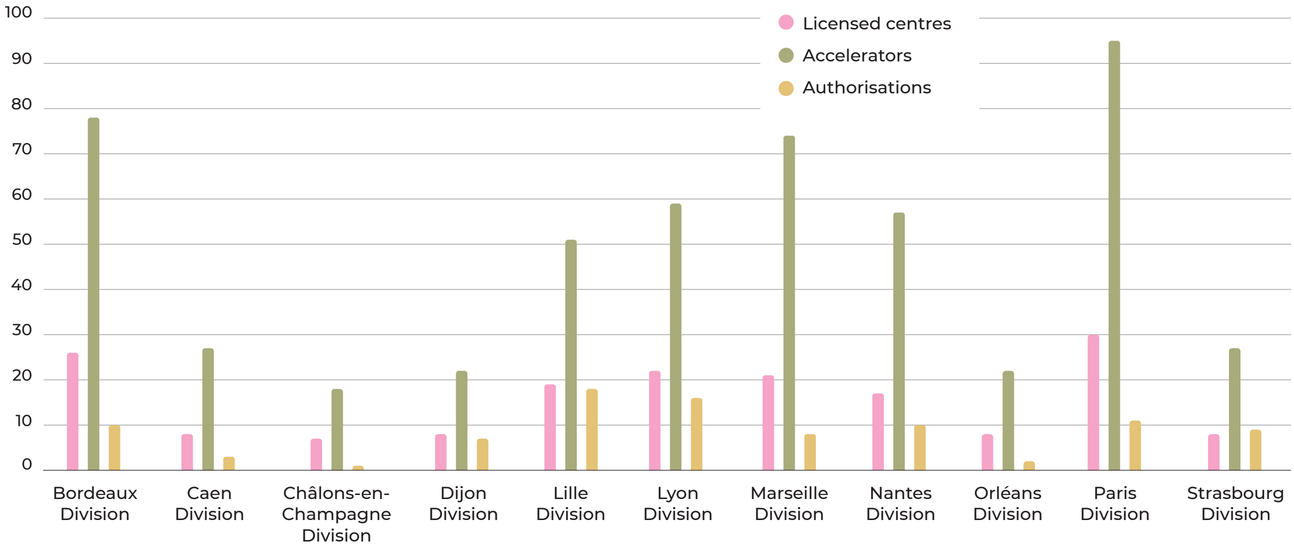
- **Helical radiotherapy**

Helical radiotherapy, or tomotherapy, enables radiation treatment to be delivered by combining the continuous rotation of an accelerator with the longitudinal movement of the patient during the treatment. The technique employed is similar to the principle of helical image acquisitions obtained with computed

4. In 2018, 201,352 people with cancer were treated by radiotherapy in 4,249,055 sessions (source: INCa Observatory).

GRAPH 5

Breakdown, by ASN regional division, of the number of centres and external-beam radiotherapy accelerators inspected and the number of new licenses or license renewals issued by ASN in 2019



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.

In 2018, there were 27 devices of this type installed in France (source: Radiotherapy observatory, INCa 2019).

2.1.3 Stereotactic radiotherapy

Stereotactic radiotherapy is a treatment method that aims at delivering high-dose radiation to intra-or extracranial lesions with millimetric accuracy through multiple mini-beams which converge at the centre of the target. 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 used more and more frequently to treat cerebral metastases, but also for extra-cranial tumours.

This therapeutic technique chiefly uses three specific types of equipment, such as:

- Gamma Knife®, which uses more than 190 cobalt-60 sources, permits very precise irradiation. Gamma Knife® acts like a veritable scalpel over an extremely precise and delimited zone (5 units in service);
- robotic stereotactic radiotherapy; CyberKnife® is a miniaturised linear accelerator mounted on a robotic arm (19 units in service);
- multi-purpose linear accelerators equipped with additional collimation means (mini-collimators, localisers) that can produce mini-beams.

2.1.4 Radiotherapy using a linear accelerator coupled to a magnetic resonance imaging system

A first linear accelerator coupled to a Magnetic Resonance Imaging (MRI) system was installed in the Paoli-Calmette Institute in Marseille at the end of the first half of 2018.

The combining of these two technologies (linear accelerator and MRI) has raised new questions regarding its clinical use, in terms not only of measurement and calculation of the dose delivered to the patient but also of the quality control of the complete machine concerning both the accelerator and the imaging device. Following an expert assessment by IRSN, ASN authorised entry into service of this new technique at the end of 2018.

In 2019, two other centres were licensed to possess and use this type of machine, namely the Georges François Leclerc centre in Dijon and the ICM Val d'Aurelle in Montpellier.

2.1.5 Contact radiotherapy

Contact therapy or contact radiotherapy is an external-beam radiotherapy technique. The treatments are delivered by an X-ray generator using low-energy beams varying from 50 to 200 kV (kilovolts). These low-energy beams are suitable for the treatment of skin cancers because the dose they deliver decreases rapidly with depth.

2.1.6 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.

In April 2016, the French National Authority for Health (HAS) published the results of the assessment of this practice. 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. Intraoperative radiotherapy has been one of the techniques used to treat small cancers of the breast for 4 years now; it is developing little, but its assessment is continuing.

2.1.7 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. Compared with existing techniques, the dose delivered around the tumour to irradiate is lower, therefore the volume of healthy tissue irradiated is drastically reduced. Hadron therapy allows the specific treatment of certain tumours. In June 2016, the INCa published a report on proton therapy treatment indications and possibilities.

Hadron therapy with protons is currently used in three centres in France:
- in the Curie Institute of Orsay (equipment modified in 2016);
- in the Antoine-Lacassagne Centre in Nice (new equipment installed in 2016);
- in the François-Baclesse Centre (ARCHADE project) in Caen (commissioned in 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 each year. The claimed biological advantage is 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.

2.2 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 metre to 2.5 metres 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).

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, which is 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.

2.3 Radiation protection situation in external-beam radiotherapy

The safety of radiotherapy treatments has been a priority area of ASN oversight since 2007. An inspection programme was defined for the 2016-2019 period, and its broad lines were communicated to all the radiotherapy departments in early 2016. The inspections focus on the ability of the centres to deploy a risk management approach and, depending on the situation found by the inspectors, they also address the management of skills, the implementation of new techniques or practices and the command of the equipment.

ASN has continued its graded approach to inspection:
- 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 frequency for the centres displaying vulnerabilities or risks, especially certain centres having required tightened inspections (Lucien Neuwirth Cancerology Institute in Saint-Priest-en-Jarez, the Peupliers Private Hospital in Paris) and the continuation of the tightened monitoring of the Private Radiotherapy Centre of Metz, renamed the Private Institute of Radiotherapy of Metz during 2019, following a change of ownership.

ASN inspected 73 centres in 2019, representing 42% of the national total. In 2018, it inspected 79 centres, or 45% of the national total. In two years, about two-thirds of the French radiotherapy centres have been inspected, some of them twice.

2.3.1 Radiation protection of external-beam radiotherapy professionals

When the radiotherapy facilities are correctly designed, the radiation risks for the medical staff are limited due to the protection provided by the walls of the irradiation room.

The results of the inspections carried out in 2019 reveal no major problems in this sector:
- The effective designation of Radiation Protection Expert-Officers (RPE-Os) was confirmed in the majority of the centres inspected.
- The radiation protection technical controls were carried out in about 90% of the centres inspected and were satisfactory.

Auvergne – Rhône-Alpes

Compliance notice served on the Lucien Neuwirth Cancerology Institute (ICLN) in Saint-Priest-en-Jarez (Loire *département*)

The Lucien Neuwirth Cancerology Institute (ICLN), situated in Saint-Priest-en-Jarez (Loire *département*), is a public institution specialised in fighting cancer and which exercises external-beam radiotherapy and brachytherapy activities.

Since 2017, ASN has put in place tightened monitoring of this institute, mainly on account of relational difficulties within the radiotherapy department. This has resulted in the institute undergoing four inspections in two years.

During the last inspection carried out on 9 and 10 July 2019, the ASN inspectors found the medical physics unit to be in a very vulnerable situation. They noted that responsibilities were not adequately defined, foremost among these being the verification and validation channels, and the division of roles between the medical physics service provider and the personnel of the medical physics unit. The work of the outside service providers, found to be highly fragmented, is a risk factor (by increasing the number of points of contact between professionals) which must also be taken into account.

ASN considers that the ICLN's responses following this inspection were not satisfactory and would not reduce the risks for patients: ASN therefore gave ICLN formal notice to comply with certain regulatory provisions concerning organisation, human resources and risk management.

The person responsible for nuclear activities was notified of these provisions on 18 December 2019. ASN will verify in 2020 the actions taken by the ICLN to comply with this notice.

2.3.2 Radiation protection of radiotherapy patients

The assessment of the radiation protection of radiotherapy patients is based on the inspections focusing on implementation of the treatment quality and safety management system, made compulsory by ASN resolution 2008-DC-0103 of 1 July 2008. Since 2016, these inspections have included verifications of the adequacy of the human resources, and in particular the presence of the medical physicist and internal organisation procedures for tracking and analysing adverse events –or malfunctions– recorded by the radiotherapy centres.

The presence of a medical physicist during the treatments was confirmed in almost 90% of the inspected centres. A medical physics organisation plan is also available in about 90% of the centres.

The assessment shows that the detection of adverse events, their reporting (internally or to ASN) and their recording are deemed satisfactory on the whole. On the other hand, the analysis of these adverse events is only satisfactory on the whole in 46% of the inspected centres, which represents a regression of 28% with respect to 2018:
- The analysis of the causes of events is still too succinct, often not going beyond the immediate causes.
- Similarly, the analyses of recurrent events are still poorly developed, even though they should constitute alert signals for the centre.

The improvement in practices through experience feedback and the assessment of the effectiveness of the corrective actions were deemed satisfactory in only 27% of the centres inspected, which is stable with respect to 2018 and had dropped by 10% with respect to 2017. Although the majority of these procedures involve representatives of all the medical professionals who contribute to the treatment process, some of the personnel –the physicians in particular– do not involve themselves, which reduces the effectiveness of the procedures.

In order to achieve real continued improvement in treatment quality and safety, further progress must be made in the monitoring and evaluation of the corrective actions put in place, in the involvement of all the personnel and in the utilisation of experience feedback to assess and enrich the prospective risk analysis, required by the abovementioned ASN resolution 2008-DC-0103 of 1 July 2008.

In addition to the verifications performed, the ability of a centre to deploy a risk management procedure was again subject to specific investigations in 2018. These investigations reveal that:
- Although the requirements for the management of quality and safety in radiotherapy departments set by the abovementioned resolution are satisfied on the whole, there are still disparities between centres. The prospective risk analysis for example, which is mandatory, is only available and complete in half of the inspected centres.
- More generally, further to the inspections carried out since 2016, ASN considers that implementation of the risk management procedure is only satisfactory on the whole in half of the inspected centres. These are the centres in which management has defined a policy with shared, assessable and assessed operational objectives, has 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.

Lastly, ASN notes again in 2019 that the technical, organisational or human changes are not sufficiently anticipated. The impact a change can have on the operators' activity is not always analysed, despite the fact that these changes can weaken the existing lines of defence. The lessons learned from the inspections carried out in 2019 show that, when a new technique is deployed, in only 40% of the cases do the centres have adequate command of project management, and in only 25% of the cases do they have adequate command of the installation of the new equipment.

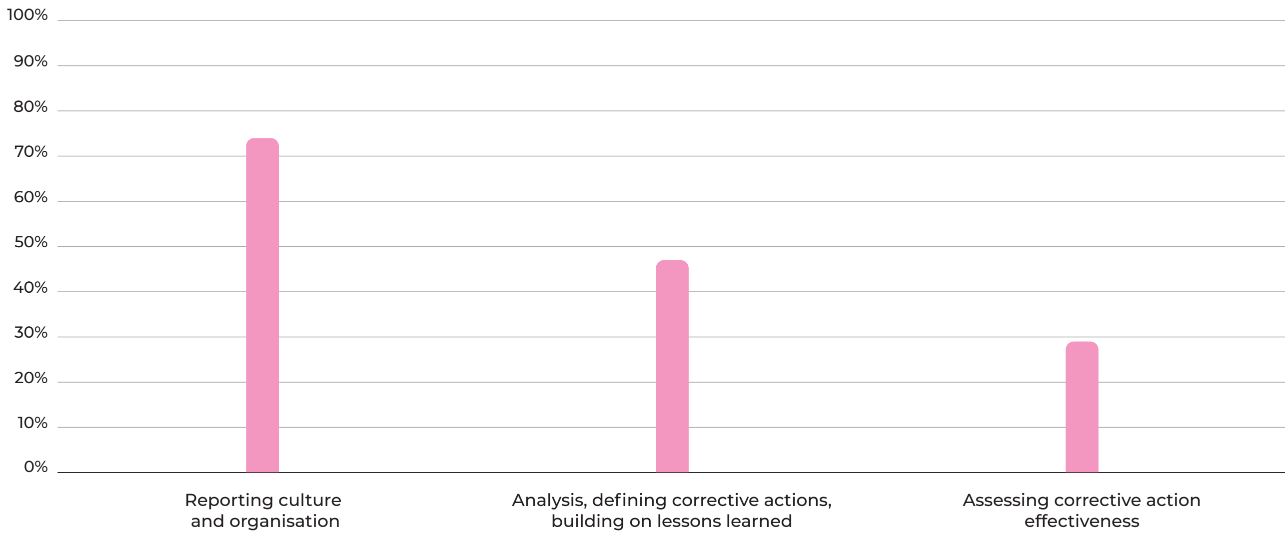
2.3.3 Significant events in external-beam radiotherapy

In 2019, 145 significant events concerning radiotherapy were reported. In the last few years, ASN has noted a significant reduction in the ESRs reported by radiotherapy departments. In effect, some 200 ESRs were reported per year in 2014 and 2015. This phenomenon must be analysed with the assistance of the radiotherapy professionals to find out the reasons for this drop in numbers. This drop stabilised in 2019, with the number of reported events equivalent to the 2018 figure.

Most of the events reported in 2019 concern patient radiation protection, and the majority of them are not expected to have any clinical consequences.

GRAPH 6

Percentage of conformity of the facilities concerning the management of events giving rise to corrective actions in 2019



57% of the events reported in 2019 were rated level 1 on the ASN-SFRO scale. Three events in 2019 were rated level 2 on the ASN-SFRO scale. These three events concern the stereotactic treatment of the target twice in the same session, a wrong-side error in the treatment of a cancer of the oral cavity and a wrong-side error in a proton radiotherapy treatment of an eyelid lesion.

As in the preceding years, these events reveal organisational weaknesses in:

- the management of the movement of patients' medical files;
- the validation steps which are insufficiently explicit;
- the keeping of patients' files in a manner that provides an overall view and gives 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 an impact on treatment amplitudes, or the deployment of a new technique or practice, are all risk factors.

Île-de-France

Tightened inspection of the radiotherapy centre of the Peupliers Private Hospital (Paris)

After observing organisational malfunctions during the inspection of 18 March 2019 in the radiotherapy centre of the Peupliers Private Hospital of the Ramsay-Santé group, ASN conducted another inspection on 21 and 22 October 2019. This inspection ran in parallel with a control visit by the Île-de-France Regional Health Agency (ARS). It emerged from this new inspection that the centre's radiotherapy activities are carried out at a sustained pace with persistent understaffing, leaving the medical personnel little margin to cope with unexpected and unforeseen events. This leads to a work situation that is a potential source of risks and errors for the patients. The shortcomings concerning themedical organisation, medical physics, the work of the radiographers, and shortcomings in themanagement of the quality management system, the prospective risks analysis, document management and the reporting and analysis of adverse events have given rise to a cross-checking procedure that will continue in 2020.

SUMMARY

In radiotherapy, the safety fundamentals are in place (equipment verifications, medical staff training, quality and risk management policy) and the quality initiatives are progressing. The prospective risk analyses however remain relatively theoretical and are insufficiently deployed prior to organisational or technical changes. Given the maturity of the sector with regard to patient radiation protection, ASN is reducing its inspection frequencies, but given the diversity of situations encountered, the centres displaying vulnerabilities or particular risks will continue to be subject to particular scrutiny and more frequent monitoring in 2020.

"Wrong-side" errors, the need to remain attentive throughout the radiotherapy pathway of the patient

So-called "wrong side" (or laterality) errors are frequent causes of ESRs reported to ASN and most often rated level 2 on the ASN-SFRO scale. ASN, in collaboration with the professionals, published a *Radiotherapy Patient Safety* bulletin on this subject (Bulletin No. 6) in 2014.

Since then, out of a total of 29 events rated level 2 and two events rated level 2+ over the 2014-2019 period, 9 "wrong side" errors have been reported, 2 of them in 2019.

These errors can occur at various stages from the beginning to the end of a patient's radiotherapy treatment pathway:
- when preparing the medical prescription, whether handwritten or computerised, by failing to consult the documents of the medical file (surgical or anatomy/pathology report) to check the laterality;
- during imaging, due to an error or lack of left/right position indications on the images;
- during dosimetric planning;
- when defining the patient positioning references;
- when carrying out one or more radiotherapy sessions.

To prevent these errors, it is vital to ensure traceability of all the paired organs in all the documents throughout the patients' treatment pathway. Any doubt must be lifted by a collegial review of the radiotherapy file. Lastly, the active participation of the patient or the person accompanying them is key to preventing this type of error.

3. Brachytherapy

Brachytherapy allows specific or complementary treatment of cancerous tumours.

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 uses three techniques (detailed below), depending on the indications.

Sixty-two brachytherapy centres are licensed by ASN, and 49 of them use the High Dose-Rate (HDR) technique. ASN issued 31 licenses in 2019. The majority of them concerned the updating of an existing license.

3.1 Description of the techniques

3.1.1 Low Dose-Rate (LDR) brachytherapy

- **delivers dose rates of between 0.4 and 2 Gy/h (grays/hour);**
- **by means of permanently implanted iodine-125 seeds or temporarily implanted caesium-137 seeds.**

Indications:
- Treatment of prostate cancers. Permanent implantation in the patient's prostate gland of seeds with a unit activity of between 10 and 30 MBq (megabecquerels). A treatment requires about one hundred seeds, representing a total activity of 1 to 2 GBq (gigabecquerels).
- Treatment of certain eye tumours by temporary implants of iodine-125 placed in a silicone insert (8 to 24 grains per disk), enclosed in a gold-titanium plaque. The seed size is the same as for prostate treatment, but the activity is higher (about 200 MBq per grain). The implants are put in place in the operating theatre under general anaesthetic and the treatment lasts from 1.5 days to one week, with hospitalisation of the patient.
- Treatment of tumours of the endometrium or the uterine cervix by brachytherapy with caesium-137. The treatment is delivered in a shielded hospital room using a caesium-137 afterloader (activity of about 8.2 GBq). The treatment involves 2 to 5 days of hospitalisation. This technique is used very little, pulsed dose-rate brachytherapy being the preferred treatment.

3.1.2 Pulsed Dose-Rate (PDR) brachytherapy

- **delivers dose rates of between 2 and 12 Gy/h;**
- **using sources of iridium-192 with a maximum activity of 18.5 GBq and applied using a specific after-loader.**

Indications: mainly gynaecological cancers, more occasionally bronchus or oesophageal cancer, and exceptionally breast and prostate cancers.

This technique requires patient hospitalisation for several days in a room with radiological protection appropriate to 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 advantages with regard to radiation protection:
- 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 provision for accident situations related to the operation of the source after-loader and to the high dose-rate delivered by the sources used.

3.1.3 High Dose-Rate (HDR) brachytherapy

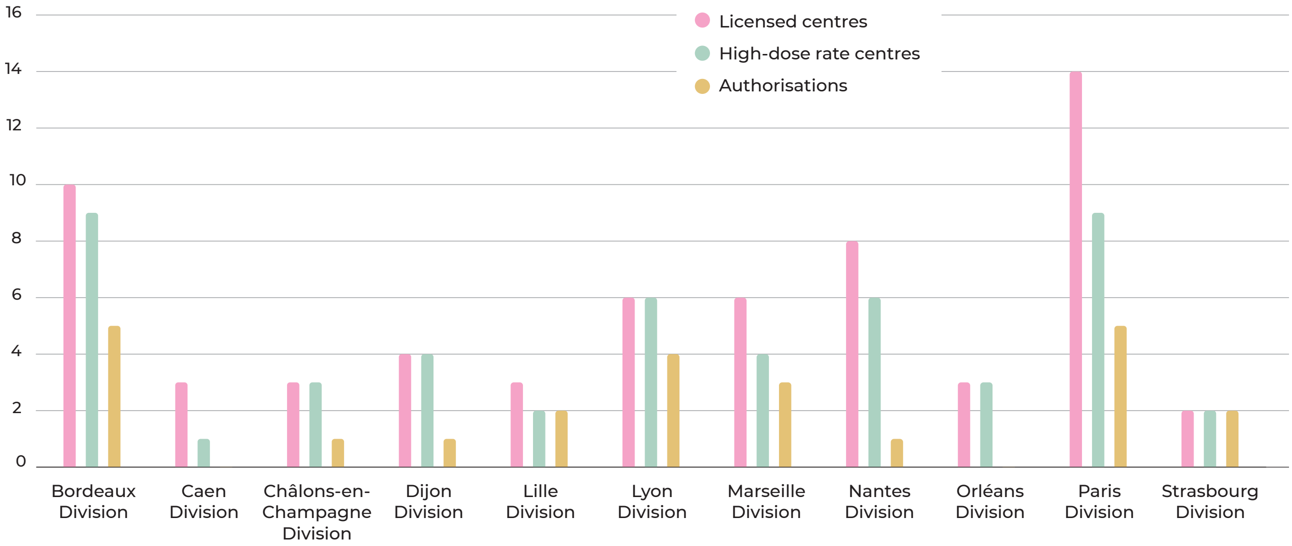
- **delivers dose-rates in excess of 12 Gy/h;**
- **using sources of iridium-192 with a maximum activity of 370 GBq and implemented with a specific afterloader (some afterloaders use a high-activity cobalt-60 source).**

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.

Indications: mainly gynaecological cancers, occasionally the treatment of prostate and bronchus cancers, and exceptionally ear, nose and throat cancers. This technique is also indicated in the treatment of keloid scars.

GRAPH 7

Breakdown, by ASN regional division, of the number of brachytherapy centres, and more precisely, high dose-rate brachytherapy centres and the number of new licenses or license renewals up to date in 2019



3.2 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.

3.3 Radiation protection situation in brachytherapy

In the same way as for external-beam radiotherapy, the safety of brachytherapy treatments has been a priority area of ASN oversight since 2007. In addition, because high-activity radioactive sources are used, the questions of the management of these sources and of potential emergency situations associated with their use must also be taken into account.

In 2019, as in 2018, 21 centres practising brachytherapy were inspected, meaning that two thirds of the centres have been inspected over the last two years.

3.3.1 Radiation protection of medical professionals

The occupational radiation protection measures deployed in 2019 by the brachytherapy departments were considered satisfactory on the whole. Nevertheless, improvements can still be made in the additional training to cope with emergency situations. In slightly more than half of the centres inspected, no simulated situation exercises were held (high activity source jammed, for example), or there is no procedure covering this situation.

ASN considers that efforts must still be made to reinforce the radiation protection training of medical professionals when high activity sources are held.

3.3.2 Radiation protection of patients

As with external-beam radiotherapy, the radiation protection of brachytherapy patients is assessed from the inspections concerning the implementation of the treatment quality and safety management system.

The presence of medical physicists in sufficient numbers for the activity is observed in nearly 90% of the centres inspected. A medical physics organisation plan is also available in about 90% of the centres.

- **The treatment quality and safety management system**
The qualitative result of the inspections carried out in 2019 has shown that the majority of brachytherapy departments inspected have deployed the quality management system, with the support of the external-beam radiotherapy departments. They nevertheless present the same shortcomings with regard to the prospective risks analysis and no improvement has been seen in this area compared with 2018.

The effectiveness of corrective actions put in place following adverse events is found to be insufficient in about 57% of the centres inspected in 2019, as in 2018, which leaves considerable room for improvement given that the situation has not changed.

The prior validation of HDR brachytherapy treatments is formalised in just 52% of the cases, which is still insufficient given the risks associated with the use of high-activity sources. Here again, the situation has not changed with respect to 2018.

Maintenance and quality controls – The majority of the centres have an inventory of the medical devices and a register for recording maintenance operations and quality controls. In the absence of an ANSM decision defining the baseline requirements for the

Source jamming: comply with the conditions of use of the devices and provide training in emergency situation management

Two significant radiation protection events involving sources becoming jammed due to equipment faults were reported to ASN in 2019. They occurred during Pulsed Dose-Rate (PDR) treatment of gynaecological cancers.

In the first case reported, the source was subject to friction inside the afterloader, causing the source to retract to the storage position where it jammed. This means there were no consequences in terms of dose to the tumour to treat or to healthy organs. It was nevertheless necessary to reschedule the treatment and change the equipment. The friction of the source inside the incriminated afterloader was caused by obsolescence of the equipment used beyond the maximum time recommended by the manufacturer, which is normally 3 years. Re-usable equipment of this type has to undergo numerous sterilisation cycles which can cause wearing of the surfaces and materials, therefore it is assigned a service life that must not be exceeded.

In the second case, shortly after the start of the last pulse –in the middle of the night– the device emitted an alarm while the source was blocked in the treatment position. The duty personnel were unsettled by contradictory information indicated by the device, with a red light prohibiting access to the treatment room, and the "treatment interrupted" light remaining on. Illumination of the "treatment interrupted" light normally means that the source is retracted into the device, which was not the case. The duty personnel were able to perform emergency withdrawal of the treatment equipment (the afterloader, the source and the sheath) from the patient and place it in the container provided for that purpose. It turned out that it was not the right container and consequently its cover could not be closed. The intervention of the treatment device manufacturer allowed the recovery and disposal of the incriminated source.

This event formed the subject of an incident notice because it was rated level 1 on the International Nuclear and Radiological Event Scale (INES), in view of the noncompliance with certain in-house procedures when the duty personnel intervened. However, there were no dosimetric consequences for the patient or the personnel of the centre.

quality controls of brachytherapy devices, the quality controls implemented result from the past practices and are based on the recommendations of the manufacturers or medical professionals.

Maintenance of the HDR and PDR afterloaders is ensured by the manufacturers. More specifically, the manufacturers perform the afterloader operating verifications when the sources are replaced. The brachytherapy units rely on these verifications to guarantee correct operation of the devices. The source activity is verified at each delivery and source removal verifications are also carried out.

3.3.3 Management of sources

Management of the brachytherapy sources is satisfactory. All the centres inspected record the tracking of source movements, transmit the source inventory to IRSN and store the sources waiting to be loaded or collected in a suitable place.

The organisation in place enables the category of each source or batch of sources to be identified in 53% of the centres inspected. 80% of the centres did not deliver the authorisations that authorise people to have access to the high activity sources, therefore progress is still to be made.

Areas for improvement have also been identified regarding the safeguarding of access to the high activity sources, given that only 38% of the centres inspected in 2019 have put in place appropriate measures to prevent unauthorised access to these sources. ASN will remain attentive to the progress to be made and this inspection theme shall be a priority in 2020 for the centres holding high-activity sealed sources.

3.3.4 Emergency situations and management of malfunctions

Two events involving the jamming of the source in a PDR applicator were reported in 2019. They did not lead to overexposure of either the personnel or the patients.

Describing these events aims to draw attention to the need to comply with the technical conditions of use of these devices and give a reminder of the obligations concerning training in emergency situation management and conducting exercises.

3.3.5 Significant events in brachytherapy

In 2019, 15 ESRs were reported in brachytherapy, one of which was rated level 2. This event concerned a prostate cancer treated by brachytherapy with permanent implants.

In addition to the two source jamming events described above, there was one case of interruption of a PDR brachytherapy treatment when the patient removed the treatment material herself. It was decided to stop the treatment.

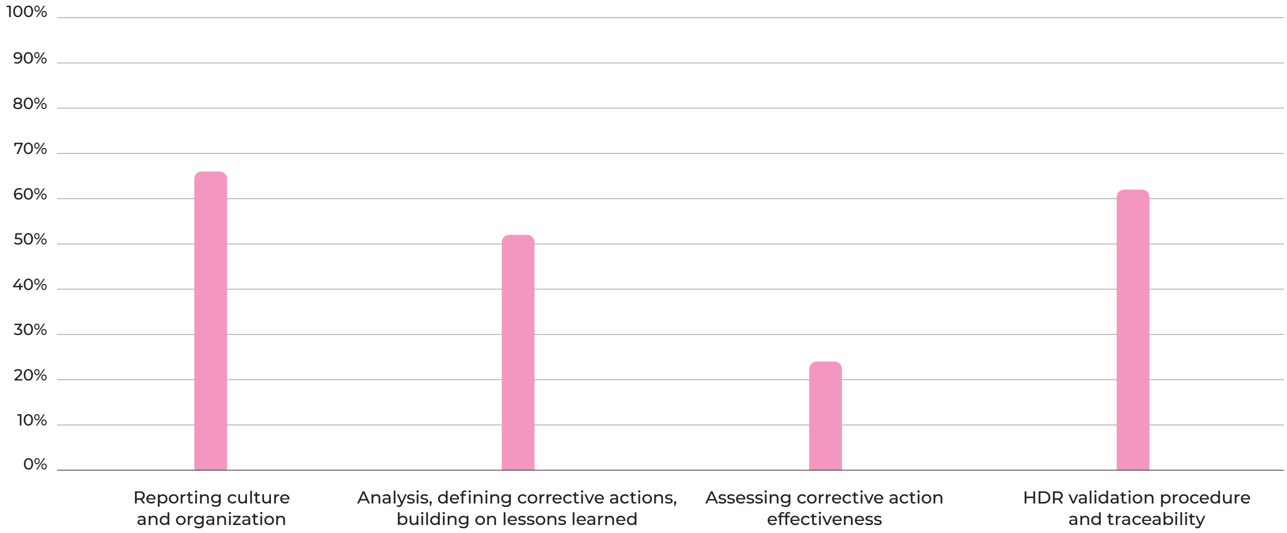
The analysis of these events underlines that the control of risks in brachytherapy must be based on appropriate quality controls and the implementation of organisational measures to better manage the informing of the patient, the sources and emergency situations.

SUMMARY

With regard to health care safety, the brachytherapy situation is comparable to that of external-beam radiotherapy. Occupational radiation protection and the management of high-activity sealed sources are considered satisfactory on the whole, but the standard must nevertheless be maintained through continuous training actions. In the current context, increased attention must be devoted to safeguarding access to prevent unauthorised access to these sources.

GRAPH 8

Percentage of conformity of the facilities concerning the management of events giving rise to corrective actions in 2019



4. Nuclear medicine

4.1 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.

An investigation conducted in early 2018 with all the nuclear medicine units licensed by the ASN regional divisions enabled an inventory of the equipment pool in 2017 to be drawn up, and provided information on the number of procedures performed using the different technologies and on the human resources. The data collected for 2017 are presented below.

According to this investigation, the total annual number of nuclear medicine procedures in France is about 1,537,000 of which about 900,000 are Single Photon Emission Scintigraphy (SPECT), 125,000 procedures with semiconductor camera detection and about 500,000 Positron Emission Tomography (PET) procedures (see point 4.1.1.).

• Nuclear medicine departments

At the end of 2019, this sector of activity comprises 233 nuclear medicine units; the number of Internal Targeted Radiotherapy (ITR) rooms is stable, varying from 158 to 155.

These units group the patient management facilities (*in vivo* diagnosis) and in a small number of them, a medical biology activity using unsealed sources (*in vitro* diagnosis). Lastly, slightly more than 80 departments participate in research protocols involving humans.

Some fifty *in vitro* diagnostic laboratories were inventoried by ASN in 2019, but this number is tending to drop due to the gradual phasing out of this activity in favour of analysis methods that do not use radionuclides.

The ASN regional divisions issued 133 nuclear medicine licenses in 2019. They concerned more specifically changes of cameras or license extensions to permit the use of new radionuclides.

• Medical dispensaries

When a medical dispensary is authorised in a health care centre, the room in the nuclear medicine department in which the radiopharmaceutical drugs are prepared, called the “nuclear pharmacy” or “radiopharmacy”, is part of the medical dispensary. There are 128 nuclear pharmacies among the 233 nuclear medicine units in public health care institutions and non-profit private health care institutions, such as the cancer centres. The radio-pharmacist is primarily responsible for managing the radiopharmaceutical drug circuit (procurement, possession, preparation, control, dispensing and traceability) and the quality of preparation. The radiopharmacist may be assisted by hospital pharmacy dispensers or radiographers.

• The equipment

Apart from the cameras used in the nuclear medicine units, some 400 radiation-proof enclosures are installed in the departments, divided roughly equally between “low energy” (1 to 2 per department) and “high energy” (1 to 6 per department) enclosures.

There are also nearly 110 automated or semi-automated devices for preparing radiopharmaceuticals marked with fluorine-18 and about 60 automated injection devices.

• Management of effluents from nuclear medicine departments

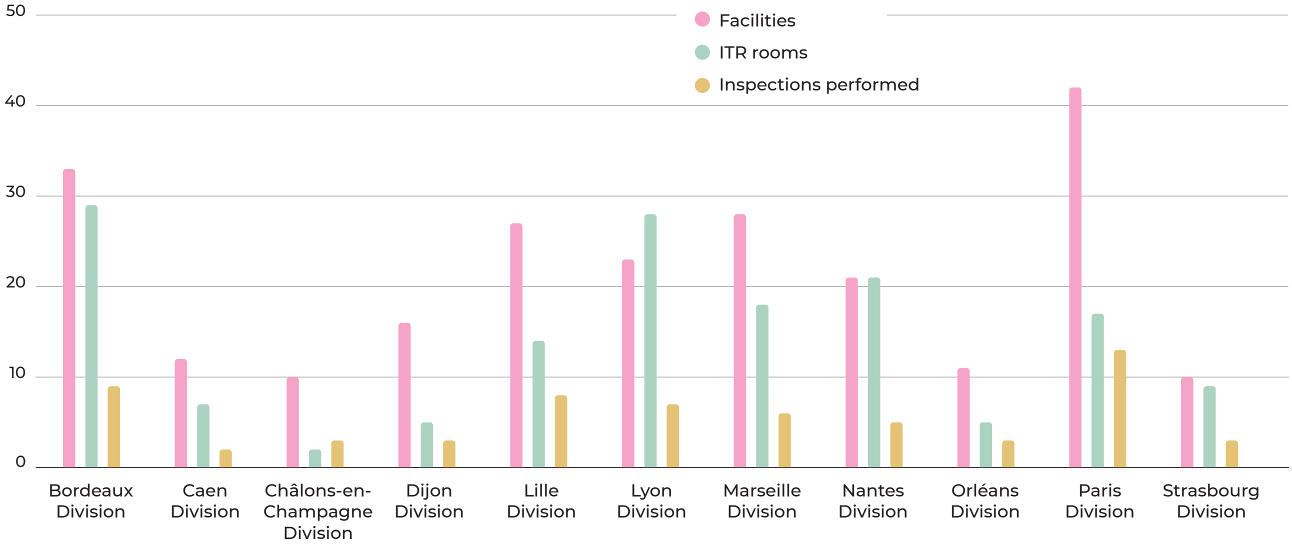
The 15 recommendations of the report[(5)] of the Working Group “Discharging into the sewage networks of effluents containing radionuclides from nuclear medicine departments and research laboratories” (GTDE) were published in June 2019 on *asn.fr*. The principal objectives of these recommendations are to:

- allow the updating of the contaminated effluents discharge authorisations provided for in Article L. 1331-10 of the Public Health Code, issued by the authorities responsible for managing the collective public sewage network;

5. *asn.fr/Informer/Actualites/Quinze-recommandations-sur-le-deversement-d-eaux-usees-faiblement-contaminees*

GRAPH 9

Breakdown, by ASN regional division, of the nuclear medicine facilities licensed by ASN, the number of hospitalisation rooms dedicated to internal targeted radiotherapy and the number of inspections performed in these facilities by ASN in 2019



- supplement the waste and effluent management plans of nuclear medicine departments and research laboratories that use unsealed radioactive sources mentioned in Article R. 1333-16 of this Code.

Their implementation will allow a better estimate of the impact of the discharges by considering:
- the radioactive sources held and used by the nuclear medicine departments or research laboratories;
- the conditions of management and disposal of these effluents in the facilities in which these activities are exercised;
- the theoretical modes of exposure of the professionals involved in maintenance work on the sewage network structures and in the operation of urban wastewater treatment plants.

All this information can be usefully transmitted by the facility to the authority examining the discharge authorisation.

The impact can be estimated where necessary as an initial approach based on the CIDRRE (French acronym standing for "Calculation of the radioactive discharges into the networks") digital method and tool developed by IRSN and also accessible on its website.

When this report is published, ASN asks the nuclear medicine departments and research laboratories to update their waste and effluents management plan in accordance with the recommendations of the working group. It points out that the management plan must include the procedures for monitoring the discharge effluents in accordance with Article R. 1333-16 of the Public Health Code and ASN resolution 2008-DC-0095 of 29 January 2008. The aforementioned resolution and ASN Technical Guide No. 18 of 26 January 2012 will be subject to updating.

4.1.1 *In vivo* diagnosis

This technique consists in examining an organ or a function of the organism with a specific radioactive substance –called a RadioPharmaceutical Drug (RPD)– 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 3, 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, Fluoro-DeoxyGlucose (FDG), 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 RPDs marked with other positron emitters, notably gallium-68, are starting to be used. PET cameras equipped with the Time Of Flight (TOF) system allow a lower activity RPD to be injected while still obtaining satisfactory image quality.

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 can also be equipped with a CT scanner (SPECT-CT).

CIDRRE: a tool for studying the dosimetric impact that radionuclide discharges have on sewage network workers

In June 2019, IRSN put on line a new calculation tool for estimating the doses likely to be received by sewage network and wastewater treatment plant personnel who can come into contact with radioactive effluents discharged by medical laboratories or nuclear medicine departments.

This digital model called CIDRRE (French acronym for "Calculation of the impact of radioactive discharges into drainage networks"), provides an estimation of the impact of radionuclide discharges on the sewage system workers and workers spreading sludge from wastewater treatment.

The culmination of a project launched in 2012 on the initiative of ASN, CIDRRE is accessible to all the stakeholders (network managers, persons/entities responsible for nuclear activities) under the discharge authorisations provided for in Article L. 1331-10 of the Public Health Code.

The calculation provides dose estimates at the different work stations concerned, based on conservative assumptions. In practice, a nuclear medicine department shall run the calculation using, for example, the total administered activities of the various radionuclides over one year as the input data. These results can be taken into consideration by the employers of sewage network personnel in their procedure for assessing the risk mentioned in Article R. 4451-14 of the Labour Code.

The regulations set the exposure limit of the personnel at 1 mSv/year so that they do not enter into the categories of specially monitored workers. The estimates calculated during the CIDRRE test phases gave exposures that were always below the 1 mSv limit.

TABLE 3

Main radionuclides used in diverse *in vivo* nuclear medicine explorations

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
Osteoarticular process	Technetium-99m, fluorine-18
Renal exploration	Technetium-99m
Oncology – search for metastases	Technetium-99m, fluorine-18, gallium-68
Neurology	Technetium-99m, fluorine-18

The installation of semi-conductor cameras (CZT –Cadmium Zinc Telluride), which have very high detection sensitivity, is continuing to develop, particularly in health care centres performing a large number of examinations of the myocardial function. These cameras effectively provide for faster and more comfortable scintigraphic imaging and give a more reliable diagnosis. Research in this area is continuing with the installation in 2018 of a CZT 3D and whole body gamma-camera allowing spatial viewing of the entire body.

According to the survey conducted with the nuclear medicine units in 2018, the installed pool of SPECT and CZT cameras comprises:

- 423 SPECT cameras, of which 70% are coupled to a computed tomography (CT) scanner, accounting for 924,000 procedures per year;
- 51 semi-conductor cameras (CZT), of which 7 are coupled to a CT scanner, accounting for 125,000 procedures per year.

The installed pool of PET cameras comprises:

- 158 PET cameras, all coupled to a CT scanner, accounting for 486,000 procedures per year;
- 4 PET cameras coupled to an MRI system, accounting for 2,016 procedure per year.

4.1.2 *In vitro* diagnosis

This is a medical biology technique that enables certain compounds contained in biological fluid samples taken from the patient, such as hormones or tumoral markers, to be assayed, without administering radionuclides to the patient. This technique uses assaying methods based on immunological reactions (reactions between antigens and antibodies marked with iodine-125), hence the name Radio Immunology Assay or radioimmunoassay –RIA). 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 kilobecquerel.

4.1.3 Internal targeted radiotherapy

Used for therapeutic purposes, the aim of the administered RPDs is to deliver a high dose of ionising radiation to a target organ for curative or palliative purposes. Two areas of therapeutic application of nuclear medicine can be identified: oncology and non-oncological conditions (treatment of forms of hyperthyroidism, synoviorthesis).

Several types of cancer treatment can be identified:

- treatments administered by nonspecific systemic route (thyroid cancer by iodine-131, non-Hodgkin lymphoma by monoclonal antibodies marked with yttrium-90, prostate cancer which has spread to the bones by radium-223, treatment

of neuroendocrine or prostate cancers by molecules marked with lutetium-177 (lutetium therapy));
- treatments administered by selective routes (treatment of liver cancers by administering microspheres marked with yttrium-90 through a catheter placed in an 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 iodine-131 with activities varying from 1.1 GBq to 5.5 GBq.

According to the 2018 survey of nuclear medicine units, in 2017:
- 6,377 patients received a treatment administering iodine-131 (with hospitalisation);
- 270 patients received a treatment administering lutetium-177;
- 426 patients received a treatment administering yttrium-90, 230 of them with SIR-Spheres® and 196 with TheraSphere®;
- 101 patients received a treatment administering radium-223.

For therapeutic purposes, there are 155 Internal Targeted Radiotherapy (ITRs) hospital rooms distributed over 44 nuclear medicine units (see Graph 9).

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. One can also treat inflammatory diseases of the joints using colloids marked with yttrium-90, erbium-169, or rhenium-186. Finally, radioimmunotherapy can be used to treat certain lymphomas using yttrium-90 labelled antibodies.

More than 6,500 patients were treated without hospitalisation in 2017, chiefly with iodine-131 and, to a lesser extent, for synoviortheses or palliative treatment of metastatic pains.

4.1.4 Research in nuclear medicine involving humans

Nuclear medicine research conducted on humans has been particularly dynamic in the last few years, with the regular introduction of protocols involving new radionuclides and vectors. Research focusing on the use of new tracers is continuing as much in diagnostic imaging (fluorine-18-fluoroestradiol, development of peptides marked with gallium-68, cardiac applications of iodine-124, exploration of pulmonary ventilation by aerosols marked with gallium-68, etc.) as in therapy (development of new molecules marked with lutetium-177, molecules marked with copper-64, etc.).

The use of new RPDs 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.

4.2 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 example). 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.

• Compliance with ASN resolution 2014-DC-0463
Nuclear medicine units must satisfy the rules prescribed by ASN resolution 2014-DC-0463 of 23 October 2014 relative to the minimum technical rules of design, operation and maintenance to be satisfied by *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 and will be updated in 2020.

Compliance was required by 1 July 2015 for nuclear medicine facilities and by 1 July 2018 for internal targeted radiotherapy rooms. However, departments licensed before 1 July 2015 which did not meet these requirements had to comply with them if they underwent major modifications.

Since 1 July 2015, the ASN regional divisions radiation protection inspectors have assessed the compliance of the facilities during inspections:
– For the radionuclide handling rooms, the rooms in the nuclear medicine sector and the provisions for lung examinations, the data show that virtually all the departments comply with the requirements concerning the ventilation system, with the exception of the ventilation system for lung examinations which is not always independent of the system for the rooms in the nuclear medicine sector.
– For the ITR rooms, a first compliance assessment had been carried out before July 2018 on the basis of the inspections conducted between 2015 and 2017: the inspectors at the time found that about half of the structures were noncompliant (independent ventilation and negative pressure).

• Compliance with ASN resolution 2017-DC-0591
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 13 June 2017[(6)].

• Compliance with ASN resolution 2008-DC-095
Like all facilities producing waste and effluents contaminated by radionuclides, they must comply with the provisions of ASN resolution 2008-DC-0095 of 29 January 2008[(7)] setting the technical rules that the disposal of effluents and waste contaminated by radionuclides must meet. Premises must be dedicated to these activities, as must specific equipment for monitoring the conditions of effluent discharges (tank filling levels, leakage alarm systems, etc.). The compliance of the facilities intended to accommodate the effluents and wastes produced by nuclear medicine departments is verified regularly (see point 4.3.3.).

6. ASN resolution 2017-DC-0591 of 13 June 2017 setting the minimum technical design rules to be met by premises in which devices emitting X-rays are used.
7. Order of 23 July 2008 approving ASN resolution 2008-DC-0095 of 29 January 2008 setting the technical rules to be met for the elimination of effluents and waste contaminated by radionuclides, or liable to be so contaminated owing to a nuclear activity, issued in application of the provisions of Article R. 1333-12 of the Public Health Code.

ASN inspection in the nuclear medicine department of the Angoulême Hospital Centre – November 2019

4.3 Radiation protection situation in nuclear medicine

62 nuclear medicine departments, i.e. 27% of the facilities, were inspected in 2019.

4.3.1 Radiation protection of nuclear medicine professionals

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 RPDs, and a risk of internal exposure through accidental intake of radioactive substances.

The results concerning radiation protection of professionals (see Graph 10) show that the radiation protection measures implemented by nuclear medicine departments are generally satisfactory on three points, namely the appointing of a RPE-O dedicated to this activity (and holding a valid certificate issued by the employer in all the departments inspected), the analysis of the dosimetric results of the medical staff, and the consistency between the delimiting of restricted areas and the results of the working environment verifications.

Two areas for improvement have nevertheless been brought to light, namely the refreshing of personnel training and the coordination with outside companies (only 30% of departments have established coordination measures with all these companies).

Furthermore, the radiation protection technical verifications have been carried out over the last two years at the regulatory frequency for all the sources and devices and for the radioactivity measuring and detection devices, in nearly 90% of the 62 departments inspected. Where applicable (35 departments), the identified nonconformities have been corrected.

4.3.2 Radiation protection of nuclear medicine patients

The radiation protection of nuclear medicine patients can also be considered satisfactory in the departments inspected in 2019. The 37 departments (out of the 62 inspected) that carry out therapeutic or diagnostic procedures using iodine-131 do effectively hand over a written document to the patient in accordance with the Order of 21 January 2004 and the recommendations of the SFMN. The external quality controls of the last two years have moreover been carried out on all the medical devices at the correct frequency and any nonconformities discovered have been remedied in 81% of the departments. In all the other cases, either the control has not been carried out at the regulatory frequency, or it has not covered all the devices concerned.

Nevertheless, the organisation put in place for the intervention of medical physicist, indicating the duties and time of presence on site, is only fully defined in 73% of the departments. In 27% of the cases, the Medical Physics Organisation Plan (POPM) does not cover all the requirements of ASN Guide No. 20 or, to a lesser extent, the medical physics organisation described in the POPM is insufficient with regard to the risks associated with the activity.

4.3.3 Protection of the general public and the environment

The questions relating to protection of the public and the environment are dealt with satisfactorily in many of the centres inspected (see Graph 11).

Thus, nearly 90% of the departments have a deliveries area that complies with the requirements of ASN resolution 2014-DC-0463 of 23 October 2014 (dedicated and protected). In about 85% of the departments the activity concentration of the effluents discharged after decay complies with the regulatory limits (10 Bq/L –becquerels per litre) for contaminated effluents after storage, or 100 Bq/L for effluents from the rooms of patients treated with iodine-131).

Further progress must nevertheless be made:
- in departments other than nuclear medicine department that use unsealed sources, since only about 77% of them have carried out non-contamination verifications at the end of therapeutic procedures in accordance with the planned protocol;
- 66% of the inspected departments had complete and functional traceability of alarm device verifications.

4.3.4 Significant events in nuclear medicine

Out of the 62 departments inspected, 42 have a system for recording adverse events. These departments analysed the events and reported them to ASN.

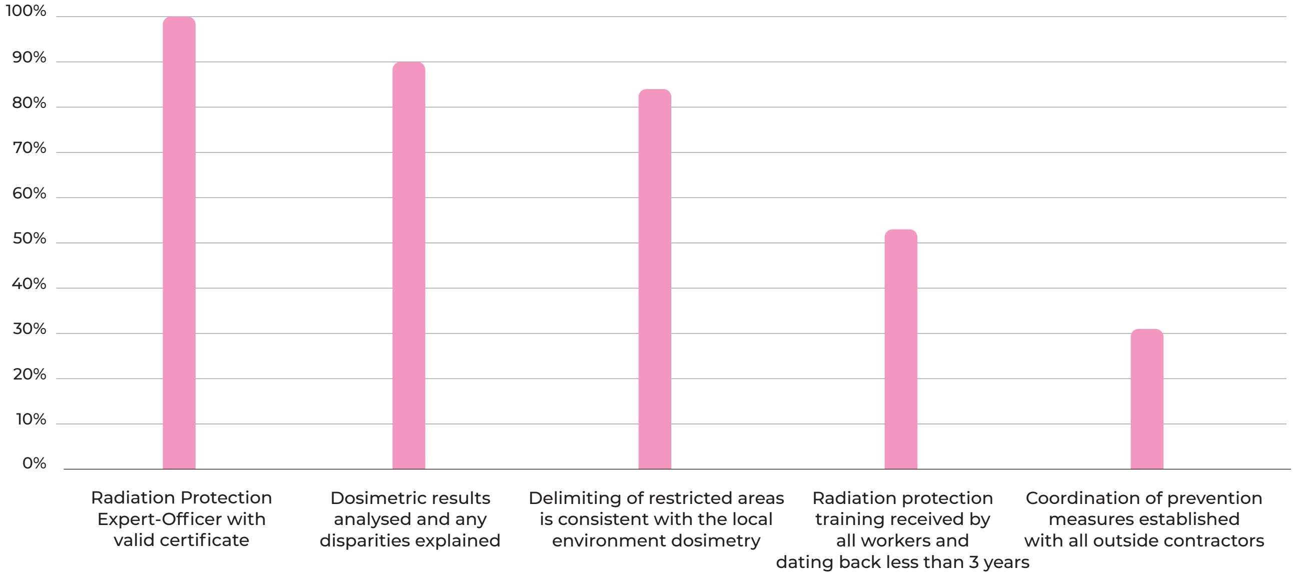
145 ESRs were reported in 2019, which is 15% less than in 2018.

As in the preceding years, most of the notified events concerned patients examined for diagnostic purposes (69%). The majority of the reported events have no expected clinical consequences.

• Significant events concerning patients (100 ESRs, or 69% of the reported ESRs)
The majority of the ESRs reported in nuclear medicine and concerning patients are linked to errors in administering an RPD to a patient (interchanging of syringes or of patients), to dose errors (adult dose injected into a child, injection of a higher or lower activity than that prescribed, etc.) or to errors during the preparation of the medication (interchanging of bottles). One case concerns a person who was administered a therapeutic dose of iodine-131 as an outpatient, whereas he was supposed to undergo a scintigraphy examination with iodine-123. One centre

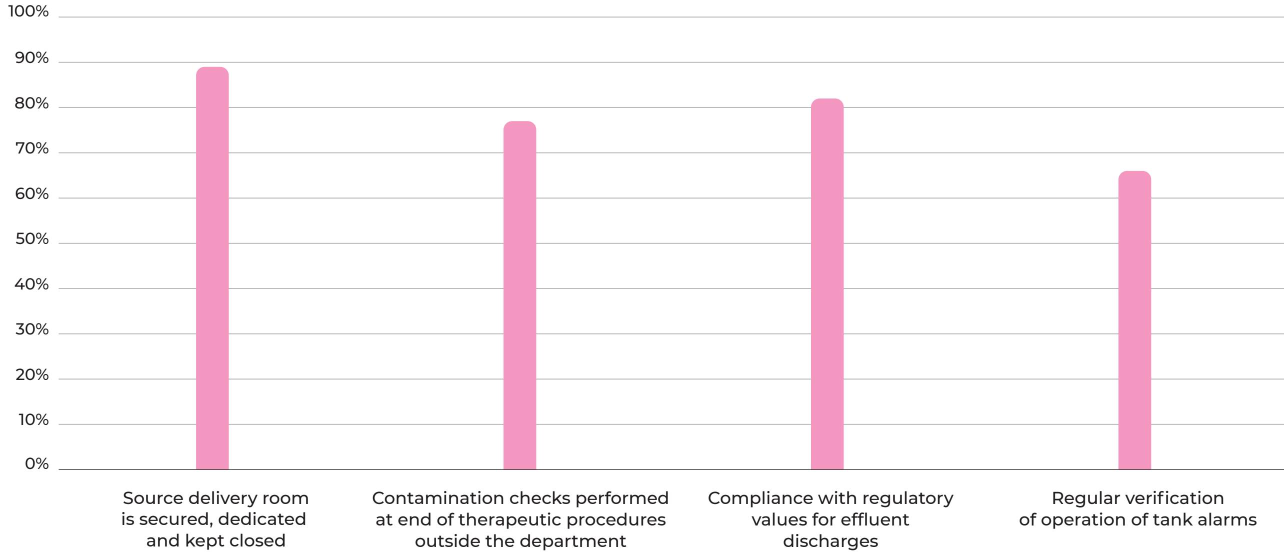
GRAPH 10

Percentage of conformity of the nuclear medicine departments inspected with regard to radiation protection of medical professionals in 2019



GRAPH 11

Percentage of conformity of the nuclear medicine departments inspected with regard to protection of the public and the environment in 2019



also reported the administration of a fluorodeoxyglucose (FDG) activity that was 6 times higher than the prescribed activity on a cohort of 7 patients.

Three significant events concerned therapeutic procedures, one patient being treated with iodine-131 with an activity three times higher than planned, another receiving an iodine-131 capsule that was overdosed by 17%, while the third case involved a leak of an RPD marked with radium-223 at the connection between the tube and the short catheter of the injection system.

• Significant events concerning medical professionals (7 ESR, i.e. 5% of the reported ESRs)

Seven significant events concerning medical professionals were reported in 2019, including external contaminations, one dosimeter failure and one incorrect manipulation of an RPD injection device. One notable event concerns the exposure of a worker with whom the regulatory annual exposure limit at the extremities (500 mSv) was exceeded (rated level 2 on the INES scale). The nuclear medicine department conducted investigations to determine the cause of exceeding the exposure limit, without success. The inspection, however, brought to light malfunctions in the management and analysis of the dosimetric devices.

• Significant events concerning the public (18 ESRs, i.e. 12% of the notified ESRs)

Virtually all these events concerned exposure of the foetus in women unaware of their pregnancy. The doses received had no consequences for the child (ICRP, 2007). The way in which female patients are questioned to find out whether they might be pregnant varies greatly from one centre to the next. In one case, the foetus was exposed during a therapeutic procedure. The centre had not applied the SFMN recommendation, which is to always perform pregnancy testing by taking a blood sample rather than a urine sample, the latter being less reliable. One reported event concerns the limited exposure of people to ionising radiation due to the proximity of pipes carrying radioactive effluents.

• Significant radiation protection events concerning radioactive sources, waste and effluents (16 ESRs, i.e. 11% of the reported ESRs)
The majority of these ESRs are associated with the dispersion of radionuclides (radioactive effluents leaking from pipes or tanks, or discharging effluents before allowing time for radioactive decay), the unauthorised discharging of effluents to the environment (emptying of tanks, etc.) or the disposal of waste *via* an inappropriate route. Another notable event was the contamination of the floor of a room by lutetium-177 during handling of the drug vial. This event also led to a medical devices vigilance report. One centre reported the dispersion of effluents caused by a leak in the wastewater drainage pipe from the toilets of the ITR rooms onto the public thoroughfare situated below the rooms, within the grounds of the centre. Work has been carried out to replace sections of the wastewater drainage network.

• Other events (4 ESRs, i.e. 2% of the reported ESRs)
The other events concerned, for example, the loss of medical staff dosimetric data due to a computer failure.

SUMMARY

The radiation protection of patients and professionals in nuclear medicine is dealt with satisfactorily. The training efforts must also be maintained in this sector. In addition, the coordination of preventive measures during work by outside contractors (for equipment maintenance, cleaning of the premises, etc.) must be improved. One of the radiation protection challenges is also to ensure good management of radioactive effluents, which is all the more important given that therapies administering high activities to patients are going to increase in number, leading to an increase in the discharged radioactivity.

5. Fluoroscopy-guided interventional practices

5.1 Overview of the techniques and the equipment

Fluoroscopy-guided interventional practices group "*all the imaging 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 equipment**

The equipment items used are either fixed C-arm devices installed in the interventional imaging departments in which vascular specialities (neuroradiology, cardiology, etc.) are carried out, or mobile C-arm radiology devices used chiefly in operating theatres in several surgical specialities, such as gastroenterology, orthopaedics and urology.

The detectors present on the devices with C-arms 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.

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 personnel most often work in the immediate proximity of the patient and are also exposed to higher dose levels than in other interventional 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.

• **The health care centres**

On the basis of the codes of the common classification of medical procedures and the activity data reported by the health care centres to the Agency for Information on Hospital Care (AIHC), 903 centres performing fluoroscopy-guided interventional practices involving risks (with regard to radiation protection) in one or more disciplines have been inventoried. The distribution of the number of centres by category of fluoroscopy-guided interventional practice is shown in Graph 12.

In 2019, the ASN regional divisions sent some 390 acknowledgements of notification of fluoroscopy-guided interventional procedures.

5.2 Technical rules for the fitting out of medical rooms

The rooms in which fluoroscopy-guided intervention procedures are carried out, operating theatres and interventional imaging rooms must be organised in accordance with the provisions of ASN resolution 2017-DC-0591 of 13 June 2017 mentioned in point 4.2.

Few centres are in compliance with this resolution because the signalling and safety systems are often absent; as for the technical reports, of those that do actually exist, many are incomplete. ASN has noted that the interventional radiology departments comply with this resolution to a greater extent than the operating theatres.

5.3 Radiation protection situation in fluoroscopy-guided interventional practices

For several years now, significant radiation protection events have been regularly reported to ASN in the area of fluoroscopy-guided interventional practices. Although these events represent just a small proportion of all the medical events reported to ASN, they most often have serious consequences with the occurrence of tissue damage (radiodermatitis, necrosis) in patients having undergone particularly long and complex interventional procedures. In addition to these events, which underline the major radiation exposure risks for the patients, are those concerning professionals, whose exposure can lead to the exceeding of regulatory limits, particularly at the extremities (fingers).

On account of the radiation exposure risks, ASN carries out a large number of inspections in this sector. In 2019, 199 departments were inspected. These inspections were carried out in interventional imaging departments (rooms dedicated to interventional vascular and osteoarticular radiology, to neuroradiology and to cardiology) and surgical departments (operating theatre) performing fluoroscopy-guided interventional procedures. 60% of the inspections in 2019 were carried out in operating theatre departments.

Professional seminars in the area of fluoroscopy-guided interventional practices

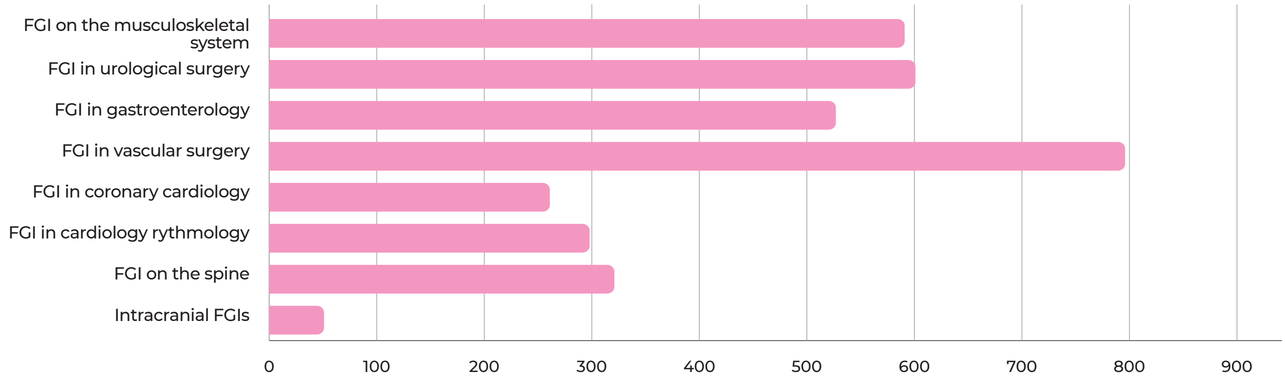
In view of the increase in the risks associated with the use of interventional imaging procedures, ASN organised several regional professional seminars in 2019 (in Lille, Lyon, and Nancy) in order to raise the awareness of all the medical players and to stimulate interchanges between practitioners regarding their experience, good practices and difficulties.

These seminars allowed the dissemination of wide-ranging information, from regulatory news to the presentation of innovative cutting-edge techniques applied on multimodal platforms and concerning the radiation protection of medical staff and patients alike. The strong participation of representatives of all the medical centres of the regions concerned and the great diversity of medical professionals represented –surgeons, radiologists, physicists, RPE-Os, radiographers, health executives, etc.– testified to the interest the medical sphere holds for the control and improvement of radiation protection in fluoroscopy-guided interventional practices.

The discussions arising from these seminars highlighted the specific nature of the risks associated with these medical practices, due firstly to continuous innovation and secondly to updating of the regulations. Consideration of organisational and human factors and the mobilisation of professionals in a collective work effort are success factors to drive progress in radiation protection.

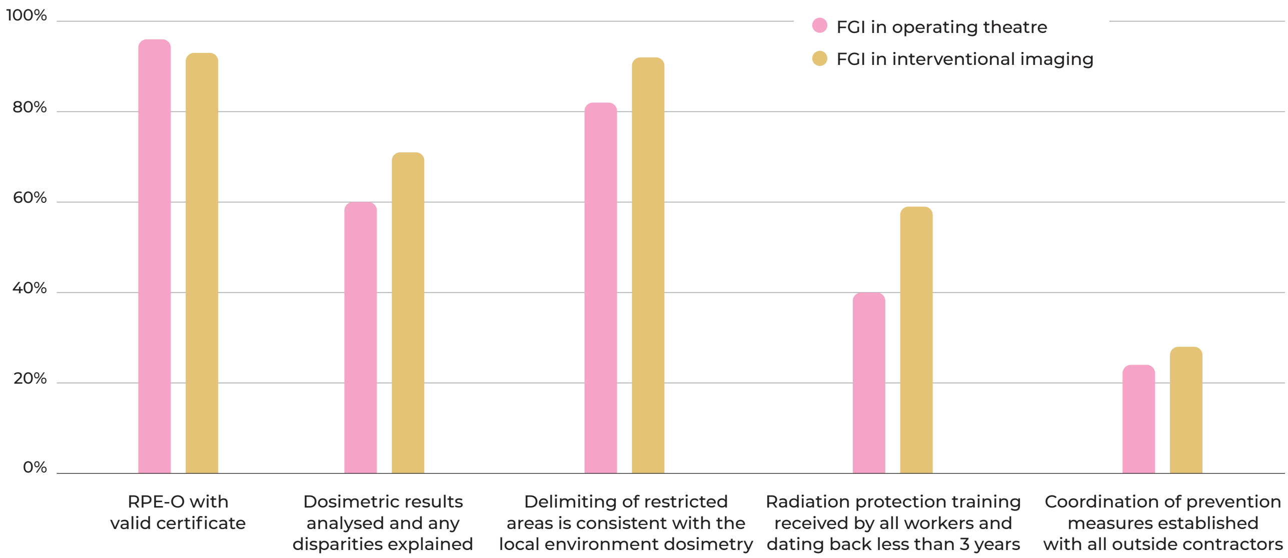
GRAPH 12

Breakdown of the number of centres by category of fluoroscopy-guided interventional practices



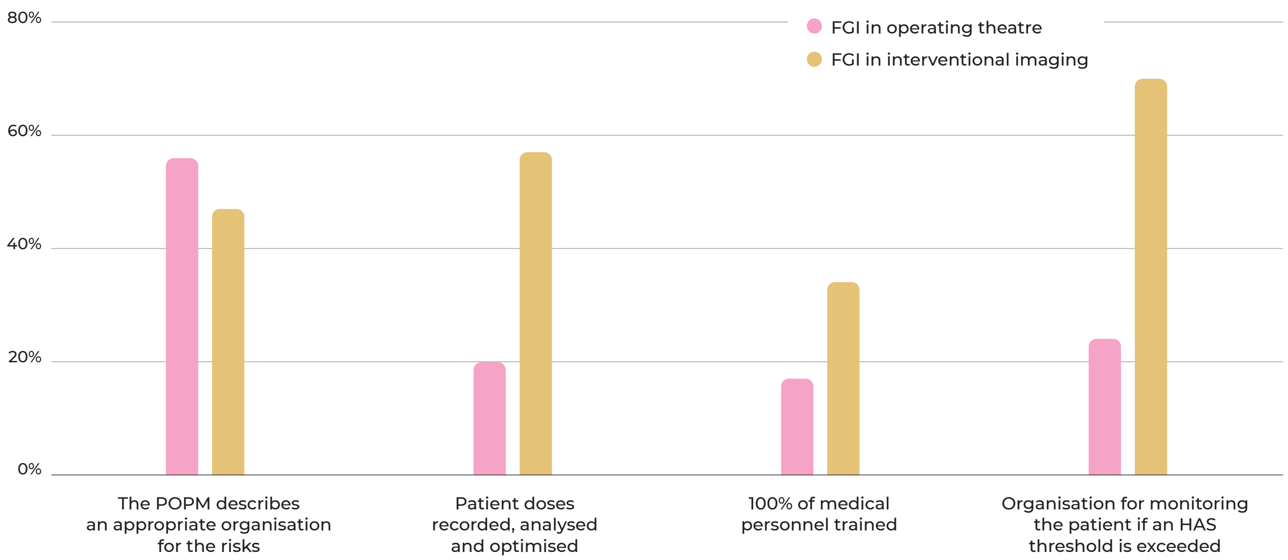
GRAPH 13

Percentage of conformity of the facilities inspected with regard to radiation protection of medical professionals in 2019



GRAPH 14

Percentage of conformity of the facilities inspected with regard to radiation protection of patients



Fluoroscopy-guided interventional practices in the operating theatre: the recommendations of the Advisory Committee for Radiation Protection in Medical and Forensic Applications of Ionising Radiation (GPMED)

Fluoroscopy-Guided Interventional (FGI) practices in the operating theatres are in full expansion, in both the diversity of the procedures and the number of specialist areas concerned and the medical devices used. If radiation protection in FGI procedures performed on fixed X-ray equipment has significantly improved in the last decade, ASN inspections highlight shortcomings in procedures performed in the operating theatre. The radiation exposure risks for each patient are usually low. On the other hand, occupational exposure risks are increasing due to the large number of procedures carried out. The risks are primarily linked to a poor culture in the basic rules of radiation protection. Significant progress remains to be made in surgical procedures.

In 2019, with a view to improving radiation protection during FGI procedures in operating theatres, a working group of the GPMED of ASN put forward 20 recommendations based on 4 themes:
- quality and risk management;
- the responsibilities of each player;
- radiation protection training;
- the radiation protection tools to develop.

• Characteristics of the inspected centres and departments

Within these 199 inspected centres, 322 departments were visited (194 operating theatre departments, 128 interventional imaging departments comprising 53 cardiology –coronary angiography departments, 39 cardiology– rhythmology departments, 34 vascular and osetoarticular interventional radiology departments and 2 neuroradiology departments):
- of the 194 operating theatre departments, 181 had at least one mobile C-arm, 10 had fixed C-arms and 3 had mobile CT scanners;
- of the 128 interventional imaging departments, 107 had at least on fixed C-arm, 13 had mobile C-arms and 8 had fixed CT scanners.

To summarise, in more than 80% of the inspected interventional imaging departments, the procedures are carried out using fixed C-arms, whereas in the operating theatres the physicians mainly use mobile C-arms (93%) to guide their surgical procedures. It is also observed that evermore efficient medical devices are installed in the operating theatres. These are mobile CT scanners or fixed C-arms in the "hybrid" rooms, which combine the characteristics of a conventional surgical room with those of an interventional imaging room; the combination enables the surgeon to perform "mini-invasive" surgery with 2D and 3D imaging. Fixed CT scanners coupled to fixed C-arms are also beginning to be installed in health care centres.

5.3.1 Radiation protection of medical professionals

• In interventional imaging departments and in operating theatres

Occupational radiation protection seems to be taken into account effectively, with the appointment of an RPE-O (in about 96% of the departments inspected), and radiological zoning of the facilities (more than 85% of the departments inspected).

However, the lack of training of the medical professionals in occupational radiation protection (refresher training for all the personnel provided in only about 20% of the departments inspected), especially practitioners working in operating theatres, is a recurrent inspection finding. The occupational radiation protection training of the medical and paramedical professionals who use machines with fixed C-arms in dedicated rooms also remains low, even if they are on the whole better trained.

Although collective radiation protection equipment is available for the interventional imaging departments, it is still too rarely present in the operating theatres.

A substantial improvement is expected in the coordination of prevention measures with the outside contractors working in the interventional imaging departments and operating theatres, where ASN observes that few prevention plans are signed with all the service providers (only 26% of the inspected centres have a document signed by all the outside contractors formalising the coordination of prevention measures).

• More specifically in the operating theatres

In 73% of the inspected sites the operating theatre professionals have dosimetric monitoring devices that are appropriate for worker exposure and in sufficient quantity. This is still insufficient, but nevertheless a distinct improvement compared with 2018.

The lack of appropriate dosimetric monitoring for certain fluoroscopy-guided procedures, particularly at the extremities, and the absence of medical monitoring of the practitioners, make it difficult to assess the radiation protection situation of these professionals in the operating theatres. ASN nevertheless observes improvements in the departments having been inspected previously.

There are still organisational difficulties for the RPE-Os who do not always have the means or the necessary authority to perform their duties in full. Furthermore, the time allocated to their duties is not always appropriate, particularly in some centres which rely on the RPE-O to ensure patient radiation protection. ASN notes that the RPE-Os analyse the dosimetric results in order to detect incorrect practices and remedy them, above all in the interventional imaging departments. In operating theatres in the private sector, dosimetric monitoring, medical monitoring and, where applicable, employee monitoring, represent a recurrent difficulty.

• Radiation protection technical verifications

Radiation protection external technical verifications were carried out in 85% of the interventional imaging departments and about 74% of the operating theatres. In both cases, the nonconformities observed previously had either been or were being corrected in just 66% of the inspected facilities when the inspection took place. There is room for progress in meeting the required verification frequencies, but an improvement is nevertheless noted.

5.3.2 Radiation protection of patients

The findings established on completion of the inspections in 2019 with regard to patient radiation protection confirm the observations made over the last few years (see Graph 14).

ASN thus still observes low involvement of medical physicists in the departments practicing FGI procedures, and shortcomings in the description of the medical physics organisation in the POPMs (the duties and times of presence of the medical physicist according to the activities are not specified). This slows down implementation of the optimisation principle. Close collaboration between the operator and medical physicist and the regular presence of the latter would allow, among other things, the equipment to be better used, with the application of protocols adapted to the procedures performed, recording of the delivered doses and the evaluation in the light of dosimetric reference levels to be defined locally. When medical centres use outside companies proposing medical physics services, it is observed that few centres embrace the optimisation approach. These observations were noted in particular in the operating theatres, where the optimisation approach is rarely put in place.

• In interventional imaging departments and in operating theatres

The observed shortcomings concern firstly a lack of training of medical professionals in patient radiation protection, and secondly, deficiencies in application of the principle of procedure optimisation, as much in the adjustment of the devices and the protocols used as in the practices.

ASN observes that although doses are recorded, they are rarely analysed (34% for operating theatres, 62% for interventional imaging departments). Patient monitoring in cases where the exposure threshold is exceeded (skin exposure threshold) defined by the HAS[8] is not very satisfactory, particularly in the operating theatres (55% for operating theatres and 78% for interventional imaging departments).

Reference levels for the most common examinations are 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 patient dose archiving and analysis systems currently being deployed facilitate the development of local reference levels and alert levels per machine and per type of procedure. These systems are an asset for determining the doses previously received by the patient and for monitoring the patient.

The third-party quality controls of the medical devices are generally carried out at the right frequency and on the day of

Diagnostic reference levels: optimisation tools

Through resolution 2019-DC-0667 of 18 April 2019, ASN updated the Diagnostic Reference Levels (DRL) used by the medical professionals in medical imaging procedures. The DRLs are not dose limit values; they enable the professionals to assess their practices through comparison with these reference values with a view to optimising the ionising radiation doses delivered to the patients while still preserving image quality to achieve the desired clinical objective. These levels are defined for the most common procedures but also for those involving the highest exposures and must be updated regularly to take account of changes in practices and technologies. This resolution requires the party responsible for the nuclear activity to carry out dosimetric evaluations in the adult and in paediatrics. The ASN resolution also introduces for the first time DRLs for certain FGI procedures, along with the notion of diagnostic guide value, which is lower than the DRL, as a second optimisation reference.

8. *Improving patient monitoring in interventional radiology and fluoroscopy-guided procedures –reducing the risk of deterministic effects– HAS.*

"The theatre of errors", or how do you create a practical workshop for raising radiation protection awareness in the operating theatre?

The FGI procedures carried out in operating theatres are constantly increasing, as much in the number of procedures as in the medical indications. More and more surgeons and physicians from different disciplines can apply them.

If, for the patient, the dose risk associated with a single procedures may be low, the same cannot be said for the medical professional. The reason for this is that the professionals perform procedures that repeatedly expose them to ionising radiation. This can lead to significant exposure levels though the cumulative effect of the doses in the course of their professional life. Awareness of the radiological risk is an increasing necessity, especially in the operating theatre where the radiation protection culture is still poorly developed.

Practical and operational aids must therefore be used to better mobilise the professionals with regard to radiation protection. That is the aim of this document applied to the operating theatre.

Produced in collaboration with the Lariboisière Hospital (Public Health Service – Paris Hospitals), it aims to give the medical professionals in charge of worker and patient radiation protection the information they need to set up practical and collegial workshops on radiation protection. The concept of the "theatre of errors" is to propose a "game of errors" based on work situations.

The practical workshop enables operating theatre professionals to embrace good worker and patient radiation protection practices through a simulation in real operating theatre situations. The participants must view and identify the errors intentionally slipped into the operating theatre simulation. The aim of the final debriefing is to correct errors and reiterate the good practices. The tool provides the rules, the methodology and the steps for carrying out a simulation with a multidisciplinary team. This document echoes one of the recommendations of the GPMED working group on the FGIs in the operating theatre: broad awareness-raising of medical professionals with active, pragmatic teaching approaches that are adapted to professional practices and constraints.

Signification radiation protection events (ESR) in fluoroscopy-guided interventional practices: the importance of training the professionals in the command of the medical device

An ESR having caused a radiodermatitis was reported to ASN. It occurred following two failed attempts –three weeks apart– to implant a triple-chamber defibrillator. The cardiologist then referred the patient to a colleague of the CHRU (Regional University Hospital Centre). The radiodermatitis subsequently resolved itself without any complication.

The analysis of this event primarily revealed a weakness in the system of induction and training of newly recruited medical professionals. A new organisation has been put in place to reinforce the training pathway of any newly recruited personnel. This formalised pathway provides more specifically for an assessment of the practitioners level of command of radiation protection rules and practices, delivery of training in occupational and patient radiation protection, along with qualification in the use of the image intensifier, registering of the training certificates, providing work procedures/instructions relative to radiation protection and the signing of a radiation protection charter.

the inspection any previously detected nonconformities had been or were being corrected, equally well in the operating theatres as in the interventional imaging departments.

• **More specifically in the operating theatres**

The medical personnel in the operating theatre has insufficient knowledge of the reference dose levels for the types of procedure performed. The theatre C-arms, due to their mobility, are more rarely connected to the centre's archiving systems than the fixed C-arms of the interventional imaging departments.

5.3.3 Significant events relating to fluoroscopy-guided interventional practices

An events recording system is in place in more than 75% of the health care centres inspected. 27 significant events were reported in this area in 2019.

Among these events:
- 13 concerned overexposure of patients, some of which led to deterministic effects such as transient hair loss (alopecia) (2 cases) or slight erythema (1 case);
- 9 concerned exposure of medical professionals;
- 5 concerned pregnant women exposed during a FGI examination; these women were unaware of their pregnancy at the time of exposure.

The majority of the ESRs concerning patient overexposures were due to long and complex procedures. Some of these patients had undergone several procedures to stabilise their illness.

The ESRs reported for medical professionals were due to accidental overexposures: two cases occurred when stowing the ionising radiation emitting device (device powered on), in other cases it was during a surgical procedure (personnel not protected, including two pregnant staff members).

One medical professional received a high level of exposure to the hands during FGI practices. As the regulatory annual exposure limit was exceeded, this ESR was rated level 1 on the INES scale. The centre concerned was inspected in early 2019.

The other cases concern dosimeter malfunctioning and intentional exposure of a dosimeter.

This year there is an increase in operating theatre ESRs reported, with the number exceeding that for interventional imaging departments (16 of the 27 ESRs). The inspections in the last few years, carried out mainly in the operating theatres, have raised radiation protection awareness among the medical professionals.

SUMMARY

In the field of FGI practices, ASN considers that the important measures it has been recommending for several years are not always sufficiently implemented to improve the radiation protection of patients and professionals, particularly for surgical procedures performed in the operating theatres. The inspections frequently reveal deviations from the regulations, in the radiation protection of both patients and medical staff, and ASN is notified of events concerning interventional practitioners who have exceeded the dose limits for the extremities. The radiation protection situation is however significantly better in the departments that have been using these technologies for a long time, such as the imaging departments performing interventional cardiology and neurology activities. Extensive work to raise the awareness of all professionals is needed in order to help medical, paramedical and administrative professionals in facilities, so that they have a clearer perception of the implications, notably those professionals working in operating theatres.

In ASN's opinion, the continuous training of the professionals and the involvement of the medical physicist probably constitute the two key points to guarantee the doses delivered to patients during interventional procedures.

6. Medical and dental radiodiagnosis

6.1 Overview 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. A guide intended for general practitioners (*Guide to Good Medical Imaging Examination Practices*) indicates the most appropriate examinations to request according to the clinical situations.

6.1.1 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.

ASN was consulted and gave a favourable opinion on the draft resolution relative to the internal and external quality controls of digital mammography facilities. This resolution updates the controls performed on the 2D mammographs and provides for external quality controls on tomosynthesis devices.

Tomosynthesis is a new three-dimensional breast imaging technique that is developing in Europe without any form of quality control. The evaluations 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 validated 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 (multidetector-row CT scanner, also known as a multislice or volumetry 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[9]. 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). Computed tomography can thus provide consistent image quality at reduced doses. The devices can also be equipped with dose-reduction tools.

• 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 (e.g. an emergency doctor), who is not a radiologist, to perform the radiological examination and then send the results to a radiologist in order to obtain an interpretation of the images. If necessary the radiologist can guide the radiological operator during the examination and imaging process. In this case, the doctor on the scene is considered to be the doctor performing the procedure and assumes responsibility for it.
- Tele-expertise, which is an exchange of opinions between two radiologists, where one asks the other –the "expert radiologist" (teleradiologist)– for a remote confirmation or contradiction of a diagnosis, to determine a therapeutic orientation or to guide a remote examination. The data transmissions are protected and preserve medical secrecy and image quality.

Teleradiology involves many responsibilities which must be specified in the agreement binding the practitioner performing the procedure to the teleradiologist. The teleradiology procedure

9. 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.

The resolution relative to quality assurance in medical imaging entered into effect on 1 July 2019

In France, medical applications represent the primary source of artificial exposure of the public to ionising radiation. This medical exposure is increasing, mainly due to the increased number of examinations using computed tomography (CT) scanners. In order to control the doses delivered to patients undergoing medical imaging examinations, and thereby contribute to enhanced safety for the patients, ASN has defined new quality assurance requirements in medical imaging. ASN resolution 2019-DC-0660 of 15 January 2019 applies to computed tomography, FGI practices, diagnostic nuclear medicine and conventional and dental radiology.

The main objective of this resolution is to control the doses delivered to patients undergoing medical imaging examinations. The person/entity responsible for its application is the person/entity responsible for the nuclear activity. The resolution defines the quality assurance system, formalises the work station training and qualification processes, sets out two fundamental principles of radiation protection, namely the justification for the procedures and the optimisation of doses, describes the steps of the experience feedback process by reinforcing the recording and analysis of events that could lead to accidental or unintentional exposure of persons during a medical imaging procedure.

This resolution is applicable in accordance with a "graded" approach, proportionate to the radiological risk for the exposed persons.

is a medical procedure in its own right, like all other imaging procedures, and cannot be reduced to a simple remote interpretation of images. Teleradiology therefore fits into the general health care organisation governed by the Public Health Code and obeys the rules of professional ethics in effect.

The teleradiology Charter published by the French Professional Council of Radiology (G4) was updated in 2018. This third version[10] updates the Charter in the light of practices and the regulations in force, particularly with regard to personal health data and the recommendations of the CNIL (French National Commission for Data Protection and Liberties). It details the organisation of the two parts of teleradiology (telediagnosis and tele-expertise). In addition, a guide to good practices concerning the quality and safety of teleimaging procedures[11] was published in May 2019 by the French National Authority for Health (HAS). It enables the HAS to make important clarifications concerning the proper use of "medical imaging examinations with remote interpretation". It has the particularity of also addressing nuclear telemedicine, deployed with the aim of providing uniform coverage of the country. This guide does not consider either mammography, which cannot be done by teleradiology because it necessitates clinical examination of the patient, including palpation, or tele-ultrasonography.

6.1.2 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 reiterating the rules associated with the possession and utilisation of portable X-ray generating devices. "*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 Heads of the European Radiological protection Competent Authorities (HERCA), for which the use of such devices should be reserved for incapacitated patients, for forensic medicine and military field operations (HERCA Position Statement on Use of Handheld Portable Dental X-ray Equipment, June 2014).

6.2 Technical layout rules for medical and dental radiodiagnosis facilities

• 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.

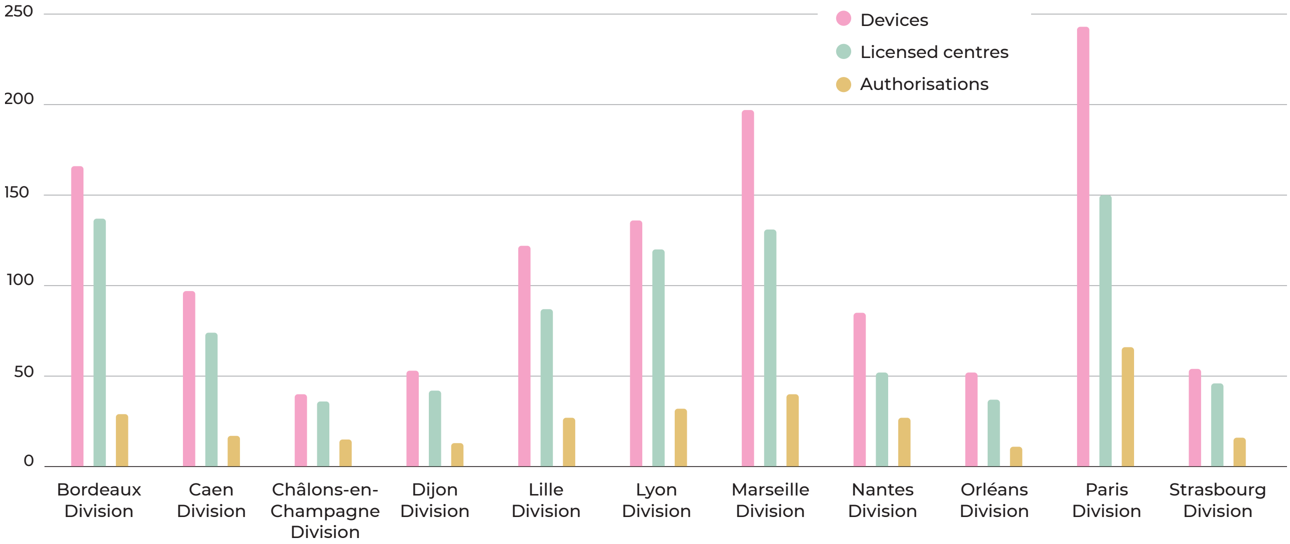
Mobile facilities, but which are often used in the same given room, such as the X-ray generators used in operating theatres, are to be considered as fixed facilities.

Radiological facilities must be fitted out in accordance with the provisions of the new ASN technical resolution 2017-DC-0591 of 13 June 2017 (see point 4.2). 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. A technical report demonstrating conformity of the facility with the requirements of the ASN resolution is to be drawn up by the person or entity responsible for the nuclear activity.

10. *sites.google.com/site/g4radiologie/vie-professionnelle/teleradiologie/guides-et-recommandations*
11. *has-sante.fr/jcms/c_2971634/fr/teleimagerie-guide-de-bonnes-pratiques*

GRAPH 15

Breakdown, by ASN regional division, of the number of CT scanners and the number of licenses created or renewed in 2019



6.3 The radiation protection situation: spotlight on the CT scanner

More than 900 facilities possess 1,245 CT scanners and are covered by an ASN license. Graph 15 shows the distribution of CT scanners by geographical zone covered by the ASN regional divisions, and the distribution of the 293 licenses examined in 2019.

In a report published in September 2018, IRSN notes that the average age of the installed pool of CT scanners is higher in the public sector than in the private sector.

The ASN regional divisions carried out 38 inspections in 2019. They focused specifically on sites with CT scanners used to examine patients arriving in the emergency department (whether the scanner is dedicated solely to that use or not).

These inspections concerned 15 health care centres; they were based on ASN resolution 2019-DC-0660 of 15 January 2019 relative to quality assurance in medical imaging.

The majority of the inspected centres are in the public sector (14 out of 15). Only 2 of them had a CT scanner dedicated to the emergency department's activity. According to the information collected, each scanner performs some 8,000 procedures per year on average.

On the whole, the organisation of the emergency department including access to the CT scanner, particularly in the middle of the night (between midnight and 6 a.m.), is formalised in the majority of the centres 11 out of 15). Written procedures indicate the patient management actions.

Job sheets exist for each category of medical professionals. Eight of the 15 centres have trained more than 85% of their medical professionals in radiation protection, while the others have trained between 65 and 85%. The work station qualification pathway remains to be defined, however.

A request is normally drawn up for each examination and validated by a radiologist or a teleradiologist (this is the case in one centre). However, no procedures are formalised in writing.

The medical physics organisation is systematically described in a POPM, but the ASN inspections find that the medical physicists are not allocated enough time to fulfil their duties.

An optimisation procedure is in place (optimised examination protocols, collection and analysis of Diagnostic Reference Levels (DRLs), etc., with the utilisation of a Dose Archiving and Communication System (DACS) in half the inspected centres.

The scanner quality controls are carried out at the required frequencies and any nonconformities are corrected.

Radiation protection events are reported and analysed in half the inspected centres.

6.4 Significant events reported in medical and dental radiodiagnosis

285 significant radiation protection events were reported in medical and dental radiodiagnosis:
- 91 in conventional radiology, of which 56 concerned women unaware of their pregnancy;
- 2 in dental radiology;
- 192 in computed tomography.

SUMMARY

Given the expansion of the installed pool of CT scanners, diagnostic examinations using computed tomography contribute very substantially to the collective dose received by the public, as medical imaging is the leading source of artificial exposure of the public to ionising radiation. The medical justification for these procedures is as yet insufficiently operational, owing to the insufficient training of the prescribing physicians, or even the lack of availability of other diagnostic means (MRI, ultrasonography). In July 2018, ASN published a second plan of action for controlling ionising radiation doses delivered to persons during medical imaging. This plan aims to reinforce the justification of the procedures and the optimisation of the ionising radiation doses delivered to the patients.

They chiefly concern women unaware of their pregnancy (116 cases), deficiencies in practices (patient identity error, wrong protocol) (61 cases) and situations of exposure of medical professionals (8 cases). The detection of possible pregnancies by the medical staff needs to be improved.

7. Blood product irradiators

7.1 Description

The irradiation of blood products is used to prevent post-transfusion reactions in blood-transfusion patients. The blood bag is irradiated with a 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 2019, the inventory stood at 29 irradiator devices equipped with X-ray generators.

7.2 Technical rules applicable to facilities

A blood product irradiator must be installed in a dedicated room designed to provide physical protection (against fire, flooding, break-in, etc.). Access to the device, which must have a lockable control console, must be limited to authorised persons only.

The fitting out of premises accommodating irradiators equipped with X-ray generators must comply with the provisions of ASN resolution 2017-DC-0591 of 13 June 2017.

8. Synthesis and prospects

ASN considers that the radiation protection situation in the medical sector remained stable in 2019; no particular deficiency was detected in the areas of radiation protection of medical professionals, patients, the public or the environment. Further progress must still be made however, to better anticipate the arrival of new machines, or even new technologies and radiopharmaceuticals, for example, but also to improve the level of radiation protection culture in non-specialist users of ionising radiation. Such is the case with surgeons who are increasingly required to perform fluoroscopy-guided procedures in the operating theatres.

The year 2019 was marked by the gradual updating of the regulatory framework governing patient radiation protection, with the publication of several ASN resolutions, particularly those concerning quality assurance in medical imaging, the modification of the provisions for entry into effect of the resolution concerning training in patient radiation protection and the updating of the diagnostic reference levels.

ASN is going to continue developing its inspection programme, giving priority to radiotherapy, nuclear medicine and FGI practices. The preparation of the new registration system applicable to FGI practices involving risks and to CT scanners is in line with the graded approach developed by ASN.

ASN has published recommendations concerning the discharging of artificial radionuclides into the public sewage networks, and proposals are currently being made regarding the management of contaminated effluents, to accompany the announced development of cancer treatments based on the administration of new radio-pharmaceutical drugs.

For imaging, an experience feedback committee has been set up to study these events; the development of a communication scale applicable to significant radiation protection events, like the one which has existed since 2008 in radiotherapy (ASN-SFRO scale) is still envisaged.

In radiotherapy, nuclear medicine and FGI practices, ASN is keeping track of the work on the licensing system reform led by General directorate of the health care offering and is particularly attentive to the deployment of the clinical audits announced by the professionals. The work to better anticipate and manage the organisational and technical changes was resumed in 2019, with volunteer radiotherapy centres, assisted by the professionals, hospital federations and health care institutions.

A Committee for analysing new practices or techniques using ionising radiation (Canpri) was set up in 2019. It comprises members from learned societies and professional associations involved in radiotherapy and medical imaging, and health care institutions. Its first analysis concerns an arrangement combining a self-shielding technology with a linear accelerator. Currently in the course of CE marking, this neurosurgical medical device could bring an alleviation in the environment of this type of accelerator and it is necessary to ensure that worker radiation protection is maintained.

The production –in partnership with a health care centre– of a teaching aid to raise radiation protection awareness in operating theatre staff introduces a new approach on the part of ASN that fits in with its duty to inform the various audiences to continue improving the radiation protection of medical professionals and patients.

ASN participated for the first time in a European public health congress in order to raise radiation protection awareness among these specialists from the associative sector working with the public and patients, who are influential in hospitals and health care institutions. This enabled contact to be made with the French National School of Public Health (EHESP), in order to raise radiation protection awareness in the public health residents and student hospital directors.

08.

SOURCES OF IONISING RADIATION AND THEIR INDUSTRIAL, VETERINARY AND RESEARCH APPLICATIONS

CHAPTER 08

Sources of ionising radiation and their industrial, veterinary and research applications

The 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 properly 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 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 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 regulatory developments started to bring substantial changes in the oversight of industrial, research and veterinary activities as of January 2019. They also concern the extension of the notification system to certain nuclear activities that use radioactive sources and will continue steadily in the coming years.

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 7) and activities not regulated under the Basic Nuclear Installations (BNIs) System (these are presented in chapters 10, 11 and 12).

1. Industrial, research and veterinary uses of ionising radiation

1.1 Uses of 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 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 most commonly used radionuclides are carbon-14, cobalt-60, krypton-85, caesium-137, promethium-147 and americium-241. The source activity ranges from a few kilobecquerels (kBq) to a few gigabecquerels (GBq).

The 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 frequently used sources are carbon-14 –with an activity of 3.5 megabecquerels (MBq)– or promethium-147 (with an activity of 9 MBq). These measurements are used for air quality monitoring by verifying the dust content of discharges from plants.
- Paper weight measurement: a beam of beta radiation passes through the paper and hits a detector situated opposite. The signal attenuation on this detector indicates the density of the paper, and therefore its weight per unit area. The sources used are generally krypton-85 or promethium-147, with activities of 3 GBq at the most.
- 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 measured 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. The sources generally used are americium-241 (with an activity of 1.7 GBq) or caesium-137 – barium-137m (with an activity of 37 MBq).
- Density measurement and weighing: the principle is the same as for the above two measurements. The sources used are generally americium-241 (with an activity of 2 GBq), caesium-137 – barium-137m (with an activity of 100 MBq) or cobalt-60 (with an ac-tivity of 30 GBq).
- Soil density and humidity measurement (gammadensimetry), particularly in agriculture and public works. These devices function with a source of caesium-137 and a pair of americium-beryllium sources.
- 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.

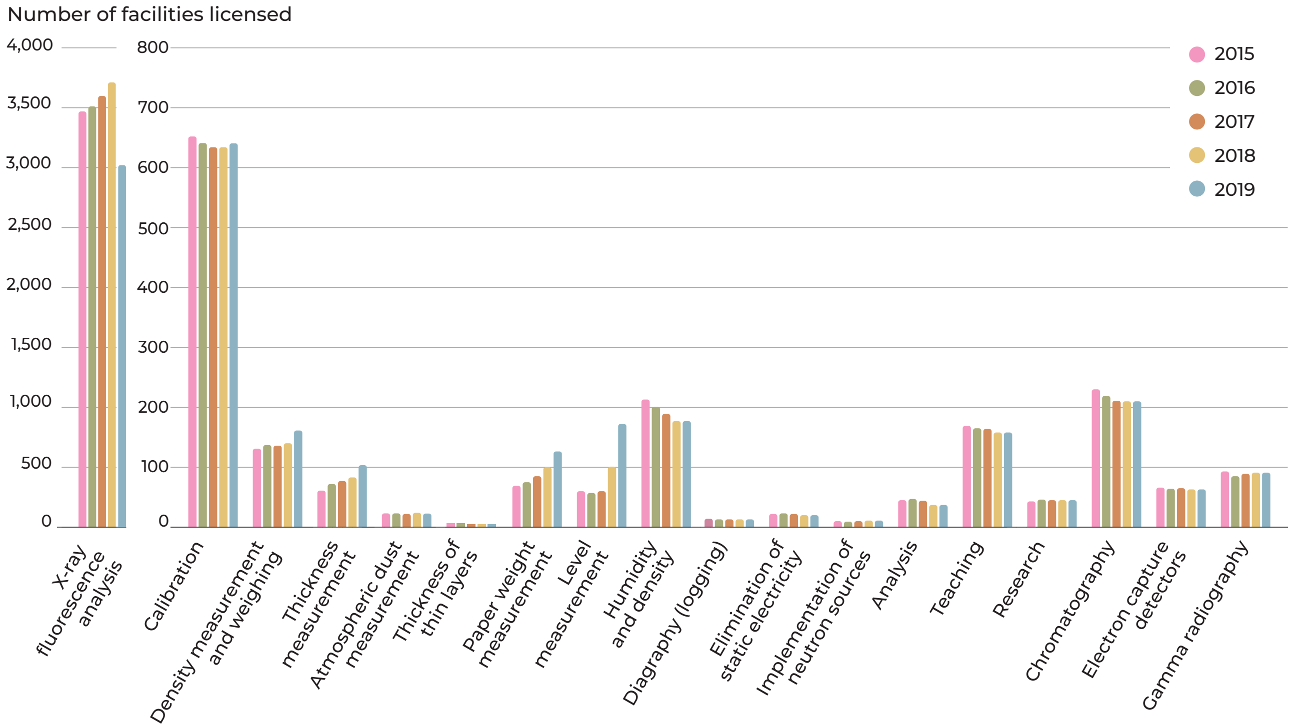
1.1.2 Neutron activation

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 is used to determine the concentration of atoms in the analysed material.

This technology is used in archaeology to characterise ancient objects, in geochemistry for mining prospecting and in industry (study of the composition of semiconductors, analysis of raw mixes in cement works).

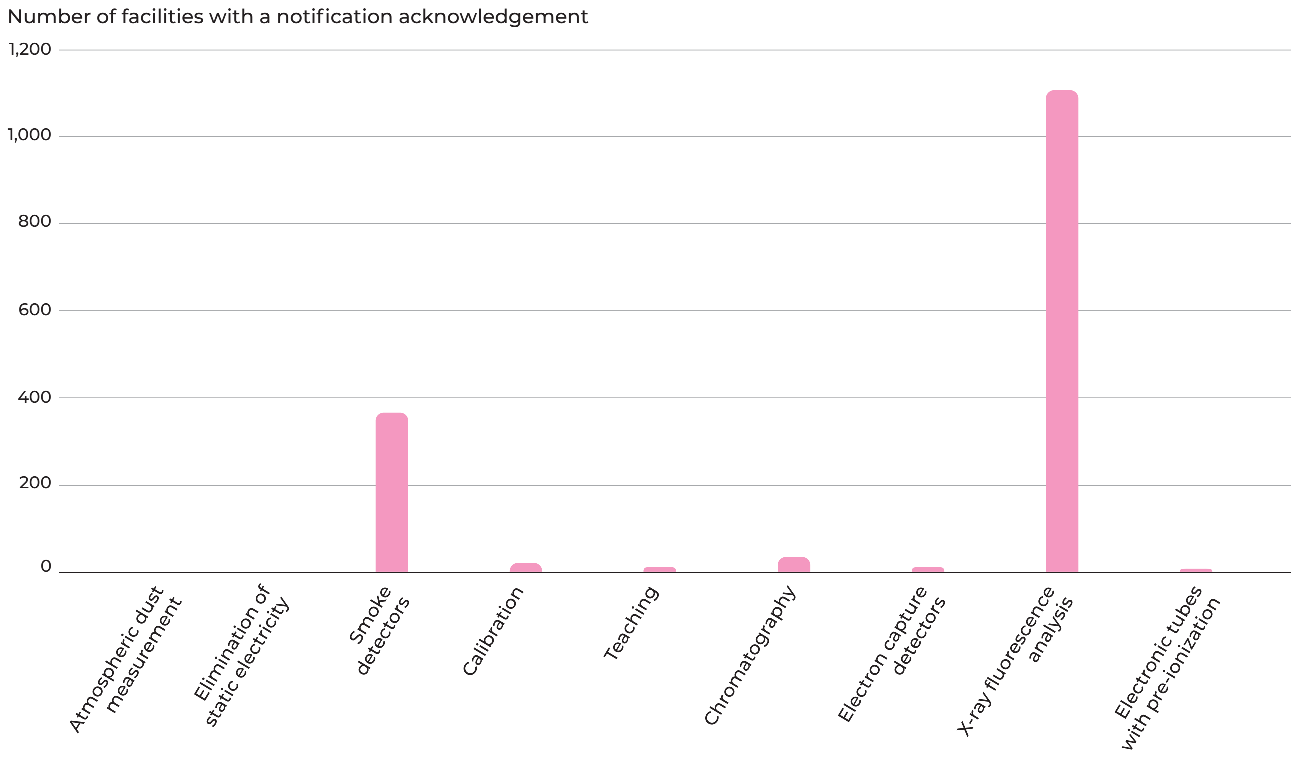
GRAPH 1A

Use of sealed radioactive sources



GRAPH 1B

Breakdown of notifications by end-purpose in 2019



Given the activation of the material analysed, this requires particular vigilance with regard to the nature of the objects analysed. Articles R. 1333-2 and R. 1333-3 of the Public Health Code prohibit 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 2.2.1).

1.1.3 Other common applications

Sealed radioactive sources can also be used for:
- industrial irradiation, particularly for sterilization (see point 3.2.1);
- gamma radiography which is a non-destructive inspection method (see point 3.3.1);
- 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 by X-ray fluorescence. This technique is used in particular for 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 1 January 1949 in case of sale, a new rental contract, or work significantly affecting the coatings in the common parts of the building.

Graphs 1A and 1B show the number of facilities using sealed radioactive sources for the identified applications under the licensing and notification systems respectively. They illustrate 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 activities, and if it does, it appears in Graph 1A and the following diagrams for each activity;
- the breakdown between the licensing system and the notification system (sealed sources and electrical devices emitting ionising radiation) for a given end-use is not yet stabilised, because the changes of administrative system concerning the nuclear activities newly subject to notification since 1 January 2019, will extend through to 31 December 2023 (see point 2.4.2).

1.2 Uses of unsealed radioactive sources

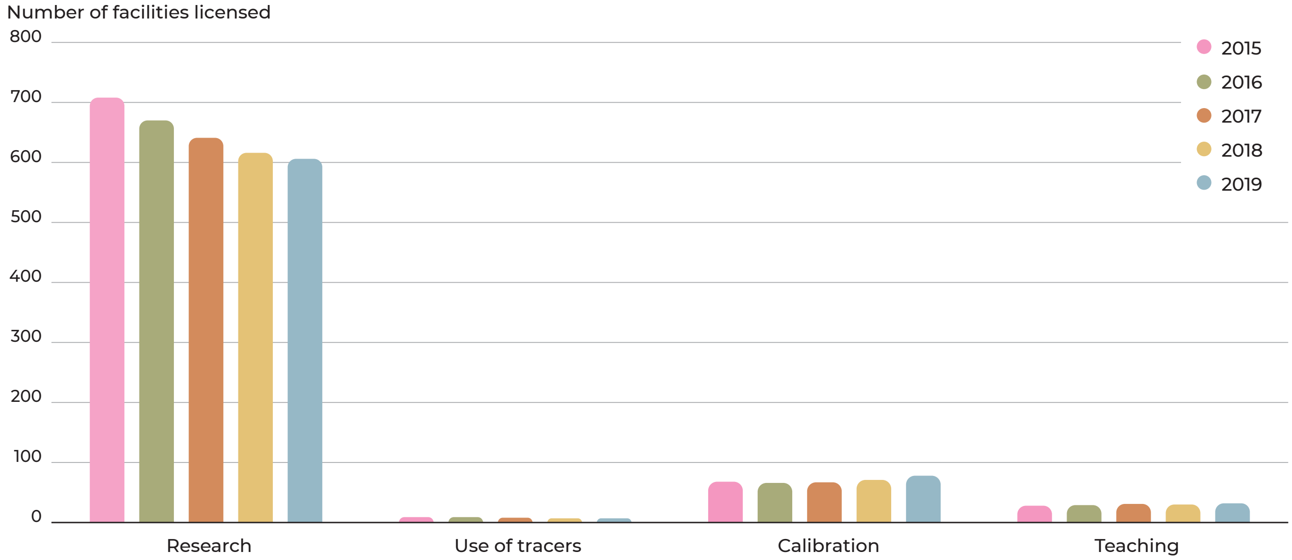
The main radionuclides used in the form of unsealed sources in non-medical applications are phosphorus-32 or 33, carbon-14, sulphur-35, chromium-51, iodine-125 and tritium. They are used in particular in research and in the pharmaceutical sector. They constitute a powerful investigative tool in cellular and molecular biology. Using radioactive tracers incorporated into molecules is common practice in biological research. There are also a number of industrial uses, for example as tracers or for calibration or teaching purposes. Unsealed sources are used as tracers for measuring wear, detecting leaks or friction spots, building hydrodynamic models and in hydrology.

As at 31 December 2019, the number of facilities authorised to use unsealed sources stood at 723.

Graph 2 specifies the number of facilities authorised to use unsealed radioactive sources in the applications inventoried in the last five years.

GRAPH 2

Use of unsealed radioactive sources



1.3 Uses of electrical devices emitting ionising radiation

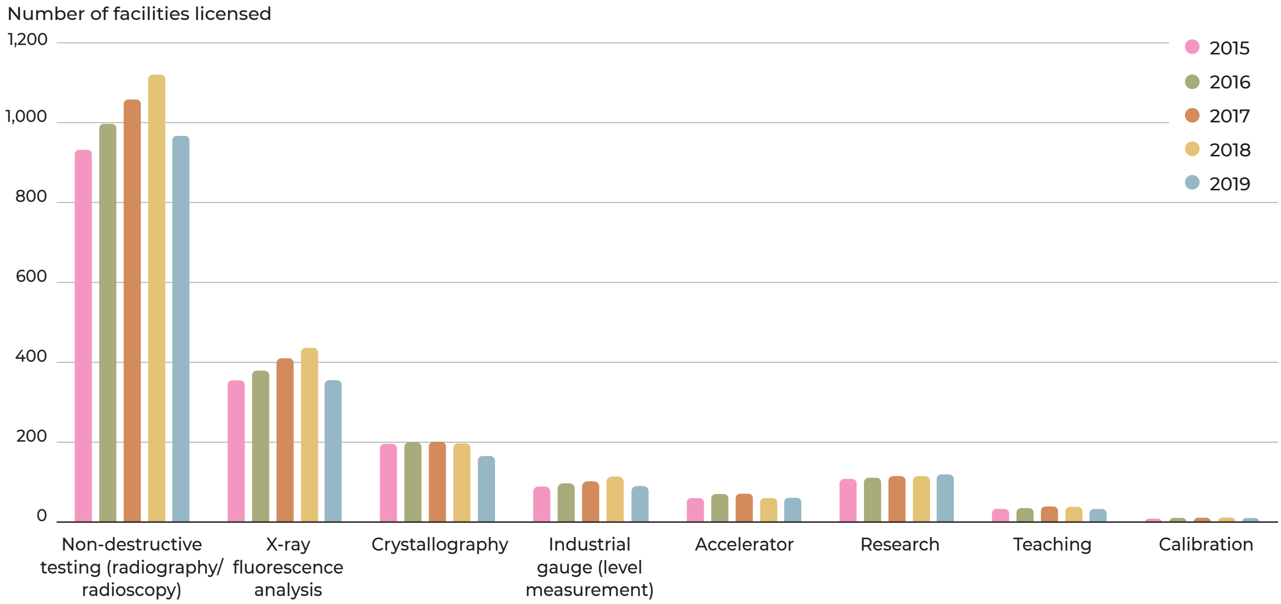
1.3.1 Main industrial applications

In industry, electrical devices emitting ionising radiation are used mainly in non-destructive testing, where they replace devices containing radioactive sources.

Graphs 3A and 3B show the number of facilities using electrical devices generating ionising radiation in the listed applications under the licensing or notification system respectively. They illustrate the diversity of these applications and their development over the last five years. This development 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, measures to bring the professionals concerned into compliance are very widely engaged in many activity sectors.

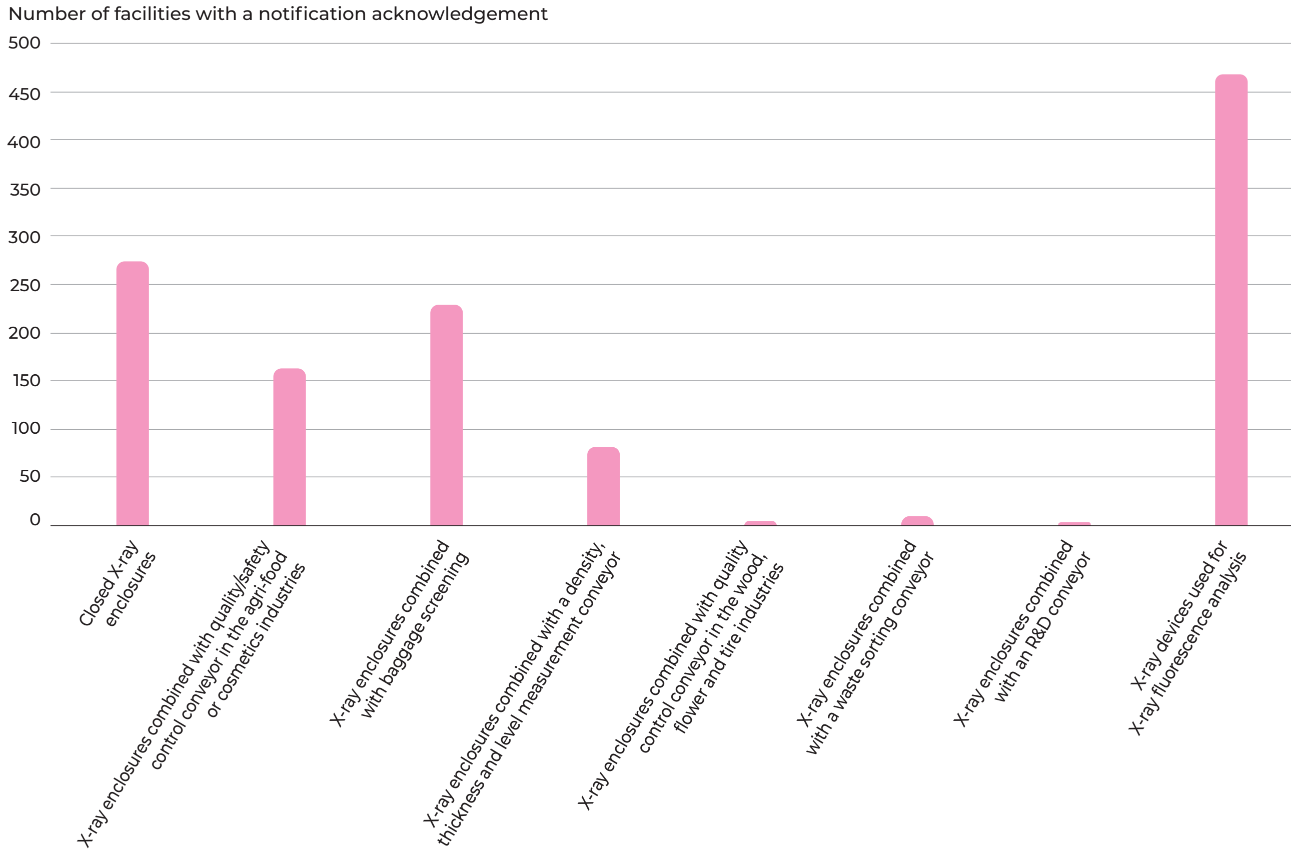
GRAPH 3A

Use of electrical devices generating ionising radiation (veterinary sector excluded)



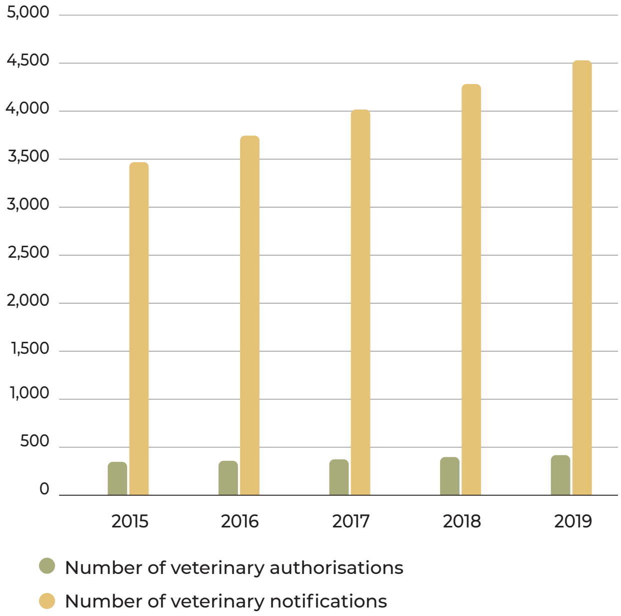
GRAPH 3B

Breakdown of notifications of ionising radiation generators by end-purpose in 2019



GRAPH 4

Use of electrical devices generating ionising radiation for veterinary activities



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.), 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 increase in the 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 nevertheless lead to worker exposure levels that are comparable with those resulting from the use of devices containing radioactive sources.

- **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 areas are used for screening large baggage items and hold baggage in airports, as well as for air freight inspections. These devices are supplemented by tomographs, which give a series of 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. 1333-18 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 used for the analysis of metals and alloys.

- **Measuring parameters**
These devices, 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 devices 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.

- **Industrial radiography**
Radiography for checking the quality of weld beads or for the fatigue inspection of materials is detailed in point 3.1.

1.3.2 Veterinary diagnostic radiology

In 2019, the profession counted 18,548 veterinary surgeons, some 12,500 non-veterinarian employees (counted in full-time equivalents) and 8,053 veterinary practices and clinics. Veterinary surgeons use diagnostic radiology devices for purposes similar to those used in human medicine. Veterinary diagnostic radiology activities essentially concern pets:
- some 5,500 veterinary clinics in France have at least one diagnostic radiology device;
- about fifty 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, external-beam radiotherapy and interventional radiology.

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 portable X-ray generators, used indoors –whether in dedicated premises or not– or outside in the open air.

In order to better ensure compliance with regulatory requirements, ASN introduced a notification system in 2009 for what were called "canine activities" involving less serious radiation risks (see point 2.4.2). This simplification has led to regularisation of the administrative situation of a growing number of veterinary clinics (see Graph 4) with more than 90% of the clinics being notified or licensed.

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.

With regard to veterinary facilities, the administrative situation has been continuously improving for a number of years now. At the end of 2019, ASN counted 4,948 notified or licensed facilities out of approximately 5,500 veterinary clinics using ionising radiation in France.

Among the veterinary activities, those performed on large animals outside specialised veterinary facilities (under "worksite" conditions), are considered to be those with the most significant radiation risks, more specifically for persons external to the veterinary practice team 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 license applications and performing inspections:
- worker dose monitoring by active dosimetry and in-house radiation protection checks;
- setting up radiological zoning;
- the need to better address the radiation protection of persons external to the veterinary practice who participate in the diagnostic radiology procedures.

The conventional radiology activities performed on pets (called "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) and addressed 463 veterinary clinics. 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 sectors.

During this campaign, ASN detected no major shortcomings, save exception, and considers that the organisation of radiation protection in pet care veterinary clinics is satisfactory on the whole:
- the third-party radiation protection checks and the formalised processing of any nonconformities detected during these checks;
- the verification of conformity of the radiology rooms;
- the frequency of on-site visits of certain external Radiation Protection Expert-Officers (RPE-O).

Alongside this, through its various oversight actions, ASN has seen the results of the efforts made by the veterinary professional bodies in the last few years to comply with the regulations and has noted good field practices in the inspected veterinary clinics, and more specifically:
- the presence of in-house RPE-Os in the majority of clinics;
- worker occupational exposure monitoring by passive dosimetry;
- the virtually systematic use of personal protective equipment;
- an approach to optimise the conditions of the diagnoses conducted in nearly all the clinics performing diagnostic radiology on large animals.

In addition to the abovementioned dematerialised control approach, local *in situ* control actions are still carried out regularly by the ASN regional divisions, for example the Strasbourg division, which carried out some ten inspections of veterinary clinics that use ionising radiation.

The extensive nationwide commitment of the profession to harmonising practices, raising awareness, training student veterinary surgeons and drafting framework documents and guides is considered very positive by ASN, which regularly takes part in meetings with the profession's national bodies (more particularly the veterinary radiation protection commission) jointly with the General Directorate for Labour (DGT).

1.3.3 The other uses of 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. 1333-106 of the Public Health Code.

This category includes, for example, devices generating ionising radiation but not used for this property, namely ion implanters, electron-beam welding equipment, klystrons, certain lasers, certain electrical devices such as high-voltage fuse tests.

Lastly, some applications use particle accelerators (see point 3.3.1).

08

2. Regulation of industrial, research and veterinary activities

2.1 The authorities regulating the sources of ionising radiation

ASN is the authority that grants the licenses, receives the notifications and will issue the registration decisions, in accordance with the regulatory regime 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. This concerns more specifically:
- The radioactive sources held, manufactured and/or used in installations licensed under the Mining Code (Article L. 162-1) or, for unsealed radioactive sources, those 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 he delivers, radiation protection requirements for the nuclear activities carried out on the site.
- The installations and activities relating to national defence, for which Defence Nuclear Safety Authority (ASND) 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. 1333-118 of the Public Health Code.

These provisions do not exempt the licensee 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 ASN licensing under the Public Health Code.

Since the publication of Decree 2014-996 of 2 September 2014 amending the nomenclature of the ICPEs, some facilities previously licensed by Prefectoral Order under the Environment

Code for the possession and use of sealed radioactive sources are now regulated by ASN. The requirements applicable to these installations are now those of the Public Health Code. The transitional period set in Article 4 of the abovementioned Decree, which provided that the license or notification issued under the former section 1715 continued to be valid and deemed a license or notification under the Public Health Code, on condition that no change was made to the nuclear activity, for a maximum period of five years, that is to say until 4 September 2019 at the latest, has now ended. These activities must therefore have a license or a notification acknowledgement issued by ASN under the Public Health Code.

Only the facilities possessing unsealed radioactive substances or managing radioactive waste in quantities exceeding 10 m^3 for either of the activities are subject to the Environment Code regulations as classified installations (excluding the medical sector and particle accelerators). Any sealed radioactive sources also possessed or used by these establishments are regulated by ASN.

Nuclear materials are subject to specific regulations provided for in Article L. 1333-1 et seq. 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.

2.2 Unjustified or prohibited activities

2.2.1 Application of the ban on the intentional addition of radionuclides in consumer goods and construction products

The Public Health Code states "*that any addition of radionuclides [...] to consumer goods and construction products is prohibited*" (Article R. 1333-2). 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. Article R. 1333-4 of this same Code provides that waivers to these prohibitions can, if they are 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 construction, after obtaining the opinion of ASN and of the High Council for Public Health (HCSP).

ASN considers that granting waivers to the regulations must remain very limited. It was implemented for the first time in 2011 for a waiver request concerning the use of a neutron analysis device in several cement works (Order of 18 November 2011 from the Ministers responsible for health and construction, ASN opinion 2011-AV-0105 of 11 January 2011 and ASN opinion 2011-AV-0124 of 7 July 2011). It was then used in 2014 for light bulbs containing very small quantities of radioactive substances (krypton-85 or thorium-232), serving mainly for applications requiring very high intensity lighting such as public places, work places, or for certain vehicles (Order of 12 December 2014 of the Ministers responsible for Health and Construction, ASN opinion 2014-AV-0211 of 18 September 2014).

A waiver request to allow the addition of radionuclides (tritium) in some watches was also denied (Order of 12 December 2014, ASN opinion 2014-AV-0210 of 18 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 two cement works, the third cement works mentioned in the initial Order of 2011 having closed (Order of 19 April 2017 of the Ministers responsible for health and construction respectively, ASN opinion 2017-AV-0292 of 7 March 2017). In 2019, two waiver applications for the use of neutron analysis devices were granted, the first for a third cement works of the Larfarge-Holcim group (Order of the Ministers responsible for health and the ecological transition of 4 December 2019, ASN opinion 2019-AV-0333 of 1 August 2019) and the second for the Euralpin Lyon Turin Tunnel (Order of the Ministers responsible for health and the ecological transition of 19 August 2019, ASN opinion 2019-AV-0326 of 21 May 2019). A third request concerning renewal of the waiver granted in 2014 for the addition of radionuclides to discharge lamps received a favourable opinion from ASN (ASN opinion 2019-AV-0340 of 26 September 2019).

2.2.2 Application of the justification principle for existing activities

The justification of existing activities must be reassessed periodically in the light of current knowledge and technological changes in accordance with the principle described in point 2.4.1. 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 transient 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 the 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 developed for smoke detection. Optical devices now provide comparable detection quality, and can therefore satisfy the regulatory and normative fire detection requirements. ASN therefore considers that smoke detection devices using radioactive sources are no longer justified and that the seven million ionic smoke detectors installed on 300,000 sites must be progressively replaced.

The regulatory framework governing their withdrawal was put in place by the Order of 18 November 2011 and the two ASN resolutions 2011-DC-0252 and 2011-DC-0253 of 21 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.

Eight years after the implementation of the new regulatory system for Ionisation Chamber Smoke Detector (ICSD) removal and maintenance activities, ASN has, as at 31 December 2019, issued 367 notification acknowledgements and eight national licenses (issued to industrial groups with a total of 120 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.

With regard to the monitoring of the pool of ICSDs, in 2015, in collaboration with ASN, the French Institute for Radiation Protection and Nuclear Safety (IRSN) set up a computerised system enabling the professionals working in this sector (maintenance technicians, installers and removal companies) to file annual activity reports on line. 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 labels the companies that comply with the regulations relative to radiation protection and fire safety. The list of QUALDION-labelled companies is available on the association's website. ASN participates with the association in communication campaigns targeting the holders of ionic detectors and the professionals (Expoprotection trade fair, Mayors' trade fair, etc.).

- **Surge suppressors**

Surge suppressors (sometimes called lightning arresters), not to be confused with lightning conductors, are small objects with a very low level of radioactivity used to protect telephone lines against voltage surges in the event of lightning strike. These are sealed devices, often made of glass or ceramic, enclosing a small volume of air containing radionuclides to pre-ionise the air and facilitate electrical 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. However, there can be a risk of exposure and/or contamination, albeit very low, if these objects are handled without precautions or if they are damaged. ASN issued a reminder to the company Orange (formerly *France Télécom*), which has begun an experimental process to identify, remove, sort and dispose 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 issuing a license governing the removal of all surge suppressors containing radionuclides present on the Orange network in France and their interim storage on identified sites. The search for a disposal route is in progress in collaboration with Andra, the French National Agency for Radioactive Waste Management. This removal plan 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 15 January 2008 which set the removal deadline at 1 January 2012) and in certain installations under Ministry of Defence responsibility (Order of 1 October 2007 which set a removal deadline at 1 January 2014).

ASN nevertheless expects all existing radioactive lightning conductors to be removed and transferred to Andra, given the risks they can represent, depending in particular on their physical condition. For several years now ASN has been working to raise professional awareness of the radiation risks 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 and 2, L. 1333-8, and R. 1333-104 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 recovered by Andra. The current rate of removal is about 350 per year.

2.3 The regulatory changes

2.3.1 Tightening the regulation of electrical devices generating ionising radiation

ASN considers that the regulatory oversight of suppliers of electrical ionising radiation generators is still insufficient, when the placing of devices on the market is so vitally important for the optimisation of the future radiation exposure of users. The work carried out by ASN in this area, which at present is directed towards the use of these generators, particularly in enclosures, has led to the publication of ASN resolution 2017-DC-0591 of 13 June 2017 setting the minimum technical design rules applicable to facilities that use X-rays.

This resolution came into effect on 1 October 2017. It replaces ASN resolution 2013-DC-0349 of 4 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.

ASN considers that these provisions, which are directed exclusively at the use of these devices, must be supplemented by provisions concerning their actual design.

This is because, for electrical devices used for non-medical purposes, there is no equivalent of the CE marking that is mandatory for medical devices, certifying conformity with several European standards that cover various aspects, 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 in collaboration with the Electrical Certification and Testing Entity for *Bureau Véritas* (LCIE), the Alternative energies and Atomic Energy Commission (CEA) and IRSN, draft texts have been produced with the aim of defining minimum radiation protection requirements for the design of X-ray generators; 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 to adapt the regulatory framework and subject the distribution of devices generating ionising radiation to licensing, in the same way as for radioactive sources. In 2019, ASN worked on various scenarios for regulating the design of industrial radiology devices which must now be discussed with the Labour Department (DGT).

2.3.2 Implementation of oversight of the protection of ionising radiation sources against malicious act

Although the safety and radiation protection measures provided for by the regulations guarantee a certain degree of protection of ionising radiation sources against the risk of malicious acts, they cannot be considered sufficient. Reinforcing of the oversight of protection against malicious acts targeting sealed radioactive sources has therefore been encouraged by the International Atomic Energy

08

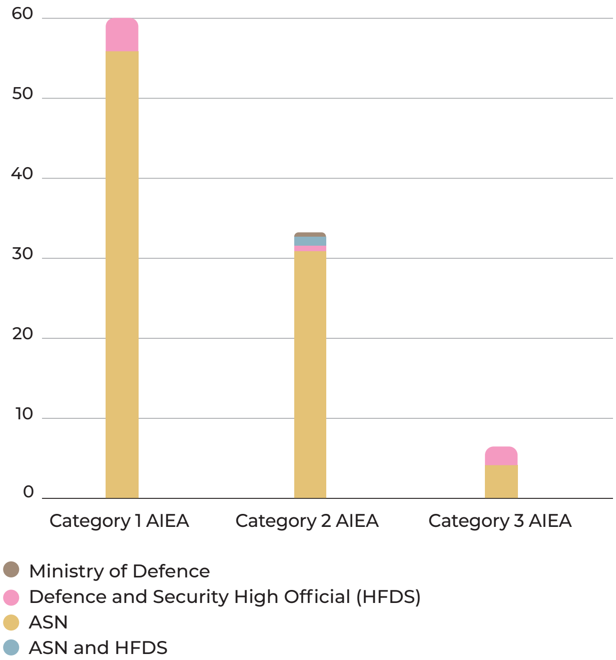
Categorisation of radioactive sources

Radioactive sources have been classified by the IAEA since 2011 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 must not under any circumstances be considered as proof 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. This IAEA work has been taken up in an Appendix to the Public Health Code amended by Decree 2018-434 establishing various provisions in the nuclear field. Nevertheless, the IAEA categories 4 and 5 have been grouped together in category D of this Code.

GRAPH 5

Breakdown of the oversight of protection of sources against malicious acts



The sources in category A of the Public Health Code (PHC) correspond to the IAEA category-1 sources.

The PHC category-B sources correspond to:
- the IAEA category-2 sources, and
- the IAEA category-3 sources contained in a mobile or portable device..

The PHC category-C sources correspond to the IAEA category-3 sources not contained in a mobile or portable device.

Agency (IAEA), which published a Code of conduct on the safety and security of radioactive sources, approved in 2003 and supplemented since then by two application guides. As of 2004, France confirmed to the IAEA that it was working on applying the guidelines set out in this Code.

• The organisation adopted for the oversight of protection against malicious acts

Measures implemented to ensure radiation protection, safety, and protection against malicious acts have many interfaces. Generally speaking, ASN's counterparts in other countries are responsible for oversight in these three areas.

In France, the protection against malicious acts concerning nuclear materials used in certain points of vital importance is coordinated by the services of the Defence and Security High Official (HFDS) of the Ministry responsible for energy (Ministry of Ecological and Solidarity-based Transition).

The changes in regulations adopted since early 2016 have led to an organisation for oversight of 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 the Ministry of Defence, oversight of the sources in the locations placed under its authority;
- to ASN, oversight of the security of sources held by the other persons/entities responsible for nuclear activities.

The process necessary to set up this oversight, initiated by the Government in 2008 with the assistance of ASN, resulted in Ordinance 2016-128 of 10 February 2016 and then Decree 2018-434 of 4 June 2018 introducing various provisions concerning nuclear activities. These texts, which amend the Public Health Code, divide up the oversight duties of the various installations as indicated above, by including protection against malicious acts in the risks that must be taken into account by those responsible for nuclear activities and by the regulatory bodies when reviewing the licensing applications.

• The sources and installations concerned

Oversight of source security concerns all sources of ionising radiation that is to say all the devices that could cause exposure to radiation. The majority of the regulatory provisions are however taken to increase the security of the sources presenting the greatest security risks: this concerns radioactive sources of categories A, B and C as defined in the Public Health Code, which stems directly from that of the IAEA. The protection requirements are proportionate to the intrinsic dangerousness of the sources. The graded approach therefore implies stricter obligations for the sources (or batches of sources) in category A than in category C. Sources that are not in categories A, B or C are classified in category D.

In the civil sector, there are slightly more than 5,000 sources presenting such security risks held by end-users in some 250 installations in France. These sources are used essentially for industrial purposes (irradiation, radiography, measurements, etc.) or medical purposes (such as telegammatherapy and brachytherapy). Due to their frequent movements when on worksites, industrial radiography sources present particular security risks.

If sources of different categories are stored together, the lower category sources may be subject to the stricter security measures applicable to the higher category sources.

• **Regulatory work**

The Decree modifying the regulatory part of the Public Health Code taken in application of Ordinance 2016-128 of 10 February 2016 (Decree 2018-434 introducing various provisions with regard to nuclear activities) was published on 4 June 2018. It contains several provisions concerning the protection of sources against malicious acts, and more specifically:

- the classification of ionising radiation sources and batches of radioactive sources into category A, B, C or D (R. 1333-14);
- the prompt notification to various administrative authorities, and the local law enforcement agencies, of any actual or attempted malicious act or loss concerning a source of ionising radiation or a batch of radioactive sources of category A, B or C (R. 1333-22);
- the sending of documents that could facilitate malicious acts by separate, specially identified mail (R. 1333-130);
- the nominative and written authorisations to be delivered to the persons having access to ionising radiation sources or batches of radioactive sources in category A, B or C, transporting them, or having access to information concerning the protection of such sources or batches of sources against malicious acts (R. 1333-148).

In 2019, the working group coordinated by the HFDS of the Ministry responsible for the environment and in which ASN participates, continued and finalised its work to prepare a draft Ministerial Order setting technical and organisational requirements to protect ionising radiation sources (or batches of sources) against malicious acts. This work drew on the findings made during some 250 preparatory visits conducted by ASN between 2011 and 2016. At the end of the first quarter of 2019, some industry players and stakeholders were invited to give their comments and observations on a preliminary draft. This resulted in numerous improvements to the texts.

This draft received a favourable opinion from ASN on 26 September 2019, subject to a few minor modifications (ASN opinion 2019-AV-0339 of 26 September 2019); the Ministerial Order was signed on 29 November 2019 and published on 11 December 2019. It will enter into force on 1 January 2020 for new sites and, for already licensed sites, in two stages: the organisational and human provisions within 6 months and the systems for protection against malicious acts 18 months later. The Order covers both the installations and transport.

The requirements aim more specifically, on the basis of a graded approach associated with categories A, B, C and D, to set up an in-house organisation addressing security matters to:

- limit or delay the theft of radioactive sources through access control measures, reinforcement of physical barriers and their openings (doors, windows) and protection of information (access limited to duly authorised persons);
- detect an actual or attempted malicious act (theft in particular) as early as possible;
- take action or alert the local law enforcement agencies after preparing their on-site actions.

These security principles are based on physical systems (barriers, access control, boundary-crossing detection, alarms, etc.) and organisational measures (security policy, training, equipment verifications, exercises, records, etc.) necessary for overall protection effectiveness.

For obvious reasons to restrict access to sensitive information, some of the provisions of this Order were not published in the *Journal Officiel* (Official Journal). ASN has therefore informed individually all the persons/entities responsible for nuclear activities that it regulates.

Review of the first inspections relating to the protection of ionising radiation sources against malicious acts

In 2019, during ASN inspections in facilities holding sealed radioactive sources of category A, B or C, the first four regulatory provisions applicable since 1 July 2018 relative to their protection against malicious acts were verified in 60 industrial facilities and 21 medical centres. The following conclusions can be drawn:

- The **classification of radioactive sources** or batches of sources into the different categories has been carried out on slightly less than half the facilities (42% for the industrial sector and 53% for the medical sector), while the remaining facilities have applied the classification only partially (28% and 40% respectively), or not at all (30% and 6% respectively).
- The **individual authorisations** that the person responsible for the nuclear activity must issue to grant access to these radioactive sources or batches of sources, their transportation or access to the information relative to the means or measures for protecting them, have been granted to only a small extent. Only 30% of the industrial facilities have issued such authorisations and no medical centre has issued them satisfactorily. The provisions are partially satisfied on 20% of the industrial facilities and 20% of the medical centres: the authorisations are thus only issued to some of the people who need them or without considering the real needs to have them. In the other cases (50% and 80% respectively), no authorisation was granted.
- Nevertheless, the **measures taken to prevent unauthorised access** to the sources were deemed satisfactory for the large majority of industrial facilities (97%), whereas in the medical sector only slightly more than a third of the centres (38%) to date meet the applicable measures. This situation will obvioulsy change once the protection systems (physical in particular) prescribed by the Order of 29 November 2019 relative to the protection of ionising radiation sources and batches of sources in categories A, B, C and D against malicious become applicable.
- Lastly, the **majority of the source inventories** held by the facilities are consistent with the national inventory held by IRSN (complete correspondence in 72% of cases for the industrial sector and 73% for the medical sector), thus allowing rapid identification of the holding entity and site if necessary.

International think tank on alternative technologies

Radioactive sources present radiation exposure and safety 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 Nuclear Security Summit in Washington in April 2016, France was the initiator of an international initiative now supported by 31 countries 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 the use of these technologies.

In this context, since April 2015 ASN has, along with the National Nuclear Security Administration (United States), initiated an informal think tank involving several countries working on the subject of replacing high-activity radioactive sources by alternative technologies. The aim of this group, which meets once a year, is to foster greater awareness of the benefits of such alternatives and to share experience feedback from each country in this respect. ASN has contributed to these meetings by presenting the operations carried out by the French blood transfusion agency, in application of the principle of justification, to replace those of its irradiators that use radioactive sources by electrical irradiators that emit X-rays. ASN also invited 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 2018, during the International Conference on Nuclear Security organised by the International Atomic Energy Agency (IAEA), the subject of alternative technologies was addressed by several presentations and two panel sessions, and the relevance of this think tank was underlined.

The meetings of the think tank continued in 2019. Other foreign licensees shared their experience, particularly in the use of electrical irradiators emitting X-rays for research activities. These regular meetings provide the opportunity to highlight both successful initiatives in the implementation of alternative technologies and difficulties in the development or implementation of these technologies which must be the subject of further consideration and complementary work.

2.4 Licensing and notification of ionising radiation sources used for industrial, research or veterinary purposes

2.4.1 Integration of the principles of radiation protection in the regulation of non-medical activities

With regard to radiation protection, ASN verifies application of the three major principles governing radiation protection which are written into the Public Health Code (Article L. 1333-2), namely justification, optimisation of exposure and dose limitation.

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 generic prohibition is declared, or the license required for radiation protection purposes is not issued or is not extended. For the existing activities, the elements supporting implementation of the justification principle are recorded in writing by the person responsible for the nuclear activity, and are updated every five years and whenever there is a significant change in available knowledge or techniques.

Optimisation is a notion that must be considered in the technical and economic context, and it requires a high level of involvement of the professionals. ASN considers in particular that the suppliers of devices are at the core of the optimisation approach (see point 4). 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 reported significant events.

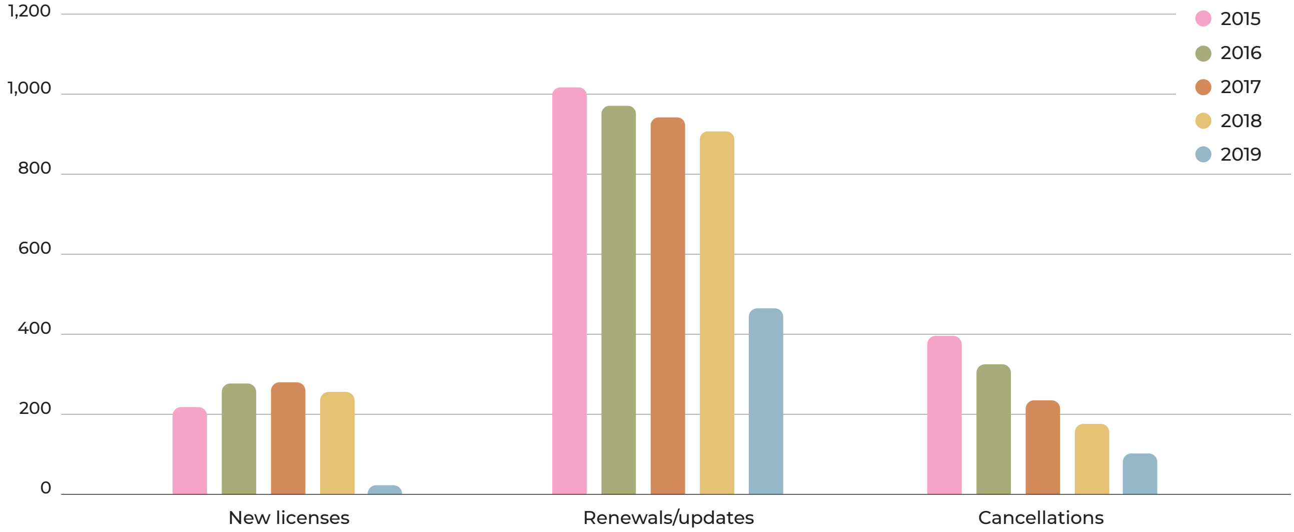
2.4.2 Applicable licensing and notification systems

Applications relating to the possession and utilisation of ionising radiation are examined by the ASN regional divisions, while those concerning the manufacture and distribution of sources or devices containing sources are examined at the ASN head office by the Department of Transport and Sources (DTS). The entry into effect on 1 July 2018 of Decree 2018-434 of 4 June 2018, introducing various provisions in the nuclear field, introduces a third administrative system lying between the notification system and the licensing system: this is a simplified authorisation system called the “registration system”.

ASN has prepared a nomenclature to allocate the various categories of nuclear activities to one of these three systems, whose implementation begins on 1 January 2019 with the entry into effect of the ASN resolution extending the notification system to new nuclear activities which until now were subject to licensing (see the “notification system” heading below). The draft resolution relative to the nuclear activities coming under the future registration system was also prepared in 2019. This system will concern certain sources of ionising radiation, coming as sealed or unsealed radioactive sources and electrical devices emitting X-rays for which the risks and adverse effects resulting from their possession or use can be prevented through compliance with the specific general requirements set out in the draft resolution. This draft resolution defines, in addition to the abovementioned requirements, the content of the simplified licensing application (the information and supporting documents to provide are greatly reduced in comparison with the standard licensing application) and the conditions licensees must comply with when exercising the nuclear activity. The outline for this draft resolution underwent public consultation in August and September 2019. The responses allowed the consolidation of the draft resolution which should be made available for consultation during the 1st quarter of 2020.

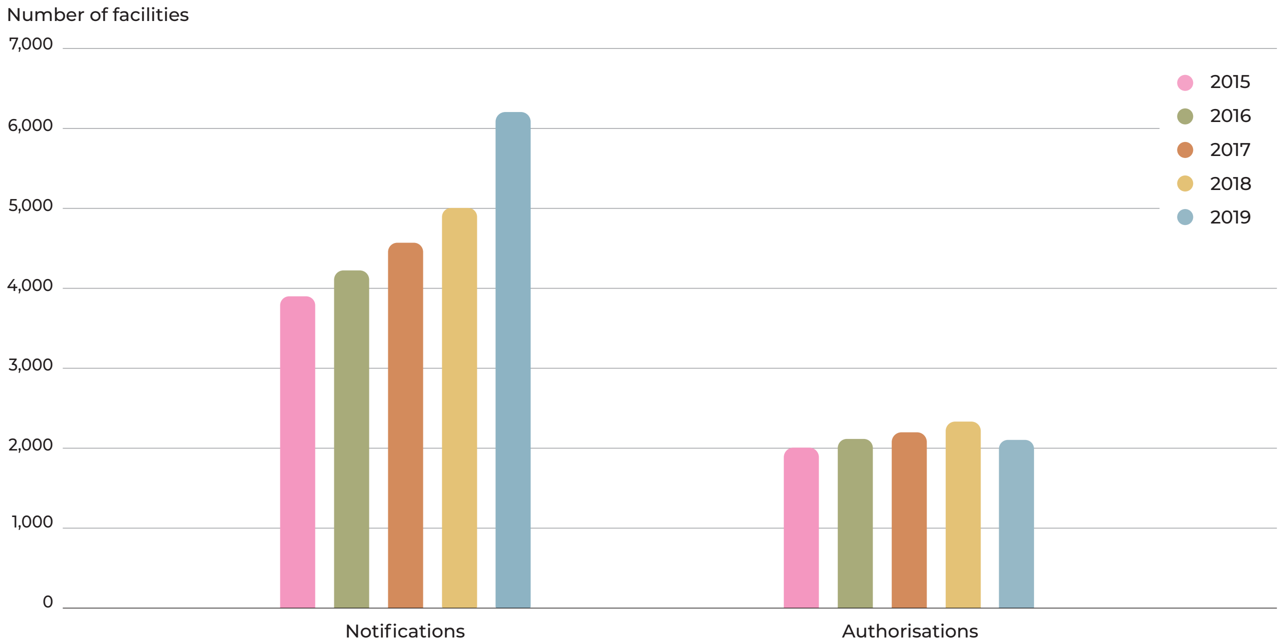
GRAPH 6

Radioactive source "user" licenses issued each year



GRAPH 7

"User" licenses and notification acknowledgement issued for electrical devices generating radiation



Administrative tracking of radioactive sources

Articles R. 1333-154, 156 and 157 of the Public Health Code provide for the prior registration by IRSN of transfers of radioactive sources and Article R. 1333-158 for administrative tracking of these sources.

ASN resolution 2015-DC-0521 of 8 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 1 January 2016, takes into account the existing mode of functioning and supplements it as follows by:

- grading source administrative tracking 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.

• The licensing system

Small-scale nuclear activities stand out by their considerable diversity and the large number of licensees involved. The licensing system is designed to regulate the nuclear activities involving the greatest radiation protection implications, for which ASN checks, when reviewing the license application, that the applicant has identified the risks and that the easures intended to limit their effects have been studied and planned for. To support this licensing process, ASN has produced licensing application forms adapted to each activity which are available on *asn.fr*.

These forms are designed for the licensing applications to be formulated by the representative of a legal person, although it is possible for a physical person to apply for a license. These forms 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 22 July 2010 must be held by the applicant and kept at the disposal of the inspectors in the event of inspection. On completion of the examination, and provided that the measures described by the applicant are satisfactory, a limited-term (usually 5 years) license is issued for the exercise of the nuclear activity.

• The notification system

As part of the allocation of the nuclear activity classification into the three administrative systems introduced by the abovementioned Decree, ASN wanted to implement a more graded approach, proportionate to the risks.

Its initial work focused on the notification system. Notification is a simple procedure which does not require the submission of any supporting documents. It is particularly suited to the nuclear activities that present the lowest risks for people and the environment. Since April 2018, those responsible for a nuclear activity in the industrial, research or veterinary sectors that comes under the notification system, can carry out the notification procedure *via* the ASN "on-line services" portal.

Through ASN resolution 2018-DC-0649 of 18 October 2018 approved on 21 November 2018 (see the "Regulatory news" sheet in the introduction to this report), ASN has extended the list of activities subject to notification. The notification system extension should concern about 6,000 companies or individuals which were previously subject to the licensing system. However, it will not be possible to accurately quantify the number of companies or individuals until a five-year term is reached (31 December 2023). This is because, in accordance with the principle of grandfathering, the licenses issued before 1 January 2019 act as notification acknowledgements until the license reaches term, on condition that in the interim there is no change in the nuclear activity. This means that a number of nuclear activities, though now subject to notification, are still covered regulated by a license.

2.4.3 Statistics for 2019

• Suppliers

In view of the fundamental role played by the suppliers of radioactive sources or devices containing them in the radiation protection of future users (see point 2.4.1), ASN exercises tightened oversight in this field. During 2019, 72 radioactive source supply license applications or license renewal applications were examined by ASN, and 41 inspections were carried out (all ionising radiation sources combined).

• Users

Case of radioactive sources

In 2019, ASN examined applications and issued 18 new licenses, 462 license renewals or updates and 100 license cancellations. Graph 6 shows the licenses issued or cancelled in 2019 and the trend for these data over the last five years. ASN also issued in 2019, for the first time, 1,207 notification acknowledgements for sealed radioactive sources. The entry into effect of ASN resolution 2018-DC-0649 of 18 October mentioned in point 2.4.2 is the main reason for the very large drop in the number of licenses issued and, conversely, the increase in notification acknowledgements issued and illustrates the concrete application of the graded approach to risk control.

Once the license or notification acknowledgement is obtained, the holder can procure sources. To do this, it collects supply request forms from IRSN, enabling the Institute to verify –as part of its duty to keep the national inventory of ionising radiation sources up to date– that the orders are in conformity with the license or notification acknowledgement issued to the user and the license of its supplier. If the order is correct, the transfer is then recorded by IRSN, which notifies the interested parties that delivery can take place. In the event of difficulty, the transfer is not validated and IRSN refers the case to ASN (see box below).

Cases of ionising radiation generators

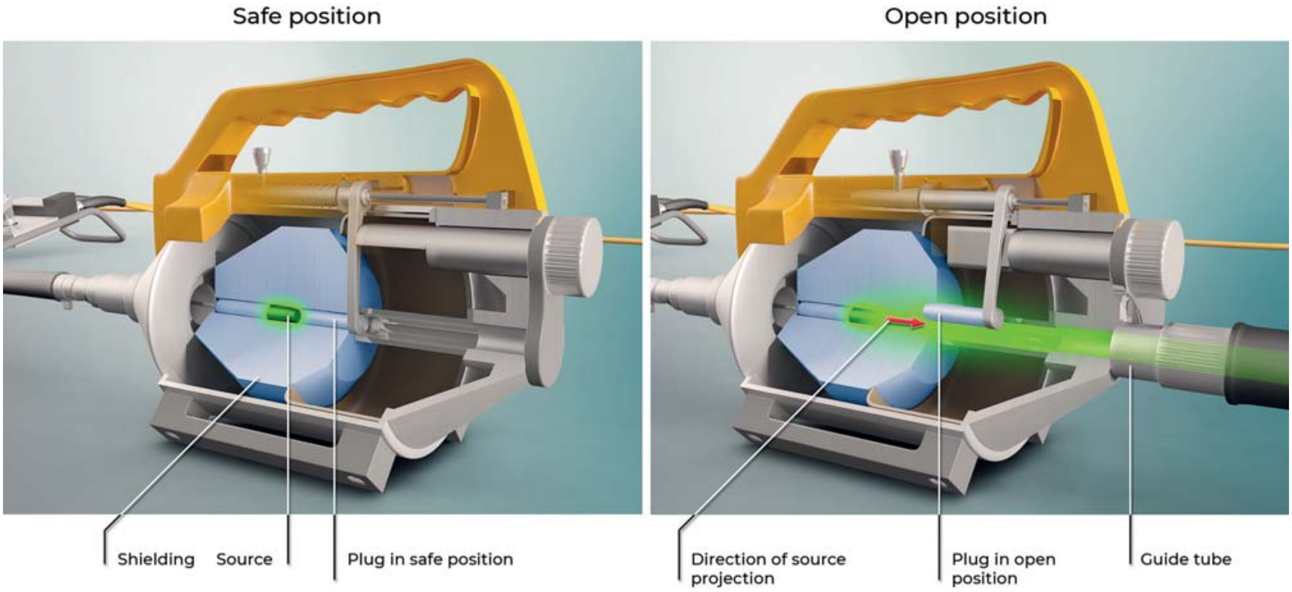
ASN has been responsible for the oversight of these devices since 2002, devices for which numerous administrative compliance actions are still required. In 2019, it granted 39 licenses and 203 license renewals for the use of X-ray generators. ASN also issued 1,188 notification acknowledgements for devices emitting ionising radiation in 2019. As with radioactive sources, the large reduction in the number of licenses issued and, conversely, the significant increase in notification acknowledgements, are the direct consequence of the entry into effect of the abovementioned ASN resolution 2018-DC-0649 of 18 October 2018.

A total of 2,109 licenses and 6,193 notification acknowledgements have been issued for devices emitting ionising radiation since 2002. Graph 7 illustrates the trend for the last few years.

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 mSv (millisieverts) per hour and per TBq (terabecquerel) one metre from the source, as opposed to 130 mSv/h/TBq for iridium-192. Yet it can be used in place of iridium-192 in numerous industrial fields, especially the petrochemical or boilermaking industry, and it enables the cordoned-off safety area to be significantly reduced and facilitates intervention in the event of an incident. In France, less than 20% of portable devices are equipped with a selenium-75 source. The deployment of selenium-75 has receded in the last few months. This is because the production plants in Russia have encountered difficulties causing a break in supplies throughout Europe. ASN nevertheless still encourages its use given that the current problems are temporary. Furthermore, the sealed source manufacturers in the United States, who for a long time did not embrace this technology, are now proposing sources of this type. A new manufacturer has already been licensed in 2019.

Operating schematic of a gamma ray projector



3. Assessment of the radiation protection situation in applications involving radiation risks in the industrial, research and veterinary sectors

3.1 Industrial radiography

3.1.1 The devices used

• 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 device, the dose rates can reach several grays per hour at one metre from the device, depending on the radionuclide and its activity level.

As a result 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.

• Industrial X-ray radiography

Industrial X-ray radiography is used for checking the quality of weld beads or for the fatigue inspection of materials.

It is carried out using fixed devices or worksite devices employing directional or panoramic beams which substitute for gamma radiography devices if the conditions of use so permit.

These devices can also be used for more specific and therefore rarer purposes, such as radiography for the restoration of musical instruments or paintings, archaeological study of mummies or the analysis of fossils.

3.1.2 Assessment of radiation protection in industrial radiography activities

Industrial radiology activities are high-risk activities which have been an inspection priority for ASN for several years now.

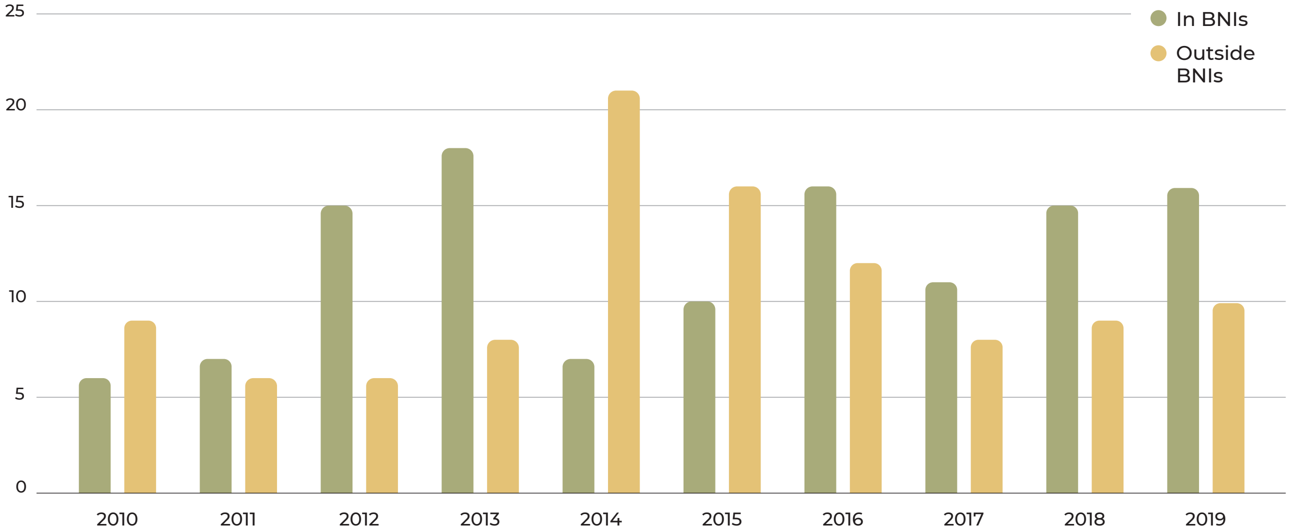
In 2019, ASN conducted 150 inspections in this area, which is an increase of about 30% with respect to the previous year. The additional inspection actions were assigned to the inspection of the activities presenting the greatest risks. They included the inspection of gamma ray projector storage facilities with, for example, a verification that the first provisions against malicious acts are properly taken into account (see box "Review of the first inspections relating to the protection of ionising radiation sources against malicious acts"), or the verification of field practices. The latter are carried out unannounced on the worksites which generally take place at night (11% increase in the number of inspections in worksite configuration, that is to say 61 inspections in 2019).

The on-line notification of worksite schedules for industrial radiography companies, put in place by ASN in 2014, facilitates the planning of these inspections. ASN notes that virtually all the licensees concerned generally use this system for the worksite notifications. This being said, the reliability of the information provided is still variable.The points to improve include:

- the updating of schedules when changes are made;

GRAPH 8

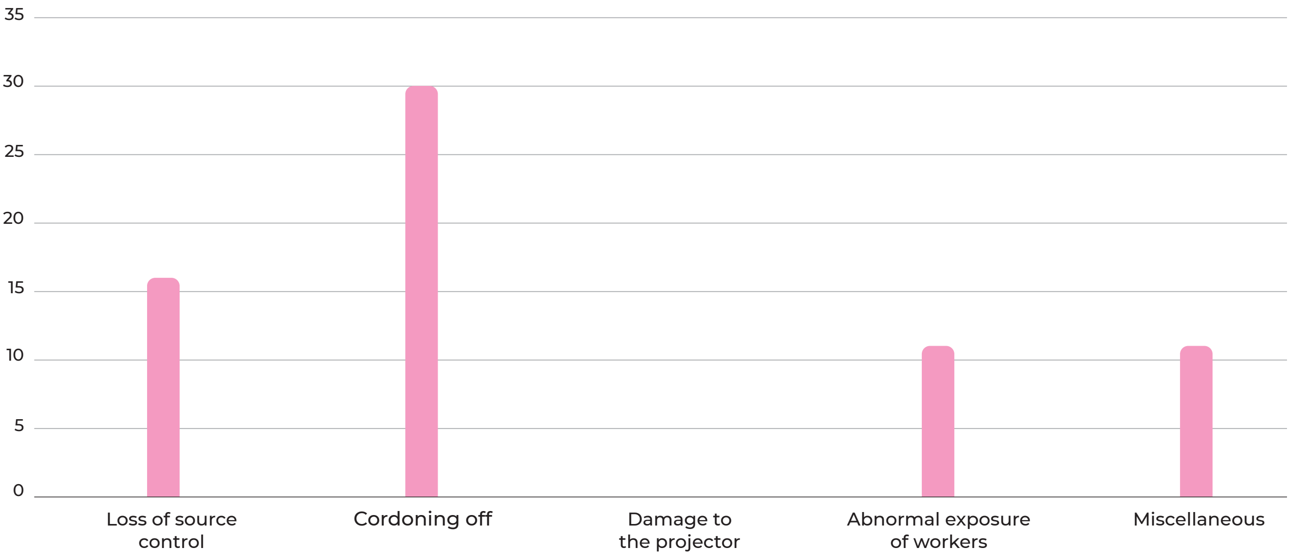
Trend in the number of industrial radiography events reported to ASN



Note: the 24 events of 2018 led to 25 notifications to ASN. One event was reported twice, by both the ordering customer and the industrial radiography contractor.

GRAPH 9

Main causes of industrial radiography events reported to ASN over the 2017-2019 period



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.

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 urban areas. 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 cable. 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 ISO standards. However, equipment failures can never be ruled out, especially in the event of poor upkeep of the equipment In the last few years, incorrect manipulations have also been observed further to source jamming incidents.

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 2019, in Spain, an employee of a non-destructive testing company was exposed to about 200 mSv (whole body) by entering a gamma radiography bunker when the iridium-192 source was not in the safe position. The door-opening slaving system for prohibiting access to the bunker during the emission of ionising radiation, did not function due to the failure of the dose rate measuring system. This event was rated level 2 on the International Nuclear Events Scale (INES).**
- **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 were several persons said they handled it. Twenty people in all were reportedly exposed, with most severely exposed person reportedly receiving a dose of 1 gray (Gy). The 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 Gy. 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.**
- **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 and noticed that the source was protruding from the source applicator He tried to push the source into the device with his finger The estimated dose received at the extremities is 38 Gy.**

- the accuracy of the worksite location information (not to be confused with the address of the ordering company);
- the completeness of the worksite notification.

From its inspection findings, ASN considers that, on the whole, the risks are properly taken into account, with the exception of the cordoning off of work zones at temporary worksites. ASN also underlines the persistence of some significant differences between companies in the way the risks are taken into account.

ASN observes that the large majority of companies maintained the necessary rigour to meet the regulatory requirements with respect to the radiation protection advisor (less than 5% noncompliance observed) and worker dosimetric monitoring (less than 10% noncompliance observed). Likewise, the inspectors observed that the persons/entities responsible for nuclear activities complied with the authorised radioactivity limit per radionuclide and the frequency of the verifications conducted by an organisation approved for radiation protection controls or by IRSN, these having effectively been carried out for all the sources and devices at the required frequency in more than 9 cases out of 10.

The inspectors also noted that newly arrived workers likely to access cordoned-off areas under Articles R. 4451-24 and R. 4451-28 of the Labour Code had received information in more than 80% of the companies concerned inspected in 2019 compared with 67% in 2018. However the content of the training of workers classified under Article R. 4451-57 of the Labour Code could be considerably improved by integrating all the aspects specific to the company (such as the safety procedures and instructions, lessons learned from significant radiation protection events, etc.).

Conversely, ASN is still concerned by the deficiencies observed in cordoning off the work zones on temporary worksites. The findings from the inspections carried out in 2019 show a worsened situation compared with 2018, with 46% of the cases displaying cordoning-off deficiencies in 2019 compared with 27% in 2018.

ASN points out that the work area must be cordoned off before the work begins and, in all events, before the radiography equipment is installed. To ascertain that cordoning off ensures compliance with the regulatory dose rate values, it is vital to take at least one measurement and to record the result. Cordoning off must be continuous and signal lights must be provided in sufficient quantity. Cordoning off is effectively the main safety barrier in worksite configurations, particularly to prevent unintended exposures.

Consequently, ASN remains extremely vigilant regarding this point, which is systematically checked during worksite inspections; moreover, penal enforcement actions have already been proposed.

With regard to application of the principles of justification and optimisation, the long-term reflections undertaken by the non-destructive testing 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.

Furthermore, France has a large network of fixed industrial radiography facilities (88 gamma radiography facilities are licensed in France in 2019), enabling 70% of the professionals to propose industrial radiography services in bunkers. ASN considers the risks of incidents and the workers'occupational exposure are generally well controlled by the licensees when radiography is performed in a bunker complying with the applicable regulations. Despite the availability of such facilities, the inspectors still observe too often that parts that undergo radiography on worksites, particularly those scheduled at night in workshops, could have been easily moved to a bunker. Apart from optimising doses for the workers, it would also eliminate the risk of having to temporarily shut down the workshop in the event of an incident.

ASN considers that the ordering customers have a key role to play to improve radiation protection in industrial radiography, by favouring industrial radiography services in licensed fixed facilities.

Furthermore, through its inspections in 2019, ASN continues to note that the establishing of occupational risk prevention plans between the radiography company and its ordering customer needs to be improved. This shortcoming shows that worksite job preparation is not always commensurate with the risks of such activity.

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 stakeholders. The ASN regional divisions and other regional administrations concerned also regularly organise regional awareness-raising and discussion symposia for which the players of this professional branch show a real interest.

Lastly, it is to be noted that as in 2018, no incident was rated level 2 or above on the INES scale in 2019. A relatively large number of significant events are still related to loss of control of the source when using a gamma ray projector. However, these events were correctly diagnosed by the operators and the persons concerned did not undertake any inappropriate or prohibited operations. The safeguarding operations were thus better mastered and no secondary incidents were observed. The causes of these events are diverse, the main ones being indicated in Graph 9.

3.2 Industrial irradiators

3.2.1 The devices used

Industrial irradiation is used for sterilising medical equipment, pharmaceutical or cosmetic products and for the conservation of foodstuffs. It is also a means of voluntarily modifying the properties of materials, for example, to harden polymers.

These consumer product irradiation techniques can be authorised because, after being treated, these products display no residual artificial radioactivity (the products are sterilised by passing through radiation without themselves being "activated" by the treatment).

Industrial irradiators often use cobalt-60 sources, whose activity can be very high and exceed 250,000 TBq (terabecquerels). Some of these installations are classified as BNIs (see chapter 12). In many sectors, X-ray generators are gradually replacing high-activity sealed sources for the irradiation of products (see point 1.3.1).

Making safe and recovering a cobalt-60 source in gamma radiography: a long process…

During a maintenance operation in October 2010, the cobalt-60 source loaded in a GMA 2500(*) remained jammed inside the bunker of the *Aciéries Hachette et Driout* steelworks in Saint-Dizier (Haute-Marne *département*). None of the actions undertaken on the electric remote control box or on the cable accessible in the reserve guide tube outside the bunker succeeded in unjamming the source. The dose rate inside the bunker was not compatible with human intervention inside the bunker. It took four years for the companies NUVIA Process and the device manufacturer ACTEMIUM NDT-PES (Non Destructive Testing Products & Systems) mandated by *Aciéries Hachette et Driout* to develop an intervention protocol approved by ASN. This protocol started to be implemented in autumn 2019 after ASN had granted the steelworks time to make provisions for the funding necessary for this intervention, with ASN having also ensured that access to the bunker was lastingly prohibited.

This intervention protocol comprises two phases. The first phase was carried out in October 2019 by NUVIA Process using remotely controlled robotic tools. During this intervention, the source was located thanks to a gamma camera, the guide tube containing the source was placed on the ground then covered with biological protections using a robot. This lowered the dose rate inside the bunker sufficiently to make a subsequent human intervention possible.

The second phase is to be carried out by the ACTEMIUM NDT-PES technicians and should allow the entire guide tube and irradiation device to be dismounted and video-inspected with a borescope, and then connected to a suitable container to make the source safe and be able to transport it.

The difficulties and the times required to set up this intervention clearly illustrate the benefits of substituting high-energy gamma radiography technologies, particularly those using cobalt-60 sources, by technologies that do not involve ionising radiation, or by electrical devices.

* *High-capacity automatic gamma radiography device.*

An irradiator at CEA Saclay out of service for several months

On 1 July 2019, at the end of an irradiation campaign in the DOSEO facility of the French Alternative Energies and Atomic Energy Commission (CEA) Paris Saclay (used for research applications and brachytherapy metrology applications), the operator of the Gammabeam X200® (manufactured by the Canadian company Best Theratronics), working from the control console, did not manage to return the cobalt-60 source to the safe position inside the internal shielding provided for that purpose.

This source is a high-activity sealed source of category A (residual activity on the day of the incident of about 250 TBq), the category that presents the greatest radiation exposure risks. Consequently, given the level of ionising radiation in the bunker containing the irradiator, all access to the bunker was prohibited.

After examining a specific protocol that led to ASN issuing an approval, a robotic intervention was carried out in the bunker at the end of July 2019 by the group INTRA, one of the few French companies with the means necessary to operate in such radiological environments. The remotely-controlled robots removed the irradiation phantom(*) from the direct beam of the device (thereby eliminating the radiation diffused by the phantom), placed a lead shield in front of the direct beam exit (thereby eliminating the risk of a worker crossing it later) and produced a detailed mapping of the ambient radiation level inside the bunker.

The reduction in the ambient radiation level and the detailed mapping should thus allow human intervention on the device in the near future in order to return the irradiation source to the safe position. This intervention would consist in using a specific tool to push the source into the safe position inside the internal shielding of the device.

The probable cause of the failure of the irradiator was reportedly the loss of the compressed air supply that enables the source to move. As the compressed air supply is situated inside the bunker, it is not possible to repair it when the source is not in the safe position. The exact cause will be confirmed after conducting the investigations that will be possible once the source is returned to the safe position; ASN will be attentive to the implementation of corrective measures intended to prevent such an event from occurring again.

** Artefact constructed to simulate the scattering properties of the human body or parts of the human body such as the extremities.*

3.2.2 The radiation protection situation

BNIs excluded, ASN carried out ten inspections in this sector in 27 licensed companies (which represent a fleet of 36 facilities). These inspections show that the radiation protection organisation (in particular the appointing of a Radiation Protection Advisor) and the radiological zoning put in place on the premises of the inspected licensees are satisfactory; no significant deviations from the regulations were observed. The risk is well controlled, in particular thanks to the satisfactory verification, upkeep and maintenance of the facilities in accordance with the provisions described in the licensing applications. Only one significant radiation protection event was reported to ASN; it concerned the jamming of a source (see box opposite).

3.3 Particle accelerators

3.3.1 The devices used

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 MeV (megaelectronvolt).

Synchrotrons

The synchrotron is a member of the same circular particle accelerator family as the cyclotron (see point 4-2), but is far larger, enabling energies of several gigaelectronvolts to be achieved by means of successive accelerations. 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.

When they meet the characteristics specified in Article R. 593-3 of the Environment Code concerning the BNI nomenclature, these facilities are listed as BNIs.

Some applications necessitate the use of beams of photons or electrons produced by particle accelerators. The French fleet of particle accelerators, whether linear (linacs) or circular (synchrotrons), comprises about 60 listed facilities (excluding cyclotrons –see point 4.2– and excluding BNIs), totalling slightly over one hundred accelerators, which can be used in highly diverse areas, such as:
- 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;
- ...

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 however be used under certain specific 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. 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 people during the inspection.

3.3.2 The radiation protection situation

The use of particle accelerators presents significant radiation exposure risks for the workers; ASN is particularly attentive to these facilities and therefore inspects them regularly. In 2018, ASN put in place inspection indicators specific to particle accelerators, which now enable the radiation protection situation in this sector of activity to be better assessed on the national scale.

In 2018 and 2019, 31 centres equipped with these devices were inspected by ASN (i.e. 49% of the national fleet).

ASN considers the radiation protection situation in the facilities using these devices to be satisfactory on the whole. In effect, the key requirements for conducting this activity with a satisfactory level of radiation protection (organisation of radiation protection, training, technical verifications and design of the premises in which these devices are used) are appropriately implemented by the large majority of the licensees.

Nevertheless, the inspections also identified areas for improvement on which ASN will remain vigilant:

- compliance with the regulations concerning the frequency of third-party technical checks and the formalised processing of non-conformities detected during these checks;
- the presence of an unlocking device which can be actuated from inside the rooms in which particle accelerators are used;
- the correct functioning of the audio signal associated with the patrol procedure, which aims to confirm that nobody is in the room before authorising the emission of ionising radiation.

Lastly, with regard to experience feedback, no significant radiation protection event was reported to ASN in 2019, apart from the recurrent events associated with the use of particle accelerators in shipment security checks. Effectively, when conducting these checks the customs services take precautions (such as broadcasting information messages in several languages) to avoid the unjustified irradiation of people who could be hiding in these vehicles (see point 3.3.1). However, despite these precautions, the customs services regularly notify ASN of events relating to the exposure of people hidden in checked vehicles. Nevertheless, although this exposure is unjustified, it remains extremely low with effective doses of just a few µSv (microsieverts).

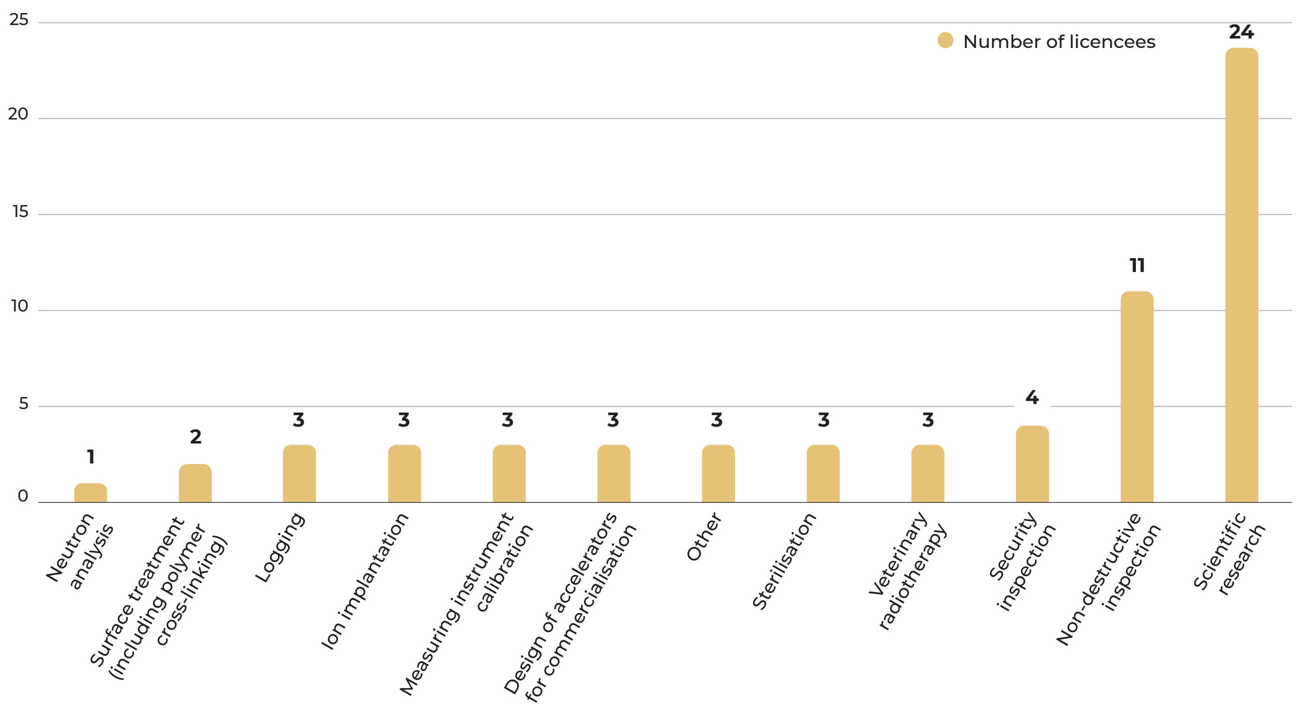
3.4 Research activities involving unsealed radioactive sources

3.4.1 The devices used

In the research sector, as at 31 December 2019, ASN counts 697 licenses issued under the Public Health Code, of which 93% are granted to public or mixed (public/private) entities. The number of licenses has been decreasing constantly for 5 years, since about 10 licenses on average are repealed each year. This reduction can essentially be explained by two factors: either the use of alternative non-ionising technologies (example: immunofluorescent[1] labelling of cells, etc.), or the grouping of the licenses of several laboratories into a single license for which the person responsible for the nuclear activity is usually the director of the newly created structure. Added to these factors, since early 2019, is the transfer of certain nuclear activities from the licensing system to the notification system (see point 2.4.2).

GRAPH 10

Distribution of particle accelerators by end-purpose



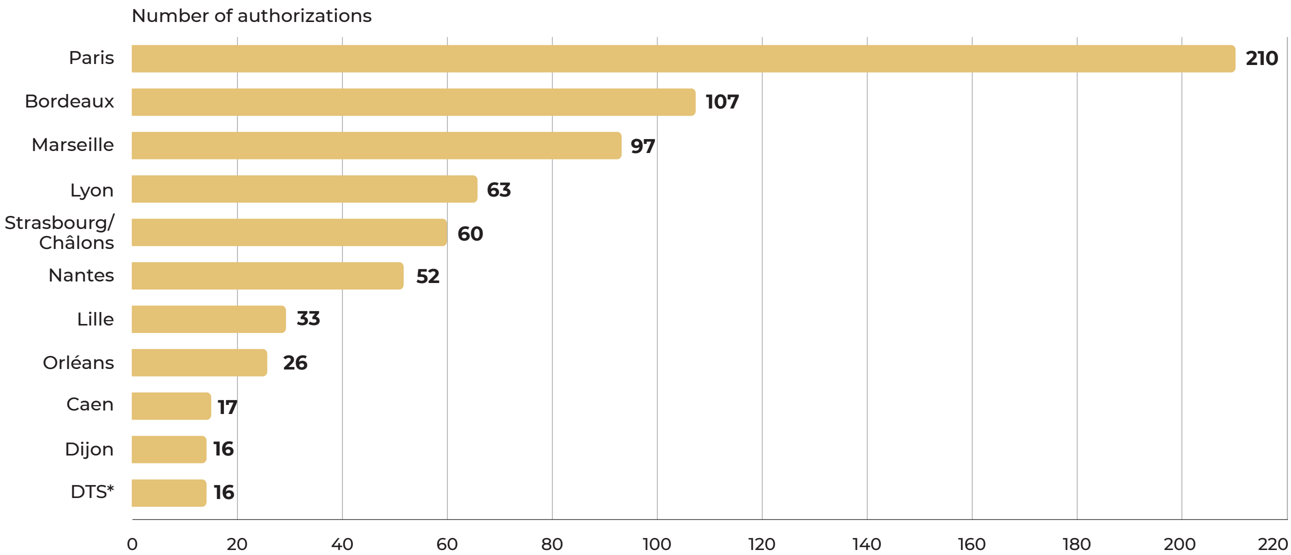
1. *Immunofluorescence is an immunolabelling technique that uses antibodies and fluorochromes.*

The first accelerator intended for inspecting freight trains in France installed at the entrance to the Channel tunnel

In 2019, ASN authorised the possession and use of a particle accelerator on the SNCF site of Fréthun (Pas-de-Calais *département*), at the entrance to the Channel Tunnel, for the inspection of goods trains travelling to the United Kingdom. The inspections performed by the French customs officers aim to confirm that consignments passing through the tunnel are safe by improving the detection of illicit products on board the train. This is the first device of this type installed on French territory. The project first required the issuing of a first license by ASN to the supplier of the device (based on an examination that focused on the design of the device and its intrinsic safety features), enabling the supplier to commission the facility and train the users. This was followed by the issuing of two further licenses, one for the possession of the device, issued to the company Eurotunnel, the other for the utilisation of the device, issued to the French customs authorities. The facility uses a particle accelerator and a detection column delivering images that are analysed by the customs officers. During the various phases of its review, ASN was particularly attentive to measures implemented to ensure the radiation protection of the workers, particularly the train drivers, and the public. The facility features the necessary means for the protection of people against ionising radiation, more specifically by disabling the triggering of ionising radiation exposures when people are within the inspection area: reinforced walls designed to attenuate the radiation, system of optical barriers to detect intrusions, intelligent cameras capable of identifying the presence of individuals and therefore stopping or preventing X-ray emission, readily accessible emergency stop device, visual and audio information provided around the site.

GRAPH 11

Distribution over the French territory, according to the ASN entity responsible for the licensing of institutions authorised to use unsealed radioactive sources in the research sector in 2019



* The Transport and Sources Department examines the research activities when they are linked to suppliers of ionising radiation sources.

These facilities and laboratories use mainly unsealed sources for medical and biomedical research, molecular biology, the agrifood business, the sciences of matter and materials, etc. They can also be suppliers of unsealed sources. They also use sealed sources for performing gasphase chromatography, liquid scintillation counting or in irradiators. X-ray generators are also used for X-ray fluorescence or X-ray diffraction spectrum analysis. Particle accelerators are used for research into matter or for the production of radionuclides.

3.4.2 The radiation protection situation

In 2019, ASN carried out 45 inspections in this sector (47 inspections per year on average over the 2017-2019 period). Generally speaking, the steps taken in the last few years have brought improvements in the implementation of radiation protection measures in research laboratories, thanks to enhanced overall awareness of radiation protection issues.

Among the observed areas of progress, ASN underlines the strong involvement of the Radiation Protection Advisors (RPA) with the research teams, resulting in better integration of radiation protection, particularly in operations involving ionising radiation sources.

The other notable improvements concern the conditions of waste and effluent storage and removal, particularly the setting up of pre-disposal checking procedures.

The way this subject is addressed nevertheless remains highly variable from one licensee to another and remains a point requiring particular attention in universities which have historically stored their disused sources and their radioactive waste, sometimes over very long periods of time, rather than disposing them regularly, which today poses two main problems:
- in view of their diversity, the waste and sources cannot be retrieved without first being precisely identified and characterised;
- the retrieval represents a significant financial cost which has not been budgeted for.

The technical, economic and regulatory difficulties concerning the disposal of legacy sealed sources therefore persist, despite entry into effect on 1 July 2015 of Decree 2015-231 of 27 February 2015 relative to the management of disused sealed radioactive sources. In effect, this text, which aims to facilitate the disposal of sealed sources, gives source holders the possibility of seeking alternative disposal routes with source suppliers or Andra without making it obligatory to return the source to its original supplier.

Paul Sabatier University in Toulouse served formal notice to remove its radioactive waste

In 2014, the ASN inspectors had observed the presence of more than 600 expired sealed sources and contaminated waste stored in two premises. These storage areas presented a very real radiation protection risk given the volume and nature of the accumulated waste, the associated risk of contamination and the difficulty in ensuring their security in the event of malicious acts.

At the time ASN had requested the removal of the waste before the end of 2017, and the transmission of a quarterly progress report.

Despite the successive chase-ups and inspections, ASN observed in 2018 that more than 370 sources and waste were still stored at the university. Furthermore, the premises displayed a confirmed risk of contamination making it necessary to wear coveralls to enter them.

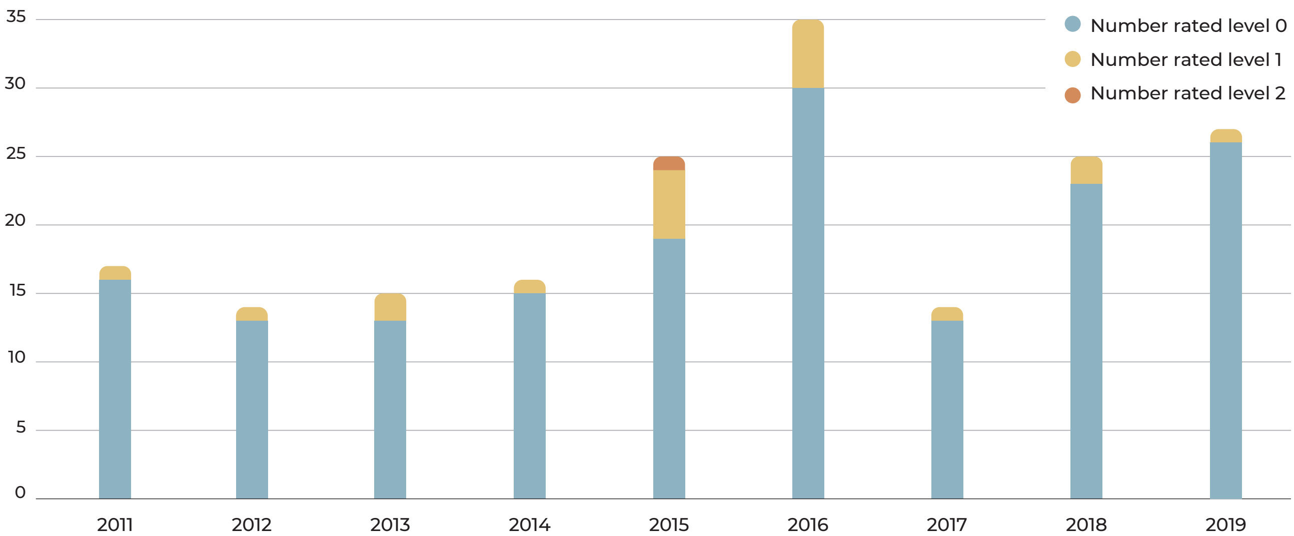
Consequently, in April 2019 ASN gave the Paul Sabatier University formal notice to remove, within one year, the 8 expired sources and 4 contaminated wastes that present the most significant radiological risks.

Further to receiving formal notice from ASN, the university sped up its source and waste removal procedures with its various suppliers and with Andra and the CEA. In 2019 it organised the removal of 8 sources and wastes out of the 12 stipulated in the formal notice to comply. An inspection shall be carried out in 2020 to verify full compliance with this notice and take stock of the progress in the removal of the other sources and wastes not covered by the administrative procedure.

In August 2019, ASN also placed a condition on the renewal of the license to hold sealed and unsealed sources by requiring the sources and wastes to be stored in non-contaminated premises provided with a surface coating that is easily decontaminated.

GRAPH 12

Trends in the number of events reported to ASN in the research sector



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.

X-ray generators rays are used for X-ray fluorescence or X-ray diffraction spectrum analyses. The use of scanners for small animals (cancer research) in research laboratories and faculties of medicine should also be noted. Particle accelerators are used in research into matter or for the manufacture of radionuclides.

ASN has identified areas for progress which will be subject to particular scrutiny in the next inspections, more particularly concerning the classification of people working with ionising radiation –which is generally overestimated by employers– and the failure to systematically put in place systems for recording and analysing adverse events and Significant Radiation protection Events (ESRs).

In effect, among the inspected entities, 27% still do not have such a system (an improvement compared with the 35% in 2018, nonetheless). In 2019, ASN recorded 27 ESRs concerning research activities (see Graph 12).

The reported significant events are essentially of three types:
- discovery of sources (41%);
- unauthorised discharging of radionuclides into the environment or waste disposal *via* the wrong route (8%);
- exposure or contamination of workers during the handling of unsealed sources (26%).

The predominance of the first two causes of ESRs tallies with findings made for the 2016-2018 period. The discoveries of sources can be explained in particular by poor overall traceability: as was emphasised above, a lack of measures in the past to dispose of the sources when the laboratories ceased their activities, and/or irregular and non-exhaustive inventorying of sources.

The unauthorised discharging of radionuclides into the environment and the directing of waste to an inappropriate disposal route are linked to the type of sources used in this sector, these being mainly unsealed sources. Such events must be reported to ASN, even in the case of misdirected waste being recovered and redirected to the appropriate disposal routes.

With regard to cases of unintended exposure or contamination of workers, their number increased slightly in 2019. The analyses have shown that the doses received by workers nevertheless remain well below the regulatory limits.

Lastly, ASN is continuing its collaboration with the General Inspectorate of the National Education and Research Administration (IGAENR), which has competence for labour inspection in the public research sector. An agreement signed in 2014 provides for mutual information sharing, which improves the effectiveness and complementarity of the inspections. An annual meeting is held to assess the functioning of this collaboration.

4. Manufacturers and distributors of radioactive sources and their oversight by ASN

4.1 The issues and implications

The aim of ASN oversight of the suppliers of radioactive sources or devices containing them is to ensure 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 2.3.1). There are about 150 suppliers with safety-significant business, and among them, 33 low and medium-energy cyclotrons are currently licensed under the Public Health Code in France.

4.2 Cyclotrons

• Functioning

As at 31 December 2019, 29 cyclotrons were in operation. Among these, 16 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.

• The assessment of radiation protection in the area of cyclotrons

ASN has exercised its oversight role in this area since early 2010; each new facility or any major modification to an existing facility undergoes a comprehensive review by ASN. The main radiation protection issues on these facilities must be considered as of the design stage. Application of industrial standards, particularly standard NF M 62-105 “Industrial accelerators: installations”, ISO 10648-2 “Containment enclosures” and ISO 17873 “Ventilation systems for nuclear installations”, guarantees safe utilisation of the equipment and brings a significant reduction in risks.

Facilities that have a cyclotron used 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. Some licensees have also installed –as close as possible to the shielded enclosures– systems for collecting and storing the gases to let them decay before being discharged, bringing a substantial reduction in the activities discharged into the environment.

Cyclotrons

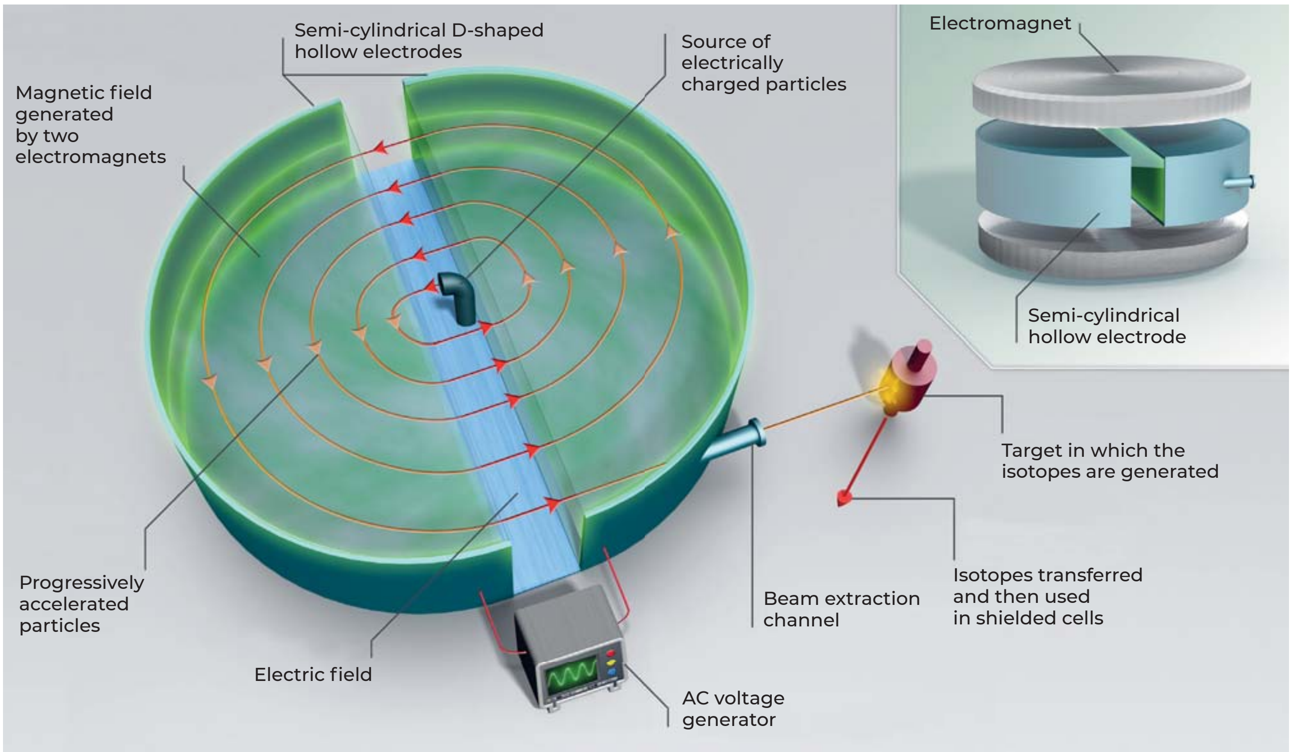
A cyclotron is a device 1.5 to 4 metres in diameter, belonging to the circular particle accelerator family. The accelerated particles are mainly protons, with energy levels of up to 70 MeV. A cyclotron consists of two circular electromagnets between which there is a magnetic field and an electrical field, 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 or carbon-11. The radionuclides are then combined with molecules of varying complexity to form radiopharmaceuticals used in medical imaging. The best known of them is ^{18}F-FDG (fluorodeoxyglucose marked by fluorine-18), which is an industrially manufactured injectable drug, commonly used for early diagnosis of certain cancers.

Other radiopharmaceutical drugs manufactured from fluorine-18 have also been developed in recent years, such as ^{18}F-Choline, ^{18}F-Na, ^{18}F-DOPA, along with other 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 fluorine-18 and carbon-11 are oxygen-15 and nitrogen-13.

The approximate levels of activities involved for the fluorine-18 usually found in pharmaceutical facilities vary from 30 to 500 GBq (gigabecquerels) per production batch. The positron emitting radionuclides produced for research purposes involve activities that are usually limited to a few tens of GBq.

Simplified diagram of the operation of a cyclotron

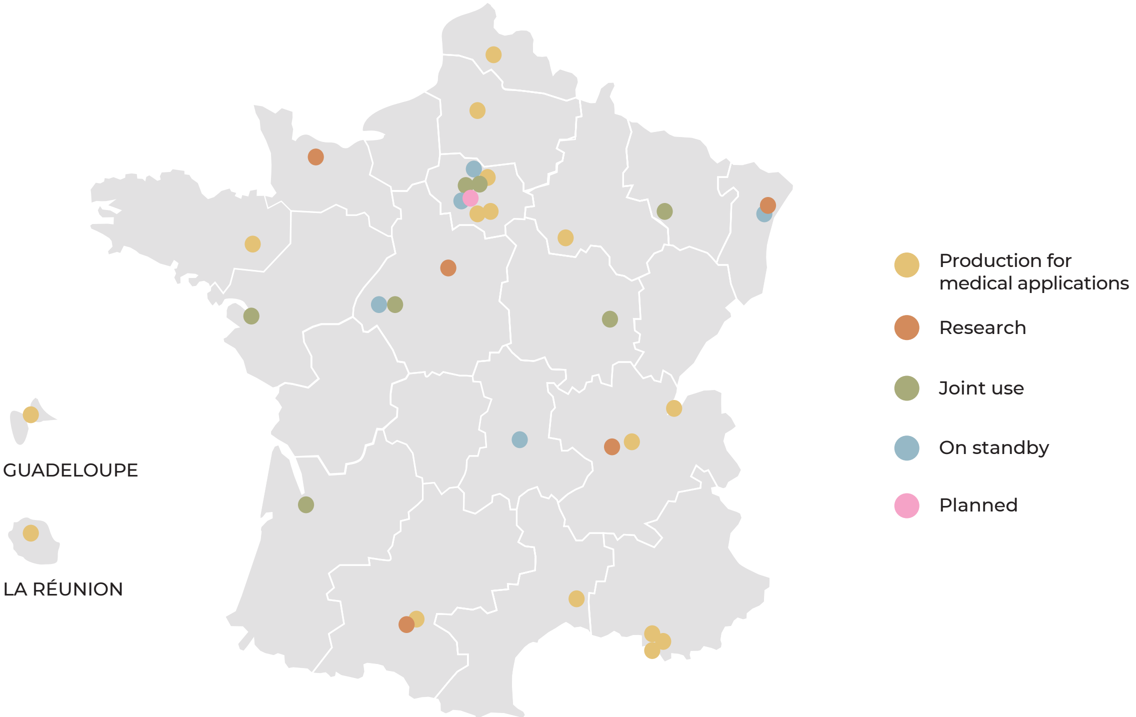


Consequently, the discharged activity levels and the short half-life of the radionuclides discharged in gaseous effluents mean there is no significant impact on the public or the environment.

ASN, jointly with IRSN, is continuing a study they began in 2016 on the gaseous discharges into the environment from these facilities. The conclusions of the first step which involved both IRSN and the licensees, served to establish general principles on managing gaseous effluent discharges in 2018, the key points of which will be taken up in a draft regulatory text (see below). Alongside this, new assessments of the impacts of discharges from the facilities situated near residential areas have been carried out using modelling tools that are better suited to near-field studies. This work will be continued in 2020 and the coming years, in accordance with a workload plan established by ASN and IRSN.

ASN performs about ten inspections at facilities of this type each year (13 in 2019). Aspects 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 occupational radiation protection, the management of internal events, monitoring and maintenance of the production equipment, inspection of the surveillance and control systems and the gaseous discharge

Location of cyclotrons in France



results. The radiation protection organisation of these facilities is satisfactory and staff are familiar with the regulations. National action plans have been put into place by the licensees and are monitored by ASN in order to ensure continuous improvement of radiation protection and safety in these facilities.

Three significant events concerning radiation protection were reported in 2019. None of these events led to significant exposure of workers or the public. One event was rated level 1 on the INES scale due to exceeding of the gaseous discharge limits set out in the license. Corrective measures were implemented by the licensee, including a system for continuous monitoring of discharges, allowing the immediate detection of any drift in gaseous effluent discharges.

There are disparities in the technical and organisational means implemented by the licensees, depending on the age of the facilities and the type of activities performed (research or industrial production). Experience feedback in this area has led ASN, assisted by IRSN, to draw up a draft regulatory text on the technical design and operating rules applicable to companies producing radionuclides using a cyclotron. This draft text was made available for consultation by the stakeholders in 2016. A revised version was produced in 2018, taking account of the observations received and including additional chapters on the control and monitoring of gaseous effluent discharges. This second version of this draft underwent a new consultation by the stakeholders in 2019. The interim conclusions are nevertheless already used when reviewing license application and defining licence conditions. Discussions with IRSN and the DGT will continue in 2020 in order to finalise this draft text and have a single regulatory baseline for the entire sector of activity concerned.

4.3 The other suppliers of sources

• Evaluation of radiation protection

Suppliers of radioactive sources, cyclotrons excluded, propose technical solutions for the industrial, medical and research sectors. Suppliers may be manufacturers of “bare” sources or of devices containing sealed radioactive sources, manufacturers of unsealed sources, or distributors who import sources from other countries. Whatever the case, ASN examines the license applications submitted by these suppliers for the sources they intend to distribute in France.

In 2019, 28 inspections of suppliers of sources other than cyclotrons were conducted at manufacturers/distributors of sealed and unsealed sources, companies involved in the dismantling and reconditioning of ICSDs, companies recovering lightning conductors and companies manufacturing and installing X-ray generators (although they do not yet have a distribution license, the utilisation of these devices is regulated, including the commissioning and maintenance operations carried out by the companies that sell them). Some of these inspections focused on foreign companies supplying products in France.

These inspections have covered about a third of the suppliers with safety-significant business, with specific inspection indicators directed at their responsibilities as source suppliers for the tracking and recovery of disused sealed sources to dispose of them appropriately considering the radiation risks they present for people and the environment.

ASN considers the radiation protection situation associated with the radionuclide distribution activity to be satisfactory on the whole. The large majority of licensees meet the main requirements and assume their responsibilities adequately (verifications prior to supply, technical verifications of the supplied sources, setting up the source recovery streams, transmission of information to IRSN). These inspections also served to inform source suppliers of forthcoming changes in the regulations, particularly those concerning the protection of radioactive sources they hold, either for their own use or for future supply to customers, against malicious acts.

However, these inspections and the analyses of significant events reports also revealed points requiring particular attention, including:

- the ability of the suppliers to prepare and perform the source commissioning, maintenance and loading/unloading operations in the devices designed for this purpose. These operations effectively require a certain amount of prior coordination between the company requesting the service and the licensed supplier in order to ensure the radiation protection of the workers (the supplier's personnel providing the service and the user's personnel when the equipment Is put back into service);
- the ability of the suppliers to fully and systematically track the sources from initial supply through to end-of-life recovery. This is because tracking is often incomplete and the expired or soon-to-expire sources (10-year administrative limit counting from the date of the 1st registration figuring on the supply form) are not identified sufficiently far in advance, which slows down the recovery procedure;
- the suppliers' vigilance in ensuring that the pre-delivery verifications are duly carried out. Half of the reported significant events reveal shortcomings in these verifications. The aim of these verifications, for which the supplier must take appropriate organisational measures (by computer blocking or verifications during the actual preparation of the order), is to ascertain that the delivery of a source will not lead to exceeding of the customer's license limits or another nonconformity that could result in a significant radiation protection event (such as the unjustified exposure of an operator);
- the ability of foreign suppliers to assume their responsibilities regarding the transmission of supply information to IRSN (and the updating of the French national inventory).

5. Conclusion and outlook

• Implementation of new administrative systems governing nuclear activities

In 2019, with the aim of stepping up its graded approach to oversight, ASN, on the basis of its nomenclature for classifying nuclear activities using ionising radiation, developed the draft resolution relative to the newly applicable registration system introduced by the abovementioned Decree 2018-434 of 4 June 2018 laying down various provisions concerning the nuclear field. Following on from this, ASN in 2020 will complete this draft resolution and prepare the update of the resolution concerning nuclear activities that are subject to the licensing system; this update will address the supply of X-ray emitting devices.

• Oversight of the protection of radioactive sources against malicious acts

ASN has been the designated authority for oversight of the provisions to protect the majority of radioactive sources against malicious acts. Publication of the abovementioned Decree brought into effect the first provisions in this respect in mid-2018: those responsible for nuclear activities must more specifically give individual authorisations for access to the most hazardous sources, including for their transport, and for access to sensitive information.

These provisions were subject to verifications during the inspections in 2019. The first inspections revealed that they are poorly known and therefore not yet well integrated. Over and beyond the fact that these are new regulatory provisions, the companies must integrate this new dimension in their corporate culture. On this account, the abovementioned Order of 29 November 2019 provides for senior management to approve a "protection against malicious acts policy" and delegate the authority and necessary resources to the person/entity in charge of the nuclear activity who is responsible for implementing it.

The fact that the first provisions of the Order, applicable as from mid-2020, have to be documented in the license modification or renewal application should speed up the implementation of these new responsibilities. At the same time, ASN will continue to verify the actual implementation of these new provisions during inspections in 2020. ASN shall also play an educational role by informing the licensees of these new regulations and explaining their details and requirements.

ASN has moreover continued the actions it had undertaken to plan ahead for its staff training and the development of appropriate tools to ensure speed and efficiency in embracing this new mission. Three or four staff training sessions are now organised each year. The training effort will continue in 2020.

Lastly, ASN will adapt the tools it already uses for the oversight of radiation protection (forms to submit license applications, explanatory guide for the professionals, provisions governing the inspections and the reporting of malicious acts). It will also ensure that regular targeted communication actions are directed towards the professionals concerned.

09.

TRANSPORT OF RADIOACTIVE SUBSTANCES

Transport of radioactive substances

The transport of radioactive substances is a specific sector of dangerous goods transport characterised by the risks associated with radioactivity. The radioactive substance transports being regulated cover a wide range of activities in the industrial, medical and research sectors. This 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). Class 7 covers radioactive substances.

The transport of radioactive substances stands out owing to its considerable diversity. Packages of radioactive substances can weigh from a few hundred grams up to 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 implications 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).

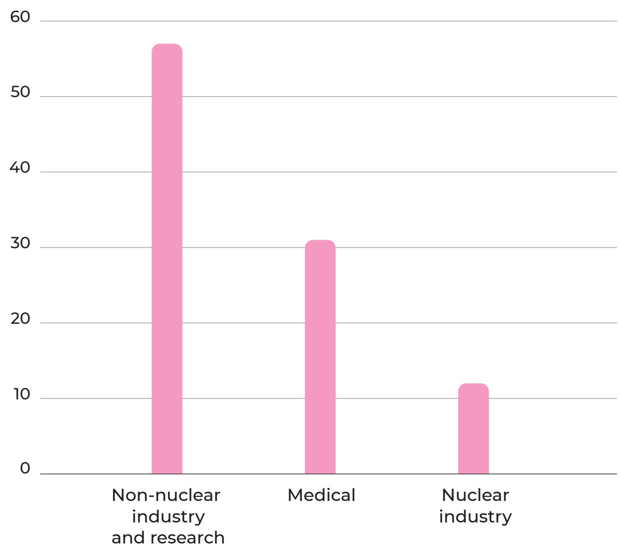
Most of the packages transported are intended for the non-nuclear industry, or for non-nuclear research: this mainly involves devices containing radioactive sources which are not used in a single location and which therefore need to be transported very frequently. For example, these could be devices 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 shipments 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.

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 transported to the nuclear medicine units, creating a large number of shipments, which have to be carried out correctly to ensure the continuity of the health care given. Most of these products have low 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 shipments are an integral part of the fuel cycle, owing to the distribution of the various facilities and Nuclear Power Plants (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

GRAPH 1

Proportion of packages transported per field of activity in%



Transport operations relating to the fuel cycle in France

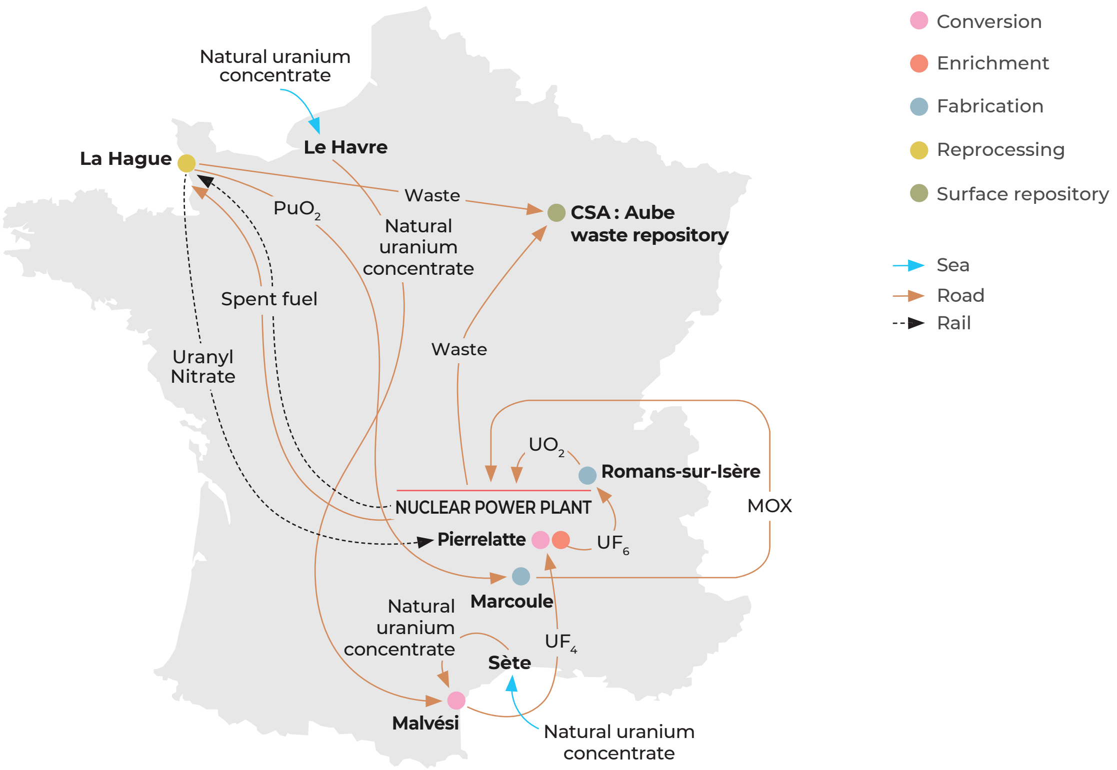


TABLE 1

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

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 Orano reprocessing plant at La Hague;
- about 100 shipments of plutonium in oxide form between the La Hague reprocessing plant and the Melox fuel production plant in the Gard *département*;
- 250 shipments of uranium hexafluoride (UF_6) used for fuel fabrication;
- 400 shipments of fresh uranium-based fuel and some fifty shipments of fresh uranium and plutonium-based MOX (mixed oxides) fuel;
- 2,000 shipments from or to foreign countries or transiting *via* France, representing about 58,000 packages shipped (industrial, A and B type packages).

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 –Basic Nuclear Installations (BNIs), laboratories, hospitals, source suppliers and users, etc.–, as well as on reports from the transport safety advisers. A summary is available on *asn.fr* ("Information" heading).

2. Regulations governing the transport of radioactive substances

Given that shipments can cross borders, the regulations governing the transport of radioactive substances are based on international requirements established by the International Atomic Energy Agency (IAEA). They are contained in the document entitled "*Specific Safety Requirements – 6*" (SSR-6), which constitutes the basis for European and French regulations on the subject.

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 shielding provided by the packaging, (the shielding reduces the radiation in 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.

In addition, radioactive substances may 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 NPPs 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 BNIs, the personnel of the companies concerned are generally unable to intervene immediately, or even to give the alert (if the driver is killed in the accident) and the first responding emergency services are unlikely to be specialists in dealing with a radioactive hazard.

Recognizing these specificities, dedicated regulations have been set up to regulate 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 ensure 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 if the implications so warrant. To ensure 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 relies on 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 preparedness and response, so that the consequences of incidents and accidents are 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 development of emergency plans and the performance of emergency exercises.

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 ensuring 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 accidents, following which the safety functions must still be guaranteed. The severity of the regulatory tests is graded according 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 implications, these packages are not subject to any reference tests. They must nevertheless comply with some general specifications, including for radiation safety, to ensure that the radiation around the excepted packages remains very low.

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%
Packages not requiring approval by ASN	Industrial packages not containing fissile radioactive substances	8%
Packages not requiring approval by ASN	Excepted packages	58%

2.3.2 Type A packages and industrial packages containing non-fissile substances

Type A packages can, for example, be used to transport radionuclides 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, fall 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 1 m.

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 industrial packages. Three sub-categories of industrial packages exist according to the hazards 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 the destruction of a type A package or an industrial package would remain manageable, provided that appropriate accident 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 implications, 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 case 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, A or B type 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 industrial 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 substances and ensure radiological protection (for type B packages) as well as sub-criticality (for packages containing fissile materials). The accident conditions are simulated by the following tests:
- A 9 m 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 colliding with 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.

The first three tests (drop, penetration and fire test) must be performed in sequence on the same package specimen. They must be performed in the most penalising configuration (package orientation, ambient 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 case provided to ASN. 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), or 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 30C metal cylinders. In the case of enriched UF_6, this cylinder is transported within 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 are no approved type C packages for civil uses.

2.4 The requirements ensuring 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 mSv/year (millisievert per year). However, this limit is not intended to be an authorisation to expose the public to up to 1 mSv. Moreover, the justification and optimisation principles applicable to all nuclear activities also apply to the transport of radioactive substances (see chapter 2).

Radiation protection is the subject of specific requirements in the regulations applicable to the transport of radioactive substances. Thus, for transport by road, the regulations stipulate that the dose rate at the surface of the package must not exceed 2 mSv/h (millisievert per hour). This limit may be raised to 10 mSv/h in "exclusive use"[1] conditions, because the consignor or consignee can then issue instructions to restrict activities in the vicinity of the package. In any case, the dose rate 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 2 metres from the vehicle for the dose received to reach the annual public exposure limit.

These limits are supplemented by requirements relative to the organisation of radiation protection within companies. The 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 arising from 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)[2]: 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 it could exceed 1 mSv/year. Finally, all the transport players 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.

Prevention of risks of exposure to ionising radiation

The joint ASN and Ministry for Labour instruction DGT/ASN/2018/229 of 2 October 2018, concerning the prevention of risks of exposure to ionising radiation, extends the scope of application of the notion of "radiological zoning", which aims to limit worker and public exposure, to the transfer of radioactive substances within a facility, its annexes or worksites. Thus, the phases of package loading or unloading on a conveyance, modification of a shipment, transhipment or temporary parking within the perimeter of a facility or its annexes can lead to the implementation of a "monitored" or "controlled" zone, depending on the characteristics of the packages carried.

On 29 March 2018, ASN published Guide No. 29 to help carriers meet their regulatory obligations relative to the radiation protection of workers and the general public. ASN intends to update this guide in 2020, to take account of the updated provisions of the Labour Code and Public Health Code resulting from the transposition of EU Directive 2013/59/Euratom (known as the "BSS" Directive). In 2020, it will continue with measures to educate professionals, dealing more specifically with changes to the regulations.

2.4.2 Package and vehicle marking

So that the workers can be informed of the level of risk arising from 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, 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 display 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.

1. 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.

2. The ALARA (As Low As Reasonably Achievable) principle appeared for the first time in Publication 26 from the International Commission on Radiological Protection (ICRP) in 1977. It was the result of a process of reflection on the principle of optimising radiological protection.

Creation of a system of authorisation for security reasons

Pursuant to Articles L. 1333-8 and R. 1333-146 of the Public Health Code, ASN intends in 2020 to revise its resolution 2015-DC-0503 on the system of notification for companies transporting radioactive substances on French territory, so that the transport operations involving the most radioactive sources will be subject to authorisation owing to their security implications. Authorisation will therefore be required for the transport of sealed radioactive sources, or batches of category A, B or C sources, as defined in Annex 13-7 to the Public Health Code.

2.4.3 Responsibilities of the various 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 substance 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 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 conveyance, the carrier and the itinerary, in compliance with the regulatory requirements.
- 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 and, more particularly, the driver, is responsible for carriage of the shipment to its destination. Their duties include checking 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 display of the orange plates and placards.
- The consignee is under the obligation not to postpone acceptance of the goods, without imperative reason and, after unloading, to verify that the requirements concerning them have been satisfied. It must more specifically perform 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 case and the approval certificate in order to guarantee that the elements important for safety are maintained in good condition.

All the transport players must set up a quality management system, which consists of a range of provisions for meeting 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 and so on. The quality management 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.

Companies which carry, load, unload or handle (after loading and before unloading) packages of radioactive substances on French territory shall notify these transport activities to the ASN, using the ASN on-line portal[3], before carrying them out. This on-line portal has been available in English since mid-2019.

In addition, the transport of certain radioactive substances (notably fissile substances) must first be notified by the consignor to ASN and to the Ministry of the Interior, seven days prior to departure. This notification stipulates the materials carried, the packagings used, the transport conditions and the details of the consignor, 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 2019, 1,509 notifications were sent to ASN.

2.5 Preparedness for and response to emergencies

The management of emergency situations is the final level of defence in depth. In the event of an accident involving transport, it should be able to mitigate 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.

Identification of the hazard during road transport

In January 2018, ASN recommended that the road transport players fill out the UN(*) number and, as applicable, the hazard identification number on all the oranges-coloured plates of the transport unit if the load is radioactive and corresponds to a single UN number, whether or not carriage is under exclusive use. If this recommendation is not followed, alternative provisions, taking account of any security constraints, shall be made by the carrier or consignor. They must ensure that the first responder emergency services arriving on the scene of an accident can rapidly identify the type of radioactive substances being transported, including if the driver is incapable of providing information and if the transport documents are inaccessible.

** United Nations.*

3. *https://teleservices.asn.fr.*

Modification of the "TMD Order": incident and accident management plan

The "TMD Order" of 29 May 2009 was modified by an Order of 11 December 2018 more specifically to clarify the contents of the radioactive materials transport incident and accident management plan. This plan must therefore in particular describe:

- the internal organisation of the company for managing an incident or accident;
- the incident or accident detection procedures, the criteria for triggering the management plan and the procedures for alerting and informing the emergency services or competent authorities;
- the technical and human resources envisaged, which could contribute to managing an incident or accident;
- how the management plan is kept up-to-date, more specifically including emergency training of the transport personnel and exercises or simulations.

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 cooperate with the public authorities to assist with the response operations, including 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 develop emergency response plans allowing the organisation and tools to be defined in advance, enabling them to react efficiently in the event of an actual 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 instructed to automatically evacuate an area with a radius of 100 m around the vehicle, unless specific information is available, and to 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. 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, Institute for Radioprotection and Nuclear Safety (IRSN) assists ASN by assessing the condition of the damaged 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). 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; the Prefect could also, if necessary, requisition the mobile units of certain nuclear licensees (such as the Alternative Energies and Atomic Energy commission –CEA, or EDF) even if the shipment in question does not concern these licensees.

As with other types of emergency, communication is an important factor in the event of a transport accident so that the population can be informed of the situation and be 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.

ASN will continue in 2020 to support adequate 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.

Finally, ASN intends in 2020 to update the Guide on the performance of risk assessments required for transport hubs able to accommodate dangerous goods. The purpose of this guide is to ensure that the risks linked to radioactive substances are adequately assessed, to enable the licensees to define any relevant measures needed to reduce them, under the supervision of the Prefect. It will also tie in with the assessments of the consequences of a severe hazard on a high-risk package, carried out as part of the stress tests performed in the wake of the Fukushima Daiichi NPP (Japan) accident on 11 March 2011. In order to learn the lessons from this accident, ASN asked the BNI licensees to carry out stress tests to examine the safety of the facilities in the event of a low-probability accident but one which could have major consequences for public health and safety and protection of the environment. As radioactive substances are transported on the public highway, the possibility of an accident of an intensity exceeding the package design criteria set by the regulations cannot be ruled out. For packages carrying the most dangerous contents, the consequences for persons and the environment could be significant.

• 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:

- 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.
- 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.
- Once the ASN and IRSN emergency centres are operational, a more detailed analysis of the situation is performed 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 produced

Radiological measurement of an industrial package prior to shipment

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.

2.6 Regulations 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 roads. However, these operations present the same risks and detrimental effects as those in the public domain. The safety of these transport operations must thus be overseen with the same rigour as for any other risk or detrimental effect generated by operation of the BNI.

This is why, since 1 July 2013, the on-site transport of dangerous goods has been subject to the requirements of the Order of 7 February 2012 setting out the general rules applicable to BNIs. This Order requires that on-site transport operations be incorporated into the safety baseline requirements for BNIs.

The Environment Code, supplemented by ASN resolution 2017-DC-0616 of 30 November 2017, defines the on-site transport operations for which authorisation must be requested from ASN. In addition, in 2017, ASN published Guide No. 34 providing the licensees with recommendations for implementing the regulatory requirements concerning on-site transport operations.

In 2019, ASN examined on-site transport authorisation applications for CEA, EDF, Orano Tricastin and Orano La Hague. In 2020, ASN will examine authorisation applications to improve the robustness of certain on-site transport systems used by Orano La Hague.

Finally, in 2020, ASN will extend the on-line notification and on-line transmission functions to deal with requests for noteworthy changes to on-site transports as set out in Articles R. 593-59 and R. 593-56 of the Environment Code.

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 the Defence Nuclear Safety Authority (ASND) 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 and so on.

3.2 Protection against malicious acts

The prevention of malicious acts consists in preventing sabotage, losses, disappearance, theft and misappropriation of nuclear materials (as defined in Article R*.1411-11-19 of the Defence Code) 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.

In the field of transport security, the IRSN Transport Operations Section (EOT) is responsible for managing and processing applications for approval of nuclear material shipments, for supervising these transports and for notifying the authorities of any alerts concerning them. This security duty is defined by the Order of 18 August 2010 relative to the protection and regulation of nuclear materials during transport. Thus, prior to any transport operation, the Defence Code obliges the carriers to obtain a transport authorisation. The EOT reviews the corresponding application files. This review consists in checking the conformity of the intended provisions with the requirements defined by the Defence Code and the above-mentioned Order of 18 August 2010.

ASN has initiated the process to update its resolution 2015-DC-0503 of 12 March 2015 relative to the notification system for companies transporting radioactive substances on French soil. This update aims to introduce an authorisation system for the transport of the most radioactive sources, in the light of their safety and security implications.

In 2019, ASN held a public consultation on the orientations it was planning to adopt for this update. In 2020, ASN will complete this update, notably focusing on the interface between the provisions set by the new regulations on the protection of ionising radiation sources and batches of category A, B, C and D radioactive sources against malicious acts (Order of 29 November 2019) and the transport regulations.

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 (MTMD) of the Ministry responsible for the environment. 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 –Interministerial Hazardous Materials Transport Committee (CITMD)– 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 Regional Directorates for the Environment, Planning and Housing (Dreals).

For the regulation of dangerous goods to be as consistent as possible overall, ASN collaborates regularly with the authorities concerned.

In 2020, as was the case in 2019, ASN will take part in the training of General Directorate for Civil Aviation (DGAC) staff responsible for the inspection of air transport of hazardous goods in order to present the specificities of class 7 and to share 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 Issuance 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 kilogramme of UF_6 must be covered by an ASN approval certificate. The designers of the package models who request approval from ASN must support their application with a safety case demonstrating the compliance of their package with all the regulatory requirements. Before deciding whether or not to issue an approval certificate, ASN reviews these safety cases, drawing on the expertise of IRSN, in order to ensure that the safety cases are pertinent and conclusive. If necessary, the approval certificate is issued with requests in order to further improve the safety cases.

In some cases the IRSN appraisal is supplemented by a meeting of the ASN Advisory Committee for Transports (GPT). The opinions of the Advisory Committees are always published on *asn.fr*. 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 actual shipment itself, for which no prior ASN opinion is generally required. This shipment may however be subject to restrictions or specific conditions for security reasons (physical protection of the materials against malicious acts under the supervision of the HFDS of the Ministry for the Environment).

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 9m drop, a compensatory measure may be to reduce the speed of the vehicle, have it escorted and choose a route avoiding such a drop height. 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.

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 endorsed by ASN, which then issues a new certificate. In 2019, 38 approval applications were submitted to ASN by the manufacturers.

ASN delivered 34 approval certificates or shipment approvals, for which the breakdown by type is shown in Graph 2. The nature of the transport operations and packages concerned by these approval certificates is shown in Graph 3.

In 2019, TN International began development work on a new packaging, called TN Eagle, designed for exclusive-use land and sea transport of spent fuel assemblies, as well as for their interim storage. At the end of 2019, ASN issued a favourable opinion on the safety options for this new package model, in the light of the new provisions of the 2018 edition of IAEA's SSR-6 regulations. In 2020, it will examine the approval application received at the end of December 2019.

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 2019, ASN carried out 91 inspections in the field of radioactive substances transport (all sectors considered). The follow-up letters to these inspections are available on *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 case, demonstrating regulatory compliance of the corresponding package model. To do this, it implements a quality management 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 as-built packagings are compliant with the specifications of the safety case.

The inspections carried out by ASN in this field aim to ensure that the manufacturer satisfactorily fulfils its responsibilities.

In 2019, ASN carried out six inspections on the manufacturing of various packagings for which ASN had issued an approval certificate, at various steps in the manufacturing process: welding, final assembly, manufacturing completion checks, assembly of internals (for immobilising the contents) and so on.

During these inspections, ASN reviews the quality management procedures implemented for the manufacture of a packaging on the basis of the design data and verifies their effective implementation. ASN ensures that the inspections performed by or on behalf of the manufacturer and any known manufacturing deviations are documented. It also visits the manufacturing shops to check the package components storage conditions, the calibration of the inspection instruments and compliance

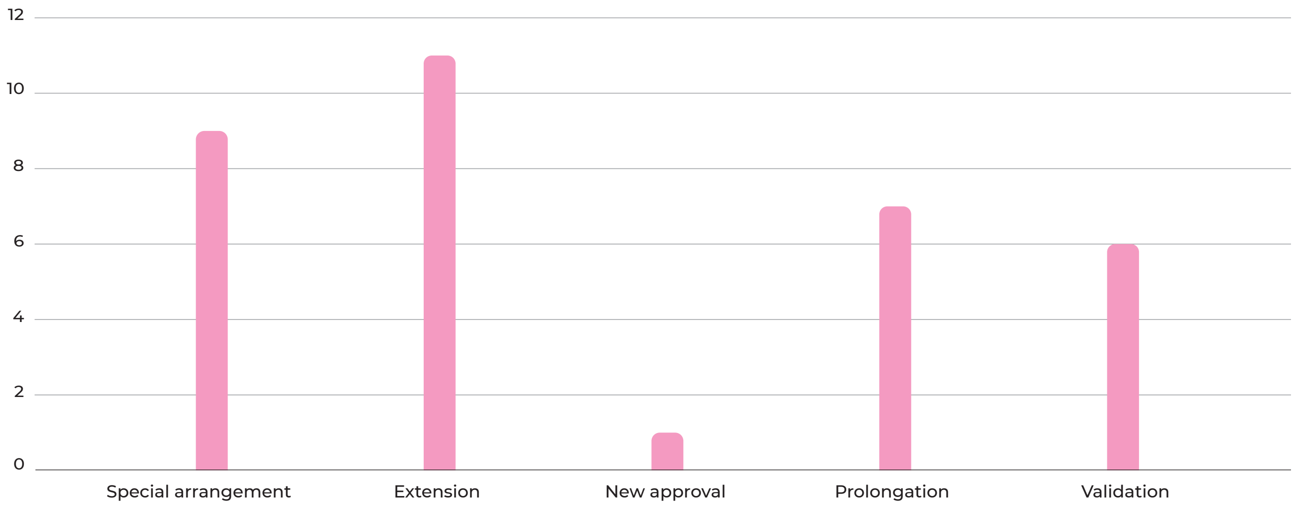
TABLE 3

Administrations responsible for regulating the mode of transport and the package

MODE OF TRANSPORT	REGULATION OF MODE OF TRANSPORT	PACKAGE REGULATION
Sea	Directorate General for Infrastructures, Transports and the Sea (DGITM) at the Ministry for the Environment. 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 the Environment.	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 for Civil Aviation (DGAC) at the Ministry for the Environment.	The DGAC has competence for regulation of dangerous goods packages in general and, in close collaboration with ASN, of radioactive substances packages.

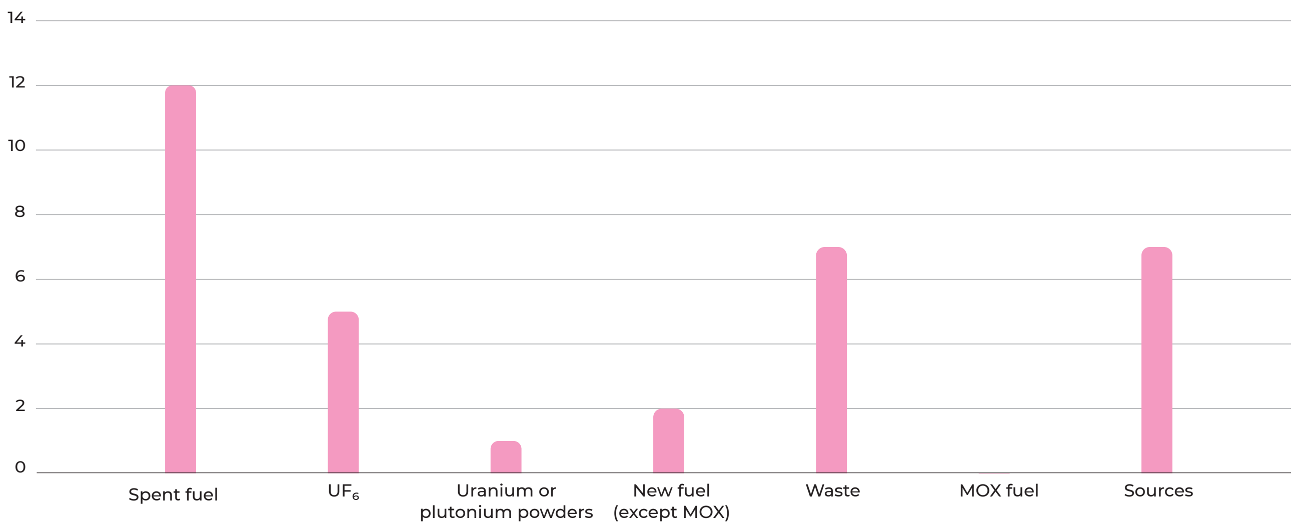
GRAPH 2

Breakdown of number of approvals according to type, in 2019



GRAPH 3

Breakdown of number of approvals according to content transported, in 2019



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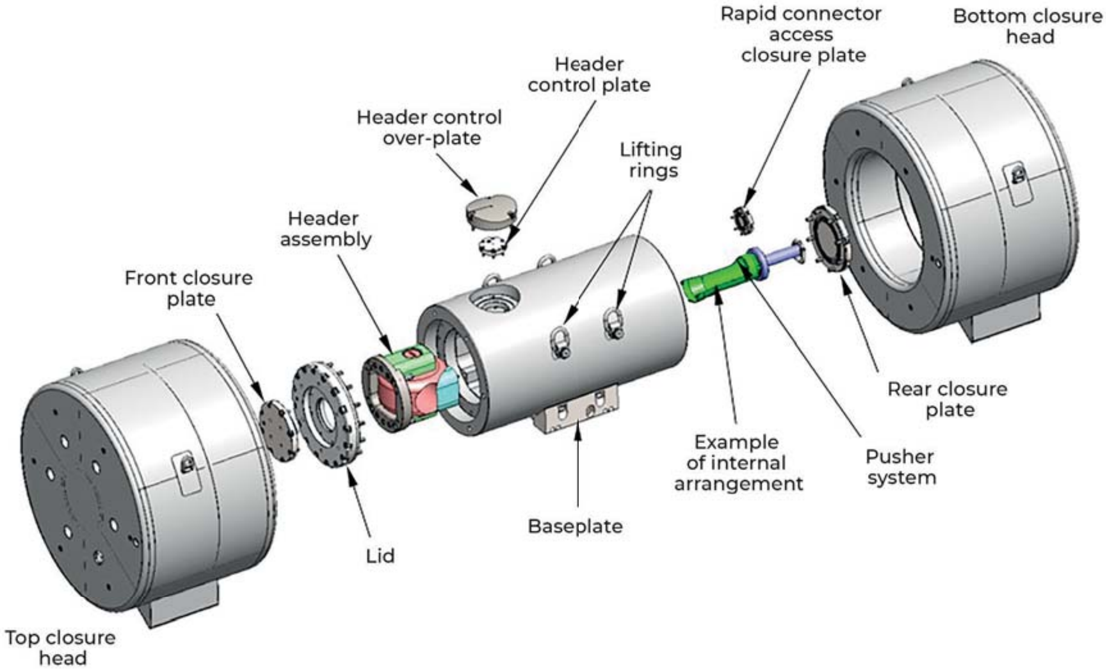
Certificate of approval for the TN Lab package



On 26 June 2019, ASN issued a type B(U) approval certificate for the new TN Lab package model developed by TN International (subsidiary of Orano). This new package model is designed for transport in the public domain of small quantities of radioactive materials in various forms, not only by road and sea, by also by air. This package is intended for research laboratories which need to ship and receive various types of fuel samples (whether or not irradiated), activated material, or radioactive sources.

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. For example, on 10 and 11 December 2019, in a plant in Germany, ASN and the German authority with competence for transport (BAM), jointly inspected, the manufacture of new DN 30 overpacks used to transport UF_6 in 30 B cylinders. One point investigated by the inspectors was how Daher, the ordering customer, monitored its subcontractor.

ASN may also inspect the manufacture of the specimens used for the drop tests and fire tests required by the regulations. 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.

In 2020, ASN intends to continue spot-check inspections of transport packaging manufacturing. This is because the irregularities detected at the Creusot Forge plant, some of which affected a few transport packagings, confirmed the importance of inspecting the packaging manufacturing and maintenance operations.

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 case and its approval certificate, even after repeated use. For approved packagings, the topics addressed during ASN inspections on maintenance activities include, 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 packaging components which must take account of any reduction in performance due to wear, corrosion, ageing, etc.

In 2019, ASN carried out three inspections on the conformity of maintenance operations. For example, on 4 November 2019, ASN inspected the maintenance carried out by the Curium company on packagings intended for the transport of radiopharmaceutical products. The ASN inspectors reviewed, among other aspects, the organisation put into place by Curium to ensure the compliance of the maintenance and inspection operations with the requirements of the safety case.

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 declaration of conformity delivered by the manufacturer attesting full compliance with the model specifications, must be available for ASN review, if needed.

The inspections carried out in recent years confirm progress in compliance with this requirement and in implementation of the ASN recommendations detailed in its guide concerning packages which are not subject to approval (Guide No. 7, volume 3).

This guide, updated in 2016, proposes a structure and a minimum content for the safety cases 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 declaration of conformity and the safety case drawn up by the relevant players, 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 shortcomings in the demonstration by some of the players (designers, manufacturers, distributors, owners, consignors, companies performing the regulatory drop tests, package maintenance, etc.) 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 is no loss or dispersion of the radioactive content under normal conditions of transport;
- 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 rate limits with the maximum authorised content.

ASN inspection of manufacture of a TN G3 package – November 2019

4.2.4 Monitoring the shipment and transportation of packages

The scope of ASN inspections includes all regulatory requirements binding on each of the transport players, 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 assurance programme, etc.

More particularly with respect to transports concerning small-scale nuclear activities, the ASN inspections confirm significant disparities from one carrier to another. The differences most frequently identified concern quality management, actual compliance with the procedures put into place and radiation protection of the workers.

ASN inspection in 2019 of packages not requiring approval

In 2019, ASN carried out five inspections on the design, manufacture and maintenance of packages not requiring approval. It more specifically inspected the compliance of the packages designed, manufactured, marketed and maintained by the CNMO company with the regulations for the transport of radioactive substances. These packages, referred to as type A under the regulations, are more specifically used to transport contaminated equipment, radioactive waste and other radioactive substances. CNMO was unable to demonstrate that it had set up an appropriate management system to control and monitor its design, manufacturing and maintenance activities regarding packagings for the transport of radioactive substances, as required by the applicable regulations. On this subject, no improvement with respect to the previous inspection in 2013 was observed.

If the consignor is unable to prove the compliance of the packages used with the regulations, the shipment cannot take place. ASN therefore required that CNMO inform its customers accordingly.

When taken individually, the packages not subject to approval represent little danger and accidents involving them have so far had limited radiological consequences. ASN must however remain vigilant given the very large number of these packages and the sometimes inadequate safety culture of those involved in their transport.

The conformity with regulatory requirements of the packages not requiring approval has improved in recent years, although some deviations persist. In 2020, ASN will therefore continue its efforts regarding the monitoring of package models not requiring approval.

Inspection of the removal of spent fuel from the Civaux NPP

In June 2019, the ASN inspectors went to the Civaux NPP to control the shipment of a package loaded with spent fuel assemblies. They focused more specifically on the site's radiological protection programme, the analysis of transport events, the activities of the Transport Safety Adviser (CST) and the oversight by EDF of contractors involved in the transport of radioactive substances. They checked the site's last two shipment files. They also checked compliance with the provisions of the package model approval certificates and the confined environment transport authorisations issued by ASN. They visited the NPP's rail siding, the buildings in which the transport operations are carried out and the stabling area where the rail wagons are loaded.

Following this examination, the inspectors concluded that the organisation put into place by the Civaux NPP to ensure the safety of the spent fuel shipment operations is on the whole satisfactory. They found that the Civaux NPP had effectively implemented the actions decided on for the EDF NPP fleet in order to prevent the risk of contamination of the wagon recovery pans.

Nonetheless, improvements are still needed to take greater account of radiation protection in transport activities, especially to ensure appropriate demarcation and signage around the wagons stabling area during spent fuel package preparation operations.

Knowledge of the regulations applicable to the transport of radioactive substances seems to be sub-standard 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. Their quality management system has not yet been formally set out and deployed, more specifically with regard to the responsibilities of each member of staff involved in receiving and dispatching packages.

More generally, in transport operations for small-scale nuclear activities, the radiological protection programmes and the safety protocols have not yet been systematically defined. ASN also found that checks on vehicles and packages prior to shipment could be improved. The inspections concerning the transport of gamma ray projectors regularly reveal inappropriate stowage or tie-down.

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 cases, including if this demonstration is provided by a third-party. In this latter case, the consignor's responsibilities require that it verify that this demonstration is appropriate, and that it monitor the third-party company in accordance with the usual methods of a quality assurance system.

As BNI licensees are increasingly using contractors to prepare and ship packages of radioactive substances, ASN is paying particularly close attention to the organisation put into place to monitor these contractors.

Finally, with regard to on-site transports within NPPs, ASN considers that the licensees must remain vigilant to the application of package stowage and tie-down rules.

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 production of plans to prepare for emergency management and stipulates their minimum contents.

This topic is reviewed during ASN inspections. For example, in 2019, an inspection on preparedness for emergency situations was held at the carrier Précotrans. The inspectors paid particular attention to the organisation in place, the material and human resources available and personnel training. They concluded that preparedness for emergency situations was satisfactory, even though the radioactive substances transport emergency plan had yet to be formally set out.

4.2.6 Analysis of transport events

The safety of the transport of radioactive substances relies, among other things, on the existence of an effective 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 developing 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 requires on-line notification to ASN of the most significant events so that ASN can ensure that the detection system, the analysis approach and the integration of operating experience feedback are effective. 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 ASN 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 No. 31 and as required by Article 7 of the Order of 29 May 2009, amended, on the transport of dangerous goods by road. This guide was entirely revised in 2017 and is available on *asn.fr*. After notification, a detailed event report must be sent to ASN within two months.

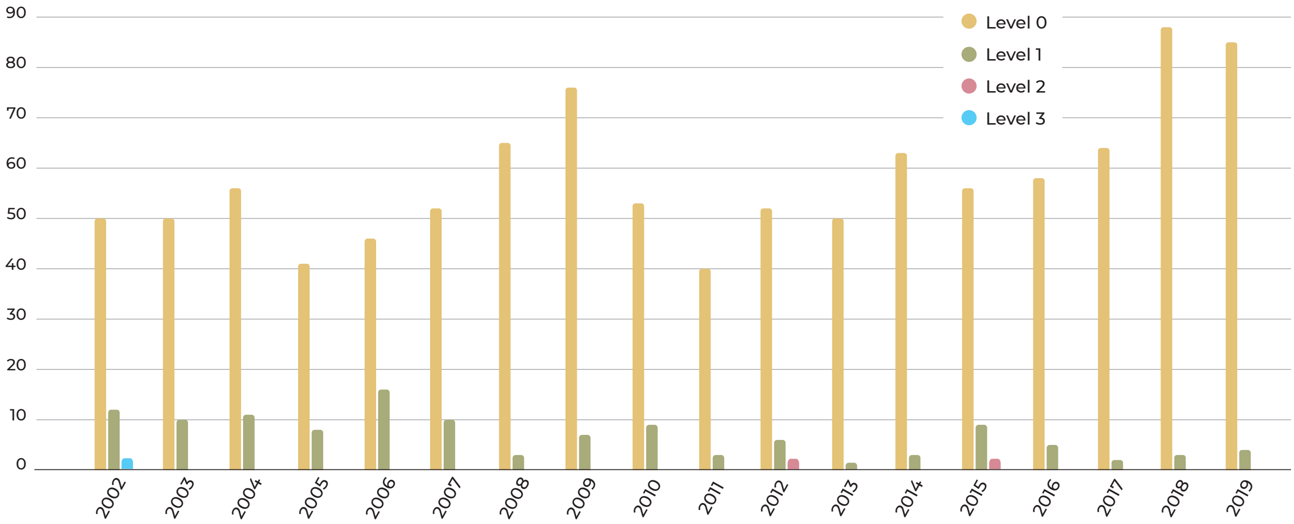
• Events notified in 2019

In 2019, in the field of radioactive substances transport, ASN was notified of 85 events rated level 0 on the International Nuclear and Radiological Event Scale (INES) and 4 events rated level 1. These figures are stable with respect to 2018. Graph 4 shows the trend in the number of significant events notified since 2002.

In addition, ASN was notified of 34 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. There is thus no obligation to notify ASN of them, although ASN nonetheless recommends that it be kept periodically informed in order to have an overview of the

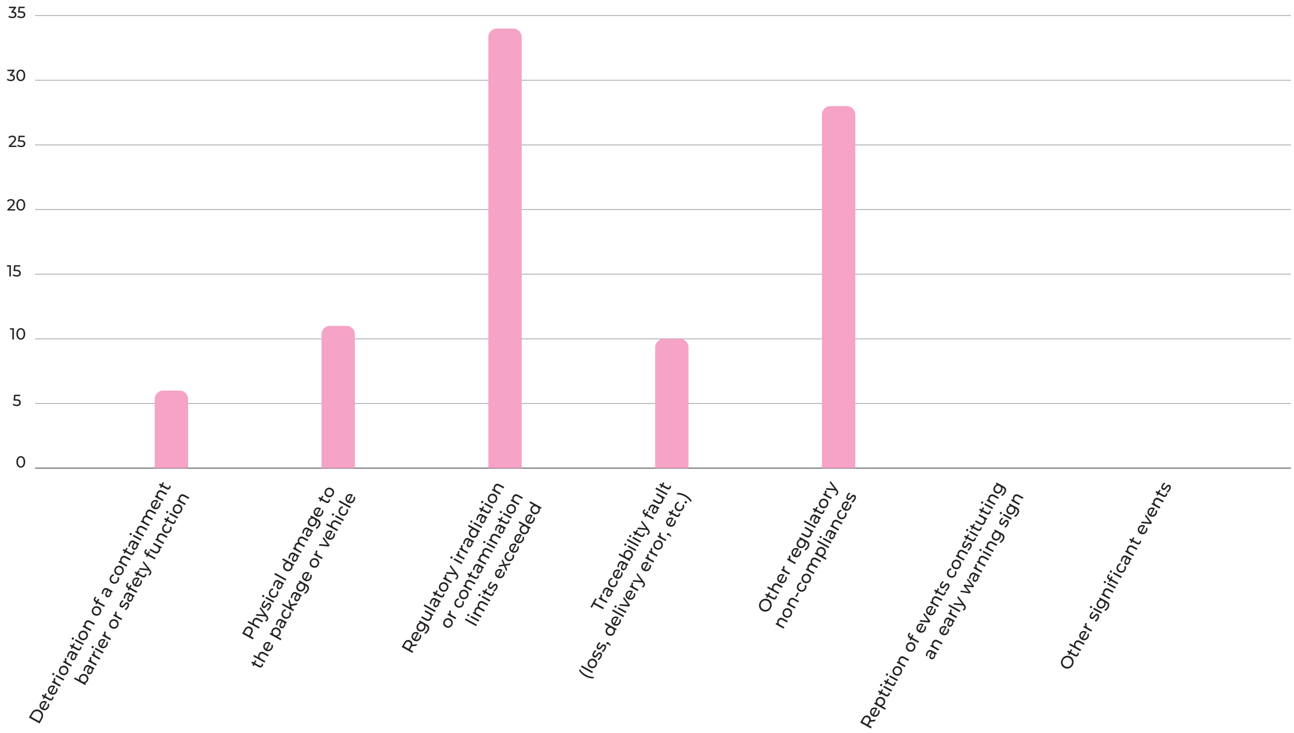
GRAPH 4

Trend in the number of significant events affecting the transport of radioactive substances notified between 2002 and 2019



GRAPH 5

Breakdown of significant events notified in 2019 by notification criterion



various events of lesser importance and detect any accumulation or any trends which could be indicative of a safety issue.

• Sectors concerned by these events

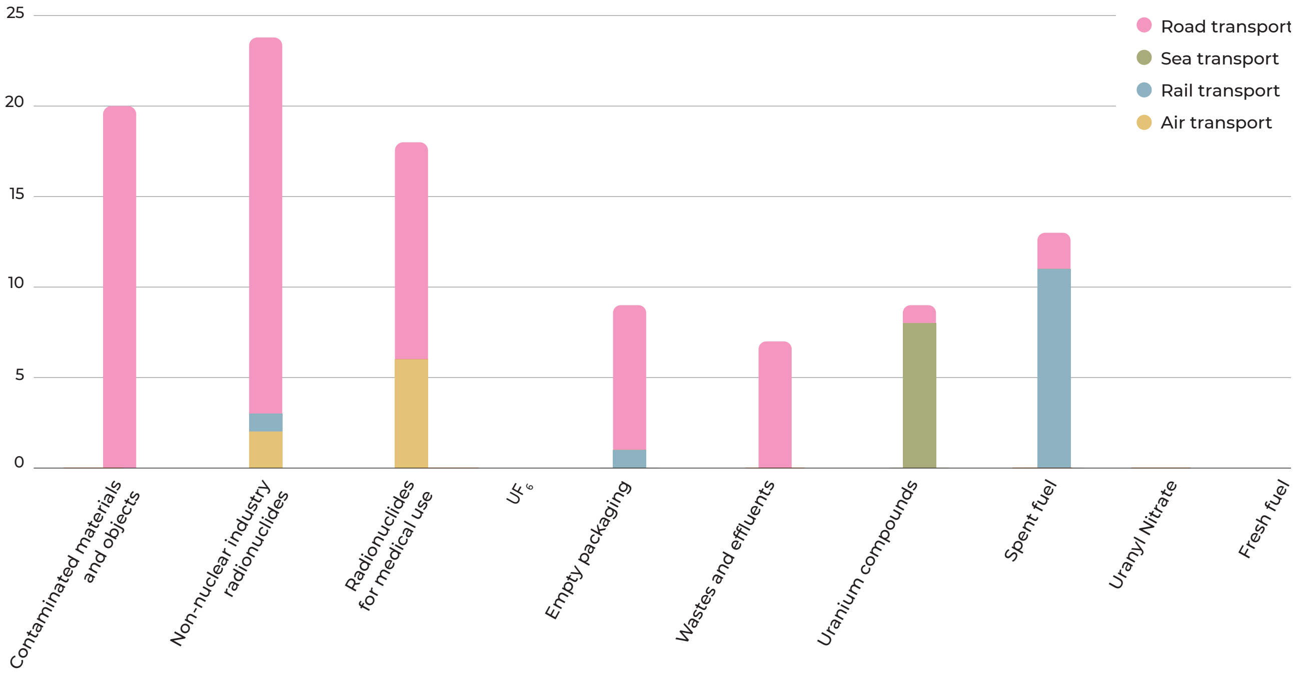
More than half of the significant events notified concern the nuclear industry. Nearly one quarter concern transports linked to the activities of the non-nuclear industry (transport of gamma ray projectors, for example). One fifth concerns the transport of radiopharmaceuticals.

When compared with the transport traffic concerned, the non-nuclear industry and medical sectors still report few transport-related events. This low rate can be explained by unfamiliarity with the process and the overall purpose of the event notification, as well as by the lesser safety implications of the radioactive contents being transported. However, ASN observes a significant rise in the number of events reported in 2018 and 2019 by comparison with previous years, which could be the result of ASN's communication actions, with the publication of its Guide No. 31 in 2017 and the creation of its on-line service for reporting events.

Graph 5 shows the breakdown of significant events reported according to notification criterion and Graph 6 presents the breakdown according to content and mode of transport.

GRAPH 6

Breakdown of notified transport events by content and mode of transport in 2019



Events related to the transport of ore from third-party countries

Recurring deviations have been observed in fuel cycle natural uranium ore transports from mines in Central Asia, Africa and Australia: on their arrival in France, contamination spots exceeding the regulation limits and damaged drums are discovered. ASN found a slight improvement in the situation by comparison with 2017 but, together with the transport stakeholders and ordering parties, is continuing to work to improve the transport conditions for these packages.

On-line notification of transport events

The publication of the Order of 11 December 2018 modifying the Order of 29 May 2009 concerning the transport of dangerous goods by road, makes the use of ASN's on-line services portal mandatory from 1 January 2019, for the notification of significant events concerning the transport of radioactive substances on the public domain. With a view to harmonisation, the capabilities of the on-line services portal were extended mid-2019 to enable the notification of dangerous goods on-site transport events within BNIs.

Notification of an event as stipulated in ASN Guide No. 31 does not replace the immediate alert to ASN in case of any emergency situation, as required by the regulations.

ASN observes that most EITs are reported by nuclear industry players, with few reports from players in the medical and non-nuclear industry sectors when one considers the transport traffic concerned. ASN does however point out that notification of EITs is not a regulatory obligation.

In 2019, four significant events rated level 1 on the INES scale were reported to ASN. Three events concerned two thefts of equipment containing low-level sealed radioactive sources used by the industry and one loss of radiopharmaceutical packages during transhipment in a foreign airport. The fourth event concerned exposure above the 20 mSv/year regulation limit of a driver transporting radiopharmaceutical products.

• Causes of events

The recurring causes of the significant events notified include the following:

- material non-conformities affecting a package: error in the hypothesis for calculating the leaktightness, loosening of fasteners during transport, procurement of partially non-conforming spares. These events had no actual consequences for safety or radiation protection. However, in the event of an accident, a non-conformity can impair the robustness of the package;
- stowage errors concerning contaminated equipment and tools transported in containers and deformation of these containers;
- the shipment of packages containing radioactive substances by unauthorised conveyance, as well as delivery errors or packages being temporarily mislaid;
- the presence of contamination spots exceeding the regulatory limits, detected on drums containing natural uranium ore transported in containers, in containers transporting contaminated equipment and tools, on conveyances which have been used to transport spent fuel packages. With regard to radiation protection, the impact of these events is low because the contamination spots detected were inaccessible.

2018 edition of the IAEA Safety Requirement on the radioactive materials transport regulations (SSR-6)

The main changes introduced into the 2018 edition of the transport regulations by comparison with the previous 2012 edition, concern:

- **improved management of the packages used both for carriage and storage operations (dual-purpose cask or DPC);**
- **the creation of SCO-III objects for the transport of unpackaged voluminous items;**
- **greater account being taken of ageing when designing packages;**
- **reinforced protection of the plugs of UF_6 cylinders;**
- **abandonment of the leaching test for LSA-III materials.**

The EIT reported to ASN are primarily deviations relating to incorrect labelling of packages, the absence of transport documents, delivery errors and the discovery of foreign objects in empty packagings used to transport spent fuel. These foreign objects are discovered during packaging maintenance operations. The analysis of these events shows that, should these foreign objects be larger or of a different nature, radiolysis or criticality phenomena may occur in certain conditions. ASN therefore requested that the licensees maintain particular vigilance when preparing for and loading fuel in the packagings.

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 IAEA Transport Safety Standards Committee (TRANSSC) which brings together experts from all countries in order to review the draft IAEA safety standards constituting the basis of regulations concerning the transport of radioactive substances. For example, with a view to constant improvement of safety levels, ASN played an active part in drafting the 2018 edition of this document, SSR-6, a French translation of which has been available since mid-2019. The publication of the IAEA Safety Guide "Advisory Material for the IAEA Regulations for the Safe Transport of Radioactive Material" (SSG-26) is expected in 2020.

4.3.2 Participation in drafting of national regulations

ASN takes part in the drafting of French regulations relative to the transport of radioactive substances. These regulations mainly consist of the Order of 29 May 2009 and the Orders of 23 November 1987 concerning the safety of ships and of 18 July 2000 concerning the transport and handling of dangerous materials in sea ports. In this respect, ASN sits on the CITMD that is consulted for its opinion on any draft regulations concerning the transport of dangerous goods by rail, road or inland waterway. ASN is also consulted by the Ministry responsible for transport when a modification of the three Orders mentioned above can have an impact on the transport of radioactive substances.

In 2019, ASN thus issued an opinion on a draft Order modifying the Orders of 23 November 1987 and 29 May 2009.

Moreover, in 2019, after considering the opinions of the CITMD, ASN renewed its approval of the Bureau Veritas Exploitation organisation for performance of conformity checks and the issuing of type approvals for tankers designed to transport radioactive substances, as well as its approval of the Form-Edit organisation for training drivers of road vehicles carrying radioactive substances.

Finally, the regulatory framework for the protection of radioactive substances against malicious acts, excluding nuclear materials already covered by a specific regulation, was reinforced in 2019: ASN ensured that transport operations, during which the substances are particularly vulnerable, were suitably incorporated into the Order of 29 November 2019 concerning the protection of ionising radiation sources and batches of radioactive sources of categories A, B, C and D against malicious acts.

Public debate on French National Radioactive Material and Waste Management Plan (PNGMDR); transport of radioactive substances

For the drafting of the new version of the PNGMDR, the National Public Debates Commission (CNDP) organised a meeting in Rouen on 4 July 2019 devoted to the topic of radioactive substances transport. After a presentation of the regulations by ASN and the Defence and Security High Official (HFDS) from the Ministry responsible for energy, followed by an implementation example at Orano, the discussions with the public mainly concerned:

- **the inherent robustness of the packages;**
- **the severity of the regulation tests with regard to the foreseeable accidents;**
- **the inspections carried out by ASN;**
- **management of accidents and the response by the public authorities;**
- **transport safety;**
- **responsibilities of the various transport players.**

4.4 Contributing to public information

Ordinance 2012-6 of 5 January 2012, modifying Books I and V of the Environment Code, extends the obligations for public information to any persons responsible for nuclear activities. Article L. 125-10 of the Environment Code sets the thresholds 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 their implementing texts, the transport of radioactive substances is subject to the issuance –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.

On *asn.fr*, ASN also provides an information file presenting the transport of radioactive substances.

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 improvement 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

A 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. France, which initiated the creation of this association, plays an active part in its work, including by presenting its views on the regulatory changes that may be needed, in particular on the occasion of the association's annual meeting.

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 radioactive 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
In relation to nuclear power plants in Belgium, French-designed packagings are sometimes used for fuel cycle shipments. 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. The exchanges more particularly concern the review of safety cases for French package models for which approval is validated in Belgium and inspection practices in each country. In 2019, the Belgian and French Authorities conducted two joint inspections, one at a carrier in France and the other in Belgium, in a plant manufacturing ASN-approved packagings.

• United Kingdom
ASN and the British regulator –Office for Nuclear Regulation (ONR)– share many subjects of interest, especially with regard to validation of English approvals by ASN and vice-versa. Bilateral contacts are held regularly to ensure good communications between these two Authorities. In 2019, prior to French validation of the English approval certificate, a joint inspection was held in Oxford on the manufacturing of the English Safkeg 2816G package.

• Switzerland
In 2012, ASN began bilateral exchange on transports with the Swiss Federal Nuclear Safety Inspectorate –called *Eidgenössisches Nuklearsicherheitsinspektorat,* ENSI in German (IFSN). Since then, ASN and IFSN have met annually in order to discuss the packaging model safety cases and the checks on the requirements associated with the correct utilization of these transport packages.

In 2019, these authorities inspected an operation to remove waste from the Leibstadt (KKL) NPP using a packaging of German design.

10.

THE EDF NUCLEAR POWER PLANTS

CHAPTER 10

The EDF Nuclear Power Plants

The electricity generating reactors are at the heart of the nuclear industry in France. Many other installations described in other chapters of this report produce the fuel intended for the Nuclear Power Plants (NPPs) or reprocess it, dispose of the waste from the NPPs or study physical phenomena related to the operation or safety of these reactors.

The French reactors are technically very similar and thus form a standardised fleet operated by EDF. Although this uniformity means that the licensee and ASN have extensive experience of their operation, it also means that there is a higher risk if a generic design, manufacturing or maintenance flaw is detected on one of these installations, as it could then affect all the reactors. ASN thus requires a high degree of reactivity and rigour on the part of EDF when analysing the generic nature of these flaws and their consequences for the protection of people and the environment, as well as when processing them.

ASN exercises extremely stringent oversight of safety, of environmental protection and radiation protection measures in the NPPs and continuously adapts it, in particular in the light of experience feedback from the design, manufacture, operation and maintenance of NPP reactor components. To monitor the safety of the reactors in operation, under construction or being planned, ASN mobilises nearly 200 staff on a daily basis in the Nuclear Power Plant Department (DCN), the Nuclear Pressure Equipment Department (DEP) and its regional divisions, and can draw on nearly 200 experts from the Institute for Radiation Protection and Nuclear Safety (IRSN).

ASN develops an integrated approach to the oversight of the facilities. It 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, environmental protection, radiation protection, occupational safety and the application of Labour Laws, at all stages. For each of these fields, it monitors all aspects, whether technical, organisational, or human. This approach requires that it take account of the interactions between these fields and that it define its monitoring actions accordingly. The resulting integrated overview enables ASN to fine-tune its assessment of the state of nuclear safety, radiation protection, environmental protection and worker protection within the NPPs.

1. General information about Nuclear Power Plants

1.1 General presentation of a Pressurised Water Reactor

By transferring heat from a hot source to a heat sink, an electricity generating thermal power plant produces mechanical energy that it converts into electricity. Conventional thermal power plants use the heat given off by the combustion of fossil fuels (fuel oil, coal, gas). Nuclear Power Plants (NPPs) use that given off by the fission of uranium or plutonium atoms. The heat produced in a Pressurised Water Reactor (PWR) leads to the creation of steam, which does not come into contact with the nuclear fuel. 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 water course (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 structures and possibly a cooling tower.

The nuclear island mainly comprises the reactor vessel, the reactor coolant system, the Steam Generators (SG) and the systems ensuring reactor operation and safety: the chemical and volumetric control, residual heat removal, safety injection, containment spray, SG feedwater supply, electrical, Instrumentation and Control (I&C) and reactor protection systems. These elements are also associated with systems providing support functions: monitoring and processing of primary effluents, water supply, ventilation and air-conditioning, back-up electricity supply (diesel electricity generating sets).

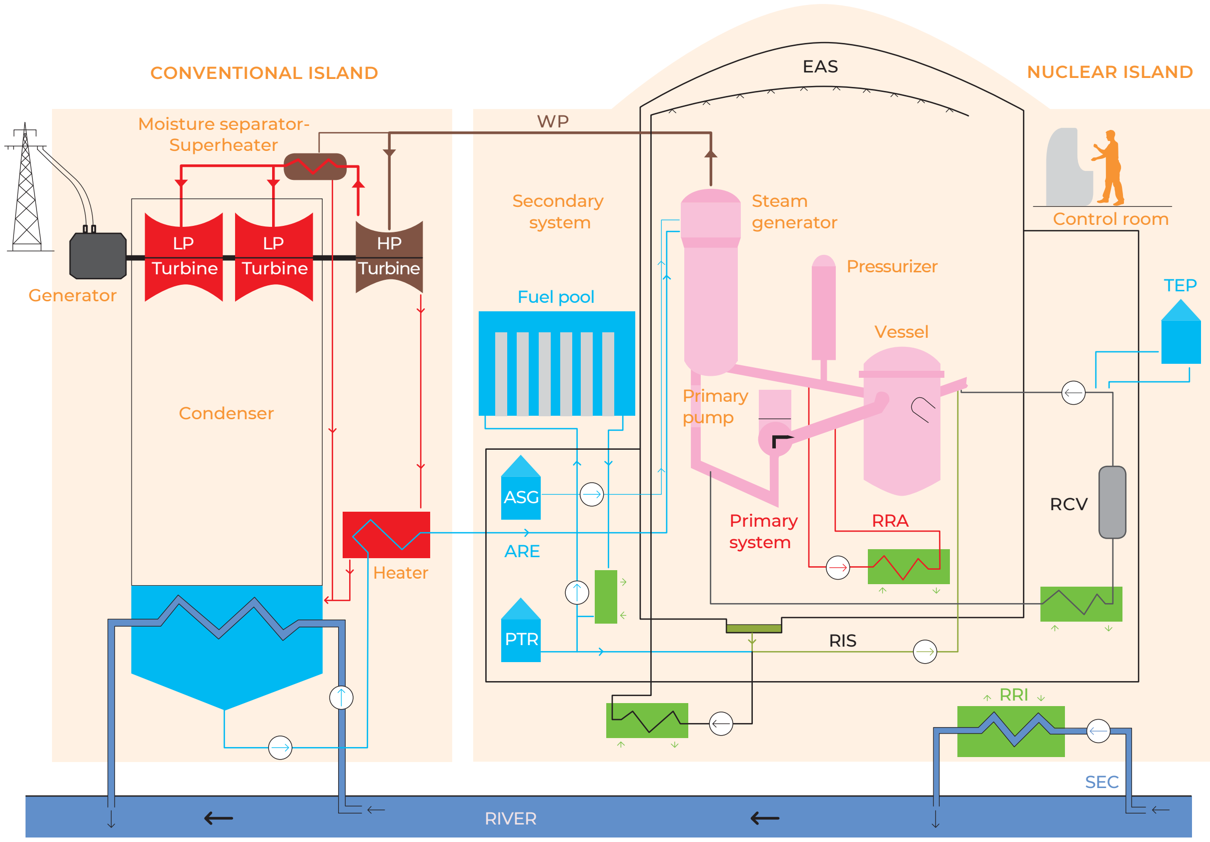
The nuclear island also comprises systems for the evacuation of steam to the conventional island, as well as the building housing the nuclear and spent fuel storage and Cooling Pool (BK). When mixed with boric acid, the water in this pool helps absorb the neutrons emitted by the nuclei of the fissile elements in the spent fuel, to avoid sustaining nuclear fission, to cool the spent fuel and to provide the workers with radiological protection.

The conventional island notably comprises the turbine, the generator and the condenser. Some components of these items take part in reactor safety. The secondary systems are partly in the nuclear island and partly in the conventional island.

1.2 The core, fuel and its management

The reactor core consists of fuel assemblies made up of "rods" comprising "pellets" of uranium oxide and depleted uranium oxide and plutonium oxide (for "MOX" fuels), contained in closed metal tubes, called "cladding". When fission occurs, the uranium

Pressurised water reactor operating principle



ARE: Feedwater Flow Control System
ASG: Auxiliary Feedwater System
EAS: Containment Spray System
PTR: Reactor Cavity and Spent Fuel Pit Cooling and Treatment System
RCV: Chemical and Volume Control System
RIS: Safety Injection System
RRA: Residual Heat Removal System
RRI: Component Cooling System
SEC: Essential Service Water System (ESWS)
TEP: Boron Recycle System
LP or HP Turbine: Low pressure or high pressure
VVP: Main Steam System

or plutonium nuclei, said to be "fissile", emit neutrons which in turn trigger other fissions: this is the chain reaction. The nuclear fissions give off a large amount of energy in the form of heat. The water in the reactor coolant system, which enters the lower part of the core at a temperature of about 285°C, heats up as it rises along the fuel rods and comes out through the top at a temperature of close to 320°C.

At the beginning of an operating cycle, the core has a considerable energy reserve. This gradually decreases during the cycle, as the fissile nuclei are consumed. The chain reaction and thus the power of the reactor is controlled by:

- the insertion of "control rod clusters" containing neutron-absorbing elements into the core to varying extents. This enables the reactor's reactivity to be controlled and its power adjusted to the required production of electricity. Gravity dropping of the control rods is used for emergency shutdown of the reactor;
- adjustment of the concentration of boron (neutron absorbing element) in the reactor coolant system water during the cycle according to the gradual depletion of the fissile elements in the fuel;
- the presence of neutron-absorbing elements in the fuel rods which, at the beginning of the cycle, compensate the excess core reactivity after partial renewal of the fuel.

At the end of the cycle, the reactor core is unloaded so that some of the fuel can be replaced.

EDF uses two types of nuclear fuel in the PWRs:

- uranium oxide (UO_2) based fuels enriched with uranium-235 to a maximum of 4.5% by mass. These fuels are fabricated in several French and foreign plants, by Framatome and Westinghouse;
- fuels consisting of a mixture of depleted uranium oxide and plutonium oxide (MOX). MOX fuel is produced by Orano's Melox plant. The maximum authorised plutonium content is currently set at 9.08% (on average per fuel assembly) giving an energy performance equivalent to UO_2 fuel enriched to 3.7% uranium 235. This fuel can be used in the twenty-eight 900 megawatt electric (MWe) reactors, for which the Creation Authorisation Decrees (DAC) authorise the use of plutonium 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 and its initial fissile material content;
- the maximum burnup of the fuel when removed from the reactor, characterising the quantity of energy extracted per ton of material, expressed in gigawatt days per tonne (GWd/t);
- the duration of a reactor operating cycle;
- the number of new fuel assemblies loaded following each reactor refuelling outage (generally one third or one quarter of the total number of assemblies).

1.3 The primary system and the secondary systems

The primary system and the secondary systems transport the energy given off by the core in the form of heat to a turbine generator set which produces electricity.

The reactor coolant system comprises cooling loops, of which there are three for a 900 MWe reactor and four for the 1,300 MWe, 1,450 MWe or 1,650 MWe Evolutionary Power Reactor (EPR) type reactors. The role of the reactor coolant system is to extract the heat given off by the core by means of circulating pressurised "primary water" or "reactor coolant". Each loop, connected to the reactor vessel containing the core, comprises a circulating pump, called the "reactor coolant pump" and a Steam Generator (SG). The reactor coolant, heated to more than 300°C, is maintained at a pressure of 155 bar by the pressuriser, to avoid boiling. The primary system is entirely situated within the containment.

The primary system coolant transfers its heat to the water of the secondary systems in the SGs. The SGs are heat exchangers which, depending on the model, contain from 3,500 to 5,600 tubes through which the reactor coolant circulates. These tubes are immersed in the secondary system, which thus boils without coming into contact with the reactor coolant.

Each secondary system primarily consists of a closed loop through which water passes, in the form of liquid in one part and in the form of steam in the other. The steam produced in the SGs is partially expanded in a high-pressure turbine and then passes through moisture separator-reheaters before entering the low-pressure turbines for final expansion, from which it passes to the condenser. Once condensed, the water is then sent to the SGs by the extraction pumps, followed by the feedwater pumps after passing through the reheaters.

1.4 The secondary system cooling system

The function of the secondary system cooling system is to condense the steam exiting the turbine. To do this, it has a condenser comprising a heat exchanger containing thousands of tubes through which cold water from outside (sea or river) circulates. On contact with these tubes, the steam condenses and can be returned in liquid form to the SGs (see point 1.3). The water in the cooling system heats up in the condenser and is then either discharged into the environment (once-through circuit) or, if the river discharge is too low or the heating too great for the sensitivity of the environment, is cooled in a Cooling Tower (TAR) –closed or semi-closed circuit.

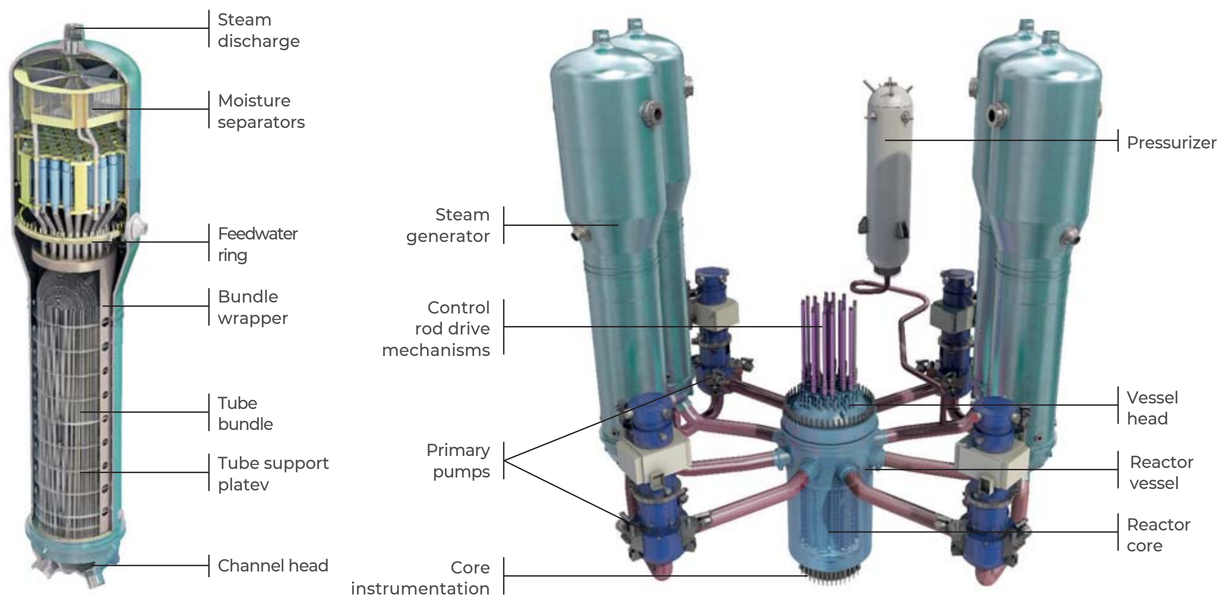
The cooling systems are environments favourable to the development of pathogenic micro-organisms. Replacing brass by titanium or stainless steel in the construction of riverside reactor condensers, in order to reduce metal discharges into the natural environment, requires the use of disinfectants, mainly by means of biocidal treatment. The copper contained in brass has bactericidal properties that titanium and stainless steels do not. Air cooling towers contribute to the atmospheric dispersal of legionella bacteria, whose proliferation can be prevented by stricter maintenance of the structures (descaling, implementation of biocidal treatment, etc.) and monitoring.

1.5 The containment

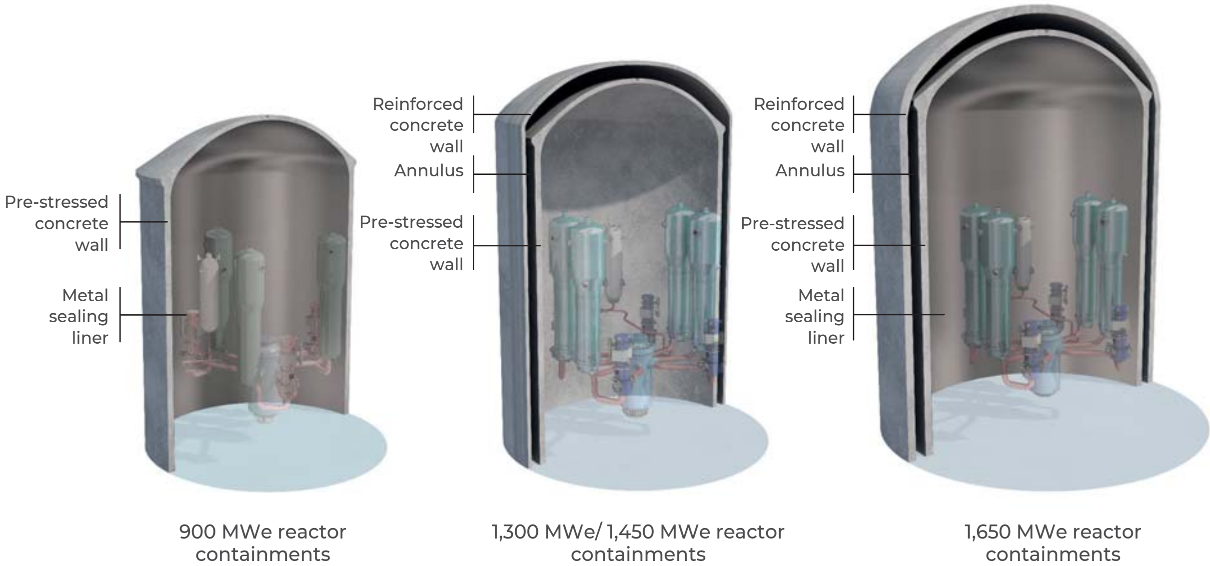
The pressurised water reactor containment performs two functions:
- the containment of radioactive substances liable to be dispersed in the event of an accident; to do this, the containments were designed to withstand the temperatures and pressures that would result from the most severe loss of coolant accident (double-ended circumferential rupture of a reactor coolant system pipe) and to ensure satisfactory leaktightness in these conditions;
- reactor protection against external hazards.

There are three containment model designs:
- Those of the 900 MWe reactors comprise a single pre-stressed concrete wall (concrete comprising steel tendons tensioned 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.
- Those of the 1,300 and 1,450 MWe reactors are made of two walls: the inner prestressed concrete wall and the outer reinforced concrete wall. Leaktightness is provided by the inner

A Steam Generator and a main primary system for a 1,300 MWe reactor



Reactor containments



wall and the Ventilation System (EDE) which, 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.
- That of the Flamanville EPR 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 and provide containment of radioactive substances. They mainly comprise the reactor's chemical and Volumetric Control System (RCV) and the reactor's Residual heat Removal System (RRA).

The role of the safeguard systems is to control and limit the consequences of incidents and accidents. This chiefly concerns the following systems:
- the Safety Injection System (SIS), the role of which is to inject water into the primary system in the event of it leaking;
- the reactor building Containment Spray System (EAS), the role of which is to reduce the temperature and thus the pressure in the containment, in the event of a major primary system leak;
- 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 The 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 Pit Cooling and Treatment System;
- the ventilation systems, which contain radioactive materials by creating negative pressure in the rooms and filtering discharges;
- the fire-fighting water systems;
- the Instrumentation and Control (I&C) 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 off-site and on-site 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. Over the next few years, these latter resources will be supplemented by an "ultimate back-up" diesel generator set for each reactor.

10

2. Oversight of nuclear safety

2.1 Fuel

2.1.1 Changes to fuel and fuel management in the reactor

In order to increase the availability and performance of the reactors in operation, EDF and the nuclear fuel manufacturers are developing improvements to be made to the fuels and to how they are used in the reactors.

EDF has standardised its fuel management methods. ASN ensures that each change to fuel management undergoes a specific safety demonstration in the reactors concerned. Any change in the fuel or its management must first be examined by ASN and may not be implemented without its consent.

As fuel behaviour is a key element in the safety of the core in a normal or accident operating situation, its reliability is crucial. Thus, the leaktightness of the fuel rod cladding, tens of thousands of which are present in each core and which constitute the first containment barrier, receives particularly close 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 is a sign of a loss of leaktightness in the fuel assemblies. During each shutdown, EDF must look for and identify the assemblies containing leaking rods, which must not then be reloaded. If the activity of the primary system becomes too high, the General Operating Rules (RGE) require shutdown of the reactor before the end of its normal cycle.

ASN ensures that EDF looks for and analyses the causes of the loss of leaktightness observed, notably by examining the leaking rods in order to determine the origin of the failures and prevent them from reoccurring. The preventive and corrective measures may concern the design of the rods and assemblies, their manufacture or the reactor operating conditions. In addition, the conditions of fuel assembly handling, of core loading and unloading, as well as preventing the presence of foreign objects in the systems and pools are also covered by operating specifications, some of which contribute to the safety case and for which EDF's compliance is spot-checked by ASN during inspections. ASN also carries out inspections to check the nature of EDF's monitoring of its fuel suppliers. Finally, ASN periodically consults the Advisory Committee for Nuclear Reactors (GPR) concerning the lessons learned from fuel operating experience feedback.

2.1.2 Assessment of the condition of the fuel and its management in the reactor

ASN considers that, in 2019, the integrity of the first containment barrier, that is the fuel rod cladding, was on the whole satisfactorily managed by all the NPPs.

The progress observed in 2018 with regard to the risk of foreign objects entering the primary system, which could then damage the first containment barrier, continued in 2019. Some sites developed good practices, for example by setting up training and awareness-raising actions intended for the personnel active on the work-sites with this specific risk. ASN considers that EDF must continue its efforts in this area.

The number of reactors with cladding defects was similar to the previous year. ASN will remain attentive to the investigations carried out by EDF on the fuel assemblies concerned, in order to determine the origin of these defects and identify the corrective measures in terms of manufacturing and operation.

In dealing with the obsolescence of the sipping machines[1] in the fuel buildings, ASN will be attentive to the correct performance of all the maintenance operations performed on this equipment. This attention will be maintained until the deployment of new mobile sipping machines currently being designed.

As in 2018, few events concerned fuel handling operations in 2019. One assembly did however snag during unloading operations in the Tricastin NPP. As this incident had already occurred on the same site in the past, ASN will pay particular attention to the effectiveness of the corrective measures taken.

In 2019, several reactors conducted a first power increase after refuelling that was long enough to require authorisation of a change to their operating baseline. The reactors concerned operated for a prolonged period of time at intermediate power, which increases the risk of rupture of the first barrier in certain accident situations. These extended power increase durations were, in the cases encountered in 2019, caused by incidents on certain secondary system equipment not important for safety. ASN considers that EDF must ensure that its facilities are available, more specifically the secondary system, before carrying out the divergence and power increase transients.

With regard to the fabrication of fuel assemblies, ASN is maintaining its vigilance following the anomalies on assemblies containing MOX encountered in 2017 (presence of large-sized plutonium enriched islands), which happened again in 2019 despite the steps taken at Orano Cycle's Melox plant. EDF reported a significant event concerning a neutron flux increase phenomenon at the bottom and at the top of the fissile column of MOX fuel assemblies, which led ASN to ask EDF in 2018 for compensatory measures pending a change to the design of these assemblies and a complete demonstration of the corresponding risks. These compensatory measures were deployed in 2019 for the lower part of the fissile column and will continue in early 2020 for the upper part. At the same time, EDF studied modified MOX fuel assemblies reducing the impact of this design anomaly and began to load them into the reactor. EDF will also be adopting particular operating measures for reactors containing MOX fuel as of the beginning of 2020.

2.2 Nuclear pressure equipment (NPE)

2.2.1 Monitoring of the design and manufacturing conformity of Nuclear Pressure Equipment

ASN assesses the compliance of the NPEs which are most important in terms of safety, said to be "level N1", which are the reactor pressure vessel, the SGs, the pressuriser, the reactor coolant pumps, the piping and the control valves and relief valves.

These regulations are a guarantee of their safety. They are defined by a European Directive on NPE and are supplemented by requirements specific to NPE.

This conformity assessment concerns the equipment intended for the new nuclear facilities (more than 200 equipment items are concerned on the Flamanville EPR) and the spare equipment intended for nuclear facilities already in service (notably the replacement SGs). ASN can be assisted in this task by organisations that it approves. These latter can be mandated by ASN with performance of some of the inspections on the "level N1" equipment and are tasked with assessing the regulatory compliance of the NPE less important for safety, said to be "level N2 or N3". The oversight by ASN and the

1. The sipping technique consists in heating water containing the assembly and monitoring the activity of this water at the outlet.

ASN inspection in the Blayais NPP – Means deployed to manage the risk of foreign objects in the systems

approved organisations is carried out at the different stages of the design and manufacture of the NPE. It takes the form of an examination of the technical documentation of each equipment item and inspections in the workshops of the manufacturers, as well as at their suppliers and subcontractors. Five inspection organisations are currently approved by ASN to assess NPE compliance: Apave SA, Asap, Bureau Veritas Exploitation, Vinçotte International and the inspection organisation of EDF users.

In 2019, the approved organisations carried out 2,219 inspections on NPE design and manufacture for the NPE intended for the Flamanville EPR and 3,501 inspections for the replacement NPE intended for the NPP reactors in operation. These inspections are performed under ASN supervision.

2.2.2 Assessment of the design and manufacture of NPE

• Actions focused on deviations and irregularities detected in the manufacturing plants

ASN's actions in 2019 to assess equipment compliance and check its manufacturing were particularly focused on the examination of the deviations detected, in particular those which had affected the stress-relieving heat treatment of the connecting welds for replacement SG components, produced at the Framatome Saint-Marcel plant.

As in 2018, the year 2019 was also marked by the follow-up to the handling of the irregularities detected in 2016 in several NPE manufacturing plants, in particular in Framatome's Creusot Forge plant. In 2019, ASN focused on the one hand on continuing to examine the impact of these irregularities on equipment compliance and, on the other, on continuing to implement the improvement plan for the Creusot Forge plant, which notably includes reinforcing the safety culture, improved management of the industrial tools and consolidation of technical skills.

Irregularities were also reported at the end of 2018 by the Framatome supplier Aubert & Duval. These irregularities affect numerous past or present equipment manufacturing operations. The investigations carried out have not yet identified any consequences for the safety of the facilities. Together with the organisations to which it gives a mandate, ASN is examining the actions of Framatome and EDF aimed at defining the scope and impact of these irregularities.

At the same time, and on the basis of these findings, ASN ensures that the manufacturers and licensees develop an organisation and means for detection of such practices within their own structures, so that the necessary steps can be taken to more effectively rule out the risks of fraud. It is also adapting its oversight practices, notably by means of a greater number of unscheduled inspections.

• Reinforcing justification of the design of NPE

ASN has regularly observed that the justifications and demonstrations provided by the manufacturers with regard to the regulations applicable to NPE, notably in terms of the satisfactory design of this equipment, are unsatisfactory. The industrial firms, EDF and Framatome 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 actions, 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, for most of the problems identified in 2015, considers that the AFCEN guides and methods published are appropriate. This approach will be repeated in the coming years so that the profession continues to make progress on certain topics and in order to learn the lessons from the initial applications of the guides and methods created.

2.2.3 Monitoring the operation of Pressure Equipment

The reactor Main Primary and Secondary Systems (CPP and CSP) 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 10 November 1999 relative to the monitoring of operation of the main primary system and the main secondary systems of nuclear pressurized water reactors. These systems are thus the subject of monitoring and periodic maintenance by EDF. This monitoring is itself checked by ASN.

These systems are subject to periodic re-qualification every ten years, which comprises a complete inspection of the systems involving non-destructive examinations, pressurised hydrotesting and verification of the good condition and good operation of the over-pressure protection accessories.

• Nickel-based alloy zones

Several parts of PWRs are made of nickel-based alloy. This type of alloy is chosen for its resistance to generalised or pitting corrosion. However, in the reactor operating conditions, one of the alloys chosen, Inconel 600, has proven to be susceptible to stress corrosion. This particular phenomenon occurs in the presence of significant mechanical stresses. It can lead to the appearance of cracks, as observed on certain SG tubes in the early 1980s or, more recently in 2011, on a vessel bottom head penetration in Gravelines NPP reactor 1 and in 2016 on a vessel bottom head penetration in Cattenom NPP reactor 3.

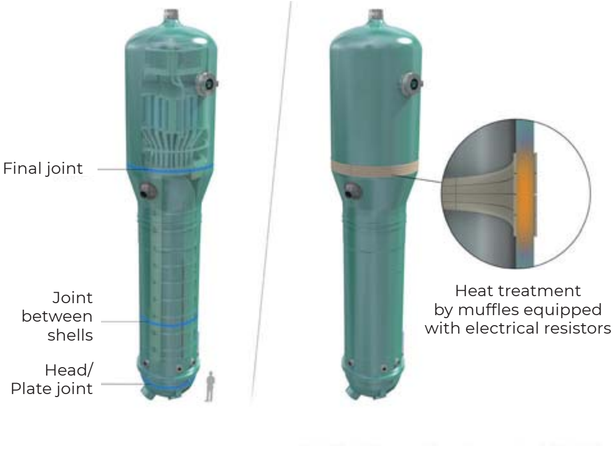
These cracks require that the licensee repair the zones concerned or isolate the part of the system concerned.

At the request of ASN, EDF adopted an overall approach to monitoring and maintenance for the zones concerned. Several zones of the main primary system made of Inconel 600 alloy are thus subject to specific monitoring. For each of them, the in-service monitoring programme, defined and updated annually by the licensee, is submitted to ASN, which checks that the performance and frequency of the checks carried out 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 PWR 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

Qualification defect in a stress-relieving heat treatment process during manufacture of the Framatome Steam Generators



In 2019, Framatome revealed that the stress-relieving heat treatment conditions for some of the assembly welds made on SG components in the past did not meet the heating uniformity and temperature range requirements. This deviation in the stress-relieving heat treatment conditions can lead to changes in the metallurgical characteristics of the materials with respect to the hypotheses considered in the design files, or insufficient relief of the mechanical stresses induced by welding.

EDF justified maintaining the integrity of the relevant equipment in service, by drawing on the results of tests performed on a representative mock-up, on material test coupons and on numerical temperature uniformity prediction models. During each reactor outage and before restart, the welds concerned are specifically checked (thickness measurements and defect search). At the same time, EDF set up a detailed characterisation programme using mock-ups and material tests. ASN called on the expertise of IRSN with regard to EDF's models and test programmes.

This deviation also affects the equipment currently being manufactured for various projects, such as the replacement SGs and the Flamanville EPR reactor.

Finally, ASN asked EDF and Framatome to carry out a review of the various processes used to determine the possible extension of this problem. This review is under way.

In 2019, ASN carried out three inspections since this deviation was reported in September 2019. These inspections confirmed the efforts made by EDF and Framatome. They found that the process was not correctly managed. Requests were made regarding strategies to characterise the behaviour of the materials and the representativeness of the hypotheses used in the safety cases.

construction at Flamanville, 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 inspection of the condition of the 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 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.

During operation, the vessel's metal slowly becomes brittle, under the effect of the neutrons from the fission reaction in the core. This embrittlement more particularly makes the vessel more susceptible to thermal shocks under pressure, or to sudden pressure rises when cold. This susceptibility is aggravated by the presence of technological flaws, which is the case for some vessels with manufacturing defects under their stainless steel liner.

ASN regularly examines the evidence to substantiate the in-service resistance of the vessels transmitted by EDF, to ensure that it is sufficiently conservative.

• 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 components of the SGs is monitored, more specifically the tubes making up the tube bundle. This is because any damage to the tube bundle (corrosion, wear, cracking, etc.) can lead to a primary system leak to the secondary system. Rupture of one of the tube bundles would lead to bypassing of the reactor containment, which is the third containment barrier. The SGs are the subject of a specific in-service monitoring programme, defined by EDF and periodically revised and examined by ASN. Following the inspections, those tubes which are too badly damaged are plugged, to remove them from service.

ASN in-depth inspection at the Gravelines NPP – Steam Generator – May 2018

• 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. The layer of deposits (fouling) that forms on the tubes reduces the heat exchange capacity. On 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 structures and which can degrade the overall operation of the SG.

To prevent or mitigate the clogging effects described above, various solutions can be implemented to limit metal deposits: preventive chemical cleaning or remedial mechanical cleaning (using hydraulic jets), replacement of material (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 increase in the pH of the secondary system. Some of these operations require a license for the discharge of some of the products used.

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, more specifically non-destructive examination of the areas potentially exposed to this risk.

• Replacement of the Steam Generators

Since the 1990s, EDF has been running a programme to replace the SGs with the most severely damaged tube bundles, with priority being given to those made of non-heat-treated Inconel 600 alloy (600 MA), and then those made of heat-treated Inconel 600 alloy (600 TT).

The campaign to replace SGs with a tube bundle made of 600 MA –some 26 reactors– was completed in 2015 with that of the Blayais NPP reactor 3. It is continuing with replacement of SGs in which the tube bundle is made of 600 TT –that is 26 reactors.

• Monitoring methods applied to main primary and secondary system Pressure Equipment (PE)

The Order of 10 November 1999 specifies that the non-destructive testing processes used for in-service monitoring of the Pressure Equipment (PE) 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 (Cofrac).

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 development and qualification processes to address new needs are in progress.

With regard to the Flamanville EPR, virtually all of the test processes for in-service monitoring of the main primary and secondary systems PE were qualified ahead of the Pre-Service Inspection (VCI) of the main primary and secondary systems, corresponding to more than 30 qualified processes specific to the EPR.

The principles of the reactor vessels in-service strength demonstration

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 to enable 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.**

2.2.4 Assessment of Pressure Equipment in operation

• The reactor pressure vessels

As part of the preparation for the fourth periodic safety reviews of the 900 MWe reactors, EDF sent ASN a dossier in 2017 substantiating the in-service strength of these reactors after 40 years of operation. This dossier was submitted to the Advisory Committee for Nuclear Pressure Equipment (GPESPN) for its opinion on 20 November 2018 and 15 October 2019. The examination concerned the defects analysed, the estimated irradiation ageing of the metal of the vessel, the thermomechanical analyses and the studies assessing the margin with respect to fast fracture of the vessels. The generic approach adopted by EDF consists in conservatively considering the mechanical properties of the vessel experiencing the worst-case irradiation embrittlement for the 900 MWe reactors.

The examination carried out *via* this generic approach is to be continued in 2020, more specifically with a further presentation to the GPESPN. Given the deadlines of the fourth ten-yearly inspection for the Tricastin NPP reactor 1 and that of the Bugey NPP reactor 2, EDF also provided a specific demonstration of the strength of the vessels of these two reactors. ASN considers that this specific demonstration is satisfactory and enables these two reactors to continue to operate beyond their fourth ten-yearly inspection.

• Cast elbow assemblies

The cast elbow assemblies are piping components installed on the main primary system of PWRs. They are present on the hot legs (C elbow assemblies) and cold legs (A, B and D elbow assemblies on the crossover legs and E elbow assemblies at the input to the vessel).

The cast elbow assemblies installed on the 900 MWe reactors were made of austenitic-ferritic stainless steel. The ferritic phase experiences ageing under the effect of the MPS operating temperature. Certain alloy elements present in the material accentuate this susceptibility to ageing. The result is a deterioration of certain mechanical properties, such as toughness and resistance to ductile tearing.

In addition, these elbow assemblies comprise shrinkage clusters or filaments, or solidification cracks, inherent in the static casting manufacturing method, which could, when combined with thermal ageing, increase the risk of fast fracture.

EDF has carried out extensive work to learn more about these materials, their ageing kinetics and to assess the fast fracture margins.

The dossier produced by EDF was examined by ASN with production of an opinion from the GPESPN on 23 May 2019. Following this analysis, ASN sent EDF requests for additional substantiation of the predicted behaviour of the aged material, identification of the flaws present in the cast elbow assemblies, analysis of the fast fracture margins of the elbow assemblies and in-service monitoring of these components. The substantiating data requests should be presented to ASN during the course of 2020.

• Regulatory reference files

The licensee is required to keep and update the regulatory reference files required by the above-mentioned Order of 10 November 1999 with regard to MPS and MSS monitoring. These files consist of design, manufacture, overpressure protection files, materials files, in-service observations and, as applicable, deviations processing files. The licensee is required to update these files as often as necessary and at periodic requalification of the main primary and secondary systems. Owing to the standardised nature of the French NPP reactors, EDF can perform a generic update of these files. For the fourth periodic safety reviews of the 900 MWe reactors, EDF carried out this update, which is particular in that the design hypotheses were initially produced for 40 years of operation.

ASN thus examined the hypotheses and methods used by EDF for updating the equipment files. The entire analysis was the subject of an opinion from the GPESPN on 8 October 2019. ASN also examined all the monitoring programmes planned for the main primary and secondary systems. Following this examination, ASN considered that the overall approach adopted by EDF is satisfactory, while nonetheless asking it to reinforce certain examinations.

• Operation of pressure equipment

ASN considers that the situation of the second containment is a point requiring continued vigilance in 2019, the year having been marked by the detection of significant levels of fouling in certain SGs on some reactors, liable to impair their operating safety. This finding revealed the inability of maintenance to guarantee a satisfactory level of cleanness.

In addition to this assessment, ASN notes that the SG replacement operations for reactors 5 and 6 of the Gravelines NPP and reactors 1 and 2 of the Flamanville NPP had to be postponed owing to the numerous deviations affecting the manufacture of these equipment items and led to operations to secure the tubes that were cracked.

The in-service monitoring of the other equipment of the MPS, pursuant to the Order of 10 November 1999, would appear to be appropriate. The detection of a crack on a vessel bottom penetration of Cattenom NPP reactor 3 in 2017, the cracking of two plugs in the SGs of Paluel NPP reactor 1 in 2016 and the perforation of the SG tubes on the 2 reactors of the Belleville and Flamanville NPPs in 2019 illustrate the risk of further damage associated with the ageing of the installations. This confirms the need to adapt the level of in-service monitoring accordingly and to bring forward the development of repair processes. The bottom head penetration of Cattenom NPP reactor 3 was repaired in 2019.

2.3 The containments

2.3.1 Monitoring the containments

The containments are monitored and tested to check their compliance with the safety requirements. More specifically, their mechanical behaviour must guarantee good tightness of the reactor building if the pressure inside it were to exceed 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 rise with leak rate measurement. These tests are required by the Order of 7 February 2012, setting the general rules concerning Basic Nuclear Installations (BNIs).

2.3.2 Assessment of the condition of the containments

• Overall management of the containment function

The organisation put into place by EDF for monitoring the activities and systems liable to have an impact on the static and dynamic containment of the facilities is on the whole satisfactory, even if not completely formalised. Locally, this results in deviations affecting certain items, which are not dealt with in good time, the consequence of which is to weaken the static or dynamic containment of the facilities.

Since 2016, EDF has implemented an action plan, the main aim of which is to check that the flow rates of the ventilation systems meet the safety requirements both for containment and for thermal conditioning of the facilities. This action plan will continue until 2025. It will enable an inventory to be drawn up of all the ventilation systems of the reactors. It makes provision for repair when necessary, plus improvements. In the coming years, ASN will therefore be vigilant with regard to the organisational and operational means implemented by EDF to ensure that compliance with the adjustments made and the good condition of the ventilation equipment concerned are maintained durably.

Improvements are also required with regard to the condition of certain components taking part in containment, such as the floor drains. During its inspections, ASN will be vigilant with regard to EDF’s maintenance of these components.

• Single wall containments with an internal metal sealing liner

The ten-yearly tests on the 900 MWe containments carried out since 2009 for their third and fourth ten-yearly inspections did not generally bring to light any particular problems liable to compromise their operation. The containment of Bugey NPP reactor 5 did however need to be repaired, following a loss of leaktightness found in 2015 in the containment metal liner towards the bottom of the reactor building. EDF also implemented specific monitoring.

The ageing of the 900 MWe reactor containments was examined by ASN with the support of IRSN in 2018 and was presented to the GPR during a session dedicated to ageing. This examination concluded that the cleanness of the outer part of the containments needed to be improved in order to prevent stagnant water, debris, moss and other vegetation. EDF has initiated visual checks on the containment domes. ASN will carry out inspections to ensure the pertinence of these checks.

• Double-wall containments

The tests on the double-wall containments performed during the first ten-yearly inspections 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 a loss of pre-stressing of certain tendons that was greater than anticipated at the design stage.

EDF then initiated major work consisting in locally applying a resin sealing coating to the interior and exterior surfaces of the inner wall of the containments of the most severely affected 1,300 MWe reactors, as well as to the 1,450 MWe reactors. This work has already been carried out on seven reactors and will continue until 2022. The tests performed since this work have all complied with the leak rate criteria.

ASN remains vigilant with regard to changes in the leaktightness of these containments and to maintaining the long-term effectiveness of the coatings.

During the 2013 examination on the effectiveness of the double-wall reactor containment function, ASN noted that the characteristics of some containments were liable to affect them through the internal swelling of the concrete prejudicial in the long-term to the performance of the confinement function of these containments. Since this examination, EDF has initiated measures to characterise and monitor the phenomena which could affect the concrete of the containments. The analyses carried out by EDF notably showed that the kinetics of the development of these phenomena are very slow and that the containments concerned suffer from no structural damage. Also on this point, ASN remains vigilant with regard to the medium to long-term development of the phenomena involved. In 2019, ASN carried out an inspection to ensure the monitoring and characterisation of these phenomena by EDF.

Modelling of the containments of the 1,300 MWe and 1,450 MWe reactors in a severe accident situation show particular behaviour, which leads to a risk of cracking in part of the thickness of the dome, in certain accident scenarios. These observations are mainly linked to the differential thermomechanical behaviour of the concrete of the dome and the metal beams. The cracking thus observed takes place well before 24 hours, corresponding to the minimum time calculated by EDF for requesting opening of the filtration system before discharge from the containment. This cracking is liable to lead to an appreciable increase in leaks through the dome. ASN notes that the results obtained following this modelling depend to a large extent on the hypotheses adopted (containment brittleness curve, representativeness of the containment model, etc.). ASN asked EDF to study this phenomenon, to assess the sensitivity of the results to the various parameters of the model and to present any modifications that would be needed to mitigate this risk.

2.4 Risk prevention and management

2.4.1 Monitoring the drafting and application of the General Operating Rules

The RGE cover the operation of nuclear power generating 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 mode operation

Operating Technical Specifications

The Operating Technical Specifications (STE), which constitute Chapter III of the RGE, define the normal operating conditions based on the facility's design and sizing hypotheses and require the systems needed for maintaining the safety functions, in particular the integrity of the radioactive substance containment barriers and the monitoring of these functions in the event of an incident or accident. They also stipulate the action to be taken in the event of temporary failure of a required system or if a limit is exceeded, situations which constitute "degraded mode" operation.

The STEs evolve to integrate the lessons learned from their application and the modifications made to the reactors. The licensee can also modify them temporarily if need be, for example to carry out an operation in conditions that differ from those initially considered in the nuclear safety case. It must then demonstrate the relevance of this temporary modification and define adequate compensatory measures to control the associated risks.

Depending on their significance, STE modifications that could affect safety require either submittal of an authorisation application to ASN or notification to ASN before they are implemented.

During NPP inspections, ASN verifies that the licensee complies with the STE and, as necessary, 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 operational control instructions and alarm sheets, and the training of the persons responsible for applying them.

Periodic tests

The Elements Important for Protection (EIP) of persons and the environment undergo qualification to guarantee their ability to perform their assigned functions in the situations where they are needed. The periodic tests of these equipment items help check their continued qualification and regularly verify that they will be available when required. The periodic test rules for equipment important for safety are incorporated into the general operating rules of the reactors. They set the nature of the technical checks to be performed, their frequency and the criteria for determining the satisfactory nature of these checks.

ASN ensures that the periodic tests on the elements important for safety are pertinent 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. During inspections, it also verifies that these periodic tests 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, are performed periodically.

The physics tests at restart are comparable to requalification tests following reloading of the core. The physics tests during the cycle 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 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

Operation in the event of an incident or accident

The strategies and reactor operating rules for an incident or accident situation are defined in the RGE. These evolve notably 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. Most of these modifications require ASN authorisation.

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. This organisation more particularly requires that each emergency team member take part in an exercise at least once a 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 releases into the environment. The implementation of these strategies requires the participation of the local and national emergency teams. These teams draw on the On-site Emergency Plan (PUI) plus the severe accident intervention guide and the emergency teams action guides in particular.

ASN periodically examines the strategies developed by EDF in these documents, in particular for the reactor periodic safety reviews.

2.4.2 Assessment of reactor operations

• Normal and degraded operation

ASN observes that the reactor operating teams are fully familiar with and proficient in the operating rules and instructions for nuclear power reactors. However, the ASN inspections in 2019 revealed that the checks on the activities performed by the operators need to be reinforced. This trend is confirmed by the analysis of the root causes of the significant events, revealing a lack of monitoring of the activities carried out in the control room by the operating team: in several NPPs the average time taken to detect a breach of the operational management rules is too long. It would appear that the sites which experienced the greatest difficulty in normal and degraded operation are those which had to manage a ten-yearly outage.

The significant events for which the analysis reveals an operating error sometimes represent more than one third of the significant events reported by a site.

Unauthorised excursion from the operating ranges remain few in number and are correctly managed, even if there are nonetheless early warning signs.

ASN notes that on certain sites, EDF implements action plans to reinforce rigorousness and process safety difficulties identified. ASN considers that the effectiveness of these plans has yet to be confirmed. It will focus a significant share of its inspections on the sites concerned. it will thus pay particular attention to EDF's ability to handle major changes to the facilities and their operating procedures, notably during the ten-yearly outages of the reactors. The steps taken by EDF to prevent inappropriate actions and decisions on the part of the operating team and reinforce rigour in application of the operating rules and alarm management, will also be the focus of increased vigilance.

The majority of the sites need to improve the scheduling and performance of the periodic tests and the analysis of their results. A lack of rigour in the preparation for the periodic tests, and deficiencies in error reduction in the work to be done, sometimes leads to the performance frequencies being exceeded and to inadequate conditions for performance of the tests. ASN's inspectors on several occasions found incorrect conclusions regarding equipment availability following periodic testing. Moreover, ASN also observes problems in the operational documentation which is sometimes inappropriate to the performance of the activities, for example owing to its volume or to errors in the test procedures. Finally, despite efforts in these areas, persistent training or skills faults are the cause of significant events in the performance of periodic tests. During its inspections in 2020, ASN will focus particular attention on the steps taken by EDF to ensure the rigour needed for performance of the periodic tests with regard to the material, documentary and human aspects.

• Operation in an incident, accident, or severe accident situation

In the same way as every year, ASN carried out several inspections in 2019 on the organisational and technical arrangements made by EDF to deal with an incident and accident situation. Two tightened inspections were notably carried out in the Chooz and Nogent-sur-Seine NPPs before application of the general operating rules resulting from the second periodic safety review of the 1,450 MWe reactors and the third periodic safety review of the 1,300 MWe reactors respectively.

During these inspections, ASN on the one hand checks the way in which the operating procedures are applied in an incident or accident situation and, on the other, the ability of certain equipment to perform its functions. These inspections almost always include a simulation involving the EDF teams. In 2019, the familiarity of the field operators with the instructions regarding the actions they are required to carry out was deemed to be satisfactory. However, as in 2018, ASN found that certain instructions contained errors, inaccuracies, or even procedures that were impossible to carry out. Although these faults were identified by EDF during its internal checks, they were not corrected before application of the documents concerned. These findings show that the steps taken by EDF in response to the ASN requests made in 2016 did not result in the anticipated effects. The cause of this situation is notably a saturation of the EDF national engineering teams owing to the workload generated by the periodic safety reviews. ASN increased its oversight of these activities and, at the end of 2019, found greater involvement by these teams in reactive processing of the deviations affecting the operating rules and instructions.

In 2019, EDF did not activate an On-site Emergency Plan (PUI) on its NPPs.

The ASN inspections on the emergency organisation and resources confirmed the findings in previous years, with a correct level of assimilation of the organisation, preparedness and management principles for emergency situations covered by a PUI.

Finally, in 2020, ASN will continue to check the application of the provisions of its resolution 2017-DC-0592 of 13 June 2017 concerning the obligations on BNI licensees in terms of preparedness for and management of emergency situations and the content of the PUI. Work to ensure compliance with the provisions of this resolution is continuing, with deadlines staggered until 1 January 2022.

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 important for safety but also industrial performance, EDF is optimising its maintenance activities, drawing on practices used 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 this 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 an AP-913 deployment review in 2016, EDF developed its practices in order to guarantee the quality of maintenance work, refocus performance monitoring on the most important equipment and systems and optimise the volume of maintenance operations.

2.4.4 Assessment of maintenance

Most of the NPPs are satisfactorily organised to successfully carry out the large-scale maintenance operations currently being performed.

However, ASN regularly notes points to be improved concerning reactor maintenance. Despite EDF's implementation of an action plan to reduce their occurrence, maintenance quality defects causing significant safety events persist at a level that is still too high, even though some of them could have been avoided by greater preparation of the activities in advance. Activity management faults are sometimes caused by problems in procuring and installing spare parts. Spare parts are regularly unavailable, or non-conforming, or their storage conditions are inadequate. Incorrectly applied national EDF documents or incorrect operational documents are the cause of inappropriate maintenance or maintenance quality defects. Poor performance of the work is too often detected belatedly, in other words only during the operations to requalify the equipment after the maintenance work. ASN also observed that the requalification tests are not always able to detect equipment defects. Finally, taking corrective measures to deal with maintenance-related deviations is sometime ineffective or only temporary.

ASN sees an improvement in the technical oversight of the work and contractor monitoring, particularly through the use of computer tools recently deployed in the NPPs.

In 2019, ASN asked EDF for a review of its maintenance policy, in particular with regard to the AP-913 maintenance method (see point 2.4.3) and the adaptations which have been implemented. In 2020, ASN will examine EDF's answers with respect to the inadequacies it has identified on this subject.

In the context of the continued operation of the reactors, the "major overhaul" programme and the lessons learned from the accident at the Fukushima Daiichi NPP, ASN considers that it is important for EDF to continue with the efforts it has already begun in order to remedy the difficulties encountered and improve the quality of its maintenance activities.

The Independent Safety Team (FIS)

At EDF, the FIS verifies the actions and decisions taken by the departments in charge of operating the installations, from the viewpoint of safety. On each Nuclear Power Plant (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 of EDF's Nuclear Production Division. Finally, the EDF internal 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.

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 28 January 2014, relating to the rules applicable to BNIs for controlling fire risks.

The way the fire risk is taken into account in the NPPs is based on the principle of defence in depth built around three levels, that is the design of the facilities, fire prevention and firefighting.

Design rules must prevent a fire from spreading and mitigate its consequences; they are based primarily on "fire sectorisation". 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 specified fire resistance duration. The main purpose is to prevent a fire spreading to two redundant equipment items performing a fundamental safety function.

Prevention primarily consists in:
- ensuring that the nature and quantity of combustible material in the premises remains below the hypotheses adopted for fire sectorisation;
- identifying and analysing the fire risks in order to take steps such as to avoid them. More specifically, for all the work liable to generate a fire, a "fire permit" must be issued and protective measures taken.

Finally, the detection of an outbreak of fire and fire-fighting should enable a fire to be brought under control and then extinguished within a time compatible with the fire resistance duration of the sectorisation elements.

ASN checks that the fire risk is taken into account in the NPPs, notably through an analysis of the licensee's baseline safety standards, monitoring of significant events reported by the licensee and inspections performed on the sites.

The important risks associated with fire have been the subject of numerous ASN requests since 2003 and ASN thus reminded EDF in 2016 that, for the purposes of the fourth periodic safety review of the 900 MWe reactors, it expected a well-structured and robust safety case based on a defence in depth approach. ASN is examining the justification methods produced by EDF. These were submitted to the GPR for analysis in 2019.

- **Explosion risks**

An explosion can damage the items essential for maintaining safety or lead to rupture of the containment and the dispersal of radioactive materials into the facility, or even into the environment. Steps must thus 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 taken into account in EDF's baseline safety requirements and organisation. ASN also ensures compliance with the "Explosive Atmospheres" (ATEX) regulations to ensure 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
Following the partial flooding of the Blayais NPP in December 1999, the licensees, under the supervision of ASN, reassessed the safety of their facilities in the face of this risk, in conditions that were more severe than before, and made numerous safety improvements, according to a schedule defined according to the risks. 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 give priority to the third periodic safety review;
– for the other reactors in service, EDF will give priority to the next periodic safety reviews (fourth reviews for the 900 MWe reactors and second reviews for the 1,450 MWe reactors).

Following the stress tests performed in the wake of the Fukushima Daiichi NPP accident, ASN considered that with regard to flooding protection, the requirements resulting from the complete reassessment carried out following the flooding of the Blayais NPP in 1999 would be able to provide the NPPs with a high level of protection against external flooding. However, ASN issued several resolutions in June 2012 asking 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 designed into the facilities. They are periodically reviewed in the light of changing knowledge and changes to the regulations, on the occasion of the periodic safety reviews.

ASN inspection at the Blayais NPP – Turbine undergoing maintenance

Basic Safety Rule (RFS) 2001-01 of 31 May 2001 defines the methodology used to determine the seismic risk for surface BNIs (except for radioactive waste long-term disposal facilities).

This RFS is supplemented by ASN Guide 2/01 of May 2006 which defines acceptable calculation methods for a study of the seismic behaviour of nuclear buildings and particular structures such as embankments, tunnels and underground pipes, supports or tanks.

The design of the buildings and the equipment important for safety in the NPPs must thus enable them to withstand earthquakes of an intensity greater than the strongest earthquakes that have occurred in the region. EDF's NPPs are thus designed for seismic levels incorporating 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 changing knowledge about seismic activity in the region of the site or about 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.

Following the Fukushima Daiichi NPP accident, ASN asked EDF to define and implement a "hardened safety core" of material and organisational measures to control the fundamental safety functions in extreme situations comparable, in the French context, with that which occurred in Japan on 11 March 2011. This "hardened safety core" shall notably be designed to withstand an earthquake of an exceptional level, exceeding those adopted in the design or periodic safety review of the installations.

In order to define this exceptional level earthquake, ASN asked EDF to supplement the deterministic approach to defining the seismic hazard with a probabilistic approach, which would be more closely in line with international best practices.

• Heatwave and drought risks
During the heat waves in recent decades, some of the watercourses used to cool NPPs experienced a reduction in their flow rate and significant warming. Significant temperature rises were also observed in certain NPP premises housing heat-sensitive equipment.

EDF took account of this experience feedback and initiated reassessments of the operation of its facilities in air and water temperature conditions more extreme than those initially included in the design. In parallel with development of these "extreme heat" baseline safety requirements, EDF initiated the deployment of a number of priority modifications (such as the increase in the capacity of certain heat exchangers) and implemented 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 its reactors, EDF has initiated a modifications programme on its facilities designed to provide protection against heat wave situations. The capacity of certain cooling systems for equipment required for the nuclear safety case will in particular be improved.

EDF has also initiated a climatic monitoring programme to anticipate climate changes which could compromise the temperature hypotheses adopted in its baseline requirements.

ASN asked EDF to take account of the operating experience feedback from the heatwaves of 2015, 2016 and 2019, and their effects on the facilities.

• Other hazards

The safety case for the EDF NPPs also takes account of other hazards such as high winds, snow, tornados, lightning, cold air temperatures, 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 NPP accident led EDF to reinforce its organisation for the management of risks relating to extreme hazards. More specifically, networks of coordinators were set up in all the NPPs to oversee the implementation of the actions defined to deal with these hazards. Annual reviews are also held to improve this organisation.

• Fire risks

ASN observes that management of the fire risk needs to be improved, even if the number of outbreaks of fire recorded in 2019 was below that in 2018.

The findings made in previous years are still relevant with regard to some of the sites inspected:
- management of premises sectorisation anomalies not always appropriate for preventing the spread of a 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 and sometimes inappropriate management of the compensatory measures defined in the fire risk assessments;
- weaknesses in the maintenance of the fixed sprinkler equipment;
- problems with the accessibility of fire-fighting equipment;
- weaknesses in the field of fire-fighting.

In 2019, as in previous years, ASN carried out inspections on the topic of the control of fire risks in all the NPPs and asked for corrective measures to be taken to remedy the findings.

ASN observes the efforts made by certain sites to carry out the corrective measures needed, with the deployment of tools and action plans, but considers that if they are to be effective, the personnel must be given greater support with assimilating them. ASN thus observed that in 2019, EDF had taken steps to reduce errors in fire risk management in the premises identified as being particularly susceptible to this hazard. Moreover, at the request of ASN, EDF in 2019 undertook to pay particular attention to the management of combustible materials brought into the reactor building, notably during the reactor outage phases.

In addition, the time taken to remedy certain deviations or to take corrective actions as a result of experience feedback needs to be reduced.

Finally, ASN asked EDF to improve its firefighting organisation, notably by reinforcing the capacity of its response resources to deal with an established fire.

• Explosion risks

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 are not always carried out satisfactorily. Furthermore, ASN observes that the updating of certain documents (notably the procedures for periodic tests or for checks on piping carrying hazardous fluids), the integration of operating experience feedback, the processing of certain deviations and the deployment of certain modifications are sometimes postponed and this is not always justified given 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. Furthermore, in 2019, EDF worked on updating Documents Concerning the Protection against Explosions (DRPCE), required by the regulations concerning the risks involved in ATEX training. This approach needs to continue and lead to the adoption of new requirements as a result of these documents, notably with regard to the adequacy of the zoning defined in the DRPCE for the equipment situated in these areas. However, ASN considers that EDF must continue to pay particular attention to this point and ensure that the explosion risk prevention approach is implemented with all necessary rigour on all the sites.

• Internal flooding risks

The provisions for the prevention and control of the internal flooding risk are also regularly checked by ASN. These inspections show that the steps taken to control 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. It is also rare for EDF to carry out internal flood situation simulation exercises in order to build up real experience feedback about this hazard.

EDF has initiated field visits 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.

Considerable efforts are required on most sites to improve control of the flooding risk, in particular with respect to:
- the maintenance of the necessary equipment (piping, floor drains, etc.);
- the risk assessments during maintenance operations and in the event of detection of a malfunction of a necessary equipment item;
- the compliance with the corrective action deadlines identified by the annual reviews;
- the training of the coordinators and awareness-raising among the EDF and contractor personnel.

In 2019, ASN thus sent requests to EDF asking it to supplement the approach adopted for improved control of the internal flooding risk, to ensure the correct operation of the floor drains, to reinforce maintenance of the piping liable to lead to internal flooding and to ensure improved management of their ageing.

• Seismic risks
More generally, the inspection programmes implemented by EDF lead it to regularly report significant safety events owing to the lack of seismic resistance of certain equipment. These events are the result of targeted inspections gradually being deployed by EDF. These non-compliances can have serious consequences in the event of an earthquake and they are thus systematically analysed. For example, in 2019, EDF reported a significant event of level 2 on the International Nuclear Events Scale (INES) owing to the lack of seismic resistance of the piping of the emergency diesel generator sets on several NPPs (see box).

On 11 November 2019, an earthquake occurred in the municipality of Le Teil. Following this earthquake, EDF implemented the operating procedure required in the event of an earthquake on the Cruas-Meysse NPP. This was because the seismic motion detected on this site reached the level requiring shutdown of the reactors so that checks could be carried out. An inspection programme was then defined and carried out before the reactors were restarted.

• Risks linked to extreme temperatures
The inspections concerning the risks associated with extreme temperatures show that EDF's organisation must 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 must also be improved.

• Lightning risks
The inspections relating to lightning reveal the need on all sites to set up reinforced organisation and oversight to improve the integration of the regulatory requirements associated with the management of this hazard.

The lightning risk assessments may be based on information which does not actually reflect the real situation on the facilities. Once again this year, ASN observed 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. EDF has defined a programme of work to improve the situation.

2.4.7 Monitoring facilities compliance with the requirements

Maintaining the conformity of the facilities with their design, construction and operating requirements is a major issue insofar as this conformity is essential for ensuring compliance with the safety case. The processes employed by the licensee, notably during reactor outages, contribute to maintaining the compliance of the facilities with the requirements resulting from this safety case.

• Reactor outages
The nuclear power reactors must be periodically shut down for replacement of the fuel depleted during the electricity production cycle. One third or one quarter of the fuel is thus renewed at each outage.

The defined requirements

The Order of 7 February 2012 states that a defined requirement is a "*requirement assigned to an Element Important for the Protection (EIP) of persons and the environment, so that it can, with the expected characteristics, perform 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 the Protection (AIP) of persons and the environment, so that it can meet its objectives with regard 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.**

These outages allow temporary access to certain parts of the facility which are not accessible during production, although with specific radiation protection precautions. They are thus put to good use for verifying the condition of the equipment by carrying out checks, tests and maintenance, as well as for performing works on the facility.

These refuelling outages can be of several types:
- Refuelling Outage (ASR) and Maintenance Outage (VP): these outages, which last a few weeks, are devoted to replacing a part of the fuel and to carrying out a verification and maintenance programme, which is more extensive during a VP than during an ASR.
- Ten-yearly Inspection (VD): this is an outage involving a programme of in-depth verification and maintenance. This type of outage, which lasts several months and takes place every ten years, enables the licensee to carry out large-scale operations such as the complete inspection and hydraulic testing of the reactor coolant system, hydrotesting of the containment or incorporation of design changes resulting from the periodic safety reviews.

These outages are scheduled and prepared by the licensee several months in advance. ASN checks the steps taken by the licensee to ensure the safety of the facility, environmental protection and radiation protection of the workers during the outage, as well as the safety of the reactor for the next production cycle.

In the light of the provisions of its resolution 2014-DC-0444 of 15 July 2014 concerning shutdowns and restarts of pressurised water reactors, the monitoring performed by ASN 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 the outage, when the licensee presents the reactor outage review, the condition of the reactor and its suitability for restart. It is after this inspection that ASN approves reactor restart, or not;
- after reactor restart, the results of all the tests performed during the outage and in the restart phase.

• The identification and processing of deviations

The checks initiated by EDF within the framework of 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 expertise in maintenance work, deterioration through ageing, organisational shortcomings, etc.

The steps taken to detect and correct deviations, specified in the Order of 7 February 2012, play an essential role in maintaining the level of safety of the facilities.

• "Real-time" checks

Carrying out periodic test and preventive maintenance programmes on the equipment and systems contributes to identifying deviations. Routine visits in the field and technical inspection and verification of activities considered to be important for the protection of persons and the environment are also effective means of detecting deviations.

• Verifications during reactor outages

EDF takes advantage of nuclear reactor outages to carry out maintenance work and inspections which cannot be performed when the reactor is generating electricity. These operations more particularly correct deviations already known, but can 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.

• 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 then carries out an in-depth review of the actual state of the facilities by comparison with the applicable safety requirements, more particularly on the basis of the in-service monitoring hitherto carried out, and lists any deviations. These verifications can be supplemented by a programme of additional investigations, the aim of which is 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, for example, 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.

• Information of ASN and the public

When a deviation is detected, EDF, in the same way as any BNI licensee, is required to assess the impacts on nuclear safety, radiation protection and protection of the environment. If necessary, EDF then sends ASN a significant event notification. As of level 1 on the INES scale, the public is informed of the events thus reported on *asn.fr*.

• ASN requirements concerning repairs

For the most important deviations, ASN published its Guide No. 21 on 6 January 2015 regarding the handling of conformity deviations. This Guide specifies 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. The Guide also recalls the principle of correction of compliance deviations as soon as possible and in any case defines the maximum times allowed.

• Significant events

EDF is required to notify ASN of and then analyse any significant events occurring in its NPPs (see chapter 3, 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 reported significant events (a summary of their analysis for 2019 is given in point 2.4.8) and monitors the processing of these events by EDF. The significant events deemed noteworthy due to their severity or their recurrent or generic nature, undergo 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.

ASN oversight of reactor outages

ASN has made changes to its oversight of reactor outages. Until now, this was primarily based on implementation of ASN resolution 2014-DC-0444 of 15 July 2014 concerning PWR reactor outages and restarts, requiring that the licensee submit a file to ASN ahead of the outage and then in support of a restart approval application.

Under its 2018-2020 strategic plan, ASN experimented with a relaxation of its documentary checks and a reinforcement of its field inspections during the course of ten reactor outages in 2019. This approach led to it performing more inspections relating to these outages. Given the positive feedback from this experiment, ASN decided to generalise this new oversight approach in 2020 for the 46 refuelling outages scheduled by EDF in 2020. These new oversight methods enable ASN's resources to be targeted on the activities with the highest risks and this oversight to be made more efficient.

Processing of deviations

A deviation is a 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 the working of an organisation.

The regulations require that the licensee identify all deviations affecting its facilities and process them. The activities related to the processing of deviations are activities important for the protection of persons and the environment. They are thus subject to oversight and monitoring requirements, the implementation of which is regularly checked by ASN.

2.4.8 Assessment of facilities compliance with the applicable requirements

ASN inspects EDF's management of the deviations affecting the NPPs. It regularly pointed out to EDF that the organisational measures adopted to deal with deviations contained shortcomings, that the traceability of the steps taken to process deviations was insufficient and that the time taken to characterise, check and process deviations and inform ASN was not always in accordance with the requirements of the Order of 7 February 2012. In 2019, EDF therefore reviewed its internal baseline requirements regarding the management of deviations, in order to improve their processing and ensure that ASN is informed reactively and in a manner proportionate to the safety issues. In 2019, ASN observed that EDF's trend towards rapid correction of a deviation was confirmed, even if efforts must be continued on this point.

The checks carried out by EDF in 2019, some of which were at the request of ASN, revealed a number of deviations involving the ability of certain systems important for safety to perform their functions, such as electricity sources, back-up systems, certain ventilation systems and systems involved in reactor cooling.

In 2019, EDF again reported several significant events concerning the emergency diesel generators, revealing defects present since they were installed or related to in-service monitoring problems. In this respect, ASN asked EDF to carry out complete conformity checks on the emergency diesels in a resolution of 19 February 2019. Numerous deviations also concerned the pumping stations, which appear to be severely degraded on certain coastal sites.

Half of the generic conformity deviations affecting several reactors and reported by EDF in 2019 concerned an equipment seismic resistance defect. Some of these deviations date back to the construction of the reactors, others have been created when implementing modifications to the facilities, including recently. It should be noted that at the end of 2019, several deviations were brought to light relating to the manufacture of components of items important to safety. This was more particularly the case with defective electrical components which led to a significant event rated 2 on the INES scale in Penly NPP reactor 2.

In 2019, ASN was also particularly vigilant with respect to controlling the conformity of the facilities during the fourth ten-yearly inspection of the Tricastin NPP reactor 1. EDF's monitoring programme was the subject of specific examination and inspections.

ASN will continue to be particularly attentive to the conformity of the facilities in 2020 and will in this respect continue its inspections of the condition of equipment and systems.

• Analysis of significant events statistics

Pursuant to the rules for the notification of significant events (see chapter 3, point 3.3), ASN received 745 Significant Safety Event (ESS) reports from EDF in 2019, along with 171 Significant Radiation protection Event (ESR) reports and 83 significant environmental protection event (ESE) reports. The number of significant events increased by about 7.5% in 2019 as compared with the previous year.

Graph 1 shows the trend since 2009 in the number of significant events notified by EDF and rated on the INES scale.

Graph 2 shows the trend since 2009 in the number of significant events according to the notification field: ESS, ESR and ESE. Events not rated on the INES scale are also taken into account.

Significant events affecting several nuclear reactors are grouped under the term generic significant events. 29 events of this type were reported in 2019 in the field of nuclear safety.

• Reactor outages

ASN observes that the activity programmes scheduled during the reactor outages are on the whole followed. 78% of the reactor outages exceeded their scheduled duration, which is a high rate, even if it fell by 10 points in relation to 2018. The actual duration of outages was 34% longer than planned. This overshoot amounts to 40% of the scheduled duration for the ten-yearly inspections.

ASN observes a correlation between the extension of the outage durations and the number of significant events reported by EDF, in particular during the ten-yearly inspections. The delays during reactor outages is one of the factors that could disorganise the teams in the field. ASN considers that EDF must improve its organisation in order to prevent these delays from being prejudicial to safety.

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 gives ASN competence for setting out requirements concerning water intake and effluent discharge

Tricastin NPP reactor 1 – Fourth ten-yearly inspection – July 2019 by BNIs (see chapter 3, point 4.1). The laws and regulatory texts concerning protection of the environment and applicable to French NPPs comprise generic texts, mainly the Environment Code, the Order of 7 February 2012 and ASN resolutions 2013-DC-0360 of 16 July regarding the control of detrimental effects and the impact of BNIs on health and the environment, and 2017-DC-0588 of 6 April 2017 regarding water intake and consumption, effluent discharge and environmental monitoring methods for PWR nuclear power reactors, as well as regulatory texts 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 discharge procedures and 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 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 control of detrimental effects and the impact of PWRs on health and the environment. These 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 chapter 3, point 4.1).

In setting these requirements, ASN uses operating experience feedback from all the reactors as the basis, while also 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.

• The impact of thermal discharges from the NPPs

NPPs discharge hot effluents into watercourses or the sea, either directly, from those NPPs operating with "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 for advance definition of the operations of NPPs in exceptional climatic conditions leading to significant warming of the watercourse.

These special provisions are however only applicable if the security of the electricity grid is at stake.

Level 2 significant event affecting the emergency diesel generator sets on the Civaux, Gravelines and Paluel NPPs

A significant nuclear safety event concerning a deficiency in the earthquake resistance of the piping of the emergency diesel generator sets in the Civaux, Gravelines and Paluel NPPs was rated level 2 by ASN in 2019.

Each reactor has two emergency diesel generator sets, which provide 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 significant event concerns a risk of damage to the pipes owing to their potential contact with the civil engineering structures of the emergency diesel generator sets in the event of an earthquake. This damage could lead to rupture of these pipes and failure of the emergency diesel generating sets.

EDF initially detected this deviation at the end of October 2018 on one of the two emergency diesel generating sets for reactors 2 and 3 of the Tricastin NPP. On 6 May 2019, EDF notified ASN that, after characterisation, it also concerned the two emergency diesel generating sets for the reactors of the Civaux, Gravelines and Paluel NPPs, as well as one of the two emergency diesel generating sets of the Fessenheim, Cruas, Saint-Laurent-des-Eaux and Nogent-sur-Seine NPPs, as well as reactor 3 of the Dampierre-en-Burly NPP, reactors 2 and 3 of the Tricastin NPP and reactor 1 of the Blayais NPP.

Repairs have been made on the reactors concerned.

• Monitoring of waste management

The management of the conventional and radioactive waste produced by the NPPs falls within the general framework of BNI waste management. The legal framework for the management of waste applicable to the NPPs comprises legislative and regulatory texts of general scope, notably the Environment Code, the Order of 7 February 2012 and ASN resolution 2015-DC-0508 of 21 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 (see "References" heading on *asn.fr*). 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.

In addition, every year, each site sends ASN a summary report on its production of waste and the corresponding disposal routes, a comparison with the results of previous years, a summary of the site organisation and the differences observed with respect to the management procedures specified in the waste management study, the list of significant events which have occurred and the outlook for the future.

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 16 July 2013 and the Order of 7 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 incident or accident situations which would lead to pollution.

The licensee must thus for instance precisely identify the location of each dangerous substance on its site, along with the corresponding 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 steps to improve its management of the pollution risk by working to improve the confinement of dangerous liquid substances on its sites.

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.

• Prevention of the health impacts caused by the growth of legionella and amoeba in certain cooling systems of the NPP secondary systems

Certain NPP cooling systems constitute environments favourable to the development of legionella and amoeba (see point 1.4).

ASN resolution 2016-DC-0578 of 6 December 2016 on the prevention of risks resulting from the dispersal of pathogenic micro-organisms (legionella and amoeba) by PWR secondary system cooling installations 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 infection, identified in proximity to the facility;
- information of the public and the administrations in the event of proliferation of micro-organisms.

Through file reviews 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.

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-is 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.

2.5.3 Assessment of control of detrimental effects and impact on the environment

• Assessment of prevention of detrimental effects, control of environmental discharges and waste management

In 2019, ASN carried out inspections on the control of detrimental effects and the environmental impact of NPPs, mainly concerning the prevention of pollution and detrimental effects, control of environmental discharges and waste management. The reactors at Paluel, Penly and Flamanville –including the EPR reactor– underwent a reinforced inspection on these topics.

EDF's organisation for controlling the detrimental effects and impact of NPPs on the environment needs to be improved on most sites and ASN considers that the licensee needs to raise its level of vigilance on this topic.

Even if ASN observes progress in the performance of methodical microbiological risk assessments and greater assimilation by the sites of the requirements of the resolution concerning these risks, it nonetheless considers that corrective measures must be taken in the management of waste and pollution prevention.

Once again in 2019, there were too many events leading to the spillage of dangerous substances. Although these situations did not lead to notable environmental impacts, they underline the need for the licensee to continue to reinforce its efforts in this area.

Following the inspection carried out in 2018, ASN issued resolution 2019-DC-0666 of 18 April 2019 to regulate the new containment structures on the Civaux site. During inspections carried out in 2019, spillage exercises once again demonstrated shortcomings in the containment of liquid dangerous substances. In addition to the remedial measures requested on the sites concerned, ASN asked EDF to produce an inventory of the situation for all of its NPPs. ASN also asked EDF to improve the monitoring and maintenance of the pipes carrying dangerous substances.

On some sites, ASN observed significant shortcomings in waste sorting, conditioning, storage and traceability of removal, that must be rapidly corrected by the licensee.

In 2019, as in previous years, ASN observed that discharges are well managed on most of the sites. However, certain events indicate occasional weaknesses.

2.6 The contribution of man and the safety organisations

The contribution of people and organisations to the safety of NPPs is a decisive factor in all steps of the plant lifecycle (design, construction, commissioning, operation, decommissioning). ASN therefore focuses on the conditions which are favourable or prejudicial to the contribution to NPP safety by the operators and worker groups. It defines the Social, Organisational and Human Factors (SOHF) as being all the aspects of working situations and the organisation which will have an influence on the work done by the operators.

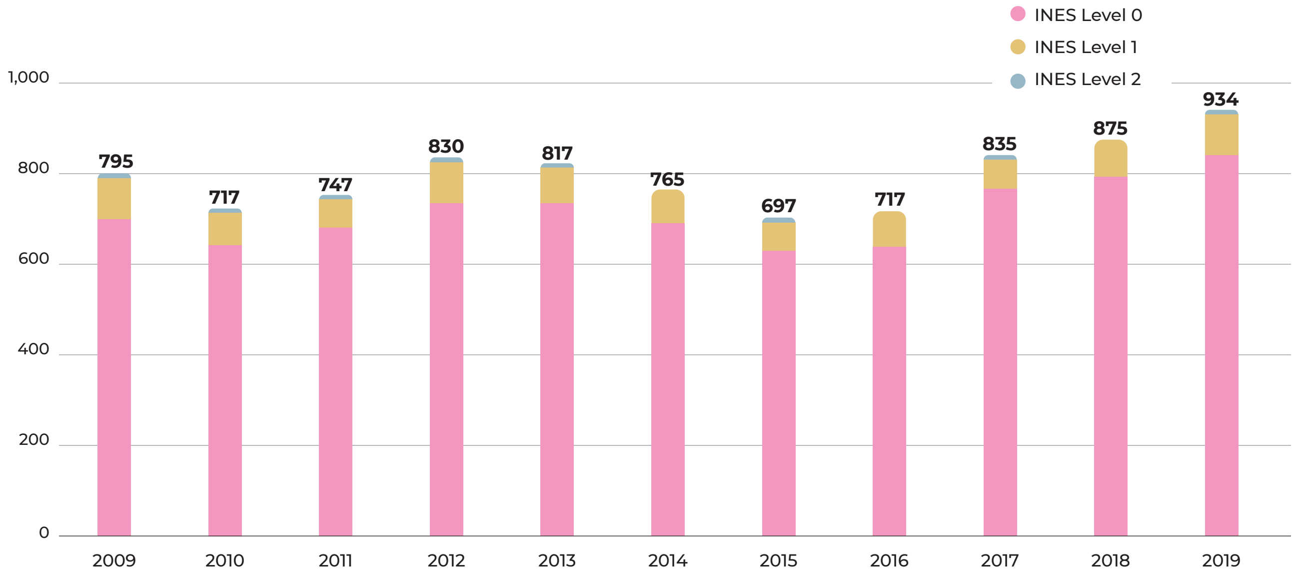
2.6.1 Monitoring how organisations work

• The Integrated Management System

The Order of 7 February 2012 stipulates that the licensee must in particular have the technical skills needed to manage the activities

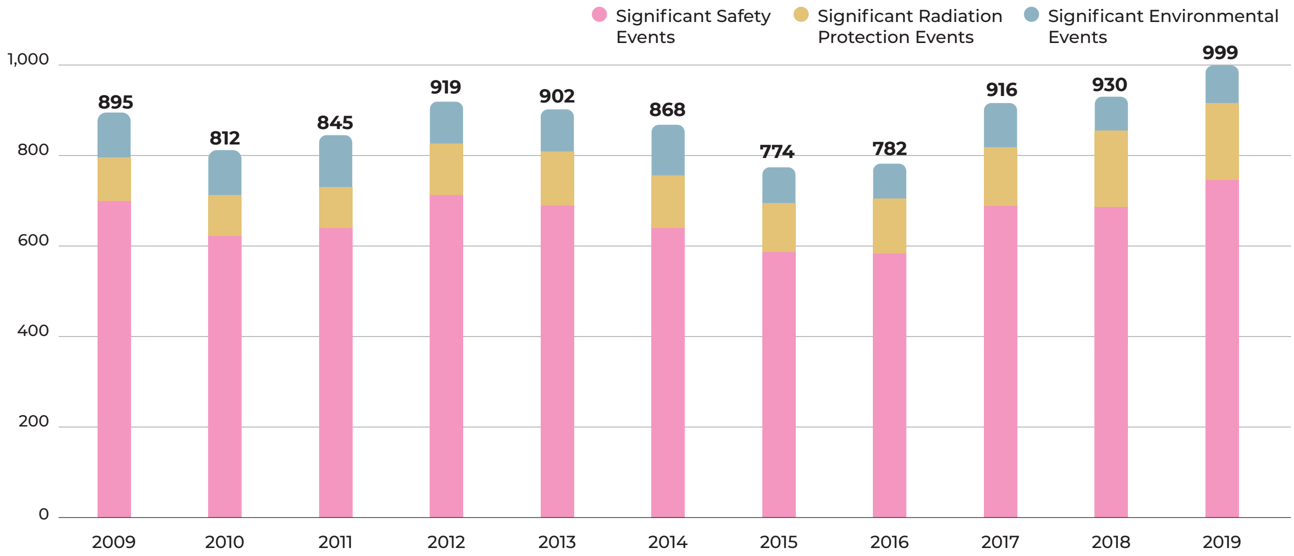
GRAPH 1

Trend in the number of significant events rated on the INES scale in the EDF nuclear power plants between 2009 and 2019



GRAPH 2

Trend in the number of significant events by domain in the EDF nuclear power plants between 2009 and 2019



involved in operation. 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 that the licensee 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. This IMS must specify the steps taken with regard to organisation and to resources of all kinds, in particular those adopted to control the activities important for the protection of persons and the environment.

ASN oversight of the working of the organisations set up by EDF aims to check the IMS implementation procedures. ASN more particularly ensures that the design or modification approach adopted by the engineering centres at the moment of the design of a new facility or a modification to an existing facility takes account of the users' needs and does not compromise compliance with the defined requirements.

More broadly, ASN monitors the organisation put into place by EDF to manage the resources needed to perform these activities.

- **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, as well as 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 as licensee with regard to the protection of persons and the environment and to be able to effectively monitor the quality of the work performed by the subcontractors. Poorly managed subcontracting is liable to lead to poor quality work

Waste storage in the Blayais NPP

and have a negative impact on the safety of the facility and the radiation protection of the workers involved.

EDF takes the necessary steps to control the risks associated with the subcontracted activities and regularly updates them. EDF has thus reinforced the preparation of outages, more particularly to guarantee the availability of human and material resources.

ASN checks the conditions surrounding the preparation for (schedule, required human resources, etc.) and performance of the subcontracted activities (relations with the licensee, monitoring by the licensee, etc.). It also checks that the workers involved have the means needed (tools, operating documentation, etc.) to perform their tasks, in particular when these means are made available by EDF.

2.6.2 Assessment of the working of the organisations and control of activities

• Working environments
ASN considers that EDF must pay greater attention to the quality of the working environments. For each worker, the licensee must guarantee working conditions which do not impair the quality of his or her work, more particularly in terms of accessibility to the premises and the identification of pathways, logistics which must not hamper the performance of an activity, the provision of tools and spares and operational documentation that is up-to-date and which must give reliable and safe information and instructions.

• Management of operational documentation
In 2018, ASN observed that for all of its NPPs, EDF needed to significantly improve its management of the operational documentation. In 2019, ASN thus reinforced its monitoring of the management of this documentation. Numerous analyses of significant events reported in 2019 still show problems relating to the operational documentation. Furthermore, ASN regularly finds that the documentation could be improved (unsuitable ergonomics, working documents that are incomplete, too generic or not up-to-date, procedures which do not take account of the reactor states or specific features of the site, etc.), and is not always rigorously applied by the workers (shortcomings in the exhaustiveness of the work monitoring files, assimilation of the files and filling out of the procedures). These weaknesses can be found in various operating domains, notably incident or accident operations, with regard to which significant improvements must be made to the documentation.

• Management of skills, training and qualifications
The organisation put into place on the sites to manage the skills, qualifications and training remains on the whole satisfactory in 2019. The implementation of the national baseline requirements on the sites, as well as the adoption of provisions such as the training committees at several levels within the organisation (shift crew, department and management) would appear to be producing good results. However, ASN is still regularly finding that the technical skills of certain workers and supervisors are insufficient (lack of knowledge of equipment, out of date knowledge of equipment which has been modified, supervisors with insufficient technical expertise of the subjects being monitored, and so on). These shortcomings are particularly noticeable on the sites where there is significant workforce turnover.

• Monitoring of subcontracted activities
ASN considers that the quality of monitoring remains on the whole stable in 2019 on all the sites, by comparison with 2018. The progress observed in 2018 in terms of preparation of the monitoring programmes is confirmed in 2019. This is due in part to efficiency, to the good assimilation of the new tool assisting with the drafting of monitoring programmes and to the performance of the monitoring actions. However, the subcontracted work monitoring procedures still reveal difficulties on certain sites (shortcomings in the monitoring of technical operations, difficulties with the transmission of defined requirements to certain contractors or, more generally, with making them aware of the issues linked to the sensitive activities, unsatisfactory control of the quality of the work done by the subcontractors).

• The operating experience feedback process
In recent years, all the NPPs have implemented a formal organisation and dedicated tools to oversee and coordinate internal and external operating experience feedback. This must however be improved on a majority of the sites. Shortcomings with regard to the detection and characterisation of the difficulties and deviations reported in the field are still present. As in 2018, the encouragement given to the contractors to transmit positive or negative findings *via* the debriefings and dedicated tools is only bearing fruit on a minority of sites. On this point, ASN strongly disapproves of the transition to a new tool for inputting the findings from the field, to which the contractors do not at present have access. ASN also noted weaknesses on most sites concerning the detection, transmission and processing of early warning signs, as well as insufficient integration of positive operating experience feedback.

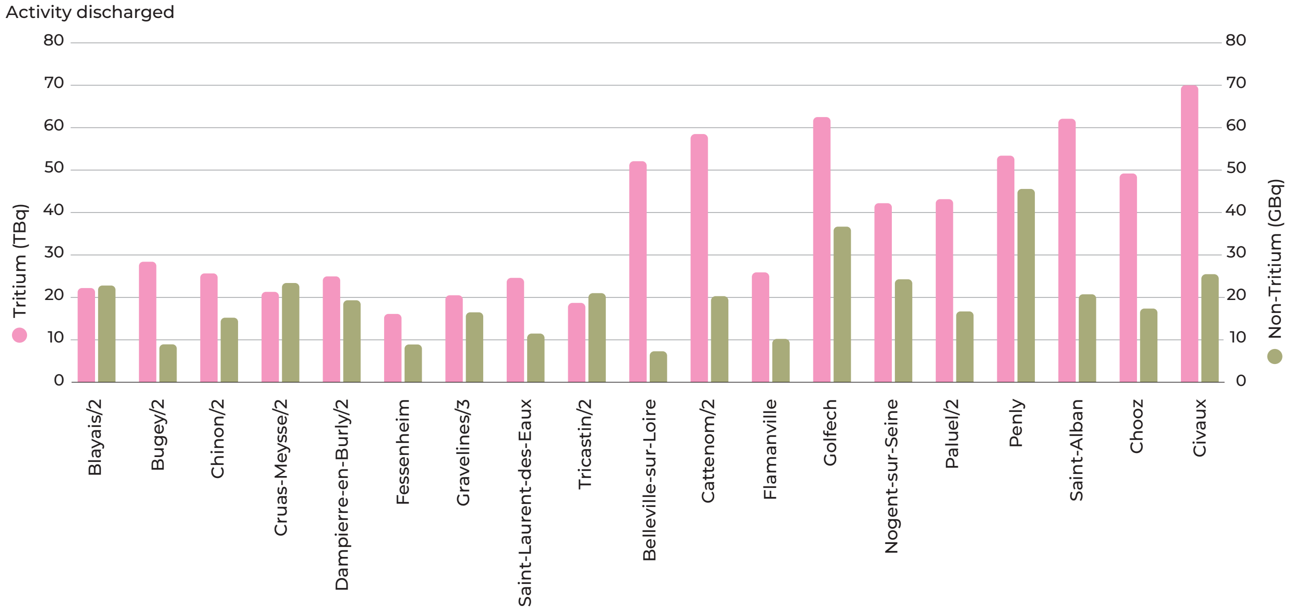
Weaknesses also persist in the exploitation of operating experience feedback from the other EDF NPPs (notably the significant events) or even from the other reactors on the same site. Many significant events reveal that external operating feedback was not adequately taken into account.

The analyses conducted by the sites further to significant events are generally appropriate and the identification of organisational causes is progressing. However, the analysis of the root causes all too often still leads to relatively unambitious measures which do not sufficiently call the organisation into question and which are no more than limited-scope awareness-raising actions for the staff, departments or contractors identified as being responsible for the deviation. Finally, too many sites are still particularly limited when it comes to assessing the effectiveness of the corrective measures.

• The overall organisational approach
Over and above the comments already made, ASN identified a number of worrying situations in 2019 (monitoring in the control room, management of operating instructions in the event of an incident or accident, radiation protection, etc.) in which the worker groups lose sight of the fact that their actions make a contribution to safety, with some deviations actually eventually being considered as normal. In this context, it would appear necessary for the organisational aspect to be dealt with more

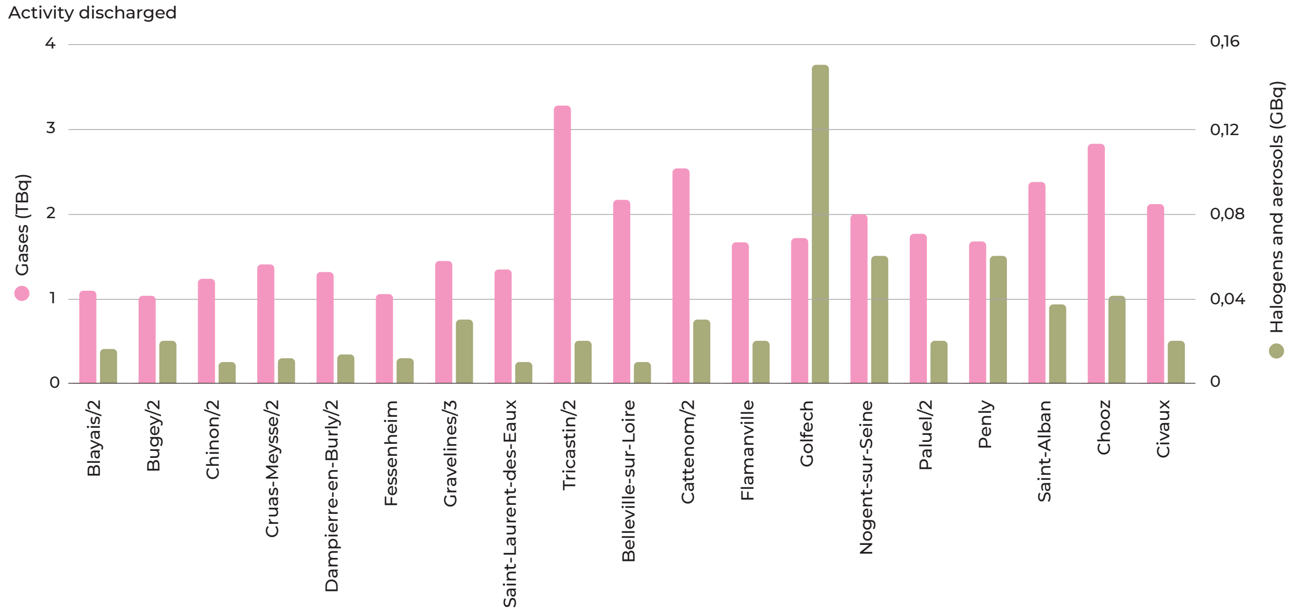
GRAPH 3

Liquid radioactive discharges for the NPPs in 2019 (per pair of reactors)



GRAPH 4

Gaseous radioactive discharges for the NPPs in 2019 (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 means: • keeping the results as they 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). Moreover, the discharge data for each site, sent to ASN by EDF, are not representative of the operating time of the facilities or activities.

systematically. ASN will focus on this point in 2020, notably through "explanatory" interview methods, during which the inspectors invite the personnel to discuss their experiences and their day-to-day working conditions.

2.7 Personnel radiation protection

2.7.1 Monitoring of personnel radiation protection

Exposure to ionising radiation in a nuclear power reactor comes primarily from the activation of corrosion products in the primary system and fission products in the fuel. All types of radiation are present (neutrons, α, β and γ), with a risk of internal and external exposure. 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 monitors compliance with the regulations relative to the protection of workers liable to be exposed to ionising radiation in NPPs. In this respect, ASN is attentive to all the workers on the sites, both EDF personnel and those of contractors.

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 more occasionally in the EDF head office departments and engineering centres), and on the occasion of 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 as applicable.

Periodic meetings are held with EDF as part of the technical dialogue with the licensee. They enable ASN to check the progress of technical or organisational projects being run to improve radiation protection.

- **Significant contamination events**

The number of reported significant contamination events concerning workers in the NPPs operated by EDF is up over 2018: seven events were reported in 2019, as compared with two events in 2018. These events, which led to exposure greater than one quarter the annual regulation limit per square centimetre of skin, were rated level 1 on the INES scale. The procedure adopted by EDF, which consists in removing the contaminating particles with a wipe when they are detected in the hot change room was implemented in most of the above-mentioned cases and helped reduce the time the workers were exposed. Generally speaking, ASN observes progress in the care given to the contaminated workers, which was the subject of corrective action requests in 2016, 2017 and 2018. There are however still deviations, in particular concerning the care given to workers in areas with a contamination risk other than the nuclear islands.

2.7.2 Assessment of personnel radiation protection

The collective dose on all the reactors increased in 2019 by comparison with 2018 (Graph 1), while the average dose received by the workers for one hour of work in the controlled area remained on the whole stable (Graph 2). The doses received by the workers are broken down as illustrated below in Graphs 3 and 4.

Graph 3 shows the breakdown of the workers according to whole body external dosimetry. It can be seen that the dosimetry for 76% of the exposed workers is less than 1 mSv (millisievert) for the year 2019, 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 2019.

Graph 1 shows the trend in the collective dose received by NPP workers over the past ten years. This graph shows an increase in the collective dose received in 2019 by comparison with 2018 and 2017. The average collective dose received in 2019 is at a level comparable to that recorded between 2013 and 2016.

Graph 4 shows the trend in whole body average individual dosimetry according to the categories of workers in the NPPs. The most exposed worker categories in 2019 are personnel in charge of heat insulation, welding, monitoring and mechanical work. The doses recorded by the most exposed workers are up by comparison with 2018.

During its inspections, ASN found that worker radiation protection within the NPPs had regressed in 2019, notably with respect to the application of radiation protection rules and the consideration of worker protection when planning the activities. Shortcomings are in particular observed in the implementation of processes for access to and demarcation of operation areas and prohibited areas, in which the dose equivalent rate is liable to be higher than 100 mSv/h (millisieverts per hour), notably reflecting an inadequate perception of the radiological risks. During the inspections carried out during reactor maintenance outages, the ASN inspectors repeatedly submit requests regarding the availability of radiation protection equipment, and regarding risk and dose optimisation assessments. They nevertheless underline that progress has been made in the implementation of worksite confinement means.

The drop in the standard of radiation protection is particularly flagrant in certain NPPs. For these NPPs, ASN has reinforced its monitoring. It observes that the steps taken by EDF are not fully bearing fruit, notably with regard to the correction of organisational deviations. ASN will be remaining vigilant on these issues during the course of 2020.

2.8 Labour Law in the NPPs

2.8.1 Oversight of Labour Law in the NPPs

ASN carries out labour inspectorate duties in the 19 NPPs, the eight reactors undergoing decommissioning and the EPR under construction at Flamanville. The workforce in an NPP varies between 800 and 2,000 people. 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, who more specifically take part in maintenance during reactor outages.

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.

Tightened environmental inspections

The "tightened" inspection campaigns carried out by ASN are a particular inspection format with a broader scope of inspection. They allow an overall assessment on a given topic for an entire site and a geographical area. Since 2015, ASN has carried out this type of inspection once per year on the topic of environmental protection. After the Rhone Valley sites and the NPPs at Blayais, Golfech and Civaux, the sites of the Normandy region (Paluel, Penly and Flamanville) underwent tightened inspections in May and June 2019.

Using a similar inspection programme of a day and a half, a team of ASN inspectors, accompanied by IRSN experts, examined the environmental protection organisation of each of these NPPs in turn.

The large size of the team deployed (up to 16 ASN inspectors and three IRSN experts per site) enabled the control of discharges into the environment, the management of non-radiological risks and the pollution prevention measures to be inspected.

On each of the sites, the duration of the inspection made it easier to hold large-scale exercises and simulations. Thus, at the request of ASN, each site tested its pollution prevention organisation by means of an exercise simulating a spillage of dangerous substances reaching the rainwater collection network.

The inspectors observed that the EDF teams on the sites had taken account of certain points raised by ASN in previous years and that the personnel demonstrated a clear desire to address environmental issues. However, documentary and organisational shortcomings observed with regard to managing the prevention of pollution led ASN to ask EDF for a national action plan on this subject.

The labour inspectorate takes part in the integrated vision of oversight sought by ASN and carries out its monitoring work in conjunction with the other activities to monitor and oversee the safety of facilities and radiation protection.

In 2019, the ASN resources for its labour inspectorate duties were:
- 14 labour inspectors, one of whom was undergoing training, assigned to its regional divisions;
- a labour director and deputy labour director in head office, responsible for running, coordinating and supporting the network of labour inspectors and providing the interface with the Ministry in charge of labour.

• Oversight of occupational health and safety regulations

With regard to occupational health and safety, the ASN labour inspections more specifically covered the following topics in 2019:
- The use of electrical installations. The inspectors are continuing to monitor the measures taken by EDF to ensure compliance with the provisions of the Labour Code.
- The worksites with asbestos risks. The labour inspectors are particularly vigilant during their inspections with regard to preventing the risk of inhalation of these fibres.
- The conformity of the working equipment and more specifically the lifting gear. The labour inspectors are still finding shortcomings.
- The fire and explosion hazards, for which the ASN inspectors revealed non-conformities. ASN provides coordinated oversight to take account of all aspects of these hazards, which are important both for worker safety and for nuclear safety (see point 2.4.6).

In addition, an inquiry is systematically held in the event of a severe accident or severe near-accident. A fatal accident as a result of worksite and handling organisation problems sadly occurred in 2019.

• International subcontracting and provision of services

Steps were taken in 2019 regarding the monitoring of notifications and the conditions for the secondment of staff from foreign companies, notably on the Flamanville EPR reactor construction site.

• Criminal and administrative procedures in progress

With regard to illegal working, ASN closely monitors the criminal proceedings instigated in previous years, more specifically through regular contacts with the Public Prosecutor's offices.

With regard to health and safety, the work done by the ASN labour inspectorate led in 2019 to the opening of two criminal procedures against EDF or its contractors owing to a lack of worksite organisation and coordination and a lack of appropriate personal protective equipment.

Administrative penalty procedures for violations of working hours regulations were initiated by the labour inspectors and monitored by the Regional Directorates for Enterprises, Competition, Labour and Employment (Direccte) who have the power to issue sanctions in this area.

2.8.2 Assessment of health and safety, professional relations and quality of employment in the NPPs

Certain occupational risk situations are still worrying and must be significantly improved: the risks linked to working equipment and more particularly to lifting gear, explosion and fire risks and electrical risks. The labour inspectorate also 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.

Tightened radiation protection inspections

Since 2011, ASN has carried out tightened inspections on the subject of protection of workers against ionising radiation. The NPPs at Chinon, Dampierre-en-Burly, Saint-Laurent-des-Eaux and Belleville-sur-Loire, situated in the Loire Valley, thus underwent a campaign of tightened inspections in September and October 2019.

Simulations were used to check the organisation for dealing with contaminated workers and processing atmospheric contamination detection alarms inside the reactor building. An unannounced night-time inspection of the steps taken to ensure the radiation protection of workers during a reactor outage was also carried out.

The inspectors observed that good practices were used on the various sites inspected. However, they did note a number of deviations indicating a lack of radiation protection culture on the sites. ASN expects coordinated action on the part of EDF so that personnel radiation protection issues are taken on board by everyone.

Finally, progress is still required in the management of joint contractor working (quality of prevention plans in particular), the use of subcontracting and foreign staff secondment situations.

2.9 Lessons learned from the Fukushima Daiichi NPP accident

Following the accident in the Fukushima Daiichi NPP, ASN adopted a range of resolutions dated 5 May 2011, requiring the licensees of the major nuclear facilities to carry out stress tests.

The conclusions of these stress tests led to an ASN position statement on 3 January 2012, which was itself peer reviewed in April 2012, under the European stress tests programme.

On the basis of the opinion of the Advisory Committees and the conclusions of the European stress tests, ASN issued a range of resolutions dated 26 June 2012, instructing EDF to implement:
- a range of corrective measures or improvements (notably the acquisition of additional communication and radiological protection means, the implementation of additional instrumentation, the extensive consideration of internal and external hazard risks, improvements in the handling of emergency situations);
- 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 local emergency centre allowing emergency management of the nuclear site as a whole in the event of an extreme external hazard;
- 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.

ASN inspection at the Chooz NPP – Entering a controlled area

ASN added to its requests with a range of resolutions dated 21 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".

More generally, ASN's requests are also part of a continuous 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 works requested, the licensee must carry out studies for the design, construction and installation of new equipment which first of all require time and secondly a schedule to optimise their implementation on each NPP. Indeed, insofar as these major works are carried out on nuclear sites which are in service, it is also necessary to ensure that their performance does not degrade the safety of the NPPs.

In 2015, EDF completed the deployment of temporary or mobile measures to enhance how the main situations of total loss of the heat sink or electrical power supplies are addressed. More particularly, connection means were installed so that, in the event of an emergency, the mobile systems can be connected to provide water. Furthermore, the FARN, which is one of the main emergency management means, was set up. Since 31 December 2015, the FARN teams have had 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). These provisions are in response to the recommendations resulting from the European peer review in April 2012 as part of the European stress tests.

EDF has also started the deployment of certain permanent resources robustly designed and organised with regard to extreme hazards in order to deal with the main situations of loss of heat sink or of electrical power supplies beyond the safety baselines currently in force and core melt accidents.

The most important measures are:
- installation of a large-capacity Ultimate Backup Diesel-generator set (DUS), requiring the construction of a dedicated building to house it; owing to the industrial difficulties encountered by EDF in their construction, ASN decided in 2019 to modify the schedule for commissioning these DUS. In parallel with this rescheduling, with the deadline now being set at 31 December 2020, ASN issued binding requirements for an increase in the robustness of the existing electricity sources. At the end of 2019, 35 DUS had been commissioned by EDF;
- the creation of an ultimate water source. As at 31 December 2019, EDF has set up the ultimate water source on the Flamanville site. EDF also initiated the creation of that on other sites and plans to complete the works at the end of 2021, except for the Blayais, Gravelines and Dampierre-en-Burly sites, for which the work will be completed in 2022;
- construction on each site of a local emergency centre capable of withstanding extreme external hazards (functionally independent in an emergency situation). In 2019, EDF completed the construction of the local emergency centre on the Flamanville site, which should be commissioned in 2020. For the other sites, EDF plans completion of the works between 2022 and mid-2025.

These measures will also be supplemented during the periodic safety reviews by implementation of the "hardened safety core". These resources were partially deployed on the Tricastin NPP reactor 1 during its fourth ten-yearly inspection.

The most important measures are:
- 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;
- the installation of a corium flooding solution which would be installed in the reactor pit, to prevent basemat melt-through in the event of core melt.

In anticipation of setting up the "hardened safety core", ASN is examining the design hypotheses for the material provisions and checking that the solutions proposed by EDF can meet the safety objectives set.

On the basis of the files transmitted by EDF and the studies carried out, ASN asked the Advisory Committee for Reactors (GPR) for 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 28 January and 10 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 7 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 2 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 Continued operation of the NPPs

2.10.1 The age of the 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 the French nuclear power reactors, were commissioned between 1980 and 1990, and seven reactors, representing 10,000 MWe, between 1991 and 2000. In December 2019, the average age of the reactors, calculated from the dates of first divergence, can be broken down as follows:
- 38 years for the 34 nuclear power reactors of 900 MWe;
- 32 years for the 20 nuclear power reactors of 1,300 MWe;
- 22 years for the four nuclear power reactors of 1,450 MWe.

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 assess 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 comprise checks on the initial design studies as well as field inspections of the equipment, or even ten-yearly tests such as the containment hydrotests. Any 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, notably taking account of the experience acquired during operation, changing knowledge, the requirements applicable to the more recent facilities and international best practices. Following these reassessment studies, EDF identifies the changes it intends to make to its facilities in order to enhance safety.

• The review process for the EDF nuclear power reactors

In order to fully benefit from the standardisation of the nuclear power reactors operated by EDF, these two parts of the periodic safety review are first of all covered by a generic studies programme for a given type of reactor (900 MWe, 1,300 MWe or 1,450 MWe reactors). The results of this programme are then applied to each nuclear power reactor on the occasion of its periodic safety review. EDF more particularly carries out a large part of the checks and modifications related to the periodic safety reviews during the ten-yearly inspections of its reactors. In accordance with the provisions of Article L. 593-19 of the Environment Code, following this periodic safety review, the licensee sends ASN a periodic safety review conclusions report. In this report, the licensee gives its position on the regulatory compliance of its facility as well as on the modifications made to remedy the deviations observed or improve the safety of the facility and, as necessary, proposes implementing additional improvements. The periodic safety review report comprises parts specified in the Environment Code.

• ASN analysis

The guidelines of the generic programmes proposed by EDF for verification of the status of the facility and reassessment of safety are the subject of an ASN position statement issued following consultation of the GPR and possibly of the 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 to allow the safety improvements envisaged by EDF.

ASN then 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 17 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 35th 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 the equipment, in the light of which ASN may supplement its binding requirements.

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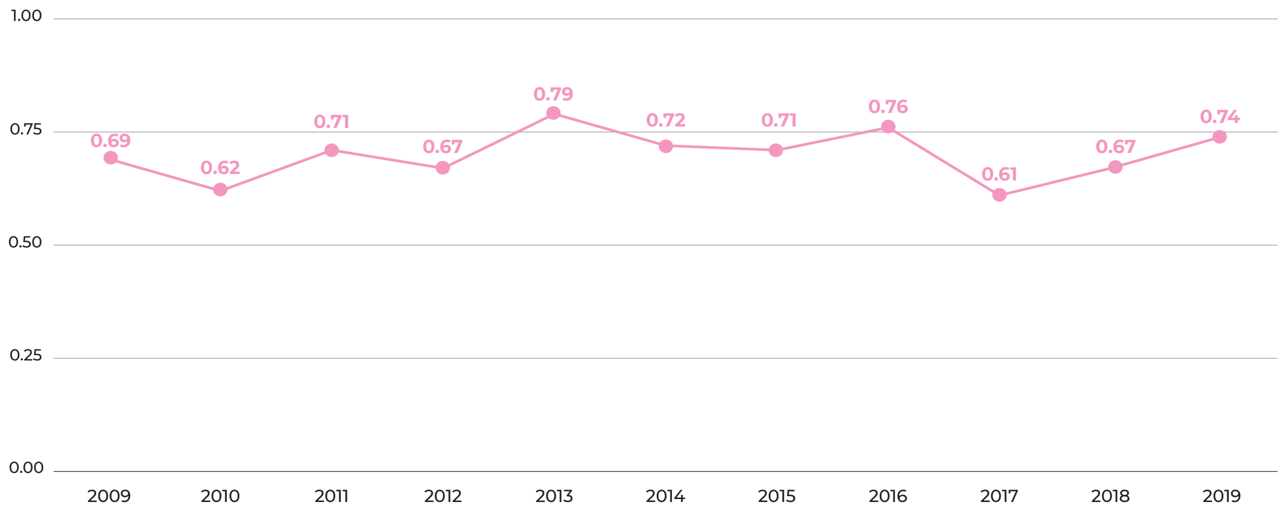
GRAPH 5

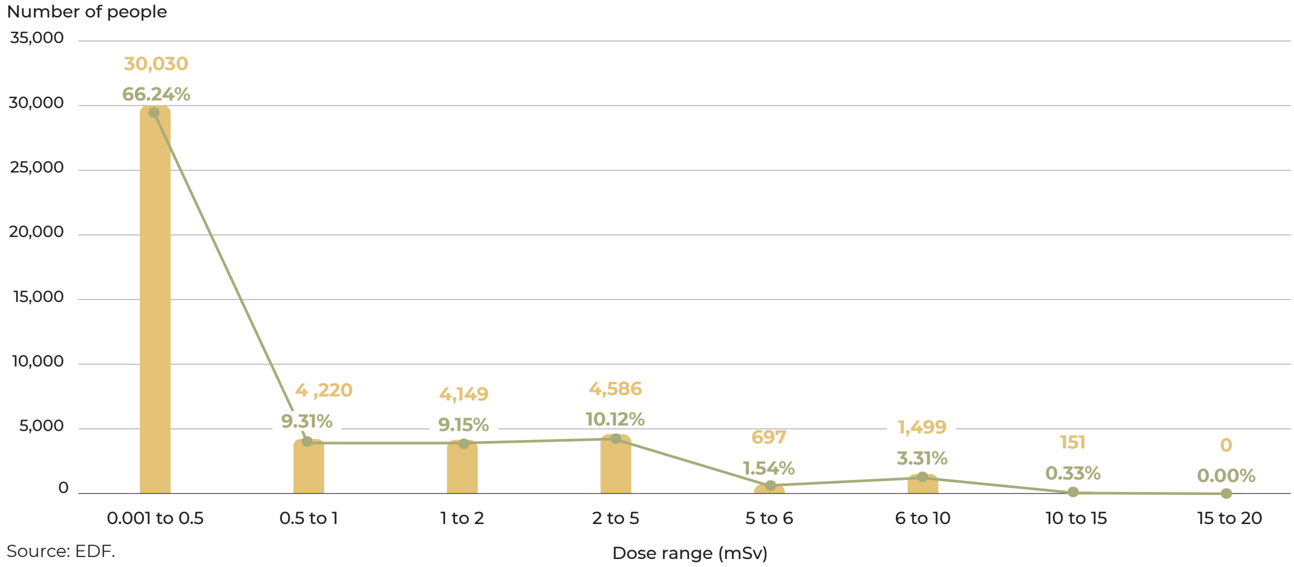
Mean collective dose per reactor (Man.Sv/reactor)



Source: EDF.

GRAPH 6

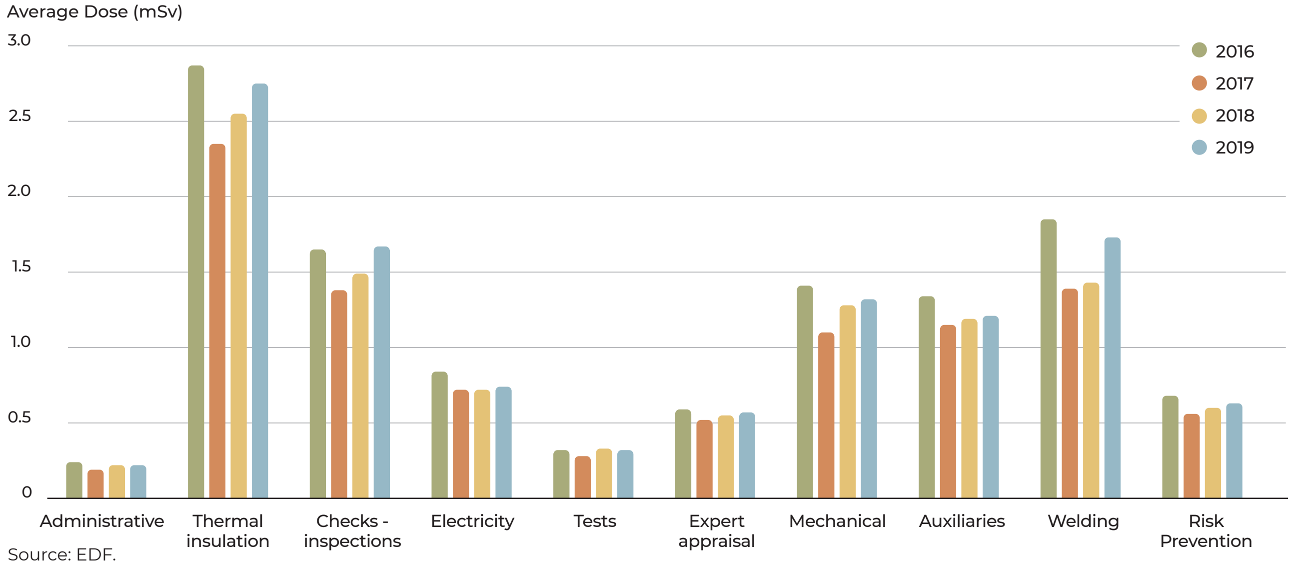
Number and percentage of workers per dose range (in mSv) for 2019



Source: EDF.

GRAPH 7

Trend in mean individual dosimetry according to the categories of trades of the workers in the NPPs



Source: EDF.

• The main challenges in managing ageing

As with 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 the ageing of an NPP, over and above simply the time that has passed since it was commissioned, a certain number of factors must be considered, more specifically the existence of physical phenomena which can degrade the characteristics of the equipment according to its usage or its 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, hardening of polymers, corrosion of metals, etc. This deterioration is generally incorporated as of the design and manufacture of the facilities and then in a programme of monitoring and preventive maintenance, as well as of repair or replacement if necessary.

• The lifetime of non-replaceable items

Non-replaceable items, such as the reactor pressure vessel (see point 2.2) and the containment (see point 2.3), are subject to close monitoring in order to check that they age as anticipated and that their mechanical characteristics remain within the limits allowing satisfactory behaviour.

• Obsolescence of equipment and its components

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

Postponed commissioning of Ultimate Back-up Diesel generator sets (DUS)

In its resolutions of 26 June 2012 issued in the light of the conclusions of the stress tests performed following the Fukushima Daiichi NPP accident, ASN instructed EDF to install an additional electricity supply means before 31 December 2018, capable of supplying the systems and components of the "hardened safety core" in the event of loss of other off-site and on-site electricity sources. In response to these requirements, EDF began the construction of Ultimate Back-up Diesel generating sets (DUS).

EDF informed ASN that for 54 reactors, it was impossible to meet the 31 December 2018 deadline for deployment of these DUS. ASN considered that the difficulties encountered by EDF were justified and that some of them still persist. They are notably the result of the scale and complexity of the operations and the particularities of certain sites.

ASN modified the commissioning schedule for the DUS owing to the technical difficulties encountered by EDF. As a counterpart to this rescheduling, with the deadline now being set at 31 December 2020, ASN issued binding requirements for an increase in the robustness of the existing electricity sources.

At the end of 2019, EDF had commissioned 35 DUS.

required. The availability of spares for this equipment is heavily dependent on any changes in the industrial network of suppliers. The end of manufacturing of certain components or the closure of the manufacturing company can lead to supply difficulties. Prior to their installation, EDF must check that 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 time required for this procedure, EDF must anticipate well in advance.

• The nuclear power reactors ageing management process
The approach adopted by EDF to managing the ageing of its facilities is built around three key points:
- Anticipate ageing as of the design process: at design and during manufacture of the components, the choice of materials and the installation arrangements must be appropriate to the planned operating conditions and take account of the known or presumed degradation kinetics.
- Monitor the actual condition of the facility: during operation, degradation phenomena other than those considered in the design can be discovered. The periodic test 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) must enable these phenomena to be detected sufficiently well in advance.
- Repair, renovate or replace the equipment: given the operating constraints that such routine or exceptional maintenance operations are liable to generate, especially when they can only be performed during nuclear power reactor outages, EDF must seek to anticipate them, in particular to take account of the time taken to procure new components, the time taken to prepare for and carry out the work, the risk of obsolescence of 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 beyond 30 years of operation, the aim of which is to demonstrate their ability to continue to function until their fourth periodic safety review 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 observed during their third periodic safety review.

This methodology comprises a first generic phase which aims to determine how ageing is taken into account for a set of similar reactors. Subsequently, on the occasion of the third periodic safety review of each nuclear power reactor, a summary file specific to the reactor is drawn up in order to demonstrate management of the ageing of the equipment and the reactor's ability to continue to function for the ten-year period following its third ten-yearly inspection.

To ensure continued operation of the nuclear power reactors beyond their fourth ten-yearly inspection, EDF reuses this type of approach, which is applied not only to all the systems, structures and components important for managing radiological risks, but also conventional risks.

2.10.3 Current period safety reviews in the NPPs

• The 900 MWe reactors
The third periodic safety review
In July 2009, ASN issued 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. It 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 its nuclear power reactors.

This generic assessment does not take account of any specific individual aspects and ASN gives a ruling on the suitability for continued operation of each nuclear power reactor, notably on the basis of the results of the conformity checks and the assessment made in the periodic safety review conclusions report for the reactor submitted by EDF.

As at the beginning of 2020, 33 of the 34 reactors of 900 MWe have carried out their third periodic safety review and have incorporated the improvements resulting from this review.

In 2019, ASN also sent the Minister responsible for nuclear safety its analysis of the periodic safety review conclusions report for the Blayais NPP reactor 1. On the basis of this analysis, ASN did not identify any elements compromising EDF's ability to ensure the safety of this 900 MWe reactor up until the next periodic safety review. Pursuant to Article L. 593-19 of the Environment Code, ASN took this opportunity to issue additional binding requirements designed to reinforce the safety of these reactors.

The fourth periodic safety review
A review with major implications
The 34 EDF 900 MWe reactors were commissioned between 1977 and 1987 and the first of them are approaching their fourth periodic safety review. The conditions for the continued

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operation of these reactors, except for the two reactors of the Fessenheim NPP, which are scheduled for final shutdown in 2020, must therefore be defined. These two reactors will be the subject of a specific periodic safety review.

For the other 32 reactors, there are a number of particular implications in this fourth periodic safety review:
- Some items of equipment are reaching their design-basis lifetime. 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 implemented by EDF.
- The modifications associated with this periodic safety review will enable the integration of the modifications specified by ASN following the Fukushima Daiichi NPP accident to be completed on these reactors.
- The safety reassessment of these reactors and the resulting improvements must be carried out by comparison with the new-generation reactors, such as the EPR, the design of which meets significantly reinforced safety requirements.

ASN position at the end of 2020 on the EDF generic studies applicable to all reactors

In 2013, EDF sent ASN its objectives for this periodic safety review, in other words, the level of safety to be achieved for continued operation of the reactors.

After examining the objectives proposed by EDF, with the support of IRSN, and following consultation of its Advisory Committees, ASN released a position statement on these objectives and issued additional requests in April 2016. EDF supplemented its programme of work and in 2018 presented ASN with the measures it envisages taking in response to these requests.

With the support of IRSN, ASN is continuing to examine the generic studies linked to this review. In 2018 and 2019, ASN more particularly obtained the opinion of its Advisory Committees on:
- management of ageing and obsolescence;
- the mechanical strength of the reactor pressure vessels;
- NPE;
- the accident studies in the safety case;
- the ability of the installations to withstand internal and external hazards;
- the probabilistic safety assessments;
- the management of accidents with core melt.

It will ask for their opinion again in 2020 with regard to the mechanical strength of the reactor vessels core zone and the results of the generic phase of this periodic safety review.

In September 2018, ASN sent EDF its initial observations on the inspections and modifications EDF intends to implement on its reactors in order to meet the objectives of the periodic safety review. At the end of 2020, ASN will issue a position statement on the conditions for continued operation of the reactors.

2019: the beginning of the fourth ten-yearly inspections

In 2019, Tricastin NPP reactor 1 underwent its fourth ten-yearly inspection, which is a major step in its fourth periodic safety review. During this outage, EDF carried out a significant part of the required inspections and will deploy the first safety improvements associated with the review. ASN will issue a position statement on the continued operation of this reactor in 2022, after its position statement on the generic studies and its examination of the periodic safety review conclusions report for this reactor, which is to be submitted by EDF in 2020.

Involving the public at each step

For the purposes of this periodic safety review, ASN has been involving the public since 2016 in the drafting of its position statement regarding the objectives proposed by EDF. This approach continued in 2018, under the aegis of the High Committee for Transparency and Information on Nuclear Security (HCTISN), in the form of a consultation on the measures planned by EDF to meet these objectives. ASN will also consult the public at the end of 2020 on the position it is to adopt on the generic phase of the periodic safety review. Pursuant to the law, a public inquiry will then be held, reactor by reactor, after submission of the periodic safety review conclusions report for each of them.

• The 1,300 MWe reactors

The second periodic safety review

In 2006, ASN ruled favourably on the generic aspects of the continued operation of the 1,300 MWe reactors up to their third periodic safety review, provided that the modifications decided upon during this review were effectively implemented.

The 20 reactors of 1,300 MWe have now all undergone their second periodic safety review and have incorporated the improvements identified by the review.

Pursuant to Article L. 593-19 of the Environment Code, ASN submitted its position in 2014 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 on this occasion set out additional binding requirements 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

At the beginning of 2015, ASN issued a position statement on the generic aspects of the continued operation of the 1,300 MWe reactors beyond thirty years of operation. ASN considers that the steps taken or planned by EDF to assess the state of its 1,300 MWe reactors and manage their ageing up to the fourth periodic safety review are acceptable. ASN also considers that the modifications identified by EDF following 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.

Further to the conclusions of the generic phase of this review, ASN intends to issue additional generic binding requirements in 2020 applicable to all the 1,300 MWe reactors, with the aim of reinforcing their safety.

Flamanville NPP reactor 1, the reactors of the Saint-Alban NPP, those of the Paluel NPP, Belleville-sur-Loire NPP reactor 2, Cattenom NPP reactors 1 and 2 and Nogent-sur-Seine NPP reactor 1 carried out their third ten-yearly inspections between 2015 and 2019. The third ten-yearly inspections for the 1,300 MWe reactors will continue until 2024.

The fourth periodic safety review

In July 2017, EDF presented a file giving the orientations envisaged for the generic phase of the fourth periodic safety review of the 1,300 MWe reactors. In 2019, ASN issued a position statement on these orientations, notably with consultation of the GPR on 22 May 2019. ASN considers that the general objectives set by EDF for this review are acceptable in principle. However, following its requests regarding the fourth periodic safety review of the 900 MWe reactors, ASN asks EDF to modify or supplement these general objectives for this safety review, to consider certain baseline requirements for reassessment of the safety of its facilities and to add study topics to its review programme.

Chronology of first criticality of the French nuclear power reactors at the end of 2019

Date of first 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.

• The 1,450 MWe reactors

The second periodic safety review

In 2011, EDF transmitted its proposed orientations for the generic study programme of the second periodic safety review for 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. ASN issued a position statement in February 2015 regarding the orientations of this second periodic safety review. It notably considers that the safety objectives for the second periodic safety review of the 1,450 MWe reactors should be defined in the light of the objectives applicable to the new nuclear power reactors and asked EDF to study measures liable to meet this requirement as rapidly as possible, with the aim of implementing them as of the second periodic safety reviews of the 1,450 MWe reactors.

Chooz NPP reactor B2 carried out its second ten-yearly inspection in 2019, while the other ten-yearly inspections of the 1,450 MWe reactors will run until 2022.

• Ageing management

With a view to continued operation beyond the fourth periodic safety review of the 900 MWe nuclear power reactors, EDF intends to reuse the ageing management approach applied since the third periodic safety review of its reactors, while reinforcing its equipment renovation and replacement projects. Ageing management, in particular for non-replaceable items whose integrity is vital for safety –such as the reactor pressure vessel (see point 2.2)– and its containment (see point 2.3), as well as obsolescence management, are essential for maintaining a satisfactory level of safety.

After considering that the steps taken or planned by EDF –notably for identifying the various equipment degradation modes, implementing the corresponding countermeasures and integrating operating experience feedback– were on the whole satisfactory, in 2013 and then again in 2016, ASN –with the support of IRSN– once more examined the ageing and obsolescence management approach and in March 2018 obtained the opinions of the GPR and GPESPN.

ASN notes that EDF has taken account of the requests it made in 2013 and 2016. ASN considers that the steps taken or planned to ensure management of the ageing and obsolescence of the structures, systems and components of the 900 MWe reactors and thus contribute to maintaining their compliance beyond their fourth periodic safety review, supplemented by the undertakings made following the examination, are satisfactory.

The programmes for equipment qualification for accident conditions are pertinent and enable this qualification to be extended beyond the fourth ten-yearly inspection. Actions are still in progress to cover all the equipment concerned.

The envisaged exceptional maintenance operations (replacements, repairs or renovations scheduled during or after the fourth ten-yearly inspections) are consistent with the ageing assessments.

The improvements identified for dealing with obsolescence are such as to guarantee satisfactory and lasting management of obsolescence.

The programme of additional investigations defined by EDF and the planned procedures for processing the results are deemed to be satisfactory.

ASN however identified weaknesses in the processing of operating experience feedback, advance planning of the decisions to be taken, the time taken to process certain generic ageing assessment sheets and the assimilation by the NPPs of the demonstration of the suitability for continued operation in the summary dossier specific to each reactor.

Finally, a small amount of additional work is required concerning ageing phenomena on several components of the main primary and secondary systems.

Moreover, the first Topical Peer Review, required by Council Directive 2014/87/Euratom of 8 July 2014, amending Directive 2009/71/Euratom establishing a community framework for the nuclear safety of nuclear installations on the subject of ageing management, confirmed that the ageing management approach adopted for EDF's nuclear reactors is appropriate. A national action plan has been drafted in response to the conclusions of this review, notably with regard to considering the specificities of the sites in their local ageing management programmes, the inspections of buried piping and the need for an ageing management programme during the lengthy construction phases of new facilities and prolonged reactor outage periods. In 2020, ASN will assess the implementation of this action plan.

2.11 The Flamanville EPR

The EPR is a PWR using a design that has evolved from that of the reactors currently in operation in France, thus enabling it to meet the following reinforced safety objectives: reduction in the number of significant events, mitigation of discharges, reduced volume and activity of waste, reduced individual and collective doses received by the workers (in normal operation and incident situations), reduced overall frequency of core melt, taking account of all types of failures and hazards and reduced radiological consequences of any accidents.

After a period of a decade during which no nuclear reactors were built in France, EDF submitted a creation authorisation application with the Ministers responsible for nuclear safety and for radiation protection, for an EPR type reactor with a power of 1,650 MWe on the Flamanville site, which was already home to two reactors of 1,300 MWe.

The Government authorised its created through Decree 200-534 of 10 April 2017, after a favourable opinion issued by ASN following the examination process. This Decree was modified in 2017 to extend the time allowed for commissioning of the reactor.

After the issue of this Creation Authorisation Decree and the building permit, construction of the Flamanville EPR reactor began in September 2007. The first concrete was poured for the nuclear island buildings in December 2007. Since then, the civil engineering work has continued and is now almost complete.

EDF aims to load fuel and start up the reactor at the end of 2022. This takes account of the time needed on the one hand to repair certain welds on Main Secondary Systems (MSS) and, on the other, to allow the end of the erection and testing operations.

2.11.1 Examination of the authorisation applications

• Examination of the commissioning authorisation application

In March 2015, EDF sent ASN its commissioning authorisation application for the installation, including the safety analysis report, the general operating rules, a study of the facility's waste management, the PUI, the decommissioning plan and an update of the facility's impact assessment. Following a preliminary examination, ASN considered that all the documents required by the regulations were officially present, but it decided that additional justifications were needed if ASN was to be able to reach a final decision on the commissioning authorisation application. ASN began the 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. Some elements still need to be provided before ASN is able to issue a position statement on the commissioning authorisation application file. In 2018, ASN more particularly issued requests for additional information regarding the general operating rules.

ASN also obtained the opinion of the GPR on 4 and 5 July 2018 concerning the safety analysis report for the Flamanville EPR reactor. This meeting was devoted in particular to the action taken following the previous GPR sessions devoted to this reactor since 2015. The Advisory Committee considers that the reactor's safety case is on the whole satisfactory and points out that some additional information is still required concerning how the fire risk is addressed and the behaviour of the fuel rods which have experienced a boiling crisis. The GPR also considers that the design and dimensioning of the back-up systems and auxiliary safety systems are on the whole satisfactory and observes that additional information is still required concerning the breaks liable to affect the fuel storage pool cooling system. In 2019, ASN submitted requests for supplements to the safety case that are needed for a final decision to be reached on the commissioning authorisation application.

• Examination of the partial commissioning authorisation application for arrival of the fuel

At the same time as the commissioning authorisation application, EDF sent a partial commissioning application for the facility, to allow the arrival of fuel on the site. ASN will adopt a position on this application in 2020.

2.11.2 Monitoring of construction, start-up tests and preparation for operation

ASN is faced with numerous challenges concerning oversight of the construction, start-up tests and preparation for operation of the Flamanville EPR reactor. These are:

- checking the quality of the equipment manufacturing and installation construction work 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 start-up tests programme is satisfactory, that the tests are correctly performed and that the required results are obtained;
- ensuring that the various stakeholders learn the lessons from the construction phase and the performance of the start-up tests, 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 licensee takes the necessary steps so that the teams in charge of operating the installation after commissioning are well-prepared.

To do this, ASN set binding requirements for the design, construction and start-up tests for the Flamanville 3 EPR reactor and operation of Flamanville reactors 1 and 2 in proximity to the construction site[2]. Compliance with these requirements is regularly checked by ASN through inspections and through examination of the commissioning authorisation application. As this is a nuclear power reactor, ASN is also responsible for labour inspection on the construction site. Lastly, ASN ensures oversight of the manufacture of the NPE that will be part of the primary and secondary systems of the nuclear steam supply system. The main steps taken by ASN in 2019 are described below.

• Oversight of the construction, assembly and test activities on the Flamanville EPR reactor site

ASN carried out 12 EDF inspections on the Flamanville EPR reactor construction site in 2019. Moreover, two EDF inspections more specifically concerning the construction site activities were carried out in the premises of the EDF Industrial Division in Saint-Denis (*département* 93).

In its construction site oversight activities, ASN devoted particular attention to the following subjects in 2019:
- defining and implementing a programme of additional checks for the quality review ASN asked EDF to conduct on the Flamanville 3 EPR reactor equipment. This request follows the shortcomings observed in EDF's monitoring of outside contractors;
- the preparation for and performance of the start-up tests for the various systems of the installation and EDF's organisation for management of the overall tests. ASN has tightened up its oversight of these tests, which must help demonstrate that the structures, systems and components of the reactor meet the requirements assigned to them. ASN notably carried out a tightened inspection devoted to the performance of hot tests;
- preparations for operation by the EDF entity that will be in charge of the Flamanville EPR after its start-up. This entity currently comprises more than 400 employees. With a view to reactor commissioning, EDF is continuing with the gradual transfer of responsibility for the operation of the structures, systems and components from the entity in charge of construction and reactor start-up operations to the entity in charge of its future operation. The steps in this process enable the future operating personnel to improve their skills, familiarise themselves with the reactor equipment, draw up operating documentation and develop the appropriate tools. Through its oversight, ASN ensures that the future operating teams take advantage of operating experience feedback and best practices employed in EDF's NPPs and that they optimise their assimilation of the working of the equipment during reactor construction and systems start-up tests; ASN also monitors operations preparation activities;
- application of a strategy for the conservation, maintenance and testing of the equipment and structures present on the construction site until the Flamanville 3 reactor is commissioned. Owing to the postponements to reactor commissioning announced by EDF, ASN makes sure that EDF continues to pay close attention to defining and complying with the requirements corresponding to the conservation, maintenance and testing of the equipment already installed and structures built, in order to ensure that requirements compliance obtained during assembly and start-up testing is maintained;
- appropriate management by EDF of protection of the environment, notably through checking implementation of integrated management between the licensee of the Flamanville 3 reactor and those of Flamanville 1 and 2.

• Oversight of the Flamanville EPR engineering activities

In 2019, ASN carried out three inspections in the EDF engineering departments on the processing of deviations, analysis of the start-up test results and qualification of equipment. On this latter point, the inspection performed in 2018 led ASN to serve formal notice on EDF to comply with the provisions of Article 2.5.6 of the Order of 7 February 2012. In September 2019, ASN carried out a further inspection on the topic of equipment qualification. ASN observed that the steps taken by EDF to ensure the traceability of qualification reservations and their processing are satisfactory. ASN therefore envisages no follow-up to the above-mentioned formal notice. Finally, ASN carried out an inspection following the reporting of a significant event regarding numerous deviations affecting a safety injection system pump. This inspection was carried out on the site of the supplier of this pump.

• Labour inspection on the Flamanville 3 EPR reactor construction site

The actions carried out by the ASN labour inspectors in 2019 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 2019, the ASN labour inspectors also carried out a number of checks on the regulatory provisions governing transnational secondment of workers.

• Oversight of NPE design for the Flamanville EPR reactor

During the course of 2019, ASN continued to assess the conformity of the NPE design of 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 Framatome (formerly Areva NP) in 2013 and 2014 and numerous technical meetings to define the additional data to be provided. In 2015, Framatome began a revision of all technical design documentation for this equipment. This latter must be substantiated to take account of the deviations observed.

The organisations approved for assessment of NPE conformity are authorised by ASN to assist it with the examination of this design documentation. Considerable activity on this topic should take place in 2020.

• Oversight of NPE manufacturing for the Flamanville EPR reactor

With regard to oversight of the manufacture of the Flamanville EPR reactor equipment, the action taken by ASN in 2019 mainly concerned deviations affecting the welds on the main steam letdown lines. ASN more specifically convened its Advisory Committee for NPE on two occasions to rule on the solution proposed by EDF.

Taking account of the opinion of the Advisory Committee, ASN considered that repair of the welds on the containment penetrations prior to reactor start-up should be the reference

2. *ASN resolution 2013-DC-0347 of 7 May 2013.*

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solution. Since then, EDF has decided to repair these welds. This subject is presented in a specific thematic sheet (see the introduction to this report).

ASN also issued a favourable opinion on the processing proposed by EDF to restore the conformity of the other welds, identified the pre-conditions for performance of these operations and checked compliance with these conditions.

ASN also initiated an analysis of the deviations which affected the stress-relieving heat treatment of the connection welds on the SG and pressuriser components carried out in Framatome's Saint-Marcel plant.

• Certifications of compliance for the Flamanville EPR reactor Nuclear Pressure Equipment (NPE)
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 and 2018, ASN issued the very first certificates. The compliance evaluation of the other NPE or level N1 nuclear assemblies will continue in 2020.

ASN also authorised the commissioning and operation of the reactor vessel in 2018.

2.11.3 Assessment of construction, start-up tests and preparation for operation of the Flamanville EPR reactor

Generally speaking, ASN considers that the organisation put into place for the Flamanville 3 EPR reactor start-up tests and preparation for its operation were satisfactory in 2019.

However, EDF must supplement its programme of additional inspections carried out as part of the equipment quality review and perform them rigorously. In addition, despite mobilising resources and significantly improving the organisation of the start-up tests, EDF must improve the management of the I&C configurations and the tests performed on the temporarily modified installations. It must also improve the utilisation of the accrued experience feedback and the implementation of the resulting corrective actions. Finally, EDF must ensure application of a strategy for the conservation, maintenance and testing of the equipment and structures present on the construction site until the reactor is commissioned. In 2020, ASN will continue its oversight of these topics and will also ensure that the main secondary systems are restored to conformity.

2.12 Studies on reactors of the future

• EPR 2
In April 2016, EDF asked ASN for its opinion on the safety options for a PWR reactor project called EPR New Model (EPR NM), being developed by EDF and Framatome.

This project aims to meet the general safety objectives for third-generation reactors. It 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. In addition, the design of this reactor will be incorporating all the lessons learned from the Fukushima Daiichi NPP 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 resources can intervene.

ASN inspection on the Flamanville EPR construction site on the subject of non-destructive testing on completion of production of the welds for the piping of the VVP and ARE systems – April 2018

ASN examined the Safety Options Dossier (DOS) for the EPR NM with the support of IRSN, taking account of the recommendations of Guide No. 22 on PWR design. At the request of ASN, the GPR met in January 2018 to examine this dossier.

In 2018, EDF sent ASN its decision to upgrade the technical configuration of the EPR NM to a new version, called EPR 2.

On 16 July 2019, ASN thus published its opinion on the safety options proposed for the EPR NM reactor and its EPR 2 configuration upgrade. ASN considers that the general safety objectives, the safety baseline requirements and the main design options are on the whole satisfactory. ASN's opinion identifies the subjects to be considered in greater depth prior to submitting a reactor creation authorisation application. Additional justifications are in particular needed on the break preclusion approach for the main primary and secondary piping, the approach for dealing with hazards, fire and explosion in particular, and the design choices for certain safety systems. In any creation authorisation application for a reactor, EDF will have to specify the additional studies and justifications provided in response to this opinion, as well as the resulting modifications to the safety options.

• Small Modular Reactors
Several Small Modular Reactor (SMR) projects are currently being developed around the world. These are reactors with a power of less than 300 MWe, built in a factory and delivered to their installation site. A French SMR project involving EDF, Technicatome, French Alternative Energies and Atomic Energy Commission (CEA) and Naval Group is currently at the preliminary design stage. ASN considers that these projects are opportunities to develop reactors with significant nuclear safety improvements.

• Generation IV reactors
Since 2000, in partnership with EDF and Framatome, CEA has been examining fourth-generation reactors, notably within the "Generation IV" International Forum (GIF). Given that CEA's Astrid project has been abandoned, the industrial deployment of Generation IV reactors cannot be envisaged before the end of this century.

3. Outlook

In 2020, ASN actions in the field of NPP oversight will more specifically concern the following topics.

• The periodic safety reviews
ASN will issue a position statement in 2020 on the conditions for the continued operation of the 900 MWe reactors beyond their fourth periodic safety review. It will notably take account of the observations of the public collected during the consultation launched in 2018 on the measures proposed by EDF in response to the objectives of this periodic safety review.

• Compliance of the facilities with their baseline design, construction and operating requirements
ASN will continue to be particularly attentive to the conformity of the facilities in 2020 and will in this respect continue its inspections of the condition of equipment and systems. It will ensure that the new EDF baseline for processing deviations is able to satisfactorily meet the regulatory obligations linked to the detection and processing of deviations and reporting to ASN.

ASN will also be particularly vigilant to EDF's correct performance of the facilities compliance inspection programme during the fourth ten-yearly inspection of the Bugey NPP reactor 2.

• Oversight of the Flamanville EPR reactor
ASN will continue to monitor the installation of equipment, the preparation for and 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.

ASN will continue to examine the commissioning authorisation application and will issue a position statement on the partial commissioning application, corresponding to the arrival of nuclear fuel on the site.

Finally, ASN will continue to examine the processing of deviations affecting the main secondary system welds, along with the conformity assessments of the NPE most important for safety.

• Oversight of Nuclear Pressure Equipment (NPE)
In recent years, oversight of NPE has been marked by three major events: the detection of carbon macrosegregation problems in certain forged components, the discovery of irregularities that could be construed as falsifications, notably within Framatome's Creusot Forge plant and on the Ancizes site of Aubert et Duval, as well as the problem of controlling weld quality on the Flamanville EPR.

In 2020, ASN will carry out work to monitor these three events and will also continue with work to prevent such problems from happening again.

11.

NUCLEAR FUEL CYCLE INSTALLATIONS

CHAPTER 11

Nuclear fuel cycle installations

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, the last uranium mines were closed in 2000, so the fuel cycle concerns the fabrication of the fuel and then its reprocessing once it has been used in the nuclear reactors.

The licensees of the fuel cycle plants are part of the Orano or EDF (Framatome) groups: Orano Cycle operates Melox in Marcoule, the La Hague plants, all the Tricastin plants since 31 December 2018, as well as the Malvési facilities. Framatome operates the facilities on the Romans-sur-Isère site.

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 consequences for safety. In this context, ASN periodically asks EDF to submit a "Cycle Impact" file prepared jointly with the fuel cycle stakeholders and presenting the consequences –for each step of the nuclear fuel cycle– of EDF's strategy for using the different types of fuel in its reactors.

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 in the Orano Cycle plants in Malvési and Tricastin. These plants, which are regulated under the legislation for Installations Classified for Protection of the Environment (ICPE), 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 Pressurised Water Reactors (PWR) require uranium enriched with the U-235 isotope. In France, uranium hexafluoride (UF_6) enrichment between 3% and 6% 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. Before it is used in the reactors, new nuclear fuel can be stored in one of the two Inter-Regional fuel Stores (MIR) operated by EDF in Bugey and Chinon.

After a period of use of about three to four years, the spent fuel assemblies are removed from the reactor and cooled in a pool, firstly on the site of the plant in which they were used and then in the Orano Cycle 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 Orano Cycle plant in Marcoule, called "Melox", 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 currently reprocessed after being used in the reactors. 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.

Other facilities are needed for the operation of the Basic Nuclear Installations (BNI) mentioned above, more particularly the "Socatri" facility, which is responsible for the maintenance and decommissioning of nuclear equipment, as well as the treatment of nuclear and industrial effluents from the Orano Cycle platform in Tricastin.

1.1 The front-end fuel cycle

Before fuels are fabricated for use in the reactors, the uranium ore must undergo a number of chemical transformations, from the preparation of the "yellow cake" through to conversion into UF_6, the form in which it is enriched. These operations take place primarily on the Orano Cycle sites of Malvési, in the Aude *département* and Tricastin in the Drôme and Vaucluse *départements* (also known as the Pierrelatte site).

On the Tricastin site, Orano Cycle operates:
- the Comurhex facility (BNI 105) for converting uranium tetrafluoride (UF_4) into UF_6;
- the Georges Besse II UF_6 ultra-centrifuge enrichment plant (BNI 168);

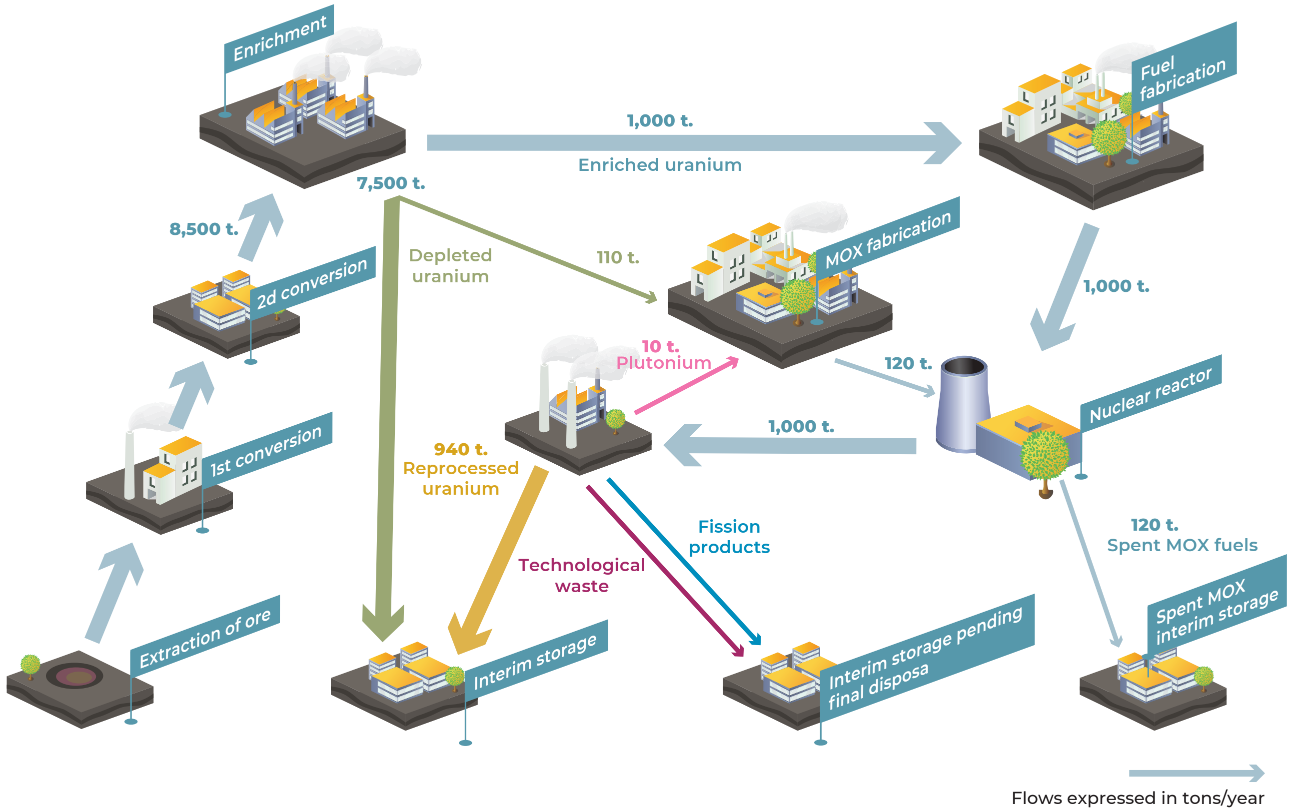
1. *Transuranic elements are chemical elements heavier than uranium (atomic number 92). The main ones are neptunium (93), plutonium (94), americium (95), curium (96). In a reactor, they are derived from uranium during secondary reactions other than fission.*
2. *Storage is temporary, while disposal is final.*

TABLE 1

Fuel cycle industry movements in 2019

	MATERIAL PROCESSED			PRODUCT OBTAINED		PRODUCT SHIPPED	
INSTALLATION	ORIGIN	MATERIAL PROCESSED	TONNAGE HEAVY METAL	PRODUCT OBTAINED	TONNAGE HEAVY METAL	DESTINATION	TONNAGE HEAVY METAL
Orano Tricastin ex-Comurhex	DBNI Marcoule	Uranyl Nitrate	0	U_3O_8	0	DBNI Pierrelatte	0
	ICPE	UF_4	1,404	UF_6	2,133	Orano storage areas Tricastin	2,133
	Malvesi						
Orano Cycle (TU5)	Orano Cycle La Hague	Uranyl Nitrate	921	U_3O_8	904	Orano storage areas Tricastin	894
Orano Cycle (W)	GB II	UF_6 depleted	6,508	U_3O_8	6,506	Orano storage areas Tricastin	6,506
	BUE		0		0		0
Orano Cycle (GB II)	Orano Tricastin	UF_6	9,448	UF_6 depleted	8,612	Defluorination	8,612
	Cameco		149				
				UF_6 enriched	1,420	Fuel manufacturers	1,420
Framatome Romans	Germany	UO_2 rods based on natural and depleted uranium	4			EDF	2,975
	Russia	UF_6 (based on enriched natural uranium)	25	Assemblies based on enriched natural uranium	642	South Africa	24
	Eurodif		323			EDF	577
	Urenco (United Kingdom)		322			China	42
	ANF Lingen (Germany)	UO_2 rods based on enriched natural uranium	8	UO_2 and U_3O_8 powder based on enriched natural uranium	4	CEA	3
Orano Cycle Marcoule Melox	Framatome Lingen (Germany)	UO_2 depleted	83	Fuel elements MOX	73	EDF	71
	Orano Cycle La Hague	PuO_2	8			EPZ (Netherlands)	2
Orano Cycle La Hague	Fuels reprocessed in the La Hague plant						
	EDF	UOX and MOX	1,214	Uranyl Nitrate	1,146	Areva NC Tricastin	1,007
				PuO_2	15	Melox Marcoule	9
	Fuels stored in the La Hague plant pools						
	EDF and other licensees	Irradiated fuel elements	10,140	-	-	-	-

Fuel cycle diagram



- the TU5 facility (BNI 155) for conversion of uranyl nitrate $UO_2 (NO_3)_2$ produced by reprocessing spent fuel at La Hague into uranium sesquioxide (U_3O_8);
- the W plant –Installation Classified for Protection of the Environment (ICPE) within the perimeter of BNI 155– for converting depleted UF_6 into U_3O_8;
- areas for the storage of uranium and thorium in various forms (BNI 93, 178 and 179);
- the Atlas analysis laboratory (BNI 176);
- a Defence Basic Nuclear Installation (DBNI) which more particularly operates the radioactive substances storage areas, virtually all of which are for civil uses;
- the Socatri facility (BNI 138) which manages waste from the Tricastin site and carries out nuclear equipment maintenance and decommissioning.

• The TU5 facility and the Orano Cycle W plant – BNI 155

BNI 155, called TU5, can handle up to 2,000 tonnes of uranium per year, which enables all the uranyl nitrate ($UO_2(NO_3)_2$) from the Orano Cycle plant in La Hague to be processed for conversion into U_3O_8 (a stable solid compound that can guarantee storage of the uranium under safer conditions than in liquid or gaseous form). Once converted, the uranium from reprocessing is placed in storage on the Tricastin site.

• The Orano Cycle 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 13).

Controlled facilities classified as ICPEs are included within its perimeter and dedicated to the fluorination of UF_4 into UF_6, so that it can be subsequently enriched in the GB II plant. Each year, they produce about 14,000 tonnes of UF_6 from the UF_4 coming from the Orano Cycle 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 24 November 2010, known as the "IED Directive" on industrial emissions (integrated pollution prevention and reduction).

• The Georges Besse II gas centrifuge enrichment plant – BNI 168

BNI 168, called Georges Besse II (GB II), licensed in 2007, 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. Under the effect of centrifugal force, the heavier molecules (containing uranium-238) are separated from the lighter ones (containing uranium-235). 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. GB II comprises two enrichment units (South and North units) and a support unit, the REC II.

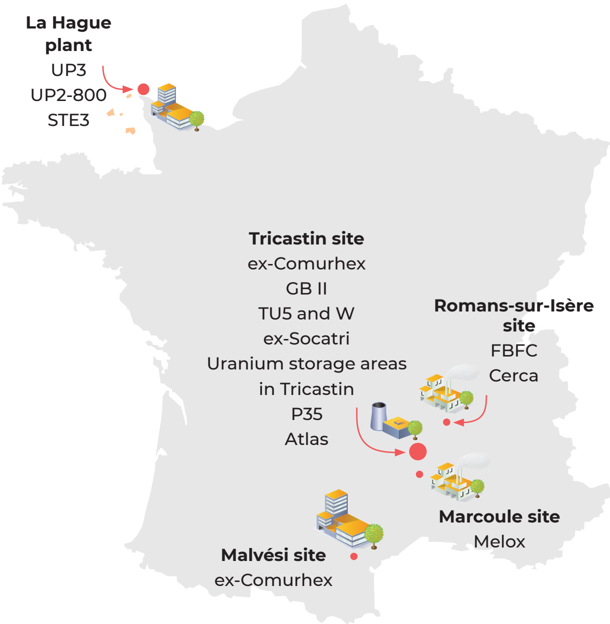
At the beginning of 2009, ASN authorised commissioning of the South unit, comprising eight modules, followed in 2013 by the North unit, comprising six modules, the first two of which are designed to enrich the uranium from spent fuel reprocessing. ASN authorised commissioning of the support unit in 2014. Enrichment of the uranium resulting from reprocessing, requiring prior authorisation from ASN, has never been implemented.

• The Atlas facility – BNI 176

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.

The Atlas facility, which complies with the most recent safety requirements, is robust to external hazards. ASN authorised its commissioning on 7 March 2017.

Installations of the fuel cycle in operation or undergoing decommissioning



• **The Tricastin uranium storage facility – BNI 178**
Following the delicensing of part of the Pierrelatte DBNI by decision of the Prime Minister, BNI 178 –or the Tricastin uranium storage facility– was created. This facility groups the uranium storage facilities and the platform's new emergency management premises. ASN registered this facility in December 2016.

• **The P35 facility – BNI 179**
Following on from the delicensing process for the Pierrelatte DBNI by decision of the Prime Minister, BNI 179, known as "P35" was created. This facility comprises ten uranium storage buildings. ASN registered this facility in January 2018.

1.2 Fuel fabrication

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 Framatome "FBFC" plant in Romans-sur-Isère (BNI 98) are placed in zirconium metal cladding 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 Framatome plant at Romans-sur-Isère called Cerca (BNI 63).

The MOX fuel, consisting of a mixture of depleted uranium and plutonium oxides, is fabricated in BNI 151 Melox, operated by Orano Cycle and located on the Marcoule nuclear site.

1.3 The back-end fuel cycle – reprocessing

• **Orano Cycle reprocessing plants in operation at La Hague**
The La Hague plants, intended for reprocessing of spent fuel assemblies from nuclear reactors, are operated by Orano Cycle.

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 10 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 22 December 2015 (ASN resolution 2015-DC-0535 and ASN resolution 2015-DC-0536).

• **Operations carried out in the plants**
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. It is then intended for the fabrication of MOX fuels in the Orano Cycle plant in Marcoule (Melox).

• **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).

These reprocessing operations also use chemical and mechanical processes, the operation of which generates gaseous and liquid effluents as well as solid waste.

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.

11

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 packaging units (solid glass or bitumen matrix).

The solid waste is packaged on-site, either by compacting, or by encapsulation in cement, or by vitrification. 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 (LLW/ILW-SL) repository at Soulaines (see chapter 14) or stored on the Orano Cycle 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 2 October 2008.

1.4 Fuel cycle consistency in terms of nuclear safety and radiation protection

The "nuclear fuel cycle" comprises the fabrication of the nuclear fuel used in the nuclear power plant reactors, its storage and its reprocessing after irradiation. Several licensees are involved in the cycle: Orano Cycle, Framatome, EDF and Andra.

ASN monitors the overall consistency of the industrial choices made with regard to fuel management and which could have consequences for safety. In this context, ASN periodically asks EDF to submit a “Cycle Impact” file prepared jointly with the fuel cycle stakeholders and presenting the consequences –for each step of the nuclear fuel cycle– of EDF’s strategy for use of the different types of fuel in its reactors.

The last “Cycle Impact 2016” file, for the period 2016-2030, produced in collaboration with Framatome, Orano Cycle and Andra, more particularly identifies the maximum thresholds (capacity saturations, maximum isotope content of fuel reached, etc.) foreseeable until 2040, on the basis of various energy mix scenarios. This update comprises a number of innovations with respect to the previous approaches initiated in 1999 and 2006:
- The study period, which habitually covered ten years, was increased to fifteen years, in order to take account of the time actually observed in the nuclear industry for designing and building any new facilities identified as being necessary for implementation of the strategy.
- Radioactive substances transport contingencies were explicitly taken into account.
- Nuclear reactor closures were 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 17 August 2015.
- The strategy for managing and storing spent fuels pending reprocessing or disposal was explained.

After examination, ASN delivered its opinion on 18 October 2018, the main conclusions of which are as follows.

ASN considers that the “Cycle Impact 2016” file provides a satisfactory presentation of the consequences of the various nuclear fuel cycle scenarios on the nuclear facilities, transport operations and waste. However, the consequences of the unforeseen events which could affect the operation of the cycle need to be studied in greater depth.

ASN underlines the need to anticipate any strategic change in the functioning of the fuel cycle by at least ten years so that it can be designed and carried out under controlled conditions of safety and radiation protection. It is a question, for example, of ensuring that –given the incompressible development times for industrial projects– the needs for new spent fuel storage facilities or for new transport packaging designs are addressed sufficiently early.

For the coming decade, it would notably appear that to avoid reaching the maximum capacity of existing storage facilities too quickly (spent fuel pools at NPPs and at La Hague facilities), any reduction in output by reactors consuming MOX fuel must be accompanied by a reduction in that from reactors consuming fuel obtained from Enriched Natural Uranium (ENU), so that all ENU spent fuels are reprocessed.

In the longer term, it will be necessary either to have new storage capacities that are significantly greater than the current and projected capacities, or to be able to use MOX fuel in reactors other than the 900 MWe reactors, which are the oldest. The time-frame required for the design and production of these options is about ten years. ASN therefore asks the industrial players to start examining these two options without delay.

Every 5 years, the Government updates the Multi-year Energy Plan (MEP). The functioning of the nuclear fuel cycle could evolve according to the orientations thus defined in this plan. ASN therefore asks the industrial players to study the safety and radiation protection consequences of implementing the MEP on the nuclear fuel cycle and its consistency at each of its revisions.

Further to this examination, the year 2019 was marked by several events which disrupted the balance of the cycle:
- The Melox plant experienced difficulties in producing MOX fuel of the required quality for the EDF fleet of reactors. The new production process in fact leads to a greater disparity in the size of the depleted uranium grains and thus a higher discard rate. This led EDF to reduce the number of MOX assemblies in the core of eight reactors. As this situation is likely to last, EDF in 2019 asked ASN for authorisation to further reduce the proportion of MOX assemblies in the cores of its reactors. ASN is examining this request and will issue a response in 2020. This situation also leads to a lesser consumption of the plutonium produced by the La Hague plants and a larger number of spent fuel assemblies in the pools. The surplus plutonium and non-conforming MOX will eventually have to be consumed.
- A fission products evaporator-concentrator at La Hague has reached a level of corrosion which means that it can no longer be used without restriction until the next annual outage for major maintenance of the plant and must thus be closely monitored until the end of its operating life.

Moreover, the other reprocessing plant at La Hague (UP2-800) had to cease operations for several months owing to corrosion of its dissolver impeller, a part that is vital to the operation of its process. Although this event had no consequences for cycle consistency, it did lead ASN to maintain particular vigilance with regard to management of the ageing of the fuel cycle back-end facilities.

These disruptions of the cycle back-end plants confirm the need identified by ASN in its opinion of 18 October 2018 for countermeasures should commissioning of the EDF centralised storage pool occur after saturation of French spent fuel storage capacity.

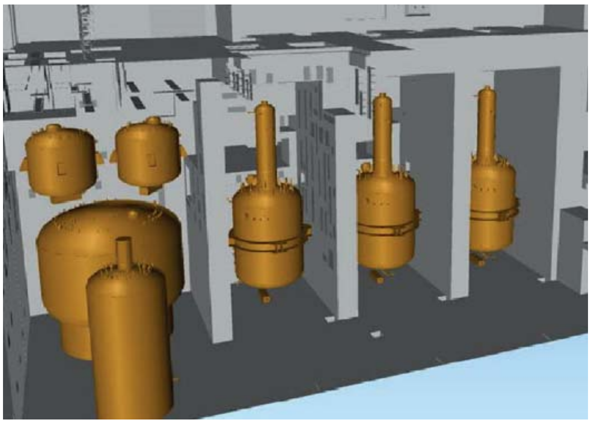
"New fission products concentration" project

The UP3-A and UP2-800 plants (BNIs 116 and 117) operated by Orano Cycle on its La Hague site comprise six evaporators concentrating fission products from the reprocessing of spent fuels, so that they can be vitrified.

Examinations had shown a level of corrosion of these evaporators that was faster than anticipated in the design. ASN thus regulated their continued operation with resolution 2016-DC-0559 of 23 June 2016, which requires new means for mitigating the consequences of any rupture of this equipment and in-depth monitoring of the corrosion phenomenon at work.

Orano Cycle decided to replace this equipment by 2021-2022 and initiated a "New Fission Products Concentration" (NCPF) project in each of its reprocessing plants. ASN issued a position statement in November 2016 on the safety options envisaged by Orano Cycle for these projects. In November 2017, ASN authorised the civil engineering work on units receiving the new fission products evaporator-concentrators. These construction sites are in progress and ASN carried out a number of inspections on them. It found that the organisation defined and implemented for the civil engineering work appears to be rigorous. Introduction of the new evaporators into their final locations started in August 2019 and was completed in November 2019. A further ASN inspection of these construction sites is scheduled for 2020.

In January and April 2019, Orano submitted applications to ASN for authorisation to install the NCPF units process in its two plants. ASN will issue a position statement on these two applications in 2020.



1.5 Outlook: planned facilities and facilities to be shut down soon

• New uranium storage facility project on the Tricastin site

In February 2015, Orano Cycle informed ASN that it wanted to create a new BNI on the Tricastin site intended for storage of uranium-bearing materials resulting from fuel reprocessing. Orano Cycle undertook work to optimise the existing storage facilities on the site in order to push back their saturation date from 2019 to 2021 and in November 2017 submitted a creation authorisation application for new storage buildings. In 2018, ASN informed the Minister responsible for nuclear safety that the content of the creation authorisation application was sufficient for its examination to take place. This project will be the subject of a public inquiry in 2020.

• "New concentration of fission products" project on the La Hague site

In order to replace the fission products evaporator-concentrators at La Hague, which are suffering from a more advanced stage of corrosion than imagined in the design, Orano is building new evaporators (see box). The authorisations concerning this particularly complex projects will be the subject of ASN resolutions in 2020.

• Construction of new storage capacity for waste packages

To anticipate the saturation of storage capacity for CSD-V (units R7, T7 and E/EV/SE), construction work on new storage facilities, known as the "glass storage extension on the La Hague site" (E/EV/LH) began in 2007. These facilities are being built module by module, with the construction of identical units called "pits". Pits 50 and 60 are under construction to increase storage capacity.

In April 2017, Orano Cycle 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

In order to be able to receive and reprocess special fuels irradiated in the Phénix reactor or in other research reactors, Orano Cycle submitted the safety options file in 2016 for a new special fuels reprocessing unit. This unit would comprise new shearing and dissolving equipment. In March 2017, ASN informed the licensee that the safety options for this new unit were on the whole satisfactory. Orano however encountered technical difficulties in developing the process, which led to a significant change in the initial design options. In the light of this, ASN granted Orano more time to submit the authorisation application for this unit.

• EDF centralised storage pool project

Given the time-frame, identified by the review of the previous "cycle consistency" file, for saturation of spent fuel storage capacity and the time needed for the design and construction of a new facility, Article 10 of the Order of 23 February 2017 setting out the requirements of the National Radioactive Materials and Waste Management Plan, instructed EDF "*to send ASN the technical and safety options for the creation of new storage capacity before 30 June 2017*".

EDF opted for a centralised storage pool, which 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. In 2017, EDF transmitted the safety options file for this project, the siting of which has not yet been specified.

Following examination of the safety options file transmitted by EDF, ASN issued its opinion in July 2019. It considered that the general safety objectives and the design options adopted are on the whole satisfactory. Additional studies and demonstrations are however required, notably concerning the design and the control of manufacturing, in order to guarantee the long-term leaktightness of the pool, as well as the external hazard levels adopted once the actual site of the facility has been identified.

2. ASN actions in the field of fuel cycle facilities: a graded approach

2.1 The graded approach according to the risks in the facilities

The fuel cycle facilities represent different risks at the different stages in the fuel cycle:

- The conversion and enrichment facilities mainly entail toxic risks (owing to the chemical form of the radioactive substances they use), criticality risks (when they use enriched materials) and the risk of dissemination of radioactive substances (in powder, liquid or crystallised form).
- The fuel fabrication facilities mainly entail toxic risks (when they have conversion units), criticality, fire or explosion risks (in the ceramic plants which use heating processes), the risk of dissemination of radioactive substances (powder or crystals) and of exposure to ionising radiation (when they use reprocessed substances).
- The spent fuel reprocessing facilities mainly entail risks of dissemination of radioactive substances (the substances used are mainly liquids and powders), of criticality (the fissile substances employed change geometrical shape) and exposure to ionising radiation (the fuels contain highly irradiating substances).

Their common point is that they never seek to create chain reactions (prevention of the criticality risk) and that they use dangerous substances in industrial quantities. Conventional industrial risks are therefore particularly present. Certain plants, such as Orano Cycle at Tricastin and La Hague or Framatome at Romans-sur-Isère, are in this respect subject to the Seveso Directive.

ASN devotes efforts to applying oversight that is proportionate to the potential risks of each facility. Each facility is more specifically classified by ASN in one of three categories defined on the basis of the scale of the risks and detrimental effects it represents. This BNI classification enables the oversight and monitoring of the facilities to be adapted, with reinforcement of the inspections and the scope of the reviews carried out by ASN for the higher risk facilities.

When the installations are substantially modified or when they are finally shut down, ASN is in charge of examining these modifications, which are the subject of an amending decree from the Government, after prior consultation of ASN. ASN also establishes binding requirements for these main steps. Finally, ASN also reviews the safety files specific to the operations of each BNI.

For each facility, ASN monitors 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 monitors the working of the organisations put into place by the licensees mainly through inspections, more specifically those devoted to safety management.

2.2 Lessons learned from Fukushima Daiichi

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 Orano Cycle and Framatome 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.

Generally speaking, Orano and Framatome designed new means to deal with extreme situations in their facilities and implemented them in good time.

More specifically, the Local Emergency Command Posts (PCD-L) on the Romans-sur-Isère and Tricastin sites were relocated to new emergency management buildings designed to withstand extreme hazards. These buildings more specifically contain a ventilation system with filtration enabling the personnel present to be protected against a toxic release from the site's facilities, neighbouring facilities or, on the Tricastin site, a radioactive release from the neighbouring Nuclear Power Plant (NPP).

With regard to the La Hague site, Orano Cycle carried out work and deployed means to ensure significant water reserves in the event of an extreme situation, and means to ensure recirculation of water under the storage pools and thus maintain a minimum water level above the fuel assemblies in the event of a leak. Finally, the site's new PCD-L emergency building, which is robust to extreme hazards, has been operational since 2019.

On the Marcoule site, Orano Cycle has begun the construction of its new emergency building, designed to withstand extreme hazards. However, this construction site is behind schedule and should be completed in 2020.

ASN considers that the progress of the post-Fukushima work and the organisational measures adopted are satisfactory at Orano Cycle and Framatome.

2.3 Periodic safety reviews of fuel cycle facilities

Since the publication of the Decree of 2 November 2007, all the BNI licensees must carry out periodic safety reviews of their facilities at least every ten years. These exercises were carried out gradually on the fuel cycle facilities. The first one concerns BNIs 151 (Melox) and 138 (Socatri) and identified numerous points on which these facilities could be reinforced. Most of this work has today been completed.

The examination of the periodic safety reviews confirmed that the subjects to be examined by the licensee during the periodic safety reviews, along with the required methodologies, should be defined during what is referred to as the orientation phase. In addition, probabilistic analyses must be added to the safety cases for all the BNIs. Following the periodic safety review of plant UP2-800 (BNI 117), Orano established a safety analysis methodology based on methods applied to Installations Classified for Protection of the Environment. This change will represent significant progress for the analysis of complex accident sequences.

Orano is being proactive in its implementation. In 2020, Orano Cycle must formally submit its probabilistic analysis methodology to ASN for all the BNIs.

The periodic safety review of BNI 98 (FBFC) demonstrated the need for improved incorporation of the hazards linked to dangerous substances into the safety case of the fuel cycle facilities, while ensuring a level of stringency at least equivalent to that of Seveso classified upper-tier facilities.

The periodic safety reviews show the importance of an *in situ* verification of the conformity of the Protection Important Component (PIC) that is as exhaustive as possible, or as representative as possible of the EIP that are not accessible. They also illustrate the need for a robust approach to the control of the ageing of fuel cycle facilities. It may be complex to develop these approaches because most of the fuel cycle facilities are unique.

ASN underlines the ambitious and rigorous methodological approach for ageing monitoring put in place within the framework of the periodic safety reviews of the La Hague installations. ASN thus considers that the method adopted by Orano for monitoring the ageing of its installations is on the whole satisfactory. In 2019, ASN inspections showed that despite very real progress, the implementation of the approach on the site could still be improved, notably in terms of the traceability of the actions to be taken. ASN will continue with its oversight, notably through inspections, in order to ensure rigorous application of the approach.

In the context of the faster than anticipated corrosion of the fission products evaporators-concentrators and other equipment in the La Hague plant, the management of ageing is a priority issue for ASN with regard to the cycle back-end facilities, which are the subject of dedicated inspections and increased vigilance in the examination of the ongoing periodic safety reviews.

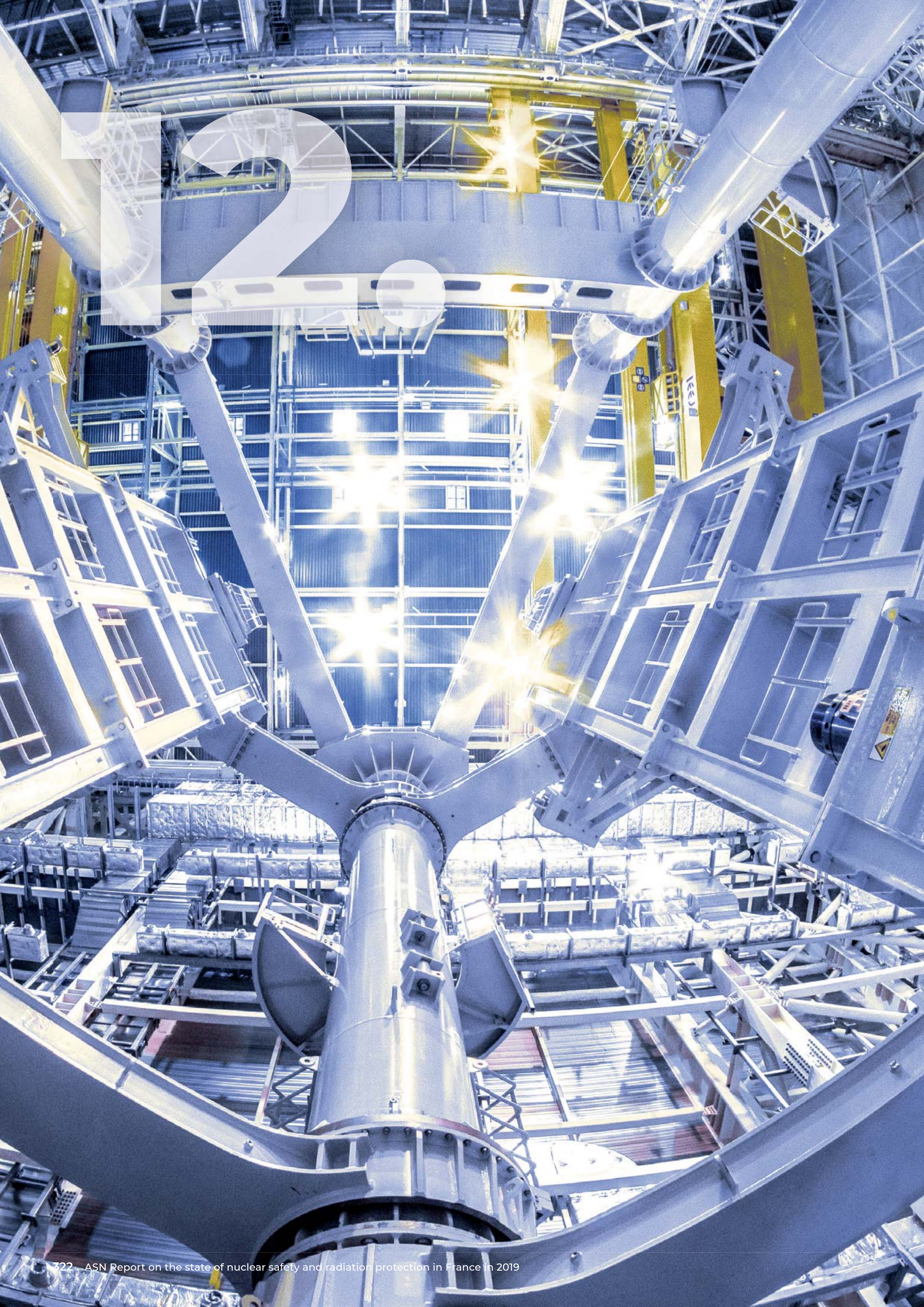
2.4 Particular regulatory actions conducted in consultation with the Defence Nuclear Safety Authority

The upcoming declassification of the Tricastin DBNI to a BNI will mean that ASN will take over responsibility for oversight of the facilities it contains. Together with the Defence Nuclear Safety Authority (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.

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 will be gradual and will 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, with the aim of minimising the number of steps involved.

Depending on their purpose, the various DBNI facilities should be grouped within existing or new BNIs. Their safety baseline requirements will then need to be brought into line with the BNI System.

12.



NUCLEAR RESEARCH AND MISCELLANEOUS INDUSTRIAL FACILITIES

Nuclear research and miscellaneous industrial facilities

Nuclear research or industrial facilities differ from the Basic Nuclear Installations (BNIs) involved directly in the generation of electricity (nuclear power reactors and fuel cycle facilities) or waste management. Traditionally, most of these BNIs are operated by the Alternative Energies and Atomic Energy Commission (CEA), but also 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, Steris and Ionisos, which operate facilities producing radiopharmaceuticals, or industrial irradiators).

The variety and the past history of the activities covered by these BNIs explains the wide diversity of facilities concerned.

1. Research facilities, laboratories and other facilities in France

1.1 Research reactors

The purpose of research reactors is to contribute to scientific and technological research and to improve the operation of the Nuclear Power Plants (NPP). Some of these facilities also produce radionuclides for medical uses[1]. They are facilities in which a chain reaction is created and sustained, to produce a neutron flux of varying density, used primarily for scientific experimentation purposes. Unlike in nuclear power plants, the energy produced by research reactors is not recovered and is in fact a "by-product" removed by cooling. The quantities of radioactive substances used are smaller than in nuclear power reactors.

An overview of the various types of research reactors present in France and the main corresponding risks is presented below.

In their design, these reactors take account of reference core melt under water (failure of the cooling system) and core melt in air (after uncovering of the core or during handling) accidents. They also take account of accidents specific to certain research reactors.

• Neutron beam reactors
Neutron beam reactors are pool type. They are mainly designed for fundamental research (solid physics, molecular physico-chemistry, biochemistry, etc.), using the neutron diffraction method to study matter. The neutrons are produced in the reactor, at different energy levels and are captured by channels in the reactor before being routed to experimentation areas.

In France, there are two neutron beam reactors in service: the Orphée reactor (BNI 101) operated by CEA in Saclay –rated power limited to 14 MWth (thermal megawatts)–, and the High-Flux Reactor –RHF (BNI 67) operated by the Laue-Langevin Institute (ILL) in Grenoble (rated power limited to 58 MWth). These reactors operate in cycles of about 50 to 100 days. The main safety issues are reactivity control, cooling and containment.

CEA took the Orphée reactor to final shutdown at the end of 2019 and the decommissioning phase for this reactor is currently under preparation.

• "Test" reactors
"Test" reactors are pool type. They are designed to study accident situations. They are able to reproduce certain accidents postulated in the safety case of nuclear power reactors in a controlled manner and on a small scale and gain a clearer understanding of the evolution of physical parameters during accidents.

In France, there is one "test" type reactor in service, Cabri (BNI 24), operated by CEA in Cadarache. The reactor, whose power is limited to 25 MWth, can produce the neutron flux needed for the experiments. The safety issues are similar to those of the other reactors: controlling the reactivity of the driver core, cooling to remove heat and containment of the radioactive substances in the fuel rods making up the core.

Modifications were made to the facility so that it could run new research programmes to study the behaviour of high burn-up fraction fuel during reactivity insertion accident situations. Reactor divergence in its new configuration was authorised in 2015. On 30 January 2018, after major renovation work, ASN authorised the first active experimental test of the facility's pressurised water loop.

• Irradiation reactors
Irradiation reactors are pool type. They are used to study the physical phenomena linked to the irradiation of materials and fuels, as well as their behaviour. As the neutron fluxes obtained by these facilities are more powerful than those in a Pressurized Water Reactor (PWR) type nuclear power reactor, the experiments enable ageing studies to be performed on materials and components subjected to a high neutron flux. After irradiation, the samples undergo destructive examination, notably in the research laboratories, in order to characterise the effects of irradiation. They are thus an important tool for the qualification of materials subjected to a neutron flux.

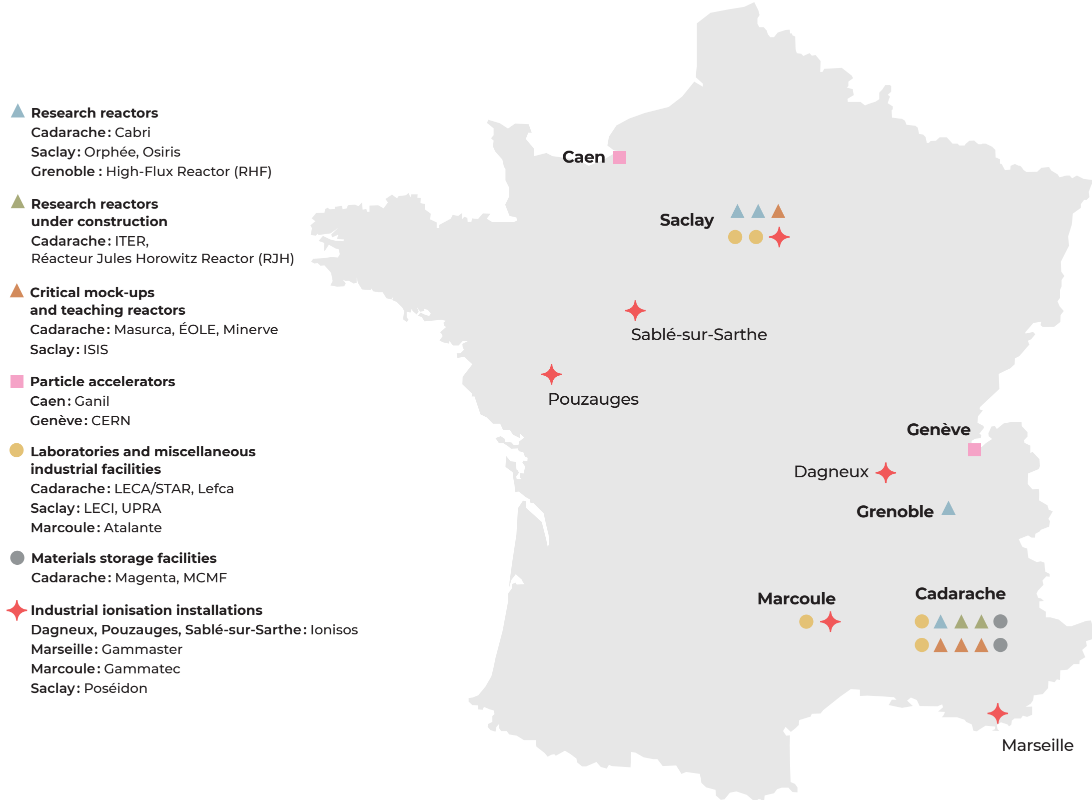
These research reactors are also significant sources for the production of certain radionuclides for medical uses.

The power of these reactors varies from a few tens to a hundred MWth. These reactors operate in cycles of about 20 to 30 days.

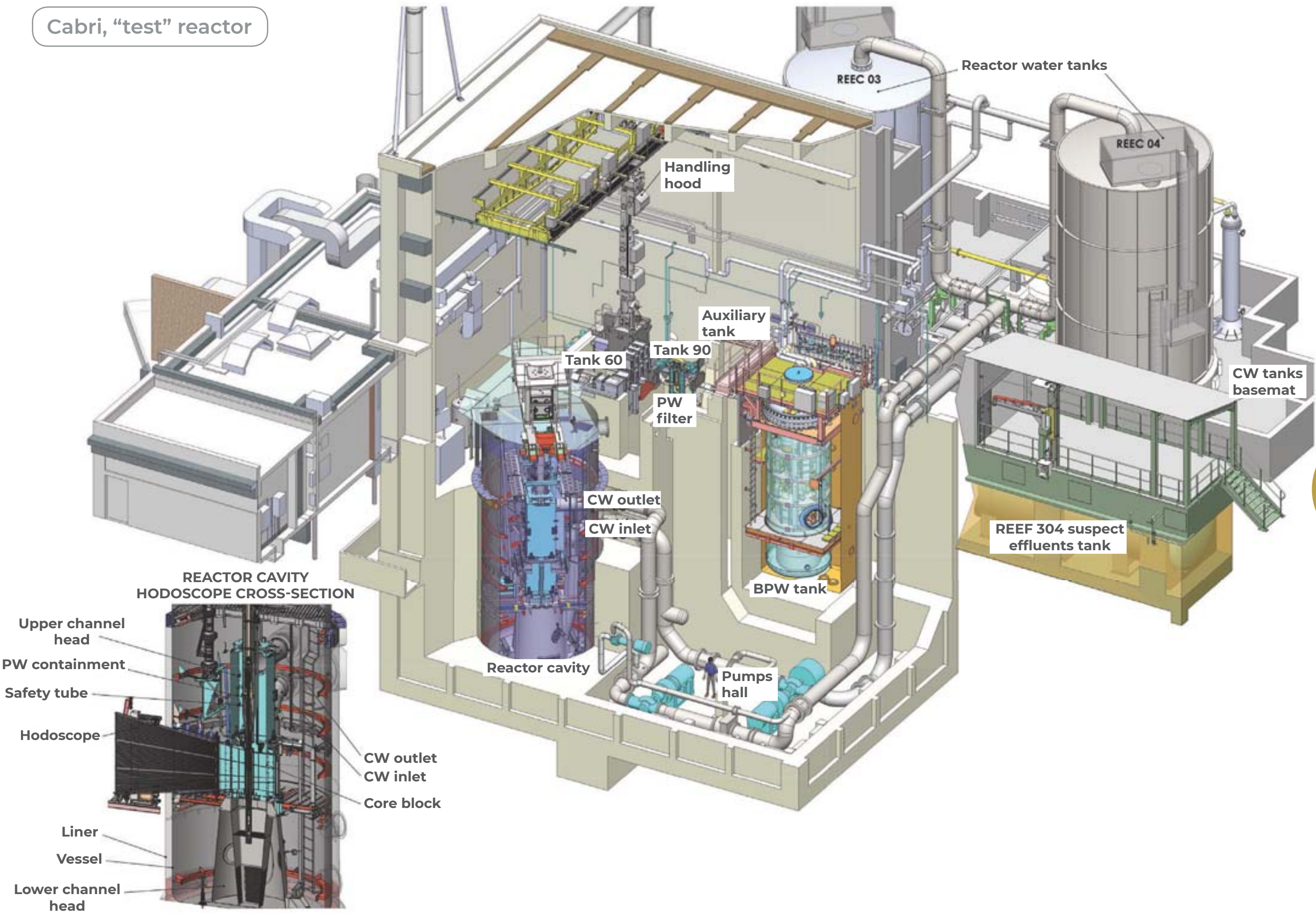
In France, no technological irradiation reactors are still in service: the Osiris reactor (BNI 40), in Saclay, was permanently shut down in 2015. The Jules Horowitz Reactor (RJH, BNI 172), which is to replace it, is currently under construction.

1. The use of radionuclides offers medical analysis and treatment possibilities: to diagnose cancers by scintigraphy and tomography, allowing detailed examination of functioning organs, or to treat tumours with radiotherapy, which uses radiation from the radionuclides to destroy the cancer cells (see chapter 7).

Research facilities in France



Cabri, "test" reactor



• Critical mock-ups
Critical mock-ups are very low power reactors (from a hundred watts to a few kilowatts). They are simple in design and their purpose is to gain more in-depth knowledge of the neutron characteristics of materials and study reactor core neutronics to validate scientific computing tools. Critical mock-ups can be adapted to the experimental programme. The cores are extensively instrumented in order to be able to exploit the results of the experiments carried out.

In France, the civil critical mock-ups, operated by CEA in Cadarache –Masurca (BNI 39), ÉOLE (BNI 42) and Minerve (BNI 95)– have all been permanently shut down prior to their decommissioning. These three facilities today represent limited risk and detrimental effects control issues.

• Teaching reactors
Teaching reactors are characterised by low power (from a few hundred watts to a few hundred kilowatts), allowing easy access to the facility and making them easy to use.

The ISIS reactor, situated within the perimeter of the Osiris research reactor (BNI 40), is a member of this reactor family. It was permanently shut down for decommissioning in March 2019. Given their lower power and small size, these facilities entail limited risks and detrimental effects.

• Fusion reactors
Unlike the research reactors previously described and which use nuclear fission reactors, some research facilities aim to produce nuclear fusion reactions.

In France, the International Thermonuclear Experimental Reactor (ITER) facility (BNI 174) is an international fusion reactor project currently under construction in Cadarache. The purpose of ITER is to scientifically and technically demonstrate control of thermonuclear fusion by magnetic confinement of a deuterium-tritium plasma, during long-duration experiments with significant power (500 MW for 400 s).

The main risk and detrimental effect control challenges for this type of facility notably include control of the containment of radioactive materials (tritium in particular), the risks of exposure to ionising radiation (significant activation of materials under intense neutron flux) and the removal of the residual heat from the reactor compartments (in particular during maintenance work).

1.2 Laboratories and miscellaneous industrial facilities

1.2.1 Laboratories

The laboratories carrying out research and development work for the nuclear sector contribute to enhancing knowledge for nuclear power production, the fuel cycle and waste management. They can also produce radio-nuclides for medical uses.

• Principles and safety issues
The main challenges inherent in these facilities are protecting persons against ionising radiation, preventing the dispersal of radioactive substances, controlling fire risks and controlling the chain reaction (criticality).

The design principles for these laboratories are similar. Special areas, called "shielded cells" allow handling of and experimentation with radioactive substances, using appropriate handling systems. These shielded cells are designed with particularly thick walls and windows, to protect the operators against the ionising radiation. They also allow the containment of radioactive materials by means of a specific ventilation and filters system. The criticality risk is controlled by strict instructions regarding the handling, storage and monitoring of the materials being studied. Finally, the fire risk is managed using technical systems (fire doors, dampers, detectors, fire-fighting equipment, etc.) and an organisation limiting the fire loading. Personnel training and rigorous organisation are also essential factors in controlling these four main risks.

• Fuels and materials test laboratories
Some of these laboratories, operated by CEA, are used to carry out a variety of experiments on irradiated materials or fuels. The purpose of some research programmes for example is to allow higher burn-up of fuels or improve their safety. Some of these facilities are also operated for fuel preparation and repackaging.

The following fall within this category of laboratories:
- Active Fuel Examination Laboratory (LECA), in Cadarache and its extension, the Treatment, Clean-Out and Reconditioning Station (STAR), which make up BNI 55;
- Laboratory for Research and Experimental Fabrication of Advanced Nuclear Fuels (Lefca, BNI 123), located in Cadarache;
- Spent Fuel Testing Laboratory (LECI, BNI 50), located in Saclay.

• Research and Development laboratories (R&D)
R&D on new technologies is also carried out for the nuclear industry in laboratories, more particularly with regard to the development of new fuels, their recycling, or the management of ultimate waste.

The Alpha facility and laboratory for transuranian elements analysis and reprocessing studies (Atalante, BNI 148), situated in Marcoule and operated by CEA, provides Orano Cycle with technical support for optimising the operation of the La Hague plants. It carries out experimental work to qualify the behaviour of nuclear glass matrices in order to guarantee the long-term confinement properties of high-level waste packages.

• Artificial Radionuclides Production Facility (UPRA)
The Artificial Radionuclides Production Facility (UPRA), situated in Saclay and operated by CIS bio international, is a nuclear facility designed according to the same principles as a laboratory (special areas for handling and experimenting with radioactive substances, using appropriate means), for the purposes of research and to develop radionuclides for medical uses. CIS bio international is a subsidiary of the Curium group, a manufacturer of radiopharmaceuticals.

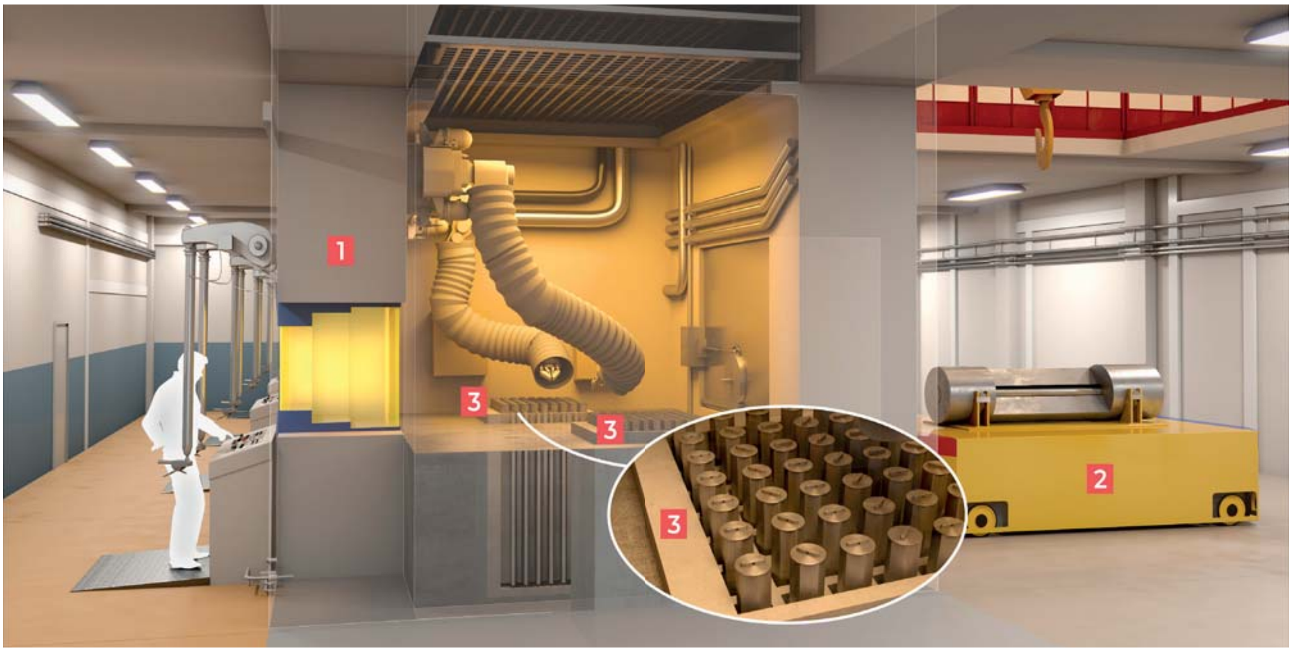
1.2.2 Particle accelerators

Some particle accelerators are BNIs. These installations use electrical or magnetic fields to accelerate charged particles. The accelerated particle beams produce strong fields of ionising radiation, activating the materials in contact, which then emit ionising radiation even after the beams have stopped. Exposure to ionising radiation is thus the primary risk in this type of facility.

• The Ganil
The Large National Heavy Ion Accelerator (Ganil, BNI 113), located in Caen, carries out fundamental and applied research work, more particularly in atomic physics and nuclear physics. This research facility produces, accelerates and distributes ion beams with various energy levels to study the structure of the atom.

• The CERN
The European Organization for Nuclear Research (CERN) is an international organisation situated between France and Switzerland, whose role is to carry out purely scientific fundamental research programmes concerning high energy particles. The CERN does not operate just one particle accelerator to study the structure of matter, but an entire chain of devices (sometimes called injectors). This chain currently comprises several linear and circular accelerators. Owing to its cross-border location, the CERN is subject to particular verifications by the French and Swiss Authorities (see chapter 6).

Active Fuel Examination Laboratory (LECA)



1: Shielded cells 2: Transfer vehicles 3: Shafts

1.2.3 Industrial ionisation installations

Industrial ionisation installations, called irradiators, use the gamma rays emitted by sealed sources of cobalt-60 to irradiate targets in the irradiation cells. These irradiation cells are designed with particularly thick walls and windows, to protect the operators against the ionising radiation. The sealed sources are either placed in the lowered position, stored in a pool under a layer of water which protects the workers, or are placed in the raised position to irradiate the target item. Personnel exposure to ionising radiation is thus the primary risk in these facilities.

The main applications of irradiators are to sterilise medical equipment, agrifood products and pharmaceutical raw materials. Irradiators can also be used to study the behaviour of materials under ionising radiation, notably to qualify materials for the nuclear industry.

These irradiators are used by:
- the Ionisos Group, which operates three facilities located in Dagneux (BNI 68), Pouzauges (BNI 146) and Sablé-sur-Sarthe (BNI 154);
- the Steris group, which operates the Gammaster (BNI 147) and Gammatec (BNI 170) facilities in Marseille and Marcoule;
- CEA, which operates the Poséidon irradiator (BNI 77) on the Saclay site.

1.3 Materials storage facilities

The materials storage facilities operated by CEA are primarily devoted to the conservation of non-irradiated (or slightly irradiated) uranium and plutonium-bearing fissile materials from other CEA facilities. This enables the laboratories (Atalante, Lefca, etc.) to be supplied according to the needs of the experiments being conducted. More recently, they have become a temporary storage solution for the fissile materials which were present in facilities that are now shutdown, such as the research reactors (ÉOLE, Minerve, Osiris, Masurca, etc.).

- **Principles and safety issues**

The main challenges inherent in these facilities are to prevent the dispersal of radioactive substances and to control the chain reaction (criticality).

The safety of these facilities is based on a series of static physical barriers (walls and doors of rooms and buildings) to prevent the dispersal of radioactive substances. When operations are carried out on these substances, static confinement is also provided by the equipment (glovebox, shielded cell) in which these operations are performed. This static confinement is supplemented by dynamic confinement consisting on the one hand of a cascade of negative pressure environments between the rooms where there is a risk of radioactive substance dissemination and, on the other, filtration of the gaseous releases into the environment. The chain reaction is controlled by strict instructions regarding the handling, storage and monitoring of the materials being stored.

- **Dedicated storage facilities**

The Magenta facility (BNI 169), commissioned in 2011 and operated by the CEA on its Cadarache site, is dedicated to the storage of non-irradiated fissile material and the non-destructive characterisation of the nuclear materials received. It is more particularly replacing the Central Fissile Material Warehouse (MCMF, BNI 53), which was finally shut down at the end of 2017.

- **Materials storage areas in BNIs**

Other radioactive material storage areas, located within a BNI, are authorised to store radioactive materials on the site, but in quantities far lower than those stored in Magenta. This is for example the case with BNI 55, called STAR, which stores spent fuels and fuels irradiated following reprocessing and/or conditioning.

1.4 Outlook: Planned facilities

A large number of CEA's facilities were built to support the French NPP fleet in the 1960s to 1970s. They are now ageing. CEA is envisaging the eventual construction of a new laboratory, called Mosaïc, to replace the LECA laboratory. At the end of 2019, CEA sent ASN the safety options for this new facility.

2. ASN actions in the field of research facilities: a graded approach

2.1 The graded approach according to the risks in the facilities

The BNI System applies to more than about a hundred facilities in France. This System concerns various facilities with widely differing nuclear safety, radiation protection and environmental protection challenges: nuclear research or power reactors, radioactive waste storage or disposal facilities, fuel fabrication or reprocessing plants, laboratories, industrial ionisation facilities and so on.

The safety principles applied to nuclear research or industrial facilities are similar to those adopted for nuclear power reactors and nuclear fuel cycle facilities, while taking account of their specificities with regard to risks and detrimental effects. ASN has implemented an approach that is proportional to the extent of the risks or drawbacks inherent in the facility. In this respect, ASN has divided the facilities it regulates into three categories, from 1 to 3 in descending order of the scale of their risks and detrimental effects for the interests mentioned in Article L. 593-1 of the Environment Code (ASN resolution 2015-DC-0523 of 29 September 2015). This BNI classification enables the oversight of the facilities to be adapted and thus focused on those with the highest risks, in terms of the inspections and the examinations carried out by ASN. For example, the research reactors, called RHF and Cabri, are placed in categories 1 and 2 respectively, while the particle accelerator, called Ganil, is placed in category 3.

2.2 The periodic safety reviews

The Environment Code requires that the licensees carry out a periodic safety review of their facilities every ten years. This periodic safety review is designed to assess the status of the facility with respect to the applicable regulations and to update the assessment of the risks or detrimental effects inherent in the facility, notably taking into account the condition of the facility, acquired operating experience, changes in knowledge and the rules applicable to similar facilities. They are thus an opportunity for upgrades or improvements in fields in which the safety requirements have changed, in particular seismic resistance, protection against fire and confinement.

To date, all the nuclear research and miscellaneous facilities have undergone a periodic safety review. For facilities which had not yet undergone a first review, the Decree of 2 November 2007 required that the licensees submit their first periodic safety review report no later than November 2017. ASN subsequently implemented an examination method commensurate with the issues in the facilities: some facilities require particular attention due to the risks they present, while for others presenting a lower level of risk, the extent of the inspections and examinations is adapted accordingly. The technical examination of all the periodic safety review reports will take several years, owing to the specific nature of each of the facilities concerned.

By 1 November 2017, CEA had for examples carried out 16 periodic safety reviews and transmitted the review reports to ASN. CEA also informed ASN that it wished to even out the workload involved in these reviews, in terms of its organisation and its resources, by bringing forward the submission of the periodic safety review reports for certain facilities in the coming decade. ASN is in favour of this approach.

In 2019, ASN continued with its on-site inspections, which were started in 2016 and are specifically devoted to the periodic safety review of the facilities. It finds that all the licensees have now better assimilated the problems relating to the review, thanks to the implementation on each site of a transverse organisation specifically devoted to this process.

2.3 Lessons learned from the Fukushima Daiichi accident

In the wake of the Fukushima Daiichi NPP accident, ASN initiated a stress tests approach for 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 required that stress tests be carried out on the BNIs with the highest risks in the light of the Fukushima Daiichi accident (batch 1). For the CEA BNIs (Masurca, Osiris and JHR) and the High-Flux Reactor (RHF) in batch 1, and in the light of the conclusions of the stress tests, ASN in 2012 ordered the implementation of appropriate organisational and material measures, referred to as the “hardened safety core”. As at the end of 2019, ASN considers that good progress has been made in this work. It notably observes that the large-scale work on the RHF research reactor has been satisfactorily finalised, notably with the construction of new and robust emergency management premises, reinforcement of the tightness of the reactor building in the event of extreme flooding and the installation or modification of back-up systems to prevent loss of coolant risks.

The stress tests were continued for a second group (batch 2) of 22 facilities with lesser safety implications. These include the UPRA, CEA research facilities (Atalante, Cabri, LECA and Orphée) and ITER. The emergency management resources in the CEA centres in Cadarache, Marcoule and Saclay were reviewed under the second batch stress tests. In 2015, ASN ordered the implementation of new emergency management means, more particularly the construction or reinforcement of the “hardened safety core” emergency centres so that they could withstand extreme climatic conditions. It finds that these projects are behind schedule on all the CEA centres, for various reasons, and that the initial deadlines were not met. With regard to the Cadarache centre, ASN agreed to the request for postponement of construction of the emergency centre buildings, given that the main risk considered for the site is associated with the Jules Horowitz research reactor (RJH), for which commissioning has been delayed. For the Saclay centre, ASN served CEA with formal notice on 6 September 2019 to send it the file justifying the design and sizing of the future emergency management buildings. This file was received in December 2019. Finally, for the Marcoule centre, ASN is still waiting for additional data on the strength of the emergency management building which has now been built (containment, accessibility, operability, habitability, etc.).

Finally, of the thirty other Laboratories, Plants, Decommissioning and Waste (LUDD) facilities with the lowest safety implications (batch 3), ASN in 2013 issued a binding requirement on the CEA facilities (Lefca, LECI, Poséidon, Magenta and STAR), the Ganil and the irradiators of the Ionisos and Steris groups, for a calendar for submission of the stress tests reports running until 2020. For these facilities, the stress tests will be examined as part of a periodic safety review, as is currently the case for the irradiators of the Ionisos group.

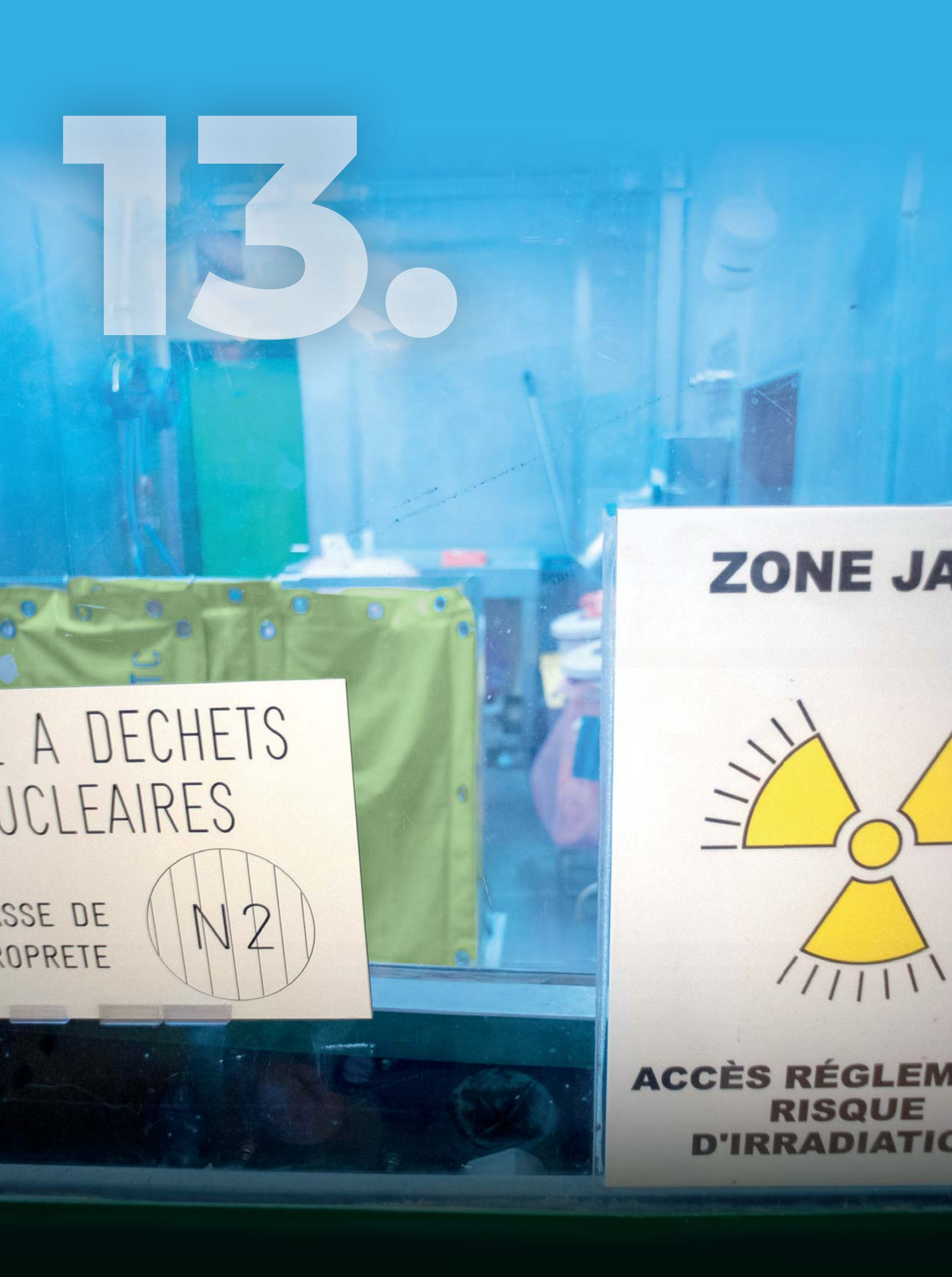
3. Assessment of research and miscellaneous industrial facilities

Some licensees of research or miscellaneous industrial facilities only operate from one to three facilities. Consequently, for each facility, the year's results are detailed in the introduction to this report per region and accompanied by the corresponding ASN assessment.

CEA however operates a large number of facilities of varying types and safety implications, such as research reactors and laboratories contributing to enhancing knowledge for the nuclear industry (NPPs, fuel cycle, waste management), along with "support" facilities for waste storage or processing of radioactive effluents.

CEA has also finally shut down numerous facilities and is preparing for or already carrying out their decommissioning. It is building a new research reactor to take over the activities of several shut down experimental reactors. The assessment of the facilities undergoing decommissioning and of waste management is also presented in chapters 13 and 14. ASN's overall assessment of the nuclear safety of the facilities operated by CEA is presented in the introduction to this report.

13.



DECOMMISSIONING OF BASIC NUCLEAR INSTALLATIONS

CHAPTER 13

Decommissioning of Basic Nuclear Installations

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 (BNIs). 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 then proceeds with Post-Operational Clean-Out (POCO) of the premises, remediation of the soils, and possibly the destruction of civil engineering structures.

The aim of the decommissioning and 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 2019 in France, 35 nuclear installations of various types (power and research reactors, laboratories, fuel reprocessing plants, waste treatment facilities, etc.) were either shut down or undergoing decommissioning, which represents more than a quarter of the BNIs in operation. As at 31 December 2019, ASN was examining 18 decommissioning files for definitively shut down facilities whose decommissioning has not yet been prescribed or whose decommissioning conditions have been substantially changed.

The year 2019 was notably marked by the publication of the conclusions of the joint examination by ASN and the Defence Nuclear Safety Authority (ASND) of the decommissioning and waste management strategy file from the Alternative Energies and Atomic Energy Commission (CEA).

1. Technical and legal framework for decommissioning

1.1 Decommissioning challenges

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. Some risks, particularly the risk of significant off-site discharges, decrease because the quantity of radioactive substances gets smaller. But the work carried out, sometimes in close contact with the radioactive substances, presents serious radiation exposure risks for the workers. Other risks increase such as the risks of dispersion of radioactive substances into the environment or certain conventional risks such as the risks of falling loads 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.

One of the major challenges in the decommissioning of an installation is linked to the very large volumes of waste produced compared with the operational waste. The scale and the difficulty of the work must be assessed as early as possible in the life of the installation (as of the design stage if possible) in order to ensure completely safe decommissioning in as short a time frame as possible.

Correct performance of the decommissioning operations is also dependent on the availability of the decommissioning "support" facilities (waste storage, processing and conditioning facilities, effluent treatment facilities) and 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 solution. This point is the subject of provisions in the Decree of 23 February 2017 establishing the provisions of the French National Radioactive Material and Waste Management Plan 2016-2018 (PNGMDR) (see chapter 14).

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 is addressed with particular attention during the assessment of the decommissioning and waste management strategies established by the CEA, EDF and Orano (see point 4).

Decommissioning of CEA's old installations and Orano's first-generation plants (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 in the decades to come, which was not anticipated and which is incompatible with the current capacities of the Cires[1], was addressed by a PNGMDR working group resulting in several lines of reflection, including the creation of a new centralised repository, the possible recycling of some of the waste or its disposal on site (see chapter 14).

1.2 The ASN decommissioning doctrine

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.

1.2.1 Immediate dismantling

Decommissioning in the shortest timeframe possible is a core principle in the regulations applicable to BNIs (Order of 7 February 2012 setting the general rules relative to BNIs). 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 17 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 retaining the knowledge and skills of the personnel 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 as of the design stage.
- The licensee anticipates decommissioning and sends its decommissioning application file before it stops operating the installation.
- The licensee has financial resources to finance decommissioning, covering its anticipated expenses by dedicated assets.
- The decommissioning operations are carried out "in as short a time as possible" after shutting down the installation, a timeframe 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 facility must lead to the gradual elimination of any hazardous substances, in particular radioactive substances, resulting from the activation or deposition phenomena, as well as any migration of contamination in the structures of the facility's premises or the soil of the site.

The ASN reference approach, as stated in its doctrine, requires that the licensees deploy decommissioning and clean-out practices taking into account the best scientific and technical knowledge available at the time and in economically acceptable conditions, with the aim of achieving a final state in which all the hazardous and radioactive substances have been removed from the BNI. 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 justification 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 delicensing must be as low as reasonably possible (ALARA principle)[2]. ASN is not in favour of introducing general thresholds and considers that it is preferable to adopt a case-by-case approach according to the intended subsequent use of the site. More specifically, reaching a threshold with exposure leading to an effective annual dose of 300 µSv (microsieverts) for the public –i.e. one third of the annual dose limit of 1 mSv (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 guide on structure clean-out operations (Guide No. 14, available on *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. In 2016, ASN also published a guide relative to the management of polluted soils at nuclear installations (Guide No. 24, available on *asn.fr*).

1.3 Decommissioning regulatory framework

Once a BNI is definitively shut down, it must be decommissioned. Its purpose therefore has to change as it is no longer that for which its creation was authorised, as the Creation Authorisation Decree notably specifies 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 on the basis of an opinion from ASN. This decree sets out, among other things, the main decommissioning steps, the decommissioning end date and the final state. As part of its oversight duties, ASN monitors the implementation of the decommissioning operations as directed by the decommissioning decree.

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.

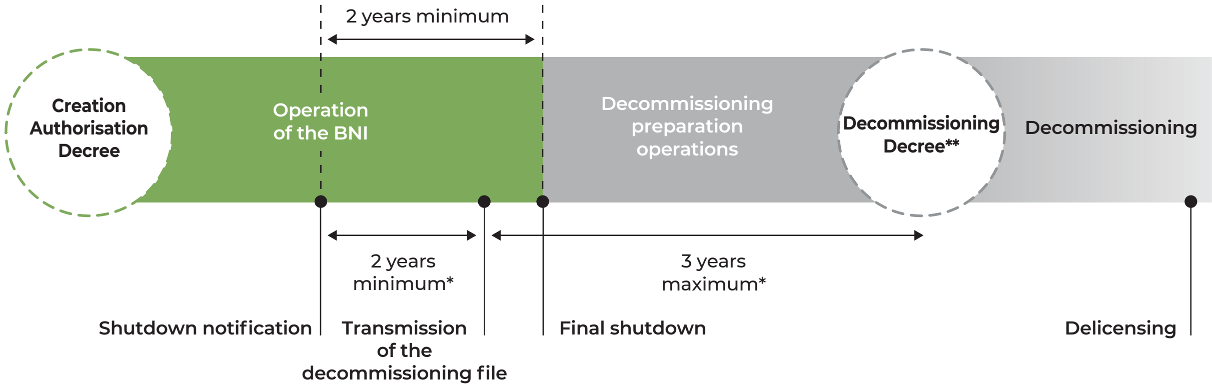
Given that installation decommissioning operations are often very long, the decommissioning decree can stipulate that some steps will be subject to prior approval by ASN on the basis of specific safety analysis files.

The Diagram below describes the corresponding regulatory procedure.

The licensee must demonstrate in its decommissioning file that the decommissioning operations will be carried out in as short a timeframe as possible.

1. *Industrial centre for grouping, storage and disposal (Cires), given this name in October 2012. When commissioned in 2003 it was known as the very low level waste disposal facility (CSTFA).*
2. *ALARA principle (As Low As Reasonably Achievable).*

Phases in the life of a Basic Nuclear Installation



* 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.

The decommissioning phase may be preceded by a preparatory stage, provided for in the initial operating licence. This preparatory phase allows for removal of a portion 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 (radiological maps, collection of pertinent data (operating history) with a view to decommissioning, etc.). The fuel in a nuclear reactor can be removed during this phase.

The Environment Code requires –as is the case for all other BNIs– that 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 regulatory framework. As part of its delicencing application, the licensee must 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 require the implementation of active institutional controls as a condition of delicensing. These may set a 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 undermining[3], etc.).

1.4 The financing of decommissioning and radioactive waste management

Articles L. 594-1 to L. 594-14 of the Environment Code define the system for ring-fencing funds to cover the costs of decommissioning nuclear facilities and managing the spent fuel and radioactive waste. This system is clarified by Decree 2007-243 of 23 February 2007 relative to securing the funding of the nuclear costs and by the Order of 21 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 covering the expected costs. They are obliged to submit triennial 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 each licensee and can prescribe the necessary measures should it be found to be insufficient or inappropriate. The administrative authority with competence for this control is the General Directorate for Energy and the Climate. 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, excluding long-term management of radioactive waste packages;
- spent fuel management costs, excluding long-term management of radioactive waste packages;
- cost of retrieving and conditioning legacy waste, excluding long-term management of radioactive waste packages;
- costs of long-term management of radioactive waste packages;
- cost of surveillance following closure of the disposal facilities.

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 reference strategy, 3) consideration of residual technical uncertainties and performance contingencies, and 4) consideration of operating experience feedback.

A Convention, signed by ASN and the DGEC for oversight of long-term costs by ASN, defines:
- the conditions in which ASN produces the opinions it is required to issue pursuant to Article 12 of the above-mentioned Decree of 23 February 2007, on the consistency of the strategies for decommissioning and management of spent fuels and radioactive waste;
- the conditions in which the Directorate General for Energy and Climate (DGEC) can call on ASN expertise pursuant to Article 15 of the same Decree.

3. Undermining is excavation by running water of the bed of a water course, banks, cliffs, or engineering structures.

2. Situation of nuclear facilities undergoing decommissioning – specific challenges

At the end of 2019, 35 nuclear facilities in France are definitively shut down or undergoing decommissioning. It is planned to shut down some ten more facilities in the coming years (see map below). These facilities are varied (nuclear power reactors, research reactors, fuel cycle facilities, support facilities, etc.) and the decommissioning challenges can differ greatly from one facility to the next. These challenges are, however, all linked to the large quantity of waste to be managed during decommissioning. The risks for safety and radiation protection are all the higher if the facilities contain legacy waste; this is the case with the Orano Cycle former spent fuel reprocessing plants or the CEA's old storage facilities.

2.1 Nuclear power reactors

2.1.1 Pressurised Water nuclear power Reactors

The first Pressurised Water Reactor (PWR) undergoing decommissioning in France is the Chooz A reactor (BNI 163). This is a small model compared with the 58 nuclear power reactors in operation. Decommissioning of Chooz A has been authorised by Decree since 2007 and presents some specific technical difficulties due to its construction inside a cavern. This makes some operations more complex, such as the removal of large components like the steam generators. Decommissioning of the Chooz A reactor vessel and its internal components is in progress and should continue in the timeframes specified in the Decree.

PWR decommissioning benefits from experience feedback from numerous projects across the world and the design of these reactors facilitates their decommissioning compared with other reactor technologies. The decommissioning of this type of installation presents no major technical challenges and its feasibility is guaranteed.

Whatever the service life of the reactors in operations, EDF will be confronted with the simultaneous decommissioning of several PWRs in the coming years and will therefore have to organise itself to industrialise the decommissioning process in order to meet the requirement to decommission each installation in the shortest time possible. The final shutdown of the Fessenheim Nuclear Power Plant (NPP) is planned for 2020. This will be the first of the 58 PWRs currently in operation to be decommissioned in France. The decommissioning of Fessenheim will thus provide EDF with considerable experience feedback for the other PWRs.

2.1.2 Nuclear power reactors other than PWRs

The nuclear power reactors that are not PWRs are all industrial prototypes. These comprise the first-generation Gas-Cooled Reactors (GCRs), the EL4-D heavy water reactor on the Brennilis site, and the sodium-cooled fast breeder reactors Phénix and Superphénix.

Some of these reactors have been shut down for several decades, which has led to loss of knowledge of the installation and its operation and loss of the skills associated with these reactors.

The decommissioning of these reactors is characterized by the lack of prior national or international experience.

As with the PWRs, decommissioning begins with the removal of the nuclear fuel, which removes 99% of the radioactivity present in the installation. As the thermal power of these reactors is relatively high –all greater than 250 MWth (megawatts thermal), their decommissioning necessitates the cutting away and removal of the activated parts of the reactor core. Remotely-operated means are therefore used in these highly irradiating zones. In view of their unique nature, specific and complex operations have to be devised and carried out to decommission them.

The GCRs have the particularity of being extremely massive and large-sized reactors, necessitating innovative cutting and access techniques under highly irradiating conditions. The decommissioning of these reactors will oblige EDF to manage significant volumes of waste. The final disposal route for some of this waste is in the process of being determined, such as the graphite bricks, for which low-level, long lived waste (LLW-LL) disposal is envisaged.

Decommissioning of the EL4-D reactor (prototype heavy water reactor) has been slowed, firstly due to the lack of prior experience in the decommissioning techniques to be used, and secondly due to unforeseen setbacks concerning the conditioning and storage facility for activated waste (Iceda, see introductory section and chapter 14).

The decommissioning of the sodium-cooled reactors (Phénix and Superphénix) has met with no major technological obstacles. The specific challenges lie chiefly in the control of the fire risk due to the presence of sodium and the safety of its treatment processes.

2.2 Research facilities

2.2.1 Research laboratories

Four research laboratories are currently undergoing decommissioning or preparation for decommissioning. These are the High Activity Laboratory (LHA) at Saclay (BNI 49), the Chemical Purification Laboratory (LPC) at Cadarache (BNI 54), the Irradiated Materials Plant (AMI) at Chinon (BNI 94) and the "Process" laboratory at Fontenay-aux-Roses (BNI 165). These laboratories, which began operating in the 1960s, were dedicated to Research & Development to support the development of the nuclear power industry in France.

Research laboratory decommissioning operations prior to delicensing are typically carried out in several steps:

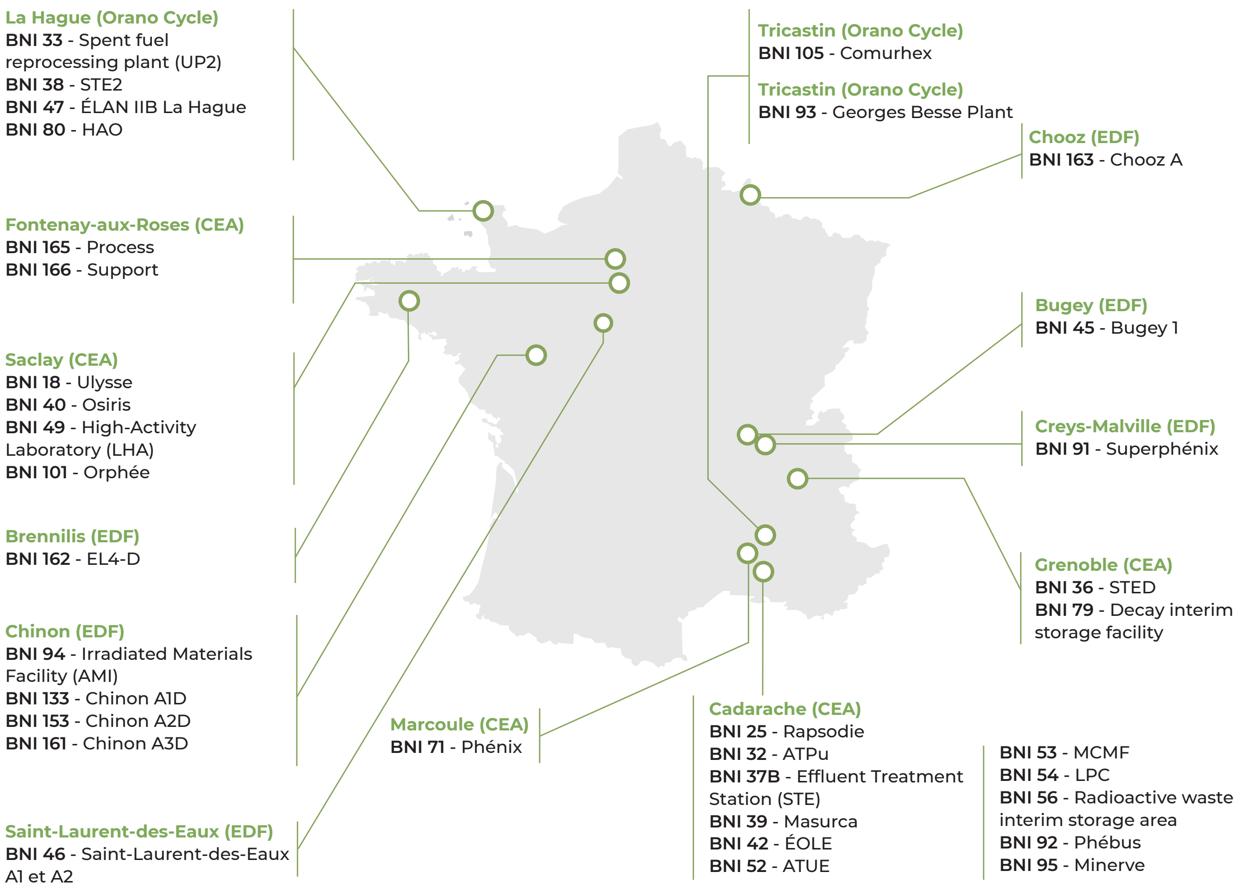
- removal of the legacy or old waste;
- disassembly of the electromechanical equipment and the reactor containments;
- cleaning out of the structures and remediation of the soils polluted by the activities of the BNI, if necessary.

Dismantling of the structures and civil engineering work, if applicable, can be carried out in the conventional manner after their complete clean-out. Nevertheless, in certain cases of highly contaminated structures, dismantling must be carried out during the decommissioning steps as their stability cannot be guaranteed once they have been cleaned out. In such cases, dismantling, which is carried out using techniques specific to the nuclear industry, is a step necessary for delicensing.

These very old facilities are all confronted with the issue of managing the "legacy" waste, stored on-site at a time when the waste management routes had not been put in place: intermediate level, long-lived waste (ILW-LL) and waste without a disposal route (e.g. asbestos, mercury, etc.). Moreover, incidents occurred during their operation, contributing to the emission of radioactive substances inside and outside the containment enclosures and to the varying levels of pollution of the structures and soils, making the decommissioning operations long and difficult.

One of the most important steps in the decommissioning of this type of facility, and which is sometimes rendered difficult due to incomplete archives, consists in inventorying the waste and the radiological status of the facility as accurately as possible

Map of the installations definitively shut down or in the process of decommissioning as at 31 December 2019



in order to define the decommissioning steps and the waste management routes. This is because incomplete understanding of the initial situations and insufficient characterisation of the waste make it necessary to revise the planned steps and lead to difficulties in packaging the waste, which is counterproductive to decommissioning progress.

When the waste is removed, very often to interim storage areas, and the main equipment remotely dismantled using the existing handling means, continuation of the decommissioning work usually necessitates opening the radioactive substance containment barriers in order to remove the last process or research equipment and the pipes using, among other things, more substantial cutting and handling equipment. The latter present risks and can lead to dissemination of radioactive material, a potential source of internal and external contamination for the operators who work at close range and must be protected. This work can moreover be carried out near radiation sources, which increases the risk of external exposure for the workers.

2.2.2 Research reactors

Eight experimental reactors are in final shutdown status at the end of 2019: Rapsodie (sodium-cooled fast neutron reactor), Masurca (critical mock-up), Phébus (experimental reactor), Osiris, Orphée ("pool" type reactors), ÉOLE and Minerve (critical mock-ups), Ulysse and ISIS (training reactors). They are all in the decommissioning preparation phase, except for Ulysse, for which decommissioning was completed in August 2019.

These reactors are characterised by a lower power output (from 100 Wth to 70 MWth) than the nuclear power reactors. When they were designed back in the 1960s to 1980s, the question of their decommissioning was not considered. One of the major decommissioning problems is the loss of memory of the design and operation of the installation. Therefore maintaining skills and the installation characterisation phase to determine its initial state (state of the installation at the start of decommissioning) are of vital importance. At the time of decommissioning, these installations usually present a low radiological source term, as one of the first operations consists in removing the spent fuel during the decommissioning preparation operations.

The risks involved in research reactor decommissioning operations evolve rapidly due to the numerous changes in the installation. The nuclear risks gradually give way to conventional industrial risks, such as the risk associated with the simultaneous management of several worksites, or the chemical risk during the clean-out phase. One of the main challenges comes from the production and management of large volumes of VLL waste, which must be stored then disposed of *via* an appropriate route.

There is a considerable amount of decommissioning experience feedback for the research reactors, given the decommissioning of numerous similar installations in France (Siloé, Siloette, Mélusine, Harmonie, Triton[4], the Strasbourg University Reactor - RUS) and abroad. Their dismantling timeframes span about ten years. Most of these reactors were demolished with conventional disposal following clean-out.

4. Triton was one of the first very compact and very flexible pool type research reactors called "MTR" (Material Test Reactor). Triton (6.5 MWth) was installed in Fontenay-aux-Roses, in 1959.

2.3 The front-end nuclear fuel cycle facilities

Two front-end nuclear fuel cycle facilities are in shutdown status. They are situated on the Tricastin site, one specialising in uranium enrichment by gaseous diffusion (BNI 93), the other in uranium conversion (BNI 105) and are in the decommissioning preparation phase. In addition, two facilities (former BNI 65 and BNI 90) which constituted the former nuclear fuel fabrication plant of Veurey-Voroize, operated by the *Société industrielle du combustible nucléaire* (SICN) belonging to the Orano group, were delicensed in 2019, after completion of the decommissioning operations and clean-out of the structures, accompanied by almost complete demolition of the buildings.

The only radioactive materials used in these plants were uranium-bearing substances. One of the particularities of these facilities lies in the presence of radioactive contamination associated with the presence of "alpha" particle-emitting uranium isotopes. The radiation exposure risks are therefore largely linked to the risk of internal exposure.

Furthermore, these are older facilities whose operating history is poorly known. Determining the initial state, particularly the pollution present in the soils beneath the structures, therefore remains an important issue. Furthermore, the industrial processes used at the time involved large quantities of toxic chemical substances (uranium, chlorine trifluoride and hydrogen fluoride, for example): the containment of these chemical substances is thus also an issue in these facilities.

2.4 The back-end nuclear fuel cycle facilities

The back-end facilities of the nuclear fuel cycle are the spent fuel storage pools, the spent fuel reprocessing plants and the facilities for storing waste from the treatment process. These facilities are operated by Orano Cycle and situated on the La Hague site.

The first processing facility at La Hague was commissioned in 1966, initially for reprocessing the fuel from the first-generation Gas-Cooled Reactors. This facility, BNI 33, called UP2-400, standing for "Production Unit No. 2–400 tonnes" (the first reprocessing plant was UP1 situated in the DBNI of Marcoule and is currently being decommissioned), was definitively shut down on 1 January 2004 along with its support facilities, namely the effluent treatment station STE2 and the spent fuel reprocessing facility AT1 (BNI 38), the radioactive source fabrication facility ELAN IIB (BNI 47) and the "Oxide High Activity" facility (HAO), built for reprocessing the fuels from the "light water" reactors (BNI 80).

Unlike the direct on-line packaging of the waste generated by the UP2-800 and UP3-A plants in operation, most of the waste generated by the first reprocessing plant was stored without treatment or packaging. Decommissioning is therefore carried out concomitantly with the legacy Waste Retrieval and Packaging (WRP) operations. This waste is highly irradiating and comprises structural elements from fuel reprocessing, technological waste, rubble, soils and sludge. Some of the waste has been stored in bulk with no prior sorting. The retrieval operations therefore require remotely operated pick-up means, conveyor systems, sorting systems, sludge pumping and waste packaging systems. The development of these means and carrying out the operations under conditions ensuring a satisfactory level of safety and radiation protection represent a major challenge for the licensee. Given that these operations can last several decades, the management of ageing is also a challenge. Taking into account the quantities, the physical and chemical forms and the radiotoxicity of the waste contained in these facilities, the licensee must develop means and skills that involve complex engineering techniques (radiation protection, chemistry, mechanics, electrochemistry, robotics, artificial intelligence, etc.). At present about ten projects of this type are underway in the former facilities. They will span several decades and are a prerequisite to the complete decommissioning of these facilities, whereas the decommissioning of the process parts of the plant is continuing with more conventional techniques.

2.5 The support facilities (storage and processing of radioactive effluent and waste)

Many of these facilities, most of which were commissioned in the 1960s and whose level of safety does not comply with current best practices, have been shut down.

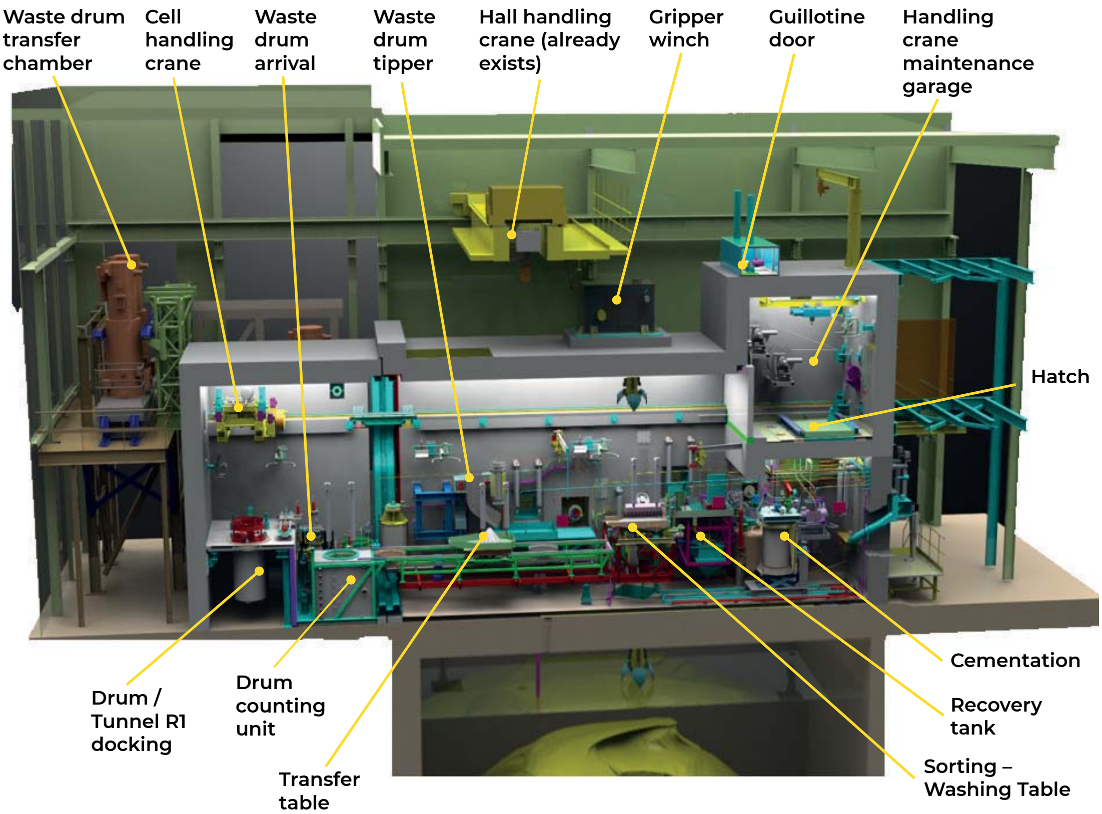
Old storage facilities were not initially designed to allow the removal of their waste, and in some cases they were seen as being the definitive waste disposal site. Examples include the Saint-Laurent-des-Eaux silos (BNI 74), the Orano Cycle plant silos in La Hague (silos 115 and 130 in BNI 38, the HAO silo in BNI 80), the pits and trenches of BNI 56 and the wells of BNI 72 and BNI 166. Retrieval of the waste from these facilities is complex and will span several decades. The waste must then be packaged and stored in safe conditions. New packaging and storage facilities are thus planned or under construction.

With regard to the Effluent Treatment Stations (STE) which also packaged the concentrates, they were shut down owing to the ageing of these facilities or the shutdown of the effluent-producing facilities. Examples include the Radioactive Effluent and Waste Treatment Station (FAR STED), BNI 37-B at Cadarache, STE2 at the La Hague plant and the Brennilis STE. The difficulties associated with the decommissioning of the STEs are closely dependent on their shutdown conditions, particularly the emptying and rinsing of their tanks.

The major difficulties associated with the decommissioning of the support facilities are as follows:

- poor knowledge of the operating history and the state of the facility to be decommissioned, which necessitates prior characterisation of the old waste and the analysis of samples of the sludge or deposits in the STE tanks. This characterisation necessitates firstly the development of methods and the use of specific equipment to take the samples, and secondly the availability of analysis laboratories;
- the difficulty in accessing the waste for retrieval was not taken into consideration in the design (silos, trenches, concrete-lined pits, cramped premises, etc.), necessitating the costly construction of infrastructures in conformity with current safety requirements and leading to long retrieval times and unforeseen events;
- the deterioration of the containment barriers, for example corrosion of waste drums or pollution of soils resulting from the occurrence of significant events during operation.

Unit for retrieval of waste from the HAO silo and Organised Storage of Hulls (SOC) pools in BNI 80



3. ASN actions in the field of facilities being decommissioned: a graded approach

3.1 The graded approach according to the risks of the facilities

ASN ensures the oversight of facilities undergoing decommissioning, as it does for facilities in operation. The BNI System also applies to definitively shut down facilities. ASN has implemented an approach that is proportional to the extent of the risks or drawbacks inherent to the facility. In this respect, ASN has divided the facilities under its oversight into three categories from 1 to 3 in descending order of the severity of the risks and drawbacks they present for the interests mentioned in Article L. 593-1 of the Environment Code (ASN resolution 2015-DC-0523 of 29 September 2015). This BNI classification allows oversight of the facilities to be adapted, thus reinforcing oversight of the facilities with major implications in terms of inspections and the depth of the examinations conducted by ASN.

The risks with facilities undergoing decommissioning differ from those for facilities in operation. For example, the risks of significant off-site discharges decrease as decommissioning progresses because the quantity of radioactive substances decreases. The requirements concerning the systems for controlling the risks associated with the decommissioning operations therefore tend to decrease as decommissioning progresses. ASN considers that it is generally not appropriate to undertake reinforcement work on a facility undergoing decommissioning that is as substantial as on a facility in operation, provided that the decommissioning is actually carried out and leads to a reduction in the hazard sources within a short period of time.

3.2 Lessons learned from Fukushima

To take into account the lessons learned from the nuclear accident that occurred at the Fukushima Daiichi NPP in Japan, ASN asked the BNI licensees to carry out stress tests, including on those facilities undergoing decommissioning.

The stress test procedure has been divided into three lots according to the safety risks inherent to the facilities. The facilities being decommissioned are essentially in lots 2 and 3.

For the facilities in lot 2, the post-Fukushima assessments have led ASN to request the removal of radioactive substances or the reinforcement of emergency management means on centres that often also have facilities in operation (see chapters 11 and 12).

For civil facilities undergoing decommissioning, the main challenges concern the La Hague site facilities. For example, the licensee has put in place operational provisions for extinguishing a fire in silo 130 following a "hardened safety core" earthquake(5). Silo 115 must also be further protected against the fire risk and ASN has asked the licensee to study measures to speed up implementation of this programme.

5. Earthquake considered for the equipment forming the "hardened safety core" of the facilities. The term "hardened safety core" was defined after the Fukushima Daiichi NPP accident to identify the ultimate equipment controlling the vital safety functions in an extreme situation (earthquake, winds, tornado, extreme flooding, etc.).

Integration of the lessons learned from the Fukushima Daiichi accident for the facilities presenting more limited risks shall be assessed by ASN on the occasion of the next periodic safety reviews. Lastly, there is no reason to perform stress tests on facilities which are nearing the end of decommissioning and will soon be delicensed.

3.3 The periodic safety reviews of facilities undergoing decommissioning

The conformity check aims to ensure that the changes in the facility due to the decommissioning work or to ageing do not call into question its conformity with the provisions of the regulatory texts and its technical baseline requirements.

Given the diversity of the facilities and the situations involved, each periodic safety review must be individually examined by ASN. ASN applies a method of examination that is adapted to the risks inherent to the facilities: some facilities warrant particular attention owing to the risks they present and may be reviewed by the Advisory Committee for Decommissioning (GPDEM) set up in 2018. For others presenting a lower level of risk, the extent of the inspections and examinations is adapted accordingly.

When a facility has been finally shut down and its decommissioning file has to be transmitted to the Minister in charge of nuclear safety and ASN, simultaneous filing of the decommissioning file and the periodic safety review conclusions report is considered to be best practice. The two files can thus be reviewed at the same time.

In 2019, ASN continued the examination of the safety review reports of some twenty facilities undergoing decommissioning that have been received since 2015. Inspections on the topic of the periodic safety review took place in 2019 on three facilities undergoing decommissioning. These inspections are used to check the means implemented by the licensee to carry out its review, as well as compliance with the action plan resulting from its conclusions. They led to several requests for corrective action and additional information.

3.4 Financing decommissioning: ASN's opinion on the triennial reports

The regulatory framework for ring-fencing the funds necessary for management of the long-term decommissioning and waste management expenses is presented in point 1.4.

On 8 June 2017, ASN published opinion CODEP-CLG-2017-022588 relative to the examination of the three-yearly reports submitted in 2016 by the licensees, concerning the accounts closed at the end of 2015.

With regard to the evaluation methodology, ASN had noted disparities in the level of detail in the submitted reports. More specifically, the EDF triennial report did not provide sufficient information for ASN to adopt a position. EDF did not present its costs evaluation reactor by reactor, yet some situations do display particularities (taking into account the operating history, the post-operational clean-out of the structures and soils, etc.). Nor does the information provided allow an assessment of the envisaged savings resulting from the experience acquired in the decommissioning of technologically similar reactors.

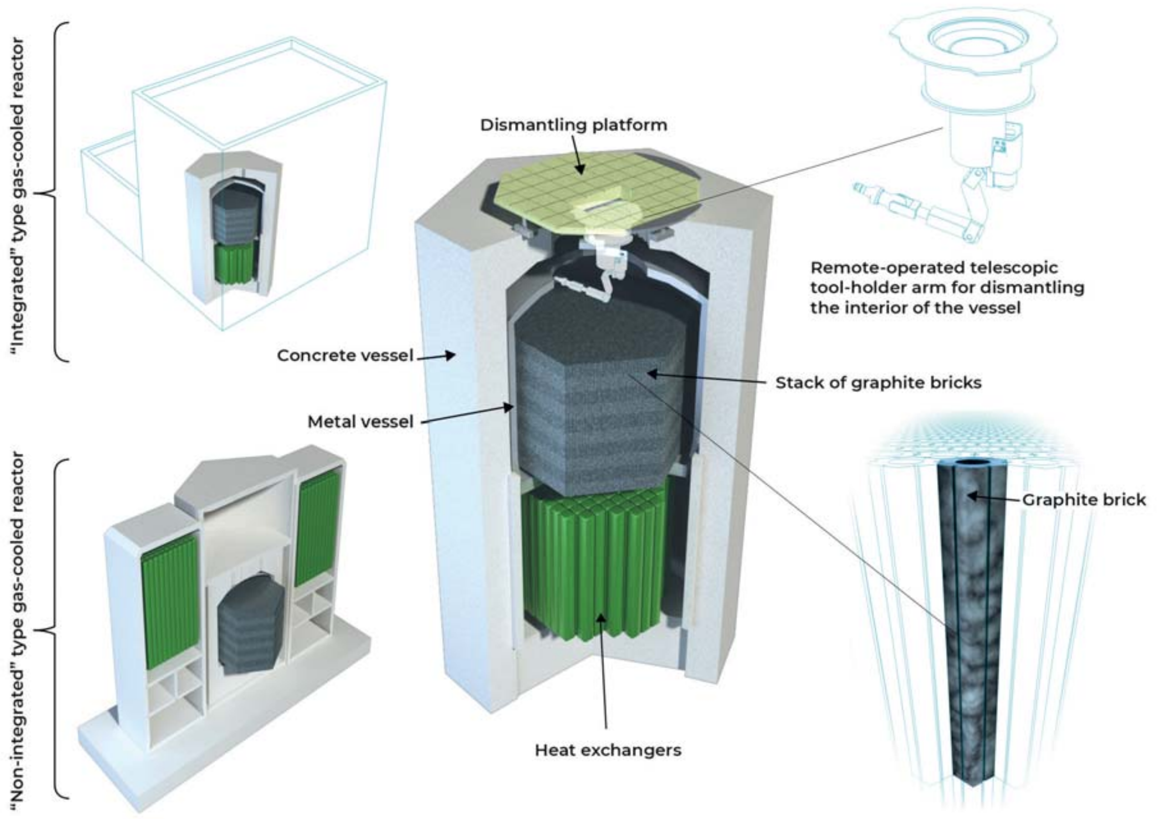
ASN had also noted that some decommissioning scenarios were based on the assumption that the radioactive waste and spent fuel treatment facilities would be available when required, and pointed out the need to assess the impact if these facilities were not to be available on the projected date. ASN recommended that for these facilities which must be created, the licensees take into consideration the hypotheses concerning their construction, operation and decommissioning. With regard to the clean-out of the civil engineering structures and remediation of soils, ASN noted that few licensees took sufficient account of the cost of soil remediation in their evaluation.

Lastly, ASN noted that the cost of facility modifications, resulting in particular from the stress tests and the works for continued operation (periodic safety reviews and EDF's "*grand carénage*" overhaul programme), were generally not explicitly taken into account.

The licensees update these evaluations annually. ASN examined the update note submitted in 2018. As before, ASN observed that some of the operations to prepare for decommissioning were not covered by ring-fenced assets. ASN, however, considers that all the operations carried out after final shutdown must be secured by the creation of ring-fenced assets. In this update review, ASN underlines the attention to be paid to costing the uncertainties linked to the management of materials (depleted and reprocessed uranium, thorium) and certain radioactive wastes (bituminised waste, LLW-LL). ASN also pointed out that the level of contamination and the corresponding management plans should be explicitly analysed.

13

ASN exploratory approach for developing oversight of the decommissioning project



In order to assess the licensee's ability to implement its decommissioning projects or its Legacy Waste Retrieval and Packaging Projects (WRP) in accordance with the stipulated timeframes, ASN has developed an exploratory approach for monitoring the progress of the decommissioning or WRP projects, allowing a combined assessment of compliance with deadlines, scope and cost, as these three aspects are closely dependent on each other in a project. With regard to the assessment of costs, and in the light of the DGEC's competence with respect to monitoring and regulating the ring-fencing of funding for the long-term costs, ASN involved it in this oversight approach from the outset.

After initial experience feedback from the monitoring of project progress by the ASN Caen regional division since 2016 on the shutdown facilities of the Orano La Hague site, ASN –together with the Directorate General for Energy and Climate (DGEC)– implemented this exploratory approach in 2019. It first of all required a more detailed understanding of the baseline requirements and project management organisation at Orano. ASN underlines the licensee's proactive attitude, which facilitated the discussions during the working meetings.

In October 2019, ASN carried out an in-depth inspection on the DFG (Low Granulometry Waste) project in BNI 33 at Orano La Hague (plant UP2-400). This project consists in retrieval of the filtration residues stored in settling tanks, units and pits in the former plant, their transfer and conditioning in a new building containing a waste homogeneous cementation treatment process.

This project is a complex one, which differs from a simple project in the number of interfaces between the project and the existing facilities, in the uncertainties with regard to the existing equipment to be reused, in the uncertainties with regard to the feasibility of the process and the packages, and in the challenge of a new facility and process to be built and commissioned.

This in-depth inspection was carried out with the DGEC, the Institute for Radioprotection and Nuclear Safety (IRSN) and the Cleanuc firm, a complex projects management expert. This inspection confirmed the benefits of new control methods applied to a complex decommissioning project. It also more clearly identified the numerous difficulties involved on many subjects with significant risk implications, along with fundamental areas for improvement.

Furthermore, the results of this exploratory approach identified methods, currently still at the testing stage, enabling Orano to inform the authorities of the progress of its projects, notably through the development of new project monitoring and tracking tools.

In 2020, ASN will assess the effectiveness of the changes implemented as a result of this inspection, notably with regard to monitoring the progress of projects at Orano. ASN will also be deploying this exploratory approach at EDF and French Alternative Energies and Atomic Energy Commission (CEA), with the same objectives, in order to ensure more global experience feedback.

4. Assessment of the licensees' decommissioning strategies

Given that numerous facilities have been shut down for several decades, with partial loss of knowledge of their operating histories, ageing structures and in some cases large quantities of waste still present, the advancement of decommissioning projects is one of the major issues for the safety of shut down facilities. Yet ASN has noted that the majority of the decommissioning projects are falling significantly behind schedule. ASN therefore asks the French Alternative Energies and Atomic Energy Commission (CEA), EDF and Orano to periodically present their decommissioning and radioactive waste management strategies, thereby providing an integrated view of the decommissioning projects and the disposal routes that are available or to be created for the waste resulting from the decommissioning operations.

As far as decommissioning is concerned, the licensees must justify the priority operations, principally through safety analyses. This prioritisation provides a means of checking that even if some projects are substantially behind schedule, the most significant resources will be devoted to operations with higher risk implications.

With regard to radioactive waste management, ASN checks the consistency with the regulatory framework and the guidelines of the French National Radioactive Materials and Waste Management Plan (PNGMDR). ASN examines with particular attention the defences against unforeseen events on a waste management facility and the plausibility of the timeframes announced by the licensees. It ensures that the licensees look ahead to the safety studies of packages and the feasibility of the packaging processes. ASN also checks the availability of the envisaged waste management routes and the support means (transport packages, treatment and storage facilities, etc.) which in practice govern the sustainability of the decommissioning strategy.

In 2019, ASN issued a position statement on CEA's decommissioning and waste management strategies files and opened a consultation on its resolution regarding the file justifying the change in decommissioning strategy for the EDF CGRs. It will issue a position statement on the Orano file in 2020. The context and the preliminary conclusions of these examinations are detailed below.

4.1 Assessment of EDF's decommissioning strategy

The first decommissioning strategy file for the EDF reactors definitively shut down (Chinon A1, A2, A3, Saint-Laurent A1 and A2, Bugey 1, EL4-D, Chooz A and Superphénix) was transmitted in 2001 at the request of ASN. Immediate dismantling was adopted as the reference strategy. This strategy has been updated regularly, in order, 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.

For the six first-generation GCRs (Chinon A1-A2 and A3, Saint-Laurent A1 and A2 and Bugey 1), EDF informed ASN in March 2016 of a complete change in strategy calling into question the technique used for decommissioning of these reactors and the rate of decommissioning. The switch from dismantling of the reactor vessel "in air" instead of "under water" as initially planned, the change in the envisaged decommissioning durations and the change in the first gas-cooled reactor to be decommissioned (Chinon A2 instead of Bugey 1), is leading to a delay of several decades in the decommissioning of all the GCRs. This new strategy includes the deployment of an industrial demonstrator to qualify the feasibility of the operations during dismantling of the reactor vessels "in air". Once this qualification has been obtained (within about ten years), EDF proposes complete dismantling of a first reactor vessel (Chinon A2), building on the lessons learned from this first dismantling and then, between 2060 and 2070, beginning the dismantling of the other five reactor vessels. ASN has drawn up draft resolutions and submitted them to a public consultation. In this draft resolution, ASN considers that EDF's development of an industrial demonstrator prior to dismantling of the reactor vessels is justified and that it is acceptable for EDF to gradually learn the lessons from experience feedback over a reasonable period of time. However, the timeframes for each of the phases will need to be periodically reviewed and could be adjusted if, in the coming decades, scenario optimisations prove to be possible.

For the other EDF facilities shut down (notably Chooz A, the Chinon AMI, EL4-D, Superphénix) decommissioning is under way and the need for dismantling as rapidly as possible is being complied with on the whole.

4.2 Assessment of Orano's decommissioning strategy

Decommissioning the old installations is a major challenge for Orano, which has to manage several large-scale decommissioning projects in the short, medium and long term (UP2-400 facility at La Hague, Eurodif Production plant, individual facilities of the DBNI at Pierrelatte, etc.). Implementation of decommissioning is closely linked to the radioactive waste management strategy, given the quantity and the non-standard and hard to characterise nature of the waste produced during the prior operations phase and the new waste resulting from the decommissioning operations.

Furthermore, Orano must carry out special legacy Waste Retrieval and Packaging (WRP) operations in old waste storage facilities. The deadlines for completion have been stipulated by ASN, particularly for the La Hague site. Furthermore, completion of these WRP operations governs the progress of decommissioning on the UP2-400 plant, as WRP is one of the first steps of its decommissioning. The WRP work is of particular importance given the inventory of radioactive substances present and the age of the facilities in which they are stored, which do not meet current safety standards. WRP projects are becoming increasingly complex owing to the interactions with the plants in operation and the site.

In June 2016, at the request of ASN and ASND, Orano submitted its decommissioning and waste management strategy. The file also includes the application of this strategy on the La Hague and Tricastin sites. The Tricastin site accommodates one DBNI, hence the joint oversight of Orano by ASN and ASND. ASN considers that Orano must increase its ability to prioritise the operations according to the risks inherent in the facilities to be decommissioned and comply with the stipulated deadlines. Orano's human and technical resources must also be increased in order to meet the deadlines for these planned projects.

ASN and ASND have mobilised substantial expertise to examine this file and will adopt a position on the strategy in 2020.

4.3 Assessment of the CEA's decommissioning strategy

CEA's decommissioning strategy is presented in the notable events part of this report.

Given the number and complexity of the operations to be carried out for all the nuclear facilities concerned, CEA is giving priority to reducing the "Potential Source Term" (TSM[6]) which is currently at a very high level in certain facilities, in particular in some of the individual facilities of the Marcoule DBNI and in BNIs 72 (in Saclay) and 56 (in Cadarache).

In their opinion of 27 May 2019, ASN and the ASND considered that, given the resources allocated by the State and the large number of facilities undergoing decommissioning, for which legacy waste retrieval and storage capacity will need to be built, it was acceptable for CEA to envisage staggering the decommissioning operations and that priority be given to those facilities in which the safety issues were greatest. The authorities underlined the fact that in the light of the calendars presented, risk reduction would not be effective for about another ten years, even in the absence of any unforeseen incidents or delays in the projects.

With regard to those facilities classified as lower priority, the authorities asked CEA on the one hand to define the safety improvement and environmental protection actions, notably as a result of the periodic safety reviews and, on the other, the principles of monitoring, upkeep and operation chosen to maintain the facilities in a sufficiently safe state, once the TSM has been removed, for a period of decades until such time as they are delicensed.

In their opinion, the authorities also drew attention to the fact that the priority given to the decommissioning of the facilities with the greater safety issues will require substantiated requests for modification of the prescribed decommissioning conditions, notably for the facilities of lower priority.

6. The Potential Source Term (TSM) corresponds to the quantity of radioactive activity that could be involved in an incident or accident. It is defined from the "source term" (activity of all the radioactive substances present in the facility) weighted by factors linked to:
- the dispersibility of the matrix (according to whether or not the radioactive substances are blocked in the materials and the nature of the blocking matrix),
- the effectiveness of the containment barriers (according to the seismic strength of the building and whether or not the ventilation is available for operation),
- the susceptibility of the source term to external hazards (the accident scenario adopted is an earthquake combined with a fire),
- the radiotoxicity of the inventory (β-γ, tritium or α spectrum).

Appendix

List of Basic Nuclear Installations undergoing decommissioning or delicensed as of 31 December 2019

INSTALLATION LOCATION	BNI	TYPE OF INSTALLATION	COMMIS–SIONED	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
Mélusine 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 (**)
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

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INSTALLATION LOCATION	BNI	TYPE OF INSTALLATION	COMMIS–SIONED	FINAL SHUTDOWN	LAST REGULATORY ACTS	CURRENT STATUS
LAMA Grenoble	(Former BNI 61)	Laboratory	1968	2002	2017: Removed from BNI list	Cleaned-out
SICN Veurey-Voroize	(Former BNIs 65 and 90)	Fuel fabrication plant	1963	2000	2019: Removed from BNI list	Buildings demolished, active institutional controls
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
Spent fuel reprocessing plant (UP2) (La Hague)	33	Transformation of radioactive substances	1964	2004	2013: Final shutdown and partial decommissioning decree	Decommissioning in process
STED and high-level waste storage unit (Grenoble)	36 and 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
Masurca	39	Reactor (5 kWth)	1966	2018	2018: Final shutdown	Preparation for decommissioning
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

INSTALLATION LOCATION	BNI	TYPE OF INSTALLATION	COMMIS–SIONED	FINAL SHUTDOWN	LAST REGULATORY ACTS	CURRENT STATUS
LPC Cadarache	54	Laboratory	1966	2003	2009: 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 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
Orphée	101	Reactor (14 MWth)	1980	2019	2019: Final shutdown	Preparation for decommissioning
Comurhex Tricastin	105	Uranium chemical transformation plant	1979	2009	2019: Decommissioning Decree	Decommissioning in process
Chinon A1D (Former Chinon A1)	133 (Former BNI 5)	Reactor (300 MWth)	1963	1973	1982: decree for confinement of Chinon A1 and creation of the Chinon A1 D storage BNI	Partially decommissioned, remaining parts confined Integrated in BNI. Preparation for complete decommissioning
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, remaining parts confined Integrated in BNI. Preparation for complete decommissioning
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 decree 2007: Decision of the *Conseil d'État* (State Council) cancelling the 2006 decree 2011: Partial decommissioning decree	Decommissioning in process. Preparation for complete decommissioning
Ardennes NPP (formerly Chooz A)	163 (Former BNI 1, 2, 3)	Reactor (1,040 MWth)	1967	1991	2007: Final shutdown and decommissioning decree	Decommissioning in process
Process 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.


14.

RADIOACTIVE WASTE AND CONTAMINATED SITES AND SOILS

CHAPTER 14

Radioactive waste and contaminated sites and soils

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 actions taken to define and set the broad guidelines for radioactive waste management.

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 of this same code. 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.

In 2018, the General Directorate for Energy and Climate (DGEC) of the Ministry for Ecological and Solidarity-based Transition and ASN petitioned the National Public Debate Commission (CNDP) prior to the drafting of the next edition of the French National Radioactive Material and Waste Management Plan (PNGMDR).

The CNDP decided to appoint a special committee to organise a public debate. The DGEC and ASN took part in all the meetings of this public debate, which was held from April to September 2019, and answered the questions from the civil society on the on-line platform provided by the special committee.

In 2019, ASN and the Defence Nuclear Safety Authority (ASND), issued a joint position statement on the decommissioning and waste management strategy of the Alternative Energies and Atomic Energy Commission (CEA), submitted in 2016. The letter addressed to the CEA underlines that the CEA's defined strategy results from an in-depth analysis and that the sequencing of the decommissioning operations seems acceptable given the means allocated by the State and the large number of facilities undergoing decommissioning. Both authorities nevertheless wonder about the robustness of the CEA's action plan and the available resources, both human and financial, and observe several vulnerabilities due in particular to the envisaged sharing of resources between centres, which means that for some operations which can only be carried out by one facility, there could problems due to capacity limitations.

Lastly, in 2019 ASN continued, in collaboration with ASND, examining Orano's decommissioning and waste management strategy file. In order to verify Orano's ability to meet the deadlines set in its strategy, ASN initiated an innovative project management inspection procedure in 2019. ASN and ASND will give their opinion on the strategy file in 2020.

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).

TABLE 1

Classification of radioactive waste

<table>
<tr><th></th><th></th><th>VERY SHORT LIVED WASTE CONTAINING RADIONUCLIDES WITH A HALF-LIFE OF < 100 DAYS</th><th>SHORT LIVED WASTE IN WHICH THE RADIOACTIVITY COMES MAINLY FROM RADIONUCLIDES WITH A HALF-LIFE ≤ 31 YEARS</th><th>LONG LIVED WASTE CONTAINING MAINLY RADIONUCLIDES WITH A HALF-LIFE > 31 YEARS</th></tr>
<tr><td>HUNDREDS Bq/g</td><td>Very low-level (VLL)</td><td rowspan="3">Management by radioactive decay on production site then disposal via disposal routes dedicated to conventional waste</td><td colspan="2">Recycling or dedicated surface disposal (disposal facility of the industrial centre for collection, storage and disposal (Cires) in the Aube département)</td></tr>
<tr><td rowspan="2">MILLIONS Bq/g</td><td>Low-level (LL)</td><td rowspan="2">Surface disposal (Aube waste disposal repository)</td><td>Near-surface disposal (being studied pursuant to the Act of 28 June 2006)</td></tr>
<tr><td>Intermediate-level (IL)</td><td></td></tr>
<tr><td>BILLIONS Bq/g</td><td>High-level (HL)</td><td>Not applicable(1)</td><td colspan="2">Deep geological disposal (planned pursuant to the Act of 28 June 2006)</td></tr>
</table>

(1) There is no such thing as high level, very short-lived waste.

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 Management of radioactive waste (with the exception of mining tailings and waste rock)

The management of radioactive waste is defined in Article L. 542-1-1 of the Environment Code. It comprises all the activities associated with the handling, preliminary treatment, treatment, packaging, storage and disposal of radioactive waste, excluding off-site transportation.

ASN oversees the activities associated with the management of radioactive waste from Basic Nuclear Installations (BNIs) or small-scale nuclear activities, other than those linked to national defence which are overseen by Defence Nuclear Safety Authority (ASND) and those relative to Installations Classified for Protection of the Environment (ICPEs), which are placed under the oversight of the Prefects.

1.1.1 Management of radioactive waste in Basic Nuclear Installations

Two economic sectors are the major contributors to the production of radioactive waste in BNIs.

First, the nuclear power sector, with the 19 Nuclear Power Plants (NPPs) operated by EDF, and the plants dedicated to the fabrication and reprocessing of nuclear fuel operated by Orano and Framatome. Operation of the NPPs generates spent fuel, part of which is reprocessed to separate the recyclable substances from the fission products or minor actinides which are waste. Radioactive waste is also produced during the operational and maintenance activities in the NPPs and the fuel reprocessing plants, like the structural waste, the hulls and end-pieces constituting the nuclear fuel cladding, and the technological waste, and the waste from the treatment of effluents such as the bituminised sludge. Furthermore, decommissioning of the facilities produces radioactive waste.

Second, the research sector, which includes civil nuclear research, in particular the CEA's laboratory and reactor research activities, but also other research organisations. Radioactive waste is produced during the operation, maintenance and decommissioning of these facilities.

This radioactive waste is managed in accordance with specific provisions which take into account its radiological nature and are proportionate to the potential danger it represents.

1.1.2 Management of waste from small-scale nuclear activities authorised under the Public Health Code

• The issues and implications

The use of unsealed sources[1] in nuclear medicine, biomedical or industrial research creates solid and liquid waste: small laboratory items used to prepare sources, medical equipment used to administer 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 used sealed sources considered as waste

Sealed sources[2] are used for medical, industrial, research and veterinary applications (see chapters 7 and 8). Once they have been used, and if their suppliers do not envisage their re-use in any way, they are considered to be radioactive waste and must be managed as such.

The management of sealed sources considered as waste, and their disposal in particular, must take into consideration the dual constraint of concentrated activity and a potentially attractive

1. Unsealed radioactive source: source for which the presentation and the normal conditions of use are unable to prevent all dispersion of the radioactive substance.

2. Sealed radioactive source: source whose structure or packaging, in normal use, prevents all dispersion of radioactive materials into the ambient environment.

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.

1.1.3 Management of waste containing 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 they produce. The term "Naturally Occurring Radioactive Material" (NORM) is used when its activity exceeds the exemption thresholds figuring in Table 1 of Appendix 13-8 of the Public Health Code. Consequently, NORM waste, for which there is no planned or envisaged use, is now considered as radioactive waste within the meaning of Article L. 542-1-1 of the Environment Code. Waste containing radioactive substances of natural origin but which do not exceed the abovementioned exemption thresholds is directed to conventional waste management routes.

NORM waste can be stored in two types of facility depending on its specific activity:
- in a waste disposal facility authorised by Prefectural Order, if the acceptance conditions stipulated in the Circular of 25 July 2006[3] relative to waste storage facilities, coming under sections 2760 of the ICPE nomenclature, are satisfied;
- in Cires[4] (Industrial centre for grouping, storage and disposal) intended for the disposal of very low-level (VLL) radioactive waste.

Some of this waste is however stored while waiting for a disposal route, in particular the commissioning of a disposal centre for low-level long-lived waste (LLW-LL).

Four hazardous waste disposal facilities are authorised by Prefectural Order to receive waste containing NORMs.

Furthermore, following the entry into effect on 1 July 2018 of Decree 2018-434 of 4 June 2018 introducing various provisions with regard to nuclear activities, the provisions of the Labour Code relative to the protection of workers against ionising radiation also apply to professional activities involving materials that naturally contain radioactive substances, which include the NORMs.

1.2 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 30 December 1991 on research into the management of radioactive waste, and then by Planning Act 2006-739 of 28 June 2006 on sustainable management of radioactive materials and waste, called the "Waste Act", which gives a legislative framework to the management of all radioactive materials and waste. A large part of the provisions of these Acts are codified in Book V, Part IV, Chapter II of the Environment Code.

The Act of 28 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 preparation of the PNGMDR, which aims to carry out a periodic assessment and define the prospects for the radioactive substance management policy. It also consolidates the missions of Andra, the French National Radioactive Waste Management Agency. Finally, it prohibits the disposal in France of foreign waste by providing for the adoption of rules specifying the conditions for the return of waste resulting from the reprocessing in France of spent fuel and waste from abroad.

This framework was amended in 2016 with the publication of the Ordinance 2016-128 of 10 February 2016 introducing various provisions with regard to nuclear activities which made it possible to:
- transpose Council Directive 2011/70/Euratom of 19 July 2011 establishing a European community framework for the responsible and safe management of spent fuel and radioactive waste, while reasserting the prohibition on 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 detailing the conditions of application of this prohibition;
- define a procedure for the administrative authority to requalify materials as radioactive waste;
- reinforce the existing administrative and penal enforcement actions and provide for new enforcement actions in the event of failure to comply with the provisions applicable to the management of radioactive waste and spent fuel.

The conditions for creating a reversible deep geological repository for high-level and intermediate-level long-lived radioactive waste are detailed in Act 2016-1015 of 25 July 2016.

1.2.1 Legal framework for the management of radioactive waste produced in Basic Nuclear Installations

In France, the management of radioactive waste in BNIs is governed in particular by the Order of 7 February 2012 setting the general rules relative to BNIs, of which Part VI concerns waste management.

BNI licensees establish 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. This absence of release thresholds for waste coming from a zone in which the waste is or could be contaminated or activated, constitutes a particularity of the French regulations. 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 licensees to present the wastes produced by the facility, whether radioactive or not, indicating the volumes, types, harmfulness and the envisaged disposal routes. The measures adopted by the licensees must consist in reducing the volume and the radiological, chemical or biological toxicity of the waste produced by recycling and treatment processes, so that only the ultimate waste has to go to final disposal.

3. *Circular of 25 July 2006 relative to classified installations –Acceptance of technologically enhanced or concentrated natural radioactivity in the waste disposal centres.*
4. *Cires: this name, which stands for* "Centre industriel de regroupement, d'entreposage et de stockage" *(Industrial centre for grouping, storage and disposal) was given in October 2012. When commissioned in 2003 it was called the* "Centre de stockage des déchets de Très Faible Activité (CSTFA)" *(Very Low Level Waste Disposal Facility). Installation subject to licensing under the system of section 2797 of the ICPEs.*

ASN resolution 2015-DC-0508 of 21 April 2015 relative to the waste management study, previously required in application of the Decree of 2 November 2007, and the assessment of the waste produced in the BNIs, details the provisions of the Order of 7 February 2012, concerning in particular:
- 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.

Further to a modification of the requirements of the procedures decree, codified in 2019 in the Environment Code, the regulations no longer require the waste management study as a specific document. All the above-mentioned management procedures must, as of 1 April 2020, be carried over to the impact study and the general operating rules of the BNIs. In 2020, ASN will update the resolution of 21 April 2015 to include this change in the regulations.

1.2.2 Legal framework for the management of radioactive waste produced by activities authorised under the Public Health Code

Article R. 1333-16[5] of the Public Health Code states that the management of effluents and waste contaminated by radioactive substances originating from all nuclear activities involving a risk of exposure to ionising radiation must be examined and approved by the public authorities. This is the case in particular for activities using radioactive substances intended for medicine, human biology or biomedical research.

ASN resolution 2008-DC-0095 of 29 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.

• Management of disused sealed sources

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;
- 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 existing 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.

Under the PNGMDR 2016-2018, Andra submitted a report in mid-2018 presenting a review of the situation regarding the acceptance of disused sealed sources considered as waste in the existing and planned disposal centres. ASN will analyse this report in 2020.

Furthermore, Decree 2015-231 of 27 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. The holders are moreover no longer obliged to demonstrate that they have contacted all the suppliers before turning to Andra. These provisions aimed to bring a reduction in the costs of collecting disused sources and provide a recovery route in all situations. ASN nevertheless notes the difficulties some holders have in getting their disused sealed sources taken back. Within the framework of the PNGMDR, the Ministry responsible for the environment and ASN are planning discussions with the holders of disused sealed sources, the suppliers and Andra, to overcome these difficulties.

• 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 the management of waste produced by small-scale nuclear activities. Since 2012, Andra operates Cires, a collection centre and storage facility situated in the municipalities of Morvilliers and La Chaise for waste from small producers other than nuclear power plants. ASN considers that the approach adopted by Andra is appropriate 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 must be managed with the waste from the International Thermonuclear Experimental Reactor (ITER) in a storage facility operated by the CEA (called the "Intermed project" at present). 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 24 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 31 December 2017, a revised strategy for the storage of tritiated waste from installations other than ITERs. Article 61 of the PNGMDR Order of 23 February 2017 moreover asks Andra to propose a management strategy for this waste pending commissioning of the abovementioned storage facilities. This strategy is currently being examined by ASN.

1.2.3 The national inventory of radioactive materials and waste

Article L. 542-12 of the Environment Code assigns Andra the task of establishing, updating every three years and publishing the inventory of radioactive materials and waste.

The last update was published in 2018. The inventory presents information concerning the quantities, the nature and the location of radioactive material and waste by category and economic sector as at the end of 2016. A prospective exercise, more detailed than for the 2015 edition, was also conducted considering four contrasting scenarios for France's long-term energy policy:
- scenario SR1 hypothesises the continued production of nuclear generated electricity, with an operating time for the current reactors of between 50 and 60 years and gradual replacement of the current reactors by European Pressurised Reactors (EPRs) and then fast-neutron reactors;
- scenario SR2 takes up the hypothesis of scenario SR1, but with a uniform 50-year operating time for the current reactors;

5. *Formerly Article R. 1333-12.*

The role of ASN in waste management

The public authorities, and ASN in particular, are attentive to the fact that there must be a management route for all waste and that each waste management step 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 complete, safe and coherent. 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 Directorate General for Energy and Climate (DGEC) as described in chapter 2. ASN also publishes the PNGMDR, its synthesis, the minutes of the abovementioned working group's meetings, the studies required by the plan and the associated ASN opinions on its website.

- scenario SR3 takes up the hypotheses of scenario SR1, but with the reactor fleet renewed only by EPRs, which implies reprocessing the spent ENU[6] fuels only, and no reprocessing of spent MOX[7] and URE[8] fuels;
- scenario SNR hypothesises the non-renewal of the reactor fleet on reaching 40 years of operation (60 years for the EPR), with early stopping of spent ENU fuel reprocessing in order not to produce separate plutonium, and stopping the reprocessing of spent MOX and ERU fuels.

This inventory constitutes an input database for preparing the PNGMDR.

1.2.4 The National Radioactive Materials and Waste Management Plan

Article L. 542-1-2 of the Environment Code, amended by the abovementioned Ordinance 2016-128 of 10 February 2016, defines the objectives of the PNGMDR:
- draw up the inventory of the existing radioactive material and waste management methods and the chosen technical solutions;
- identify the foreseeable needs for storage or disposal facilities and specify their required capacities and the storage durations;
- set the general targets, the main deadlines and the schedules enabling these deadlines to be met while taking into account the priorities it defines;
- determine the targets to meet for radioactive waste for which there is as yet no final management solution;
- organises research and studies into the management of radioactive materials and wastes, by setting deadlines for the implementation of new management modes, the creation of facilities or the modification of existing facilities.

The PNGMDR is prepared by the Directorate General for Energy and Climate (DGEC) and by ASN on the basis of the work of a pluralistic working group comprising more specifically producers of radioactive waste, licensees of the facilities managing this waste, the assessment and oversight authorities and environmental protection associations.

Practically, the PNGMDR is a document –over 200 pages in the 2016-2018 edition– that provides a detailed assessment of radioactive material and waste management methods, whether the management route is operational or yet to be implemented, then makes recommendations and sets objectives. ASN has contributed to it through seven opinions issued in 2016, the main lines of which have been included in the plan. The Decree 2017-231 and Order of 23 February 2017 set out the prescriptions of the Environment Code and the studies to conduct respectively. There are 83 such studies, each with a coordinator and a completion deadline.

In application of Article L. 122-1 of the Environment Code, the PNGMDR 2016-2018 has been the subject of an environmental assessment and an opinion from the Environmental Authority, followed by a public consultation on the website of the Minister responsible for energy. The Environmental Authority's recommendations and the contributions received during the public consultation were taken into account in the drafting of the plan and the development of regulatory requirements.

In addition, pursuant to Article L. 542-1-2 of the Environment Code, the plan was transmitted to Parliament which referred it to the Parliamentary Office for the Evaluation of Scientific and Technological Choices (OPECST) for evaluation before being made public.

The PNGMDR is accompanied by a summary presenting a concise and educational overview of the management of radioactive materials and waste and the main recommendations of the plan. An English version of the PNGMDR and its summary has also been published.

In 2019, ASN followed the progress of the work required by the PNGMDR 2016-2018, especially through the PNGMDR working group meetings. ASN also took part in all the public debate meetings preceding the development of the fifth edition of the PNGMDR (see "Notable events" in the introduction to this report), organised by the Special Public Debates Commission, and answered the questions addressed to it *via* the online platform provided by the Special commission. The conclusions of the public debate shall be taken into account in the development of the 5th edition of the plan.

1.3 Long-term management of waste –existing or projected disposal facilities

1.3.1 Very low-level waste

VLL waste comes essentially from the operation, maintenance and decommissioning of nuclear facilities. It consists mainly of inert waste (rubble, earth, sand) and metal waste. Its specific activity is usually less than 100 Bq/g (becquerels per gram) and can even be below the detection threshold of certain measuring devices.

6. ENU stands for Enriched Natural Uranium.

7. MOX (Mixed OXide) fuel is a nuclear fuel based on a mixture of oxides of uranium and plutonium.

8. URE stands for Enriched Reprocessed Uranium.

The Cires includes a VLL waste disposal facility. This facility, which has ICPE status, has been operational since August 2003.

As at the end of 2019, Cires held 396,354 m^3 of VLL waste, which represents 61% of its authorised regulatory capacity. According to the national inventory produced by Andra, the quantity of VLL waste resulting from decommissioning of the existing nuclear facilities will be about 2,200,000 m^3. According to current forecasts, the centre could be filled to maximum capacity between 2025 and 2030.

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, file the corresponding modification authorisation 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.

The management of VLL waste in France is based on the place of origin of the waste (zones in which the waste produced is or could be contaminated or activated), in order to ensure its traceability and management in specific disposal routes. The 2019 debate on the 5th edition of the PNGMDR showed the great sensitivity of the public to any regulatory changes in the management principle for this waste and the need for any such changes to be accompanied by the implementation of appropriate traceability processes, effective inspections by independent organisations, and a civil society association.

The PNGMDR will provide for the continuation of work to find additional VLL waste disposal capacities and will put forward recommendations regarding the implementation of the changes in the regulatory framework that will be envisaged with regard to safety and radiation protection, citizen associations, transparency, inspection and traceability, taking into consideration the work of the French High Committee for Transparency and Information on Nuclear Safety (HCTISN) on the subject.

1.3.2 Low and intermediate-level, short-lived waste

Low-level and intermediate-level short-lived waste (LL/ILW-SL) (in which the radioactivity comes primarily from radionuclides with a half-life of less than 31 years) comes essentially from the operation of nuclear facilities and more specifically as a result of maintenance work (clothing, tools, filters, etc.). It can also come from the post-operational clean-out and decommissioning of these facilities. The majority of LL/ILW-SL waste is placed in surface disposal facilities operated by Andra. Once these facilities are closed, they are monitored 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 facilities of this type in France, the Manche repository (CSM-BNI 66), commissioned in 1969 and closed since 1994, and the Aube repository (CSA-BNI 149) in operation (see Regional overview in the introduction to this report).

The quantity of LL/ILW-SL waste emplaced in the CSA repository totalled 344,919 m^3 at the end of 2019, which represents 34.5% of the facility's maximum authorised capacity. Added to this quantity is the waste emplaced in the Manche repository, which represents 527,214 m^3. The total quantity of LL/ILW-SL waste emplaced in the Andra facilities is therefore 872,133 m^3, to be compared with the quantity of 917,000 m^3 produced at the end of 2018. According to the data of the national inventory drawn up by Andra, this waste will represent a maximum volume of 2,000,000 m^3, on completion of decommissioning of the existing facilities. According to the estimates made by Andra in 2016 at the time of the periodic safety review of the CSA, this centre could reach its maximum filling capacity by 2060 instead of 2042 as initially forecast, this new estimate being based on better knowledge of the future waste and the waste delivery schedules.

1.3.3 Management of low-level long-lived waste

Low-level long-lived waste (LLW-LL) initially comprised two main categories: graphite waste resulting from the operation of the Gas-Cooled Reactor (GCR) NPPs, and radium-bearing waste, from the radium industry and its offshoots. Other types of waste have been added to this category such as certain bituminised effluents, substances containing radium, uranium and thorium with low specific activity, as well as certain disused sealed radioactive sources.

Furthermore, a fraction of the waste from the Orano Cycle Malvesi plant (Aude *département*) produced as from 1 January 2019 is now included in this waste category. The solid waste produced until 31 December 2018, on account of the large volumes it represents, is placed in a specific category of the national inventory called RTCU (French acronym standing for "Uranium Fuel Reprocessing Residues").

Putting in place a definitive management solution for this type of waste is one of the objectives defined by the Act of 28 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 drafted a notice in 2008 giving general safety guidelines concerning the search for a site capable of accommodating LLW-LL.

The PNGMDR 2010-2012 opened up the possibility of separate disposal of graphite waste and radium-containing waste, and asked Andra to work on the two design options:
- reworked cover disposal in an outcropping geological layer by excavation followed by backfilling;
- intact cover disposal dug in underground layer of clay at a greater depth.

The PNGMDR 2013-2015 required the various actors involved to carry out studies (characterisation and waste treatment possibilities, geological investigations on a site identified by Andra, design studies and preliminary safety analyses) so that in 2016 the State can specify guidelines for the management of LLW-LL waste. Thus, the holders of LLW-LL waste have progressed in the characterisation of their waste and in the processing possibilities, particularly with regard to graphite waste and some bituminised waste packages. More specifically, the radiological inventory for chlorine-36 and iodine-129 has undergone a significant downward reassessment.

As part of the PNGMDR, Andra submitted a report in July 2015 containing:
- proposals of choices of management scenarios for graphite waste and bituminous waste;
- preliminary design studies covering the disposal options referred to as "intact cover disposal" and "reworked cover disposal";
- the inventory of the waste to be emplaced in it and the implementation schedule.

ASN issued an opinion 2016-AV-264 on Andra's interim report on the disposal project for LLW-LL waste on 29 March 2016. Andra must more specifically detail the design assumptions for the LLW-LL repository, the 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. At the same time, ASN has started revising the general safety guidelines notice of 2008. A working group bringing together ASN, French Institute for Radiation Protection and Nuclear Safety (IRSN), Andra, the LLW-LL waste producers and representatives of civil society was thus set up in Autumn 2018. A synthesis of the work carried out will be provided in an IRSN report in 2020. The recommendations of this report will be taken into account in the revision of the general safety guidelines of 2008, which will be replaced by an ASN guide.

Lastly, in accordance with Article 7 of the Decree of 27 December 2013, Orano Cycle has submitted a study on the long-term management of the Malvési site waste already produced, stored in BNI 175 –Écrin. Various envisaged disposal concepts are presented:
- above-ground disposal;
- near-surface (40 m), reworked cover disposal, in the former open-cast mine pit;
- near-surface (40 m) reworked cover disposal, in a new pit as yet to be built.

Given the nature of the waste and the configuration of the site, ASN indicated in its opinion 2012-AV-0166 of 4 October 2012 that it is not in favour of continuing the development of this type of disposal as it considers that it does not meet the long-term safety requirements. The other two disposal options presented in the Areva study of December 2014 on the long-term management of legacy waste from the conversion process, are based on an identical concept, namely near-surface reworked cover disposal at a depth of about 40 m.

ASN moreover issued and opinion on 2 September 2019 with demands concerning:
- the inventory and radiological and chemical characterisation of the waste and mine tailings in the sector of basin B3 and of the separating embankment between basins B3 and B5;
- the disposal concept for the Uranium Fuel Reprocessing Residues (RTCU), particularly in terms of properties and expected performance for all the components of the disposal facility (cover, structure, packages, etc.);
- knowledge of the explored formations;
- the impact of the future disposal facility on the resources near the site.

1.3.4 Management of high-level and intermediate-level, long-lived waste

Following on from the Act of 30 December 1991, the Act of 28 June 2006 provides for the research into the management of HLW and ILW-LL radioactive waste to be continued along three complementary lines: separation and transmutation of the long-lived radionuclides, interim storage and reversible deep geological disposal.

• Separation/transmutation

Separation/transmutation processes aim to isolate and then transform the long-lived radionuclides in radioactive waste into shorter-lived radionuclides or even stable elements. The transmutation of the minor actinides contained in the waste is likely to have an impact on the size of the disposal facility, by reducing both the heating power, the harmfulness of the packages placed in it and the repository inventory. Despite this 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.

ASN issued an opinion 2016-AV-0259 on 25 February 2016 based on the interim report on the industrial prospects of the separation/transmutation processes submitted by the CEA in 2015 under the PNGMDR. 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 gains would not eliminate the need for a deep disposal repository and could only bring a tangible reduction in the footprint of a future repository if a sufficiently large fleet of fast-neutron breeder reactors were to be operated for at least one hundred years to ensure the consistency of the cycle as a whole.

• Storage

The second line of research and studies in the Act of 28 June 2006 concerns the storage of waste.

The long-term storage of high-level long-lived waste, which was one of the lines of research provided for in the Act of 30 December 1991, has not be retained as a definitive management solution for this type 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 28 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. This 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.

• Progress in storage

In 2013, Andra submitted a report on the research and studies carried out. This report more particularly presented the established inventory 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 facilities which, if necessary, would accept packages removed from the repository. For such facilities, Andra looked for versatility which would allow simultaneous or successive storage of packages of various types in their primary form or placed in disposal overpacks. In its study submitted in 2013, Andra stated that it had stopped its research on near-surface storage facilities.

It justified abandoning this operation in particular because of the greater complexity of this type of facility (consideration of the presence of underground water and the need for ventilation if exothermal waste was emplaced, surveillance of the civil engineering structures) and the lower operating flexibility. The multi-criteria analysis submitted in 2018 did not call into question these conclusions.

In the light of industrial experience, research and its studies, Andra issued recommendations in 2014 for the design of future storage facilities that are complementary to disposal. They concern more specifically the service life of the facilities (up to about a hundred years), their monitoring and surveillance and their modularity. Orano Cycle has integrated some of the recommendations in the design of the extension of the glass storage facilities at La Hague (E/EV-LH building) intended for high-level waste and situated in BNI 116. This extension comprises two pits: 30 and 40, commissioned in 2015 and 2017 respectively.

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 fundamental elements enabling waste package storage needs to be identified.

In its abovementioned opinion of 25 February 2016, ASN identifies several possibilities for enhancing the robustness of the French storage strategy for HL and ILW-LL waste, in a manner complementary to their disposal.

• The prospects under the PNGMDR

The studies required by 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 of 25 February 2016.

Article D. 542-79 of the Environment Code, introduced by the Decree of 23 February 2017 relative to the provisions of the PNGMDR 2016-2018, stipulates that 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 for the next twenty years at least.

In accordance with Article 53 of the Order of 23 February 2017, the CEA, EDF and Orano have defined the future storage needs for all families of HL and ILW-LL waste, covering the next twenty years at least. The CEA, EDF and Orano have also studied, within this context, how sensitive the storage needs are to shifts in the *Cigéo* schedule. All these studies have been submitted to ASN and are currently being examined.

Article 52 of the Order of 23 February 2017 requires Andra to substantiate the factors that led it to reject the option of designing near-surface storage facilities. In response to this requirement, in 2018 Andra submitted a comparative study of the different types of storage it has studied. This analysis does not reveal any decisive advantage in terms of nuclear safety favouring a near-surface facility over an above-ground facility. ASN will adopt a position on Andra's analyses in 2020.

On the basis of the ASN opinion, the PNGMDR 2016-2018 sets out several guidelines for the design of HL and ILW-LL waste storage facilities (significant design margins, simple and modular architecture, preference to passive systems, provisions for controlling the ambient storage conditions in normal, incident and accident situations, provisions for monitoring and surveillance and deviation management defined at the design stage, provisions for preserving the memory, etc.). ASN will be attentive to the integration of these recommendations in the new facilities that will be necessary pending commissioning of *Cigéo*. This concerns in particular the storage facilities for ILW-LL waste produced before 2015, which will have been packaged before 2030, in accordance with the deadline prescribed by Article L. 542-1-3 of the Environment Code.

• Reversible deep geological disposal

Deep geological disposal is called out by 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 28 June 2006 assigns Andra the task of devising a project for a deep geological disposal facility which shall be a BNI, governed by the regulations specific to this type of installation, and as such shall be 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 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 in the form of a safety Guide relative to radioactive waste disposal in deep geological formations –Safety Guide No.1.

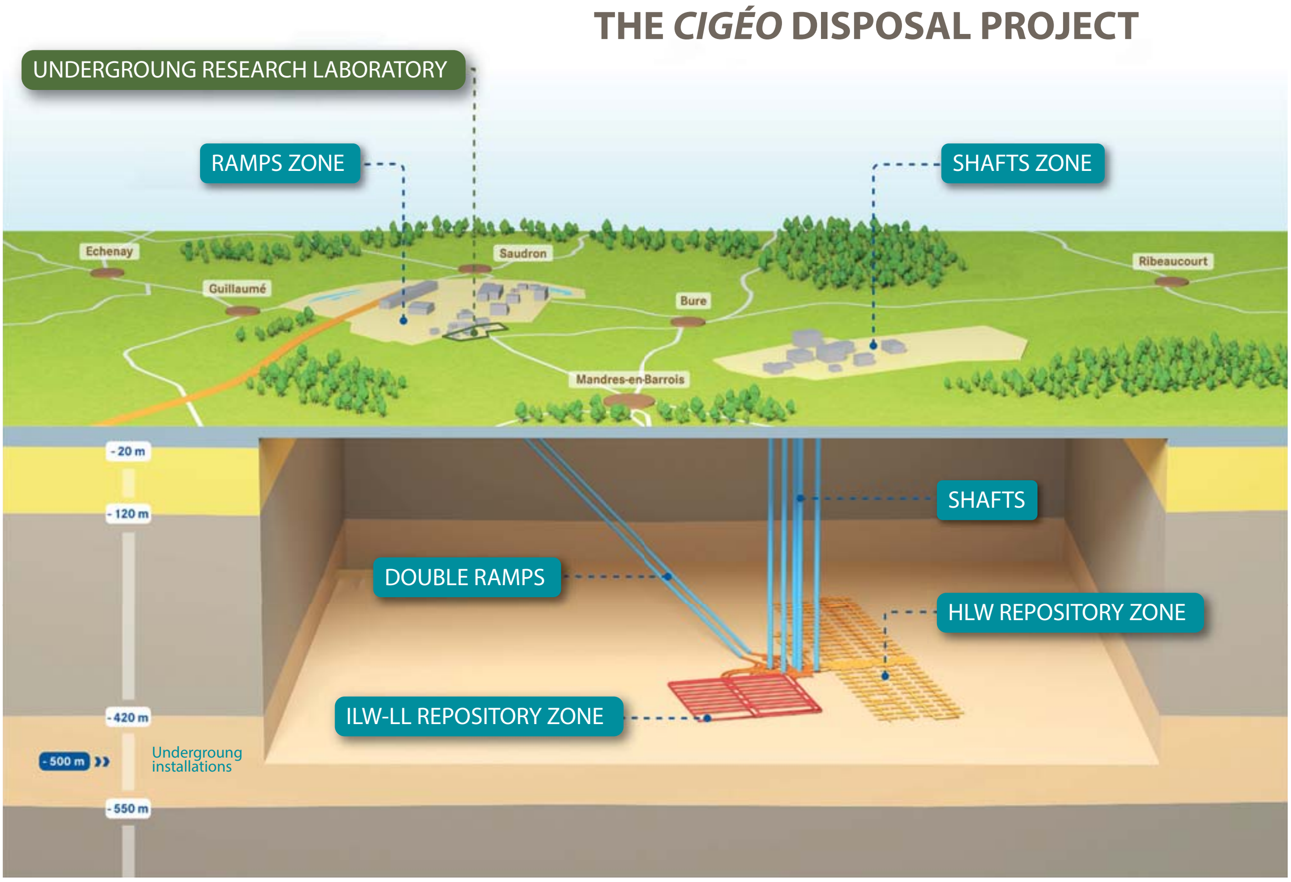
The conditions of creation of a reversible deep geological repository for HL and ILW-LL radioactive waste were specified by the Act of 25 July 2016, which defines the principle of reversibility, introduces the industrial pilot phase before complete commissioning of *Cigéo* and brings schedule adaptations concerning the deployment of *Cigéo*.

This Act 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 31 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 23 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*

Schematic Diagram of the *Cigéo* repository showing the surface and underground facilities



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.

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 by random sampling during follow-up inspections that they are carried out using processes that guarantee the quality of the results.

• Technical instructions

Pursuant to the Act of 30 December 1991, and then pursuant to the Act of 28 June 2006 and the PNGMDR, Andra has carried out studies and submitted reports on the deep geological repository. These studies and reports have been examined by ASN –referring in particular to the Safety Guide of 2008– and it has issued an opinion on them.

ASN has thus more specifically examined the reports submitted by Andra in 2005 and at the end of 2009. It issued opinions on these reports on 1 February 2006 and 26 July 2011. Andra subsequently 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 2018, on the *Cigéo* safety options file.

• The authorisation process

Examination of the creation authorisation application for a deep geological disposal facility will not start until formally requested by Andra and will be governed in particular by Book V, Title IX, Chapter III, Section 4 of the Environment Code and by Article L. 542-10-1 of the Environment Code, which is specific to deep geological disposal facilities. Andra has indicated that it wishes to file this creation authorisation application in the second half of 2020.

Further to the public debate of 2013, Andra decided to set up an industrial pilot phase before operating the facility at industrial rates. The Board of Directors of Andra had 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 19 December 2014.

• Examination of the *Cigéo* Safety Options Dossier

The filing of a Safety Options Files (DOS) marks the start of a regulatory process[9]. ASN received the DOS for *Cigéo* in April 2016. At the end of the technical examination phase, the ASN draft opinion underwent public consultation, which took place from 1 August to 15 September 2017. After analysing the resulting contributions, ASN issued its opinion on 11 January 2018. ASN also sent a letter giving recommendations on the safety options to prevent or limit the risks and asked Andra for complementary studies and substantiations (corrosion phenomena, low-pH concretes, representativeness of the hydrogeological model, surveillance strategy, etc.). The demands made in this letter take into account the suggestions and comments received through the public consultation.

The examination of the *Cigéo* DOS highlighted several issues relating to specific aspects (architecture, defining of hazards, post-accident management, etc.). Among these subjects, ASN expressed reservations regarding the disposal of bituminised waste in *Cigéo*. It considers that "*priority should be given to finding ways to neutralise the chemical reactivity of packages of bituminised waste. At the same time, design modification studies should be carried out in order to rule out the risk of runaway exothermal reactions. Whatever the case, characterisation of these packages of bituminised waste by their producers without delay is an essential prerequisite*".

The management of bituminised waste is moreover monitored under the PNGMDR, which demands several studies relative to the characterisation of these packages, their conditions of transport and the treatment possibilities (Articles 46, 47 and 48 of the Order of 23 February 2017).

In 2019, ASN made additional information requests[10] to the waste producers and to Andra further to the examination of the study submitted under Article 46. They focus more specifically on the effect of self-irradiation on the thermal behaviour of the bituminised waste packages, on the long-term swelling considering the long-term behaviour of the *Cigéo* repository and on the design changes to control the risks associated with the disposal of packages of bituminised waste.

The Minister responsible for energy and ASN moreover wanted an independent multidisciplinary assessment drawing on international practices to be conducted on this issue. The conclusions of this assessment were presented to the working group tasked with monitoring the PNGMDR (see box) in September 2019. ASN will ensure that Andra take these conclusions into account in its Creation Authorisation Application (DAC).

• From the safety options dossier to the creation authorisation application

At present, Andra is continuing the *Cigéo* project design and preparing the requisite authorisation applications. Andra plans filing a Declaration of Public Utility (DUP) application in late 2019. Andra has announced that it will submit the creation authorisation application in the second half of 2020. ASN and IRSN make regular progress assessments with Andra to check that the key issues identified in the examination of the previous Andra files have been properly taken into account. Andra must also integrate the results of the bituminised waste review in its creation authorisation application file, particularly with regard to the architecture of the ILW-LL waste disposal cells.

In September 2018, an Internet resources platform[11] dedicated to the deep geological disposal project was put on line under Government management with the participation of ASN. The principal aim of this platform is to gather the documents produced by public entities, committees, authorities, non-governmental organisations (NGOs), associations and citizens. These documents illustrate the technical and societal issues relating to the *Cigéo* project.

In the public debate relative to the fifth edition of the PNGMDR, the question of *Cigéo* governance was identified as requiring closer examination, particularly with regard to the implementation of reversibility and the objectives of the industrial pilot phase. The Special Public Debate Committee (CPDP) concludes in particular that civil society must be involved in the governance of *Cigéo*, particularly during the industrial pilot phase. ASN considers in this respect that civil society's involvement is provided for by Article L. 542-10-1 of the Environment Code, which states that the results of the pilot industrial phase shall be subject to an opinion, notably from the regional authorities concerned. Furthermore, the CPDP considers that the public must also be involved in the steps that have an impact on the reversibility of the facility, particularly package retrievability. ASN considers that the public could participate in the periodic reviews of the reversibility exercise, provided for by Article L. 542-10-1 of the Environment Code.

• The cost of the project

On 15 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 31 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).

1.4 Radioactive waste management support facilities

• Treatment

Treatment is a fundamental step in the radioactive waste management process. This operation serves firstly to separate the waste into different categories to facilitate its subsequent management, and secondly to significantly reduce the volume of waste.

The La Hague plants which process the spent fuel assemblies are involved in this process because they apply a dissolution and

9. *Article R. 593-14 of the Environment Code stipulates that* "any person who plans operating a BNI can, before initiating the creation authorisation procedure, ask ASN for an opinion on all or part of the options it has chosen to protect the interests mentioned in Article L. 593-1. 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 limiting the risks for the interests mentioned in Article L. 593.1, given the prevailing technical and economic conditions. ASN 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 Minister responsible for nuclear safety".

10. *The follow-up letters are available on the ASN website: asn.fr/Informer/Dossiers-pedagogiques/La-gestion-des-dechets-radioactifs/Plan-national-de-gestion-des-matieres-et-dechets-radioactifs/PNGMDR-2016-2018.*

11. *Accessible at cigeo.gouv.fr*

chemical treatment process to separate the cladding and the fission products. The hulls and end-pieces are then compacted to reduce their disposal footprint.

The melting and incineration facility of Cyclife France, called “Centraco”, significantly reduces the volume of the VLL and LL/ILW-SL waste that is treated there. This plant has a unit dedicated to the incineration of combustible waste, and a melting unit in which metal waste is melted down.

The radioactive effluents can also be concentrated by evaporation, like the operations carried out in Agate, the effluent advanced management and processing facility (BNI 171), with this same aim of volume reduction.

• Packaging

Radioactive waste packaging consists in placing the waste in a package which provides a first containment barrier preventing radioactive substances being dispersed in the environment. The techniques used depend on the physical-chemical characteristic of the waste and their typology, which explains the large variety of packages used. These packages are subject to approvals by Andra if they are intended for in-service disposal facilities, and to packaging agreements by ASN if they are intended to be directed towards disposal facilities still under study.

In some cases the packaging operations are carried out directly on the site of waste production, but they can also take place in dedicated facilities, like the La Hague plants, which package spent fuel hulls and end-pieces in CSD-C packages and fission products in CSD-V packages, and the effluent treatment stations such as the Stella station in BNI 35. The waste packages are sometimes packaged in the facilities in which they are to be stored, which will be the case for the ILW-SL waste packages in the Iceda facility, or directly in a disposal facility, such as Cires and CSA, which carry out these operations on a portion of the incoming packages.

• Storage

Storage, as defined by Article L. 542-1-1 of the Environment Code, is a temporary management solution for radioactive waste. The waste is kept in storage for a limited period pending its transfer to disposal, or in order to achieve a sufficient level of radioactive decay to enable it to be sent to conventional waste management routes in the particular case of very short-lived waste, which comes chiefly from the medical sector.

Some facilities (see opposite) are specifically dedicated to the storage of radioactive waste, such as Écrin, commissioned in 2018, and Cedra. This will also be the case with Iceda and once these facilities enter service. As for the CSD-C and CSD-V packages, they are stored directly in various facilities on the La Hague site pending commissioning of the deep geological repository for HL and ILW-LL waste.

• Research and development

Support facilities are used for research and development work to optimise radioactive waste management.

Among these, the Chicade facility (BNI 156) operated by the CEA on the Cadarache site conducts research and development work in low-level and intermediate-level objects and waste. This work primarily concerns aqueous waste treatment processes, decontamination processes, solid waste packaging methods and the expert assessment and inspection of waste packages.

2. Nuclear safety in waste management support facilities, role of ASN and waste management strategies of the major nuclear licensees

2.1 Nature of ASN oversight and actions

2.1.1 Nature of ASN oversight and actions, graded approach

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 (for example with respect to zoning, packaging or the checks performed by the licensee), and on the other hand the safety of the facilities dedicated to radioactive waste management (waste treatment, packaging, storage and disposal facilities). This oversight is exercised proportionately to the waste management steps and the safety implications for the dedicated facilities. Thus, the waste management BNIs are classified in one of three categories, numbered from 1 to 3 in descending order of significance of the risks and adverse effects they present. This categorisation makes it possible to define an inspection programme and to target the level of expertise required to examine certain files submitted by the licensees.

The various facilities and ASN’s assessment of their safety are presented in the introduction of this report.

2.1.2 Oversight of the packaging of waste packages

• Regulations

The Order of 7 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 23 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 issues 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 issued approvals by means of audits and monitoring actions on the package producers’ premises and on the packages received at its facilities.

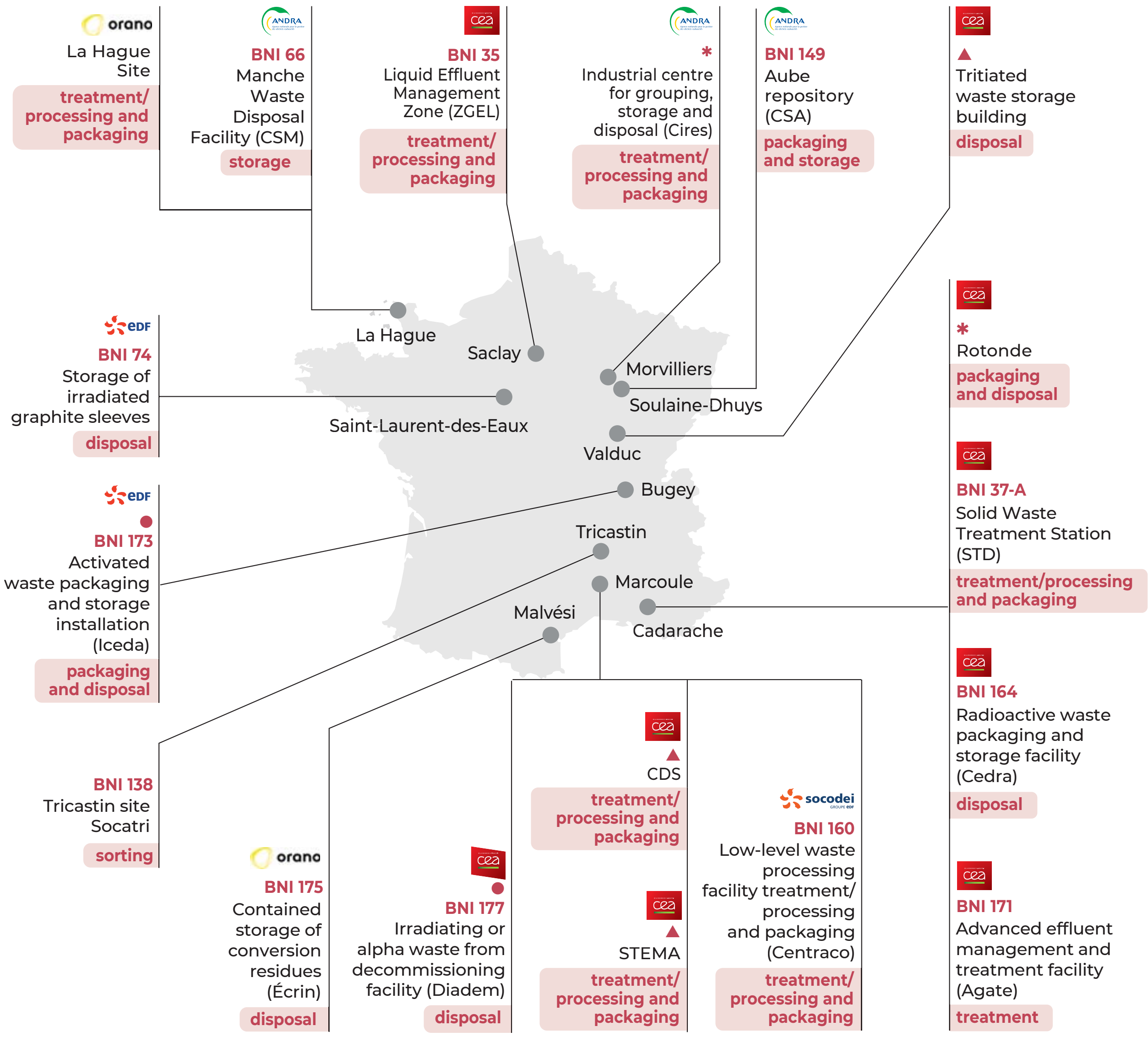
• Waste packages intended for projected disposal facilities

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, HLW-LL or ILW-LL waste.

Under these conditions, the production of packages of these types of waste is subject to ASN approval on the basis of a file established by the waste producer and called “packaging baseline requirements”. This file must demonstrate that on the basis of existing knowledge and the currently identified requirements of the disposal facilities being studied, the packages display no unacceptable behaviour.

This provision also avoids delaying waste retrieval and packaging operations.

The main support facilities for radioactive waste management



● Waiting for commissioning   * Comes under the status of ICPE   ▲ Comes under the status of DBNI

- **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 is particularly attentive to ensuring that the packages comply with the conditions of the issued packaging approvals.

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 the measures taken by the waste package producers is vital in guaranteeing package quality and compliance with the safety case of the waste repositories.

2.1.3 Developing recommendations for sustainable waste management

ASN issues opinions on the studies submitted under the PNGMDR. ASN also gives the Government its recommendations on the radioactive waste management facilities.

2.1.4 Developing the regulatory framework and issuing prescriptions to the licensees

ASN can issue ASN regulations. Thus, the provisions of the Order of 7 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. To give an example, the resolution of 23 March 2017 addresses the packaging of radioactive waste and the conditions of acceptance of the radioactive waste packages in the disposal BNIs. Its aim is to specify the safety requirements in the various stages of a management route. This resolution has been applicable since 1 July 2018.

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 *asn.fr*.

ASN indicates certain waste management requirements in two guides: 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 points 1.2.1 et 1.2.2).

Lastly, ASN is consulted for its opinion on draft regulatory texts relative to radioactive waste management.

2.1.5 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 13 (see point 1.4).

2.1.6 ASN's international action in the area of waste

ASN participates in the work of Western European Nuclear Regulators Association (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 Working Group on Waste and Decommissioning (WGWD) is tasked with developing reference levels for the management of radioactive waste and spent fuel, and for the decommissioning of nuclear facilities. The ASN resolutions enable, among other things, these reference levels to be transposed into the general regulations applicable to BNIs. 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 2019, ASN continued its actions to present the way in which the WENRA safety reference levels for waste packaging were set out in the French regulations. The WGWD considers that all the safety requirements are present in the French regulations, except for one reference level favouring the use of passive systems. ASN considers that this reference level might not be appropriate for certain types of waste management facility, and the scope of its application will be discussed in the WGWD in 2020. Furthermore, at a WGWD meeting in November 2019 dedicated to the regulatory framework governing decommissioning, ASN presented the licensees' decommissioning strategies and the principles of immediate dismantling and final condition. ASN also follows the transposition of the reference levels of the other WENRA member countries.

ASN moreover represents France on 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 European Nuclear Safety Regulators Group (ENSREG) group 2 which is responsible for subjects relative to radioactive waste management.

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. This report underwent a peer review in Vienna in May 2018. The peers showed a distinct interest in the French approach, underlining in particular the quality of its comprehensive regulatory framework, the coherence of its policy and the priority given to safety through the recognition of eight areas of good performance. They suggested that France should remain attentive to the safety of some of the older storage facilities. In 2020, ASN will coordinate the drafting of the report for the 7th Joint Convention Review.

European Directive 2011/70 establishing a community framework for the responsible and safe management of spent fuel and radioactive waste moreover requires that each European Union country's programme on these themes be assessed by a peer review. In France, this international assessment took place from 15 to 24 January 2018 as part of an Integrated Review Service for radioactive Waste and Spent Fuel Management, Decommissioning and Remediation (ARTEMIS) mission organised by the IAEA. A delegation of ten international experts met teams from the DGEC, ASN, the DGPR, IRSN, Andra, and the radioactive waste producers.

ASN also participates in several working groups set up within the framework of European Union and IAEA actions, particularly concerning the deep geological disposal of radioactive waste.

Lastly, ASN collaborates with the authorities of the countries the most advanced in the deployment of deep geological disposal. Two ASN engineers were thus received by the Finnish Nuclear Safety Authority (STUK) in 2019, to learn from its experience in the construction authorisation process for the Finnish deep geological repository, the organisation of examination process to obtain the construction decree and the associated conditions of the monitoring and surveillance programme. The lessons drawn from the time spent with the STUK include, in particular, the assimilation of part of the Finnish regulations on the subject, the good practices to adopt when examining a disposal facility authorisation file, the post-closure safety case (notably the choice and relevance of the scenarios and the management of uncertainties), the practical aspects of the inspection programme conducted during the construction of Onkalo, and comparison of the technical issues of the *Cigéo* project with those of Onkalo in Finland (cracks, leaks, excavations techniques, methods of characterising the rock and cracks, relations between the regulator and the industrial operation, etc.).

ASN's international actions are presented more generally in chapter 6.

2.2 Periodic safety reviews of radioactive waste management facilities

Basic Nuclear Installation licensees, including for radioactive waste management facilities, carry out periodic safety reviews of their facilities in order to assess the situation of the facilities with respect to the rules applicable to them and to update the assessment of the risks or adverse effects, taking into account, more specifically, the state of the facility, the experience acquired during operation, and the development of knowledge and rules applicable to similar facilities. The diversity and frequently unique nature of each radioactive waste management facility lead ASN to adopt an examination procedure that is specific to each facility.

In this context, ASN is currently examining six safety reviews of radioactive waste management facilities. The reviews concern:
- three BNIs operated by the CEA: the treatment and packaging facility BNI 35 on the Saclay site, the Chicade research and development facility (BNI 156), and the Cedra packaging and storage facility (BNI 164) on the Cadarache site;
- one BNI operated by Orano: BNI 118, the waste treatment, packaging and waste package storage facility on the La Hague site;

- two BNIs operated by Andra: BNI 149, the Aube radioactive waste repository (CSA) and BNI 66, the Manche radioactive waste repository (CSM).

A periodic safety review report should be submitted to ASN in 2020 for another facility, namely the interim storage silos of Saint-Laurent-des-Eaux (BNI 74).

2.2.1 Periodic safety reviews of radioactive waste management support facilities

The periodic safety reviews of the oldest facilities such as BNI 35 and BNI 118 present particular challenges. These safety reviews must address the control of the waste storage conditions, including legacy waste, the retrieval and packaging of this waste with a view to removal *via* the dedicated route and the scheduled post-operational clean-out of the buildings. In relation with these challenges, the safety reviews must allow control of the impacts of discharges into the environment (soils, groundwater, or seawater in the case of BNI 118).

For the most recent facilities, as is the case with Cedra and Chicade, the periodic safety reviews highlight more generic problems. The resistance of the buildings to internal and external hazards (earthquake, fire, lightning, flooding, aircraft crash) is one of the important aspects.

2.2.2 Periodic safety reviews of radioactive waste disposal facilities

The CSA and the CSM are subject to the obligation to hold periodic safety reviews. Their safety reviews have the particularity of addressing control of the risks and adverse effects over the long term, in addition to reassessing their operational control. Their purpose is therefore, if necessary, to revise the scenarios, models and long-term assumptions in order to confirm satisfactory control of the risks and adverse effects over time. The periodic safety reviews of these two facilities, although they are at different stages of progress (for the CSM, the review report was submitted in April 2019; for the CSA, ASN is finalising its examination of the review report), thus highlighting the need for increased knowledge of the long-term impacts associated with the toxic chemicals contained in the waste and of the impacts of radionuclides on the environment.

The successive safety reviews must also serve to detail the technical measures planned by the licensee to control the adverse effects of the facility over the long term, notably for the cover which contributes to the final containment of the disposal concrete blocks. The durability of the CSM cover is, along with the preservation of the site memory for future generations, the predominant theme of the periodic safety review of a radioactive waste disposal facility.

Furthermore, these safety reviews also serve to detail, over time, the measures the licensee plans to take to ensure the long-term monitoring and surveillance of the behaviour of the disposal facility.

2.3 CEA's waste management strategy and its assessment by ASN

• Types of waste produced by CEA

The CEA operates diverse types of facilities covering all the activities relating to the nuclear cycle: laboratories and plants associated with fuel cycle research, as well as experimental reactors.

CEA also carries out numerous decommissioning operations.

Consequently, the types of waste produced by CEA are varied and include more specifically:

- 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 operations (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.

The 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 main issues for the 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 the CEA has in fully managing these issues and conducting all the associated projects, especially decommissioning projects, at the same time.

• ASN's examination of the CEA's waste management strategy

ASN's last examination of the 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 certain 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. At the joint request of ASN and ASND, the CEA conducted an overall review of its decommissioning and radioactive waste management strategy and submitted the results of this work in December 2016. After examining this report, the two Authorities gave a joint opinion on this strategy in May 2019 (see box in chapter 13 for further information).

ASN and ASND consider that the CEA's facility decommissioning strategy and its updating of the waste and material management strategy are the result of an in-depth review and analysis. It appears acceptable for the CEA to envisage staggering the decommissioning operations in view of the resources allocated by the State and the large number of facilities undergoing decommissioning, for which waste retrieval and storage capacities will have to be built.

With regard to the material and waste management strategy, the two Authorities observe several vulnerabilities in the CEA's strategy, due in particular to the envisaged sharing of resources between centres, for the management of liquid radioactive effluents or solid radioactive waste for example, which means that for some operations which can only be carried out by one facility, there could problems due to capacity limitation. The two Authorities also note uncertainties concerning the management of spent fuels or irradiated materials, which will have to be clarified.

ASN and ASND have therefore made several demands of the CEA with the aim of limiting these vulnerabilities, consolidating its strategy and detailing the operations schedule.

They demand that the CEA make regular progress reports on the decommissioning and waste management projects, and ensure regular communication with the public, applying procedures appropriate to the nature of the facilities, civil or defence. Lastly, they want special measures to be implemented to monitor the progress of these projects.

2.4 Orano's waste management strategy and its assessment by ASN

The spent fuel reprocessing plant at the La Hague site presents the main radioactive waste management issues for Orano. 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 they are French or foreign. French waste is directed to the management routes described earlier, whereas foreign waste is sent back to its country of origin. On the Tricastin site, Orano also produces waste associated with the front-end activities of the cycle (production of nuclear fuel), essentially contaminated by alpha emitters.

In mid-2016, Orano (formerly 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. Moreover, Orano submitted general and particular commitments for the La Hague and Tricastin sites in 2018. In order to verify Orano's ability to meet the deadlines of its strategy, ASN initiated an innovative project management inspection procedure in 2019. ASN will give an opinion on this strategy in 2020. The last review of Orano's waste management strategy dates back to 2005 and it only focused on the Areva NC La Hague site.

• The issues and implications

The main issues relating to the management of waste produced by Orano concern in particular:

- the safety of the legacy waste storage facilities. On the La Hague site, the facilities dedicated to legacy waste retrieval, packaging and storage have to be designed, built and then commissioned. These complex projects meet up with technical difficulties which can make it necessary to adjust deadlines set by ASN (see chapter 13). Furthermore, the on-site storage capacities must be estimated with conservative margins in order to prevent premature filling to capacity. The legacy waste stored on the Tricastin site necessitates a large amount of work to characterise it and find management solutions. The storage conditions in some of the Tricastin site facilities do not meet current safety requirements and must be improved;
- the defining of solutions for waste packaging, in particular the legacy waste. These solutions require the prior approval of ASN in accordance with Article 6.7 of the Order of 7 February 2012 (see point 2.2.2). Keeping control of the packaging deadlines is a particularly important aspect, which requires the development of characterisation programmes to demonstrate the feasibility of the chosen packaging processes and to identify sufficiently early the risks that could significantly affect the project. If necessary, when the feasibility of the defined packaging cannot be determined within times compatible with the prescribed deadlines, the licensee must plan for an alternative solution, including in particular interim storage areas allowing the retrieval and characterisation of the legacy waste as rapidly as possible. Article L. 542-1-3 of the Environment Code steps up this challenge, as it requires the ILW-LL waste produced before 2015 to be packaged by the end of 2030 at the latest.

Within the framework of the Waste Retrieval and Packaging (WRP) operations, Orano is examining packaging solutions that necessitate the development of new processes, particularly for the following ILW-LL waste:

- the sludge from the La Hague STE2 facility;
- the alpha-emitting technological waste which comes primarily from the La Hague and Melox (Gard *département*) plants and is not suitable for above-ground disposal.

For other types of ILW-LL waste resulting from the WRP operations, Orano is examining the possibility of adapting existing processes (compaction, cementation, vitrification). Part of the associated packaging baseline requirements are currently being examined by ASN.

2.5 EDF's waste management strategy and its assessment by ASN

The radioactive waste produced by EDF comes from several distinct activities. It mainly comprises waste from the operation of the nuclear power plants, which consists of activated waste from the reactor cores, and waste 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 HLW and ILW-LL waste resulting from spent fuel reprocessing in the Orano La Hague plant.

• Activated waste

This waste notably comprises control rod assemblies and poison rod assemblies used for reactor operation. This is ILW-LL waste that is produced in small quantities. At present this waste is stored in the NPP fuel storage pools pending transfer to the Iceda facility once it comes into service.

• Operational and maintenance waste

Some of the waste is processed by melting or incineration in the Centraco facility, 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. After examining this file, ASN in 2017 asked EDF 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 sufficient resources to radioactive waste management, and to present the most appropriate process for the treatment of used steam generators. Lastly, the spent fuel cluster guide tubes (TGG)[12] of the EDF fleet (about 2,000) should be treated by Cyclife France at the Centraco facility. This project would comprise three successive stages (interim storage, treatment before melting, then conditioning for transfer to the CSA repository operated by Andra). The various license applications relative to this project are currently being examined by ASN.

12. The TGGs, currently stored in the pools of the NPPs serve to guide the control rod clusters inside the reactors These parts are significantly activated, especially in their bottom section. EDF considers the removed TGGs to be radioactive waste, to be processed via *dedicated disposal or treatment routes.*

• **The issues and implications**

The main issues related to the EDF waste management strategy concern:

– the management of legacy waste. This mainly concerns structural waste (graphite sleeves) from the graphite-moderated GCR 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 GCRs currently being decommissioned. In the context of the PNGMDR 2016-2018, EDF conducted a study of the reliability of the activity predictions for this waste and submitted its conclusions in December 2019. ASN will examine this report;
– the changes linked to the fuel cycle. EDF's fuel use policy (see chapter 10) has consequences for the fuel cycle installations (see chapter 11) and for the quantity and nature of the waste produced. ASN issued an opinion on the coherence of the nuclear fuel cycle in October 2018 (see chapter 11).

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: Auvergne-Rhône-Alpes, Bourgogne-Franche-Comté, Bretagne, Grand Est, Nouvelle-Aquitaine, Occitanie, Pays de la Loire and Provence-Alpes-Côte d'Azur. Ore processing was carried out in 8 plants. The former uranium mines are now almost all under the responsibility of Orano Mining.

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 distributed among 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. The mines and the mine tailings disposal sites are not subject to ASN oversight.

In the specific case of the former uranium mines, an action plan was defined by Circular 2009-132 of 22 July 2009 from the Minister responsible for the environment and the Chairman of ASN, based on the following work themes:

– monitor the former mining sites;
– improve the understanding of the environmental and health impact of the former uranium mines and their monitoring;
– manage the mining waste rock (better identify the uses and reduce impacts if necessary);
– reinforce information and consultation.

• **The long-term behaviour of the sites**

Redevelopment of the uranium processing tailings disposal sites was made possible by 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 exposure of the neighbouring populations.

The studies submitted for the PNGMDR have enhanced knowledge of:

– the dosimetric impact of the mine tailing disposal areas on man and the environment, in particular through the comparison of data obtained from monitoring 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 22 July 2009;
– the strategy chosen for the changes in the treatment of water collected from former mining sites;
– the relation between the discharged flows and the accumulation of marked sediments in the rivers and lakes;
– the methodology for assessing the long-term integrity of the embankments surrounding tailings disposal sites;
– 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.

In accordance with ASN opinion 2016-AV-0255 of 9 February 2016, these various studies are continuing under the PNGMDR 2016-2018, as is the work of the two technical working groups focusing on:

– maintaining the functions of the structures surrounding the disposal facilities for uranium ore treatment residues, the interim report on this work was published on the ASN website;
– management of the water from the former uranium mining sites.

Thus, in January 2017, Orano Mining supplemented its study on the relation between the discharged flows and the accumulation of marked sediments in the rivers and lakes. In January and June 2018, two interim reports concerning the reactivity of the mine tailings and mining waste rocks respectively were submitted by Orano Mining. The interim assessment of the management of stations treating the water from the former uranium-bearing sites received in January 2018 will be analysed by the PNGMDR technical working group dedicated to water management. The PNGMDR technical working group dedicated to maintaining the functions of the structures surrounding the residue disposal facilities shall endeavour to take into consideration the two geotechnical files of the Bois-Noirs and the Écarpière site structures, received in December 2018, when developing the methodology for assessing the stability of this type of structure.

• **Management of reused mining waste rock**

Most of the mining waste rock has remained on its site of production (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 on public land 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 22 July 2009, asked Orano Mining to inventory the mining waste rock reused on public land in order to verify compatibility of the uses and to reduce the impacts if necessary.

Orano Mining 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 8 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 mSv/year (millisieverts per year) on the basis of a radiological impact study.

In January 2018, under the PNGMDR 2016-2018, Orano submitted an assessment of the actions taken when inventorying the mining waste rock on public land. ASN is currently examining this assessment.

4. Management of sites and soils contaminated 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 natural radioactivity.

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 were radium extraction for medical and parapharmaceutical needs, from the early 1900s until 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 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 26 October 2015 defines the conditions of application of these measures.

The Regional Directorates for the Environment, Planning and Housing (Dreals) coordinate the soil information sector 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. The soil information sector development process is progressive and is not intended to be exhaustive. Ultimately these sites are to be registered in the urban planning documents.

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 2018 edition is available on *andra.fr*) and the databases of the Ministry responsible for the environment dedicated to contaminated sites and soils.

ASN oversight of the various uranium mining sites and soils contaminated by radioactive substances

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. Oversight of the conditions of management of the mine tailings or mining waste rock outside the production or disposal sites is the responsibility of the Prefect, on proposals from the Regional Directorate for the Environment, Planning and Housing (Dreal).

Consequently, the mines, the disposal areas, the mine tailings, the conditions of management of mine tailings or mining waste rock on public land and the management of sites and soils with no solvent responsible entity which are polluted by radioactive substances are not subject to ASN oversight. ASN assists the State departments at their request in the areas of radiation protection of workers and the public, and the management routes for mining waste, tailings and waste rock. In addition, under the PNGMDR, ASN issues opinions on the studies submitted in order, for example, to improve knowledge of the development of the long-term radiological impact of the former mining sites on the public and the environment.

ASN can, at the request of the competent authority, issue an opinion regarding the management of these sites. 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 has initiated a critical review of this doctrine, on the basis of experience feedback and the regulatory developments of 2018.

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.

In cases where contaminated sites and soils have no known responsible entity, the State finances their clean-out through a public subsidy provided for in Article L. 542-12-1 of the Environment Code. The French National Funding Commission for Radioactive Matters (CNAR) gives opinions on the utilisation of this subsidy, as much with respect to fund allocation priorities as to polluted site treatment strategies and the principles of assisted collection of waste.

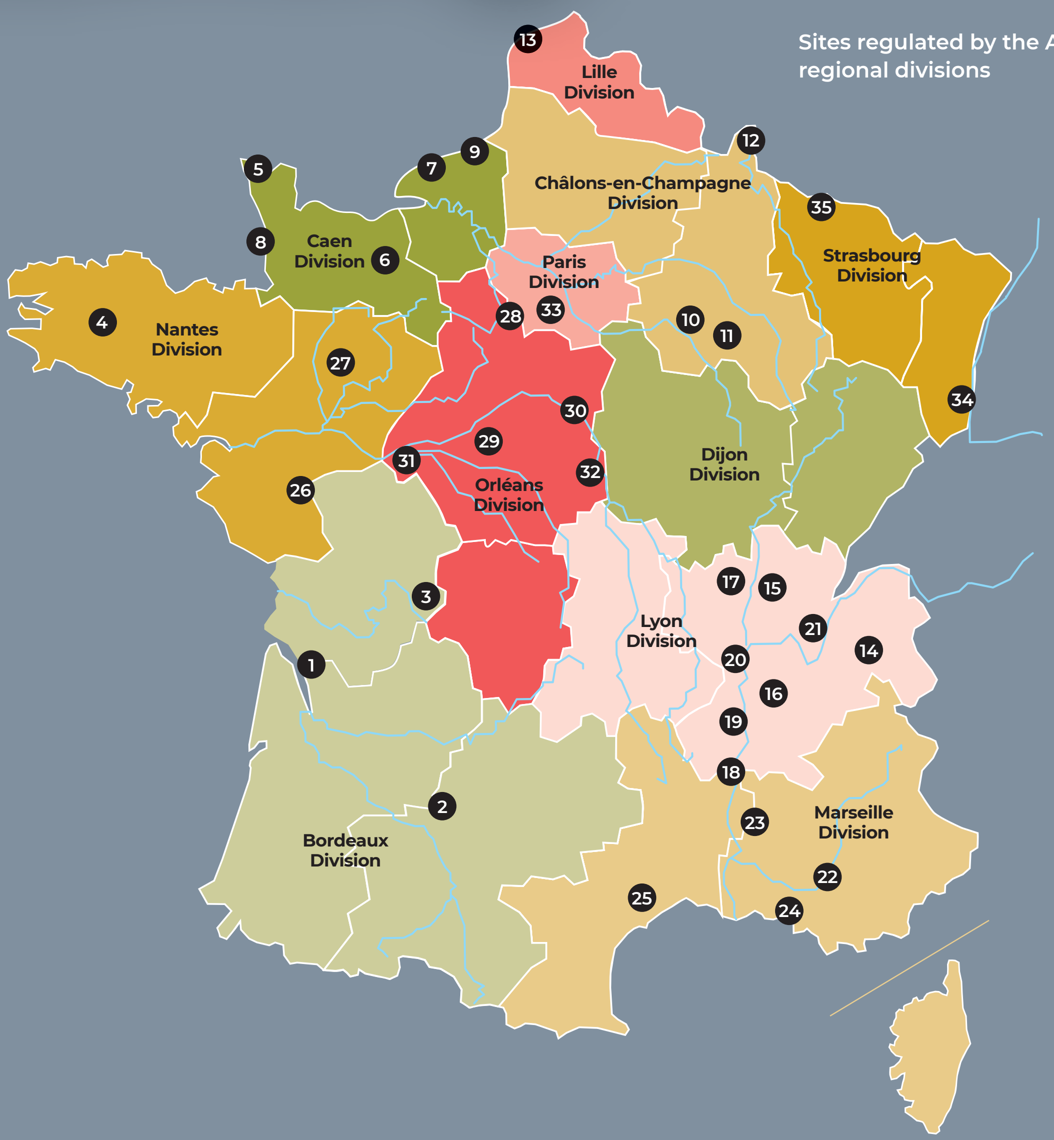
Under Article D.542-15 of the Environment Code, the CNAR comprises:
- "members by right": representatives of the Ministries responsible for the environment and energy, of Andra, Ademe, IRSN, the CEA, ASN and the Association of Mayors of France;
- members mandated for four years by the Ministries responsible for energy, nuclear safety and radiation protection (the CNAR chair, two representatives of environmental associations and one representative of a public land management corporation).

In 2019, the members of the CNAR elected Mr Didier Dubot as Chair of the Commission for a four-year mandate. The CNAR met four times in 2019, focusing in particular on the management of ongoing contaminated sites such as the Champlay site, or the management of soils from the remediation of legacy sites, such as the soils from the Bayard factory.

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 measures taken regarding management of the contaminated site.

With regard to the management of radioactive contaminated sites coming under the ICPE system and the Public Health Code, when the responsible entity is solvent or defaulting, the Prefect uses the opinions of the classified installations inspectorate, of ASN and the Regional Health Agency (ARS) to validate the site rehabilitation project and supervises the implementation of the rehabilitation measures by Prefectural Order. ASN may thus be called upon by the services of the Prefect and the classified installation inspectors to give its opinion on the clean-out objectives of a site.

Appendix



BORDEAUX DIVISION
1 ▲ Blayais 2 ▲ Golfech 3 ▲ Civaux

CAEN DIVISION
4 ▲ Brennilis 5 Factory ■ La Hague 6 ● Caen 7 ▲ Paluel
8 ▲ Flamanville 9 ▲ Penly

CHÂLONS-EN-CHAMPAGNE DIVISION
10 ▲ Nogent-sur-Seine 11 ■ Soulaines-Dhuys 12 ▲ Chooz

LILLE DIVISION
13 ▲ Gravelines

LYON DIVISION
14 ○ ● Grenoble 15 ▲ ○ Bugey 16 Factory Romans-sur-Isère
17 ○ Dagneux 18 ▲ Factory ○ Tricastin
19 ▲ Cruas-Meysse 20 ▲ Saint-Alban
21 ○ ▲ Creys-Malville

MARSEILLE DIVISION
22 ○ ● Cadarache 23 ▲ Factory ○ ● Marcoule 24 ○ Marseille
25 ○ Malvési

NANTES DIVISION
26 ○ Pouzauges 27 ○ Sablé-sur-Sarthe

ORLÉANS DIVISION
28 ● Saclay 29 ○ ▲ Saint-Laurent-des-Eaux
30 ▲ Dampierre-en-Burly 31 ▲ ○ Chinon
32 ▲ Belleville-sur-Loire 33 ● Fontenay-aux-Roses

STRASBOURG DIVISION
34 ▲ Fessenheim 35 ▲ Cattenom

TYPE OF INSTALLATION
▲ Nuclear power plant
Factory
● Research installations
■ Disposal of Waste
○ Others

LIST OF BASIC NUCLEAR INSTALLATIONS AS AT 31 DECEMBER 2019

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 Basic Nuclear Installation (BNI) regulation in the Bretagne (Brittany) and Île-de-France regions respectively. The Paris division oversees the overseas regions and the *département*[1] of Mayotte, while the Marseille division oversees radiation protection and radioactive substance transport in the Corse 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 Environment Code (Title IX of Book V). These installations must be authorised by decree issued following a public inquiry and an French Nuclear Safety Authority (*Autorité de sûreté nucléaire* –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, Section 1 entitled "Nomenclature of Basic Nuclear Installations" of Chapter III of Title IX of Book V of the Environment Code 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 French Alternative Energies and Atomic Energy Commission (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 31 December 2019, there were 124 BNIs (legal entities).

The notified BNIs are those which existed prior to the publication of Decree 63-1228 of 11 December 1963 concerning nuclear facilities and for which neither said Decree nor the Environment Code required authorisation but simply notification on the basis of the acquired rights (see 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 13) or their licensing as new basic nuclear installations.

AP

1. *Administrative region headed by a Prefect.*

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	162
5 La Hague	SPENT FUEL REPROCESSING PLANT (UP2-400) 50107 Cherbourg Cedex	Orano Cycle	Transformation of radioactive substances	33
5 La Hague	EFFLUENT AND SOLID WASTE TREATMENT STATION (STE2) AND SPENT NUCLEAR FUELS REPROCESSING FACILITY (AT1) 50107 Cherbourg Cedex	Orano Cycle	Transformation of radioactive substances	38
5 La Hague	ELAN IIB FACILITY 50107 Cherbourg Cedex	Orano Cycle	Transformation of radioactive substances	47
5 La Hague	MANCHE WASTE REPOSITORY (CSM) 50440 Digulleville	Andra	Disposal of radioactive substances	66
5 La Hague	HAO (HIGH LEVEL OXIDE) FACILITY 50107 Cherbourg Cedex	Orano Cycle	Transformation of radioactive substances	80
5 La Hague	REPROCESSING PLANT FOR SPENT FUEL ELEMENTS FROM LIGHT WATER REACTORS (UP3 A) 50107 Cherbourg Cedex	Orano Cycle	Transformation of radioactive substances	116
5 La Hague	REPROCESSING PLANT FOR SPENT FUEL ELEMENTS FROM LIGHT WATER REACTORS (UP2-800) 50107 Cherbourg Cedex	Orano Cycle	Transformation of radioactive substances	117
5 La Hague	LIQUID EFFLUENT AND SOLID WASTE TREATMENT STATION (STE3) 50107 Cherbourg Cedex	Orano Cycle	Transformation of radioactive substances	118
6 Caen	NATIONAL LARGE HEAVY ION ACCELERATOR (GANIL) 14021 Caen Cedex	G.I.E. 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
LOCATION OF INSTALLATIONS REGULATED BY THE CHÂLONS-EN-CHAMPAGNE DIVISION				
10 Nogent-sur-Seine	NOGENT-SUR-SEINE NUCLEAR POWER PLANT (reactor 1) 10400 Nogent-sur-Seine	EDF	Reactor	129
10 Nogent-sur-Seine	NOGENT-SUR-SEINE NUCLEAR POWER PLANT (reactor 2) 10400 Nogent-sur-Seine	EDF	Reactor	130
11 Soulaines-Dhuys	AUBE WASTE REPOSITORY (CSA) 10200 Bar-sur-Aube	Andra	Radioactive waste surface repository	149
12 Chooz	CHOOZ B NUCLEAR POWER PLANT (reactor 1) 08600 Givet	EDF	Reactor	139
12 Chooz	CHOOZ B NUCLEAR POWER PLANT (reactor 2) 08600 Givet	EDF	Reactor	144
12 Chooz	ARDENNES CENTRALE NUCLÉAIRE CNA-D (CHOOZ A) 08600 Givet	EDF	Reactor	163

SITE NAME	NAME AND LOCATION OF THE INSTALLATION	LICENSEE	TYPE OF INSTALLATION	BNI
LOCATION OF INSTALLATIONS REGULATED BY THE LILLE DIVISION				
13 Gravelines	GRAVELINES NUCLEAR POWER PLANT (reactors 1 and 2) 59820 Gravelines	EDF	Reactors	96
13 Gravelines	GRAVELINES NUCLEAR POWER PLANT (reactors 3 and 4) 59820 Gravelines	EDF	Reactors	97
13 Gravelines	GRAVELINES NUCLEAR POWER PLANT (reactors 5 and 6) 59820 Gravelines	EDF	Reactors	122
LOCATION OF INSTALLATIONS REGULATED BY THE LYON DIVISION				
14 Grenoble	EFFLUENT AND SOLID WASTE TREATMENT STATION (STED) 38041 Grenoble Cedex	CEA	Transformation of radioactive substances	36
14 Grenoble	HIGH FLUX REACTOR (RHF) 38041 Grenoble Cedex	Max Von Laue Paul Langevin Institute (ILL)	Reactor	67
14 Grenoble	DECAY INTERIM STORAGE FACILITY (STD) 38041 Grenoble Cedex	CEA	Storage of radioactive substances	79
15 Bugey	BUGEY NUCLEAR POWER PLANT (reactor 1) BP 60120 – 01150 Saint-Vulbas	EDF	Reactor	45
15 Bugey	BUGEY NUCLEAR POWER PLANT (reactors 2 and 3) BP 60120 – 01150 Saint-Vulbas	EDF	Reactors	78
15 Bugey	BUGEY NUCLEAR POWER PLANT (reactors 4 and 5) BP 60120 – 01150 Saint-Vulbas	EDF	Reactors	89
15 Bugey	BUGEY INTER-REGIONAL WAREHOUSE (MIR) BP 60120 – 01150 Saint-Vulbas	EDF	Storage of new fuel	102
15 Bugey	ACTIVATED WASTE PACKAGING AND STORAGE INSTALLATION (ICEDA) 01150 Saint-Vulbas	EDF	Packaging and interim storage of radioactive substances	173
16 Romans-sur-Isère	NUCLEAR FUELS FABRICATION UNIT (FBFC) 26104 Romans-sur-Isère Cedex	Framatome	Fabrication of radioactive substances	98
16 Romans-sur-Isère	NUCLEAR FUELS FABRICATION UNIT (CERCA) 26104 Romans-sur-Isère Cedex	Framatome	Fabrication of radioactive substances	63
17 Dagneux	DAGNEUX IONISATION PLANT Z.I. Les Chartinières 01120 Dagneux	Ionisos	Utilisation of radioactive substances	68
18 Tricastin	TRICASTIN NUCLEAR POWER PLANT (reactors 1 and 2) 26130 Saint-Paul-Trois-Châteaux	EDF	Reactors	87
18 Tricastin	TRICASTIN NUCLEAR POWER PLANT (reactors 3 and 4) 26130 Saint-Paul-Trois-Châteaux	EDF	Reactors	88
18 Tricastin	GEORGES BESSE PLANT FOR URANIUM ISOTOPE SEPARATION BY GASEOUS DIFFUSION (EURODIF) 26702 Pierrelatte Cedex	Orano Cycle	Transformation of radioactive substances	93
18 Tricastin	URANIUM HEXAFLUORIDE PREPARATION PLANT (COMURHEX) 26130 Saint-Paul-Trois-Châteaux	Orano Cycle	Transformation of radioactive substances	105
18 Tricastin	URANIUM CLEAN-UP AND RECOVERY FACILITY (IARU) 26130 Saint-Paul-Trois-Châteaux	Orano Cycle	Factory	138
18 Tricastin	TU5 AND W FACILITIES BP 16 – 26700 Pierrelatte	Orano Cycle	Transformation of radioactive substances	155
18 Tricastin	TRICASTIN OPERATIONAL HOT UNIT (BCOT) BP 127 – 84500 Bollène	EDF	Nuclear maintenance	157
18 Tricastin	GEORGES BESSE II PLANT FOR CENTRIFUGAL SEPARATION OF URANIUM ISOTOPES (GB II) 26702 Pierrelatte Cedex	Orano Cycle	Transformation of radioactive substances	168
18 Tricastin	AREVA TRICASTIN ANALYSIS LABORATORY (ATLAS) 26700 Pierrelatte	Orano Cycle	Laboratory for the utilisation of radioactive substances	176
18 Tricastin	TRICASTIN URANIUM-BEARING MATERIAL STORAGE YARD 26700 Pierrelatte	Orano Cycle	Storage of radioactive materials	178
18 Tricastin	P35 26700 Pierrelatte	Orano Cycle	Storage of radioactive materials	179
19 Cruas-Meysse	CRUAS-MEYSSE NUCLEAR POWER PLANT (reactors 1 and 2) 07350 Cruas	EDF	Reactors	111
19 Cruas-Meysse	CRUAS-MEYSSE NUCLEAR POWER PLANT (reactors 3 and 4) 07350 Cruas	EDF	Reactors	112
20 Saint-Alban	SAINT-ALBAN NUCLEAR POWER PLANT (reactor 1) 38550 Le Péage-de-Roussillon	EDF	Reactor	119
20 Saint-Alban	SAINT-ALBAN NUCLEAR POWER PLANT (reactor 2) 38550 Le Péage-de-Roussillon	EDF	Reactor	120
21 Creys-Malville	SUPERPHÉNIX REACTOR 38510 Morestel	EDF	Reactor	91
21 Creys-Malville	FUEL STORAGE FACILITY (APEC) 38510 Creys-Mépieu	EDF	Storage of radioactive substances	141

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SITE NAME	NAME AND LOCATION OF THE INSTALLATION	LICENSEE	TYPE OF INSTALLATION	BNI
	LOCATION OF INSTALLATIONS REGULATED BY THE MARSEILLE DIVISION			
22 Cadarache	TEMPORARY DISPOSAL FACILITY (PEGASE) AND SPENT NUCLEAR FUEL DRY STORAGE INSTALLATION (CASCAD) 13115 Saint-Paul-lez-Durance Cedex	CEA	Storage of radioactive substances	22
22 Cadarache	CABRI 13115 Saint-Paul-lez-Durance Cedex	CEA	Reactor	24
22 Cadarache	RAPSODIE 13115 Saint-Paul-lez-Durance Cedex	CEA	Reactor	25
22 Cadarache	PLUTONIUM TECHNOLOGY FACILITY (ATPu) 13115 Saint-Paul-lez-Durance Cedex	CEA	Fabrication or transformation of radioactive substances	32
22 Cadarache	SOLID WASTE TREATMENT STATION (STD) 13115 Saint-Paul-lez-Durance Cedex	CEA	Transformation of radioactive substances	37-A
22 Cadarache	EFFLUENT TREATMENT STATION (STE) 13115 Saint-Paul-lez-Durance Cedex	CEA	Transformation of radioactive substances	37-B
22 Cadarache	MASURCA 13115 Saint-Paul-lez-Durance Cedex	CEA	Reactor	39
22 Cadarache	ÉOLE 13115 Saint-Paul-lez-Durance Cedex	CEA	Reactor	42
22 Cadarache	ENRICHED URANIUM PROCESSING FACILITY (ATUE) 13115 Saint-Paul-lez-Durance Cedex	CEA	Fabrication of radioactive substances	52
22 Cadarache	ENRICHED URANIUM AND PLUTONIUM WAREHOUSE (MCMF) 13115 Saint-Paul-lez-Durance Cedex	CEA	Storage of radioactive substances	53
22 Cadarache	CHEMICAL PURIFICATION LABORATORY (LPC) 13115 Saint-Paul-lez-Durance Cedex	CEA	Transformation of radioactive substances	54
22 Cadarache	ACTIVE FUEL EXAMINATION LABORATORY (LECA) AND SPENT FUEL REPROCESSING, CLEAN-OUT AND REPACKAGING STATION (STAR) 13115 Saint-Paul-lez-Durance Cedex	CEA	Utilisation of radioactive substances	55
22 Cadarache	SOLID RADIOACTIVE WASTE STORAGE YARD 13115 Saint-Paul-lez-Durance Cedex	CEA	Storage of radioactive substances	56
22 Cadarache	PHÉBUS 13115 Saint-Paul-lez-Durance Cedex	CEA	Reactor	92
22 Cadarache	MINERVE 13115 Saint-Paul-lez-Durance Cedex	CEA	Reactor	95
22 Cadarache	LABORATORY FOR RESEARCH AND EXPERIMENTAL FABRICATION OF ADVANCED NUCLEAR FUELS (LEFCA) 13115 Saint-Paul-lez-Durance Cedex	CEA	Fabrication of radioactive substances	123
22 Cadarache	CHICADE BP 1 – 13115 Saint-Paul-lez-Durance Cedex	CEA	Research and development laboratory	156
22 Cadarache	CEDRA 13115 Saint-Paul-lez-Durance Cedex	CEA	Packaging and interim storage of radioactive substances	164
22 Cadarache	MAGENTA 13115 Saint-Paul-lez Durance Cedex	CEA	Reception and shipment of nuclear materials	169
22 Cadarache	EFFLUENT ADVANCED MANAGEMENT AND PROCESSING FACILITY (AGATE) 13115 Saint-Paul-lez Durance Cedex	CEA	Packaging and interim storage of radioactive substances	171
22 Cadarache	JULES HOROWITZ REACTOR (JHR) 13115 Saint-Paul-lez Durance Cedex	CEA	Reactor	172
22 Cadarache	ITER 13115 Saint-Paul-lez-Durance Cedex	International organisation ITER	Nuclear fusion reaction experiments with tritium and deuterium and deuterium plasmas	174
23 Marcoule	PHÉNIX 30205 Bagnols-sur-Cèze Cedex	CEA	Reactor	71
23 Marcoule	ATALANTE 30200 Chusclan	CEA	Research and development laboratory and study of actinides production	148
23 Marcoule	NUCLEAR FUELS FABRICATION PLANT (MELOX) BP 2 – 30200 Chusclan	Orano Cycle	Fabrication of radioactive substances	151
23 Marcoule	CENTRACO 30200 Codolet	Cyclife France	Radioactive waste and effluent processing	160
23 Marcoule	GAMMATEC 30200 Chusclan	Synergy Health Marseille	Ionisation treatment of materials, products and equipment, for industrial purposes and for research and development	170
23 Marcoule	DIADEM 30200 Chusclan	CEA	Storage of solid radioactive waste	177
24 Marseille	GAMMASTER IONISATION PLANT M.I.N. 712 13323 Marseille Cedex 14	Synergy Health Marseille	Ionisation installation	147
25 Malvési	CONTAINED STORAGE OF CONVERSION RESIDUES (ÉCRIN) 11100 Narbonne	Orano Cycle	Storage of radioactive substances	175

SITE NAME	NAME AND LOCATION OF THE INSTALLATION	LICENSEE	TYPE OF INSTALLATION	BNI
	LOCATION OF INSTALLATIONS REGULATED BY THE NANTES DIVISION			
26 Pouzauges	POUZAUGES IONISATION PLANT Z.I. de Monlifant 85700 Pouzauges	Ionisos	Ionisation installation	146
27 Sablé-sur-Sarthe	SABLÉ-SUR-SARTHE IONISATION PLANT Z.I. de l'Aubrée 72300 Sablé-sur-Sarthe	Ionisos	Ionisation installation	154
	LOCATION OF INSTALLATIONS REGULATED BY THE ORLÉANS DIVISION			
28 Saclay	ULYSSE 91191 Gif-sur-Yvette Cedex	CEA	Reactor	18
28 Saclay	ARTIFICIAL RADIONUCLIDES PRODUCTION FACILITY (UPRA) 91191 Gif-sur-Yvette Cedex	CIS Bio International	Fabrication or transformation of radioactive substances	29
28 Saclay	LIQUID EFFLUENT MANAGEMENT ZONE (STELLA) 91191 Gif-sur-Yvette Cedex	CEA	Transformation of radioactive substances	35
28 Saclay	OSIRIS-ISIS 91191 Gif-sur-Yvette Cedex	CEA	Reactors	40
28 Saclay	HIGH-ACTIVITY LABORATORY (LHA) 91191 Gif-sur-Yvette Cedex	CEA	Utilisation of radioactive substances	49
28 Saclay	SPENT FUEL TEST LABORATORY (LECI) 91191 Gif-sur-Yvette Cedex	CEA	Utilisation of radioactive substances	50
28 Saclay	SOLID RADIOACTIVE WASTE MANAGEMENT ZONE (ZGDS) 91191 Gif-sur-Yvette Cedex	CEA	Storage and packaging of radioactive substances	72
28 Saclay	POSEIDON IRRADIATION FACILITIES 91191 Gif-sur-Yvette Cedex	CEA	Utilisation of radioactive substances	77
28 Saclay	ORPHÉE 91191 Gif-sur-Yvette Cedex	CEA	Reactor	101
29 Saint-Laurent-des-Eaux	SAINT-LAURENT-DES-EAUX NUCLEAR POWER PLANT (reactors A1 and A2) 41220 La Ferté-Saint-Cyr	EDF	Reactors	46
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