AUTORITÉ
DE SÛRETÉ
NUCLÉAIRE

ASN REPORT

on the state of nuclear safety and radiation protection in France in 2018

The Nuclear Safety Authority presents its report on the state of nuclear safety and radiation protection in France in 2018.

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 Nuclear Safety Authority (ASN)

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 citizens and regarded internationally as a benchmark for good practice.

Roles

Regulating

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

Authorising

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

Monitoring

ASN is responsible for ensuring compliance with the rules and requirements applicable to the facilities or activities within its field of competence. Since the Energy Transition for Green Growth Act of 17 August 2015, ASN's roles now include monitoring the security of 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 notification and enforcement powers (formal notice, administrative fines, daily fines, ability to carry out seizure, take samples or require payment of a guarantee, etc.). ASN's sanctions will be enforced by a Sanctions Committees, created within ASN, in order to maintain the principle of separation between the investigative and sentencing functions.

Informing

ASN reports on its activities to Parliament. It informs the public and other stakeholders (environmental protection associations, Local Information Committees, media, etc.) about its activities and the state of nuclear safety and radiation protection in France. ASN enables all members of the public to take part in the drafting of its decisions with an impact on the environment.

In line with the principle of transparency, itsupports 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 of the situation. ASN assists the Government. It in particular sends the competent Authorities its recommendations concerning the civil security measures to be taken.

Regulation and monitoring of diverse activities and facilities

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

This regulation covers:

- 58 nuclear reactors producing nearly 80% of the electricity consumed in France, along with the Flamanville EPR reactor currently under construction;
- all French fuel cycle facilities, from fuel enrichment to reprocessing;
- several thousand facilities or activities which use sources of ionising radiation for medical, industrial or research purposes ("small-scale nuclear facilities");
- several hundred thousand shipments of radioactive substances nationwide, every year.

The support of experts

When drawing up its decisions, 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 eight Advisory Committees of Experts, from a variety of scientific and technical backgrounds.

Operations

The Commission

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

Bernard DOROSZCZUK	Philippe CHAUMET-RIFFAUD	Sylvie CADET-MERCIER	Lydie ÉVRARD	Jean-Luc LACHAUME
Chairman	Commissioner	Commissioner	Commissioner	Commissioner
13 November 2018 for 6 years	10 December 2014 for 6 years	21 December 2016 for 6 years	10 March 2017 for 6 years	21 December 2018 for 6 years
APPOINTED BY the President of the Republic			APPOINTED BY the President of the Senate	APPOINTED BY the President of the National Assembly

Impartiality

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

Independence

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

Competencies

The Commission issues resolutions and publishes opinions in ASN's *Official Bulletin*. The Commission defines ASN external relations policy both nationally and internationally. The Commission defines ASN regulatory policy. The Chairman designates the various ASN inspector categories. The Commission decides whether to open an inquiry following an incident or accident. Every year, it presents the *ASN Report on the state of nuclear safety and radiation protection in France to Parliament*. Its Chairman reports on ASN activities to the relevant commissions of the French Parliament's National Assembly and Senate as well as to the Parliamentary Office for the Evaluation of Scientific and Technological Choices.

The departments

The ASN 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 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 regional divisions assist the Prefect of the *département*[1], who is in charge of protecting the general public, and supervise the operations carried out to safeguard the facility affected by the accident.

1. *Administrative region headed by a Prefect.*

Key figures in 2018

Personnel

516
staff members

of which **318**
inspectors

84%
management

ASN Actions

1,813
inspections
representing 4,178 days
of inspection

21,602
inspection follow-up letters
available on *asn.fr*
as at 31 December 2018

20 Advisory
Committee
meetings

327
technical opinions
sent to ASN **by IRSN**

2,606
individual licenses
for facilities or activities

Budget

€84.45 MILLION

total budget for ASN

€84.3 MILLION

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

Information

Nearly **850** **answers**
to queries from the public and stakeholders

17

press conferences

63

information notices

9

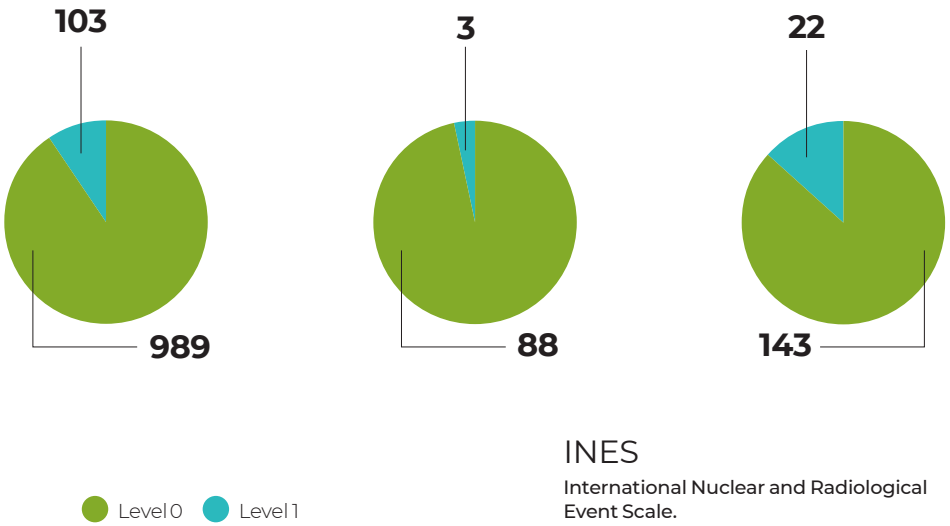
emergency exercises

Number of significant events rated on the INES scale

1,092
events in Basic Nuclear Installations

91
events in the transport of radioactive substances

165
events in small-scale nuclear facilities (medical and industry)

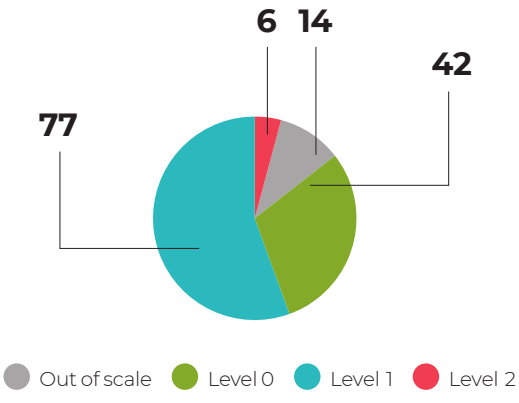


INES

International Nuclear and Radiological Event Scale.

Number of significant events rated on the ASN-SFRO scale

139
significant events



ASN-SFRO

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

ASN organisation chart as at 1st March 2019

COMMISSION

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

Chairman
Bernard Doroszczuk

Head of Private Office
Laurent Felber

GENERAL DIRECTORATE

Deputy Directors General
Julien Collet
Daniel Delalande
Anne-Cécile Rigail

Director General
Olivier Gupta

Chief Inspector
Christophe Quintin

Head of Staff
Bastien Poubeau

DEPARTMENTS

Nuclear power plant department
Rémy Catteau

Nuclear pressure equipment department
Simon Liu

Waste, research facilities and fuel cycle facilities department
Christophe Kassiotis

Transport and sources department
Fabien Féron

Ionising radiation and health department
Jean-Luc Godet

Environment and emergency department
Christophe Quintin (acting)

Legal Affairs department
Olivia Lahaye

Information, Communication and Digital Usages department
Céline Acharian

International relations department
Frédéric Joureau

General Secretariat
Brigitte Rouède

Management and Appraisal Mission
Alain Rivière

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: Patrick Berg
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

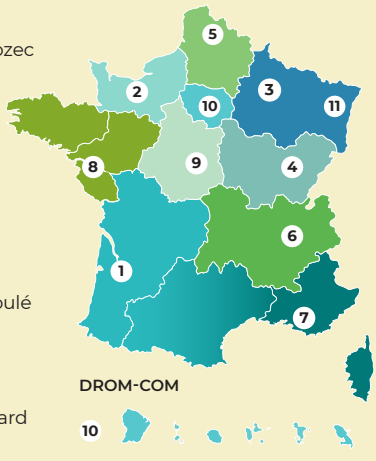
7 Marseille division
Regional representative: Corinne Tourasse
Regional Head: Aubert Le Brozec

8 Nantes division
Regional representative: Annick Bonneville
Regional Head: (acting) Yoann Terliska

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



The Caen and Orléans Divisions cover the Bretagne and Île-de-France regions respectively for the regulation and oversight of BNIs only.

Competence
Independence
Rigour
Transparency

asn.fr info@asn.fr

You can also follow ASN on the social networks

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ADVICE TO THE READER

CHANGES FROM THE 2017 EDITION

- **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 2018 is present in this report. All the regulations can be consulted on *asn.fr*, under the heading «*Réglementer*».**

Anticipation, Maintaining safety margins, Mobilisation of the competencies in the nuclear sector:

Three challenges for nuclear safety and radiation protection in France

Montrouge, 21 March 2019

Nuclear safety and radiation protection were on the whole maintained at a satisfactory level in 2018. Technical dialogue with the licensees and the activity managers enabled the subjects to be dealt with in sufficient depth, with regard to the nuclear safety and radiation protection issues.

In the nuclear field

The fuel cycle consistency analysis entailed extensive mobilisation on the part of the licensees and led to a comprehensive, up-to-date and forward-looking view of the safety issues and of the spent fuel storage capacity needs.

The EDF and Framatome review of all the dossiers concerning the forged parts produced at Le Creusot was carried out within the time-frame.

The licensees are aware that management of facilities ageing and of maintenance operations, along with compliance of the facilities with their safety requirements, still need to be improved.

For all the licensees, the recovery and packaging of legacy waste, along with decommissioning operations, are still experiencing difficulties which lead either to delays, or to changes in strategy following several years of study. In these areas, particular vigilance is required concerning the key factors that are project management and the resources allocated to execution of these operations.

Finally, an excessive number of deviations is still being found in the large-scale works carried out during reactor outages and in the manufacturing of new equipment.

In the medical field

ASN considers that the state of radiation protection remained stable in 2018 with the professionals on the whole giving satisfactory consideration to radiation protection, with the exception of fluoroscopy-guided interventional practices.

The number of Significant Radiation Protection Events (ESR) reported to ASN in 2018 rose on the whole, but the vast majority of them were level 0 or 1 on the ASN-SFRO scale and thus with no expected clinical consequences.

The persistence of radiotherapy events of a recurring nature, rated level 2 in 2018 (dose error or laterality error for example), requires an in-depth analysis of their causes and reinforcement of prevention measures.

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

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

- In the nuclear industry, time-frames are long. If something is not initiated or demonstrated in the short term, it will not be operational in 10 years' time. It is ASN's role to encourage the stakeholders to anticipate whenever nuclear safety or radiation protection are at stake.
  It does this with respect to the consistency of the nuclear fuel cycle and the management of radioactive materials and waste. In the future, it will do so for the implementation of the future multi-year energy plan, but also in the medical sector, when technological or radiopharmaceutical innovations require that specific radiation protection issues be taken into consideration beforehand.
- Faced with potential hazards, faced with the ageing of facilities or the possible discovery of a hitherto unidentified fault, the licensees must make sure that they keep sufficient margins for safety and do not seek to reduce them with a view to optimization or to justify retaining the status-quo. ASN must remain vigilant on this point.
- The nuclear sector must devote efforts to maintaining and developing the key industrial competencies vital to the quality of the work done and the safety of the facilities. Difficulties in the performance of conventional industrial operations (welding, electromechanical work, civil engineering and non-destructive testing), were encountered during the construction of new facilities and during work on facilities in operation. These difficulties have raised doubts regarding the ability of the sector to carry out the large-scale work involved in the continued operation of the existing facilities, decommissioning or the construction of new reactors, with the required level of quality.
  This situation requires a collective and strategic re-engagement by the industry on professional training and on industrial competencies, in order to achieve the level of quality and safety expected of the nuclear sector. This process, initiated notably with the creation of the French Nuclear Energy Industry Group (GIFEN), must now be intensified.

The nuclear fuel cycle: significant progress in 2018

ASN periodically examines the overall consistency of the industrial choices made by EDF, Orano Cycle, Framatome and Andra to ensure that the fuel cycle is well-managed in terms of nuclear safety and radiation protection issues.

In this context, the need for new spent fuel storage capacity was identified. EDF sent the safety options dossier for a centralised storage pool project. Following an assessment in 2018, ASN will issue an opinion in 2019.

In 2018, ASN issued its opinion on the fuel cycle consistency dossier for the period 2016-2030. It considers that this file satisfactorily presents the consequences of different fuel cycle evolution scenarios on the facilities, on transport operations and on waste. However, the consequences of unforeseen events which could affect the operation of the cycle need to be studied in greater depth. ASN underlines the risk of saturation of the spent fuel storage capacity if no new facilities are built, as well as the need to anticipate any strategic evolution in the operation of the fuel cycle at least ten years in advance.

In this respect, ASN asked the industry to examine, with regard to nuclear safety and radiation protection, the consequences of the multi-year energy plan on the nuclear fuel cycle, each time it is revised.

Prevention, detection and handling of fraud: progress made in 2018

The EDF and Framatome review of the manufacturing files for all the forged equipment from the Le Creusot plant was completed in 2018. The ASN analysis of this review on each reactor revealed no new deviation prejudicial to their safety, which would have required corrective measures prior to their restart authorisation. Some additional controls or tests however still need to be carried out. The EDF and Framatome examination of the manufacturing files of cast parts is continuing.

In 2018, ASN defined and deployed an action plan designed to optimise the prevention, detection and handling of suspected cases of fraud. At its request, the industry reinforced its measures in this area. ASN has enhanced its own oversight process with specific provision for fraud detection during the course of inspections. It also provided whistle-blowers with a new service on its website, enabling fraud or falsification alerts to be collected and processed.

Continued operation of the 900 MWe reactors: the high level of mobilisation must be maintained

In 2018, with the support of IRSN, ASN continued to examine the fourth periodic safety review of the 900 MWe reactors, in order to define the conditions in which they can continue to operate. ASN will issue a resolution on the generic part of the reactor periodic safety review at the end of 2020. The review will then be carried out reactor by reactor: it will start with Tricastin 1 and run until 2030.

The inspections performed and the deviations detected show that the compliance of the facilities with their safety requirements needs to be reinforced: Management of this compliance will thus be a key aspect of ASN oversight in 2019, more particularly during the reactor conformity checks.

Periodic safety reviews for facilities other than power reactors: an approach proportionate to the issues

Since 2017, the licensees have been carrying out periodic safety reviews of several tens of facilities (research, fuel cycle, decommissioning, waste, radiopharmaceuticals, irradiators). ASN has implemented an examination method commensurate with the issues. Some facilities warranting particular attention, owing to the risks inherent in the activity and the nature of the radioactive substances they contain, or because they were designed on the basis of old safety standards, will be subject to an in-depth examination.

Flamanville EPR: significant work still to be done by EDF

The Flamanville EPR reactor is designed to provide a higher level of safety than the reactors currently in operation.

ASN stresses the fact that EDF still has a significant amount of work to do before fuel can be loaded into the reactor, in order to demonstrate compliance of the facility with its safety requirements.

Construction work and equipment manufacturing have experienced numerous difficulties, mainly due to a loss of experience in the performance of major construction sites. These difficulties also indicate shortcomings in the licensee's monitoring of certain activities on the construction site. The approach proposed by the latter for dealing with the anomalies detected in the main steam system pipe welds is currently being examined. ASN will issue its opinion on the acceptability of this approach in 2019.

ASN will be particularly vigilant with regard to the satisfactory performance of tests prior to start-up and to the handling of any deviations. Furthermore, the results of tests performed on the EPR reactors abroad and exchanges between safety regulators will enable ASN to identify particular topics that require reinforced attention and oversight.

Waste: an issue involving numerous stakeholders

The *Cigéo* project for the deep geological disposal of high and intermediate level long-lived waste reached a major milestone in 2018, with the ASN opinion on the safety options dossier. The project as a whole has reached a satisfactory level of technical maturity. Certain subjects however still require additional work before the creation authorisation application can be submitted. ASN more particularly issued additional requests concerning bituminised waste packages and a multi-disciplinary expert review is in progress on these aspects. Andra intends to submit the creation authorisation application for this disposal centre in 2020. It will take account of the ASN opinion issued regarding the safety options dossier.

In conjunction with the Ministry responsible for Energy, ASN was closely involved in drafting the project management report and in preparations for the public debate concerning the next National Radioactive Material and Waste Management Plan, organised by the National Public Debates Commission (CNDP). This report aims to shed light on the main questions submitted to the debate, more particularly the management of materials, spent fuel storage needs, the management of very low level waste and of higher level wastes, as well as on the practical arrangements of the industrial phase of the *Cigéo* project.

In 2018, ASN also examined CEA's strategy for decommissioning and waste and materials management. Jointly with the Defence Nuclear Safety Authority (ASND), this for the first time concerned all civil and defence-related facilities. It notably examined the prioritisation of operations according to their nuclear safety and radiation protection implications, so that CEA could more efficiently manage these large-scale projects at a time of a constrained budgetary context. ASN will issue its opinion on this strategy in 2019.

Medical: persistence of points requiring particular attention and the need for anticipation

Improving the analysis and prevention of significant radiation protection events

The overall increase in the number of ESR notified indicates greater transparency, in particular in nuclear medicine and radiology (conventional and computed tomography). However, for radiotherapy, the fall in the number of ESR notified that has been observed since 2015, continued in 2018. The causes of this drop should be identified.

In 2018, ASN observed that the number of serious ESR notifications was still high. To prevent such events, with the support of a multidisciplinary expert group and as part of a continuous improvement approach, ASN aims to achieve broader publication of recommendations and summary documents intended for those in charge of the activities. Under ASN coordination and following on from the work done on radiotherapy Operating Experience Feedback (OEF), this expert group will in 2019 exploit national OEF about the most serious or frequent ESR in the imaging and nuclear medicine fields, reactively and operationally.

At the same time, in conjunction with the learned societies, a review will be carried out on the scales currently used for the ESR classification and the changes that would appear to be needed.

Continuing the graded approach to oversight

In 2019, ASN will continue to deploy tools for a graded approach to radiation protection oversight. The actions undertaken as of the end of 2017 will be supplemented by decisions concerning the new registration system, which could more particularly concern fluoroscopy-guided interventional practices and scanners.

Anticipating technological change

A committee to analyse new medical practices or technologies using ionising radiation will be operational in 2019 in order to ensure that they are deployed under the best radiation protection conditions for patients, personnel and the environment. This committee could notably recommend prospective data collection and support measures for professionals.

Source security: continued implementation of oversight

In 2018, ASN contributed to the preparation of the "Source Security" Order, which is coordinated by the Ministry responsible for Energy, and it made changes to its internal organisation for the management of sensitive information. Measures to implement source security oversight will continue in 2019.

Nuclear accident management: improvement actions to be continued

The nuclear crisis management system in France is robust. However, the emergency exercises need to be carried out in mobilisation conditions that are more representative of the organisations and they should more closely involve the populations living in the vicinity of the nuclear facilities.

ASN is working with all stakeholders to revise post-accident doctrine, so that it is simpler and more operational. The increased radius for the distribution of stable iodine tablets around the NPPs from 10 to 20 km and the performance of a major exercise will also help improve the nuclear accident management system.

International: new steps in the sharing of good practices

The first Topical Peer Review planned by the European Directive on Nuclear Safety concerned the management of nuclear reactor ageing. This review, held under the aegis of ENSREG (European Nuclear Safety Regulators Group), enables practices to be compared and led to recommendations regarding ageing management. It showed that the approach adopted by the European countries was satisfactory with regard to power reactors and that it should be extended to research reactors. In 2019, each country will draw up a national action plan to incorporate the conclusions of this review.

France hosted an *Artémis* peer review mission as required by the European Directive on Radioactive Waste Management, carried out under the aegis of the International Atomic Energy Agency (IAEA) to examine the organisation in place for managing radioactive materials and wastes. The review pointed out that the French system covered all the issues and presented many strong points, more particularly in terms of skills and the continuous progress approach. Areas for improvement were identified, for instance effective performance of dismantling as short as possible and optimisation of very low level waste management. These conclusions were made public in a report.

ASN continued its involvement in the sharing of good practices in the field of radiation protection. For example, in accordance with the justification principle, it proposed replacing the use of high-level sealed sources with an alternative technology.

ASN financial resources: the system must be more robust

The resources dedicated to the regulation and oversight of nuclear safety and radiation protection remain a sensitive subject. In its final observations issued at the end of 2018 following its inspection of ASN, the Court of Audit notably pointed out that the contribution from several budgetary programmes meant that the total cost of external oversight of civil nuclear safety in France was difficult to identify clearly. Moreover, in the light of the major issues involved in the oversight of nuclear safety, the Court of Audit recommended that financing arrangements more appropriate to ASN's duties and working methods be implemented, in order to consolidate its independence and free it from budgetary regulation mechanisms. ASN will continue to address this subject in the future.

EDITORIAL BY THE DIRECTOR GENERAL

Accountability: a duty and a requirement

Olivier GUPTA – Director General

Montrouge, 21 March 2019

Mirroring the arrival, at the end of 2018, of two new members of the Commission, including the Chairman, more than 10% of the ASN personnel were renewed during this period. In addition, several consultative groups reporting to ASN, whose mandate expired in 2018, underwent changes in composition with the arrival of new members: the Scientific Committee and five of the Advisory Committees of Experts. A sixth Advisory Committee for Decommissioning activities was also set up, in the light of the growing importance of these issues.

This major renewal in no way impeded the correct performance of ASN's duties, nor the continuity of its oversight policy and its position statements. This is notably explained by the collective nature of ASN operations. In this way, the review of the potentially falsified dossiers from the Le Creusot plant (nearly two million pages) was completed on-time. In the field of small-scale nuclear facilities, the transposition of the radiation protection "Basic Safety Standards" Directives, a major regulatory undertaking, led to the publication of a decision setting out the list of activities requiring notification.

All of the work done by ASN was carried out under the watchful eye of the regulatory authorities, peers, members of parliament and members of the general public. ASN was summoned to hearings by Parliament on fifteen occasions in 2018. It was inspected by the Court of Audit, which referred to it as a *"benchmark independent institution regarding nuclear safety matters"*. It welcomed foreign peers to address the management of radioactive materials and wastes during the course of the *Artémis* mission and again reported on its actions in this field during the IAEA Joint Convention review meeting. It is also involved in exchanges with the general public on the conditions for the continued operation of the 900 MWe reactors, as part of the consultation process around the fourth periodic safety review of these reactors.

By implementing the action principles defined in its multi-year strategic plan, ASN more particularly made progress in two areas: field inspections and international outreach.

Increasing the efficiency of ASN actions in the field

The points requiring particular attention, in all areas, are today mainly to be found in the field, as are therefore ASN's oversight actions. In 2018, the ASN inspectors carried out more than 1,800 inspections. This figure encompasses a variety of methods: from a one-day inspection by an inspector on a precise topic, to an "in-depth" review involving about ten inspectors for a week, analysing the various aspects of risk control on a site, such as the inspection held on the Gravelines NPP in May 2018.

Several changes were made to field inspections in 2018.

Firstly, ASN reinforced the targeting of inspections on the facilities and activities with the most significant potential consequences, in accordance with the graded approach principle defined in its multi-year strategic Plan.

Thus in the medical field, the inspections of fluoroscopy-guided interventional practices, where the risks are highest, were more numerous, while the number of computed tomography inspections fell significantly.

Targeting will continue to be optimised in the coming years, notably by taking advantage of innovative

projects initiated in 2018, such as the data mining of the 21,000 inspection follow-up letters, in order to cross-reference information and thus improve the pertinence of the checks.

Then, the inspection methods themselves have changed. The inspections are more modular in the small-scale nuclear sector. They are now partly defined according to the specific features of the facility or what the inspector discovers in the field. In the Basic Nuclear Installations, a new system for the oversight of reactor outages has been finalised: it intends to replace some of the off-site documentary examinations by on-site inspections. This will be trialled as of 2019.

Finally, 2018 saw the implementation of a new system to combat fraud and falsification. In addition to the creation of a portal for whistle-blowers, the first "anti-fraud" inspections were carried out to test an investigation methodology which will eventually become systematic. In 2019, specialists on this subject will be joining ASN.

Consolidating the French and European approach through international action

In 2018, ASN also continued its long-standing commitment to international actions. Over the course of the past twenty years, it has more particularly been a driving force in the development of a nuclear safety Europe, from both the technical and institutional viewpoints.

The technical work was supported by the European Nuclear Regulators Association (WENRA). As it approaches its 20th birthday, WENRA has adopted a new strategy, to which ASN made a significant contribution and which aims to consolidate the networking between the safety regulators of the various European countries, by developing comparable baseline safety requirements (whether in terms of technical requirements or inspection methods), with the support of technical organisations (such as IRSN) which are themselves also networked across Europe. In addition, to reinforce the harmonisation of the national decisions taken by each of the regulators, a consultation system will be developed, enabling the counterpart Authorities to be asked for their thoughts informally before a position is adopted on a complex subject.

Whatever the future development of nuclear energy in Europe, ASN and its European counterparts must continue to promote their high safety requirements on the world stage. To this end, WENRA has opened its doors to the leading nuclear countries outside Europe, notably the countries supporting new designs, and will now enable them to acquire associate member status. One of the concrete challenges for ASN will be to promote the safety requirements linked to the fourth periodic safety review of the 900 MWe reactors (more particularly in countries with reactors designed by Framatome).

Outlook

The roadmap for 2019 also promises to be intense, addressing a number of major issues, such as:

- the welds on the EPR main secondary systems;
- the continued preparation of the ASN opinion on the generic phase of the fourth periodic safety review of the 900 MWe reactors;
- opinions on the CEA and Orano decommissioning and waste management strategies;
- opinions on the safety options for the centralised spent fuel storage pool and the new-generation EPR project;
- the contribution to the public debate on the National Plan for Radioactive Materials and Waste Management.

Finally, ASN will continue with work to update the regulations applicable to small-scale nuclear activities.

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The engagement by the ASN teams is strong and unwavering. This commitment enables us to look with serenity towards the performance of the 2019 action programme. This work will also be made possible by the involvement of ASN's partners, members of the Advisory Committees, the Scientific Committee or the various transverse working groups, which actively contribute to the performance of ASN's duties. They have our thanks.

ASN ASSESSMENTS **PER LICENSEE** AND **PER FIELD OF ACTIVITY**

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 (NPP) in operation

ASN considers that the safety of EDF's NPPs was maintained at a satisfactory level in 2018. However, EDF must make improvements with regard to certain subjects. This is more particularly the case with managing the compliance of the facilities with their baseline safety requirements, which needs to be reinforced.

On the whole, the number of significant events in 2018 was stable in relation to 2017. No significant event exceeded level 1 on the INES scale. The verifications conducted by EDF regularly bring to light defects which affect several NPPs. Most of these defects are deviations related to the design of equipment, its installation or its maintenance and compromise its ability to perform its function in all the situations considered in the nuclear safety case.

The conformity of the facilities

As in previous years, ASN considers that the actual conformity of the facilities needs to be appreciably improved. This is more particularly the case with the seismic strength of the equipment. EDF must continue with the targeted inspections it has been gradually implementing for the past few years and which will allow regular detection of the equipment needing to be strengthened. Managing the conformity of the facilities in operation will be a major focus for ASN oversight in 2019, notably on the occasion of the fourth ten-yearly outage inspection of the Tricastin NPP reactor 1.

In 2018, EDF began a revision of its internal baseline requirements in order to improve deviations processing and ensure reactive information of ASN: this is a first step forwards. In 2018, ASN also noted that, by comparison with previous years, EDF placed greater emphasis on rapidly restoring the conformity of its facility after detecting a deviation.

In order to combat the risk of fraud, EDF has modified its inspection practices, making greater use of unannounced or cross inspections. In 2018, EDF also completed its review of the manufacturing files of the forged components produced by the Creusot Forge plant. The ASN examination of the deviations identified by this review did not reveal any new deviations in 2018 requiring repair or immediate replacement of any equipment item, but it nonetheless issued requests for additional justifications in order to back up the demonstrations provided by EDF. Examination of these additional justifications will continue in 2019.

Maintenance

EDF has taken steps to reduce the occurrence of maintenance quality defects: their number is however still too high. Some of them could have been avoided by taking greater account of operating experience feedback from other EDF reactors, including on the same site.

ASN however finds that most sites have successfully been able to carry out large-scale maintenance operations, such as the preparation for and performance of the ten-yearly outage inspections, which constitute a considerable drain on their human resources, notably those with the most experience, owing to the particularly intense maintenance phases.

ASN also considers that proactive measures must be taken by EDF to reinforce its maintenance programmes for certain equipment items. ASN in particular notes very high levels of fouling in certain internal structures of the steam generators in several reactors, which could impair their operating safety. These fouling levels are the result of maintenance that was insufficient to guarantee satisfactory cleanness. ASN considers that the in-service monitoring of the other equipment on the main primary system is carried out appropriately. In 2017, this notably led to the detection of a crack on the vessel bottom head penetration of Cattenom NPP reactor 3, with no change being observed in 2018.

With a view to the continued operation of its reactors, the "major overhaul" programme and in the light of the lessons learned from the accident at the Fukushima 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 its maintenance programmes.

ASN also observes shortcomings in the traceability and error-reduction measures concerning maintenance work. A number of anomalies are notably the result of incorrect application of a maintenance procedure, or even the inappropriate nature of the procedure itself. The workers still have to deal with constraints linked to work organisation, for which they are not responsible, such as insufficient preparation for certain activities, unplanned scheduling changes and problems with worksite coordination. The analyses carried out by the sites following significant events often lead to corrective measures that are no more than isolated awareness-raising sessions for staff, departments, or contractors identified as being responsible for the deviation. The analysis of the root causes must be taken further in order to identify any organisational weaknesses.

ASN regularly notes EDF's difficulty in ensuring appropriate and proportional monitoring of subcontracted activities, whether performed within the NPP itself or at the suppliers of goods and services. ASN however observes increased mobilisation by those responsible for monitoring outside contractors in the NPPs. It considers that EDF must further strengthen the role, the involvement and the competence of these persons, so that they can detect any inappropriate technical action at the earliest possible opportunity.

Operation

2018 was marked by difficulties encountered by EDF during post-outage reactor restarts. The scheduling, performance and analysis of the results of periodic tests are areas in which virtually all the sites need to improve. 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 management of certain sensitive activities, such as temporary system configuration changes in order to carry out periodic tests, would appear to be progressing on certain sites. This progress, which must be placed in the context of the action plans being run by EDF for several years now, still remains to be consolidated.

In recent years, EDF has reinforced its organisation for managing hazard-related risks, such as the organisation put into place to detect and eliminate the risk of falling objects in the event of an earthquake (lighting, fire-fighting resources, etc.). However, ASN regularly observes that the steps taken by EDF to prevent hazards and mitigate their consequences need to be further improved. This is in particular the case with measures concerning the fire risk.

In addition, the inspections of the emergency organisation and resources confirmed that the organisation, preparedness and management principles for emergency situations covered by an On-site Emergency Plan (PUI) have been correctly assimilated.

Continuation of reactor operations

Finally, ASN notes the ambitious steps taken by EDF to enable its reactors to continue to operate. The steps planned as part of the fourth periodic safety review of the 900 MWe reactors will thus lead to significant improvements in the safety of the installations. ASN is however still waiting for additional demonstration data on certain subjects which, at this stage of the examination, could well lead to requests for significant additional measures. This is notably the case regarding seismic resistance, the efficiency of the systems recirculating the water present at the bottom of the reactor building sumps and the need or otherwise to increase the thickness of the basemat of certain containments. EDF deployed considerable engineering resources for this review. However, ASN found that the EDF engineering teams were saturated and this must be taken into account when preparing the other reviews.

Personnel radiation protection and environmental protection

In 2018, radiation protection was addressed differently by the various NPPs, notably with respect to radiological cleanness management within the facilities and the steps taken to prevent the risk of contamination. Faced with this situation, ASN is reinforcing its oversight of implementation of the action plans requested to correct these situations on the reactors concerned.

EDF's organisation for managing 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 these topics. Despite the action plan implemented by EDF to limit the incidents of liquid spillage into the environment, events leading to such spills were still too numerous in 2018. With regard to waste management, ASN observed progress by certain sites which had previously been under-performing, but still needs EDF to significantly improve its organisation on this topic.

Individual NPP assessments

The ASN assessments of each NPP are detailed in the Regional Overview in this report. Certain sites stand out positively:

- in the field of nuclear safety: Saint-Alban/Saint-Maurice and Fessenheim;
- in the field of environmental protection: Paluel;
- in the field of radiation protection: Saint-Alban/Saint-Maurice and, to a lesser extent, Blayais and Chinon.

Other sites are on the contrary under-performing with respect to at least one of these three topics:

- in the field of nuclear safety: Civaux, Cruas, Golfech, Nogent-sur-Seine and, to a lesser extent, Belleville-sur-Loire;
- in the field of environmental protection: Blayais, Cruas, Dampierre-en-Burly, Gravelines and Nogent-sur-Seine;
- in the field of radiation protection: Cruas, Dampierre-en-Burly and Tricastin.

The Flamanville EPR reactor under construction

ASN considers that the organisation put into place for the preparation for Flamanville EPR operations is on the whole satisfactory. EDF must however further adapt its practices regarding equipment qualification and the performance of start-up tests, so that they are carried out in the planned conditions and so that their actual representativeness is correctly documented.

The deviations found on the main steam letdown pipes revealed a lack of rigorousness in the welding operations and a breakdown in EDF monitoring of its contractors. ASN therefore asked that the review of the quality of the Flamanville 3 EPR reactor equipment be extended to include a broader scope of equipment and subcontractors, while adapting the depth of the review to the specific implications concerned. The licensee proposed an approach for dealing with the anomalies detected. It is currently being examined. ASN will issue its opinion on the acceptability of this approach in 2019. EDF must be vigilant in ensuring that the necessary repairs are carried out and the worksite completed, with priority being given to the quality of the work done.

NPPs being decommissioned and waste management facilities

ASN is concerned by the delays in the main decommissioning operations for all the Gas-Cooled Reactors (GCR) and for the Brennilis reactor, as well as in the commissioning of the radioactive waste management facilities such as Iceda.

ASN considers that waiting for complete decommissioning of one GCR reactor before beginning to decommission the others, which means that the decommissioning of these reactors would then be postponed by several decades, is unacceptable if not justified by industrial experience feedback, and it asked EDF to examine possible ways of optimising the GCR decommissioning schedule.

The nuclear safety of EDF's facilities being decommissioned remains on the whole satisfactory. Progress with the decommissioning of the Chooz A and Superphénix reactors is in line with the schedules in their decrees.

Following internal contamination events affecting workers on the Saint-Laurent A site in 2016 and Chooz A in 2017, EDF implemented an action plan for improved management of the risks linked to the presence of radionuclides emitting "alpha" radiation, which is one of the main decommissioning challenges.

ASN observes that the technical dialogue with the teams in charge of the plants being decommissioned and of waste management is sometimes difficult. Generally speaking, ASN considers that EDF's files are either insufficiently detailed (for example, the general operating rules for waste management), or incomplete (for example, the environmental assessments are missing from the reviews). ASN asks that EDF provide technical data enabling the risks to be assessed and operational conclusions to be reached more rapidly. ASN also observes that the EDF three-yearly reports on the long-term costs of decommissioning of facilities contain very little detail when compared with those from the other licensees.

Orano Cycle

ASN considers that the level of safety in the facilities operated by Orano Cycle is on the whole satisfactory, with the context being less worrying following the group's recapitalisation and reorganisation.

The facilities operated by Orano Cycle are located on the La Hague and Tricastin sites and the issues involved are both chemical and radiological.

ASN considers that the level of safety of the facilities in operation on the La Hague site is on the whole satisfactory. In a very short period of time, Orano Cycle designed and implemented new means to deal with extreme situations in their facilities, notably new emergency buildings that are robust to extreme hazards, plus water make-up resources.

However, progress is still required in terms of the traceability of the inspections performed, the training of workers in charge of these inspections, the skills of the new contractors carrying out maintenance work and their familiarity with the facilities, as well as their monitoring by Orano Cycle.

ASN considers that Orano Cycle must continue the actions undertaken to improve the follow-up and processing of deviations and the corresponding operating experience feedback from the La Hague site. It considers that Orano Cycle must take better account of organisational and human factors in its modifications or in the implementation of the group's baseline safety requirements. Finally, ASN notes that Orano Cycle must improve the way its fire risk management measures interface and interact with the measures adopted for physical protection of the nuclear materials on the La Hague site.

ASN considers that ageing management, in a context of faster than expected corrosion of the fission product evaporator-concentrators and of other equipment in the La Hague plant, is a priority issue. Orano Cycle has developed an approach involving the selection of equipment for which ageing is to be monitored. The principles of this approach are acceptable but its effective implementation in the field and its traceability need to be improved.

With regard to the various Legacy Waste Repackaging (RCD) and decommissioning projects, which have major safety implications at La Hague, ASN observes significant delays in their implementation. Some delays are linked to Orano Cycle giving priority to its plants in operation, to changes in scenarios and to the need to modify design studies, which is sometimes identified only belatedly. ASN asked Orano Cycle to reinforce its project management capabilities in order to advance the RCD and decommissioning operations successfully.

ASN considers that the safety level of the facilities on the Tricastin site has progressed, notably thanks to the gradual shutdown of the oldest facilities, the commissioning of facilities with reassessed safety standards and the

completion of the work done as a result of the lessons learned from the Fukushima Daiichi accident. ASN also observes that the pooled emergency organisation and management resources now make it possible to manage an emergency situation, whichever facility is affected. The presence of a local intervention force, its organisation, the means at its disposal and the quality of the intervention are a real asset in the emergency response organisation on the Tricastin platform, where the facilities operated entail the risk of accidents that can develop rapidly. Radioactive substance transports, which are now centrally organised, are managed satisfactorily.

ASN considers that for the Tricastin site, follow-up of the undertakings made to ASN and monitoring of the contractors needs to be improved, notably to ensure the conformity of the subcontracted work.

CEA

ASN considers that the safety of the facilities operated by CEA remains on the whole satisfactory, despite a worrying budgetary context. Safety concerns surround the continued operation of facilities designed according to old safety standards. The main challenge for CEA is however to ensure the decommissioning of facilities that have been finally shut down, to recover and package legacy waste and to manage its radioactive waste and materials with no identified use.

CEA operates a large number of facilities of varying types and safety implications, such as research reactors and laboratories conducting experiments on behalf of the nuclear industry (NPPs, fuel cycle, waste management), along with storage facilities.

Some of these facilities, built to support the French NPP fleet in the 60s and 70s, are in operation, others are shut down and preparing for decommissioning, while others are currently undergoing decommissioning. The Jules Horowitz research reactor, which was authorised in 2009, is currently under construction.

The facilities in operation are today old and the future projects designed to replace some of them are uncertain (Mosaïc, Zephyr). Their postponement could lead CEA to try to continue with the operation of ageing facilities for which it would be hard to ensure compliance with current safety standards. ASN could thus be required to restrict the operating conditions, or even request the shutdown of certain facilities. CEA will be required to define and present a medium/long-term strategy for its civil nuclear research experimental facilities, with particular vigilance with regard to the credibility of the timelines and the financial resources.

ASN considers that, at all levels within the organisation of CEA, responsibility for safety must be borne by the persons with the necessary resources, skills and authority. It also considers that CEA must be attentive to preserving the resources and attractiveness of the positions dealing with safety.

ASN considers that CEA must reinforce its monitoring and its management of the activities carried out by the outside contractors and subcontractors. This is particularly important for facilities managing waste, effluents, or storage. On this subject, it would be a good idea for the best practices observed in certain facilities to be extended to all the others.

ASN recalls the need to rapidly notify it of any significant events that occur in the facilities. It also considers that the analysis of notified events should be carried out in greater depth, on the one hand to identify the relevant corrective measures and on the other to foster the sharing of experience.

With regard to the periodic safety reviews, ASN observes that 16 review reports were transmitted with no delay at the end of 2017, which represents a considerable workload for CEA. On the basis of the inspections carried out on this topic, ASN found that CEA has now better assimilated the problems relating to the review, thanks to the implementation on each site of a transverse organisation specifically devoted to these processes. ASN will be attentive to the correct performance of the works identified in the periodic safety reviews. It thus observes that CEA makes undertakings for each dossier, although sometimes without being able to ensure that the human or financial resources are actually available. This can subsequently lead to certain undertakings not being met. ASN thus observed delays in the availability of new emergency management buildings, designed to take account of the lessons learned from Fukushima, for the Saclay and Cadarache centres. The compensatory measures proposed by CEA will need to be rapidly operational. ASN remains vigilant with respect to compliance with CEA's schedule of commitments, the completeness of the dossiers transmitted, the quality of the answers to requests and compliance with the requirements.

With respect to the scope of the delays found in CEA's decommissioning and waste management projects, ASN and ASND asked CEA, in July 2015, to conduct an overall review of its strategy for decommissioning, radioactive materials and waste management, its prioritisation of operations, human resources and the efficiency of its organisation, as well as the pertinence of the amount of the financial resources allocated to these operations. CEA has implemented a new organisation, which represents significant progress. This progress will have to be confirmed in the medium-term through compliance with the highest priority project timelines.

Andra

Andra is the sole licensee of a radioactive waste disposal BNI in France. ASN considers that the licensee's organisational and technical resources are appropriate for operation of the existing centres and that the operation of these centres is satisfactory.

Over the past ten years, ASN has found a significant improvement in the approval and monitoring activities for packages of Low and Intermediate Level, Short-Lived Waste (LLW / ILW-SL). ASN hopes to see a ramp-up of the system with regard to waste packaged for the planned future facilities.

ASN considers that the design of *Cigéo* has on the whole reached satisfactory technological maturity at the Safety Options Dossier (DOS) stage. Some of the safety options, more particularly concerning the possible disposal of bituminised waste and management of the fire risk, nonetheless need to be supplemented for the purposes of the creation authorisation application. From the Andra organisation viewpoint, the fact of becoming the licensee of a facility of the scale and complexity of *Cigéo* is a real challenge.

With regard to Low Level, Long-Lived Waste (LLW-LL), the National Radioactive Materials and Waste Management Plan (PNGMDR) has set out the steps for defining and designing disposal solutions. ASN notes that the definition of the design options is behind schedule.

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

ASN ASSESSMENTS **PER FIELD OF ACTIVITY**

THE MEDICAL FIELD

In 2018, ASN considers that the state of radiation protection in the medical field remained stable, with the professionals on the whole giving satisfactory consideration to radiation protection, with the exception of fluoroscopy-guided interventional practices.

In **external radiotherapy**, the improvement in treatment safety, which has been underway for several years, continued. It is however still faced with significant technological changes, with potential risks arising when the organisational and human factors are not correctly managed. These technological changes require risk assessments, but the professionals do not as yet have complete expertise in the relevant methodology. After a marked rise in the number of Significant Radiation Protection Events (ESR) in this field of activity, ASN has observed that the numbers have fallen over the past three years. The reasons for this drop must be identified.

With regard to health care safety, the **brachytherapy** situation is comparable to that of external radiotherapy. The radiation protection of workers and the management of High-Level Sealed Sources (SSHA) are considered to be on the whole satisfactory, although this level must be maintained by means of a continuous training effort. In the current context, greater attention must be given to increased SSHA access security, to prevent unauthorised access to these sources.

The radiation protection of patients and professionals in **nuclear medicine** is dealt with satisfactorily. Also in this sector, training efforts must be maintained. 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 issues of radiation protection is also good management of radioactive effluents; this is all the more important as internal targeted radiotherapy treatments, which require the administration of high activity levels to the patients, will undoubtedly become more widespread, resulting in an increased level of discharged radioactivity.

In the field of **fluoroscopy-guided interventional practices**, ASN considers that the important measures it has been recommending in recent years are not always sufficiently followed in order to improve the radiation protection of patients and professionals during interventional practices, notably for surgery in the operating theatres. The inspections frequently reveal deviations from the regulations, concerning the radiation protection of both patients and medical staff, and ASN is regularly notified of events concerning interventional surgeons who have exceeded the dose limits for the extremities. The state of radiation protection is however far better in the units which have been using these technologies for a long time, for example in imaging units where interventional cardiology and neurology activities are carried out. 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.

For ASN, continuous training of professionals and intervention by the medical physicist are certainly the two key points for guaranteeing management of the doses delivered to the patients during interventional procedures.

The growing number of diagnostic examinations using computed tomography is contributing to a high collective dose level, with **medical imaging** being the leading source of the population's artificial exposure 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 the second action plan for the management of ionising radiation doses delivered to persons undergoing medical imaging. This plan aims

to reinforce the justification of the procedures and the 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 within the companies, even though worker dosimetry 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 licensee when this activity is performed in a bunker in accordance with the applicable regulations, ASN is still concerned by the observed shortcomings in terms of the demarcation of the operations area during site work.

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 on the whole satisfactory. 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 significant improvements concern the waste and effluent storage conditions, more particularly the adoption of inspection procedures prior to their disposal. For ASN, however, this subject remains a point requiring particular attention. 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 as yet not systematic enough.

With regard to the **veterinary uses of ionising radiation**, ASN can see the result of 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 2018, the safety of transport of radioactive substances is on the whole satisfactory. Even if a few transport operations were affected by incidents, primarily on the roads, they should be compared with the 770,000 transport operations carried out each year and led neither to dispersal of the package contents into the environment, nor to any significant exposure of humans.

The main causes of the 91 significant events concerning the transport of radioactive substances on the public highway which occurred in 2018, were:

- material non-conformities affecting a package. These however 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 day-to-day rigorousness.

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 analysis files.

ASN observes progress over previous years, as well as better application of the recommendations made in ASN Guide No. 7 (volume 3). The improvements still needed generally concern the description of the authorised contents per type of packaging, a demonstration that no radioactive content is lost or dispersed in normal transport conditions and the impossibility of exceeding the applicable dose 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 understanding the regulations applicable to these transports and the arrangements made by certain hospitals or nuclear medicine centres for the shipment and receipt 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.

NOTABLE EVENTS 2018

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Flamanville EPR reactor

Main secondary system pipe welds

At the beginning of 2017, EDF informed ASN of deviations that had occurred during welding of the main steam lines (VVP system) for the Flamanville EPR reactor.

For these pipes, EDF had adopted a «break preclusion» approach, which implies tightened design, manufacturing and in-service monitoring requirements such as to consider that a break of these pipes is extremely improbable. This choice means that the licensee does not study the consequences of a break on these pipes in the facility's nuclear safety case.

In order to achieve the expected high standard of manufacturing quality, the licensee (EDF) and the manufacturer (Framatome) defined tightened requirements, more specifically with respect to the mechanical properties. However, these tightened requirements were not specified to the subcontractor responsible for producing these welds. The inspections carried out during production showed that, for some of these welds, not all of these requirements had been met.

In addition, in March 2018, EDF identified a number of flaws during the pre-service inspection of these pipes, as required by the regulations prior to commissioning. These flaws should have been detected by the manufacturer on completion of manufacturing. This finding led EDF to implement a verification programme for all the welds on the main secondary systems, which include the VVP pipes. These new checks revealed flaws requiring repair. ASN verified the performance of these new inspections by EDF.

All of these deviations, as well as the ASN findings during its inspections, highlighted a lack of expertise in the welding operations carried out on the VVP pipes and a breakdown in EDF monitoring of its contractors.

In July 2018, EDF undertook to restore the required mechanical properties of the welds concerned by the deviations identified, except for the eight welds located in the annulus between the two containments of the reactor building, where access is harder. One of these eight welds also comprises a manufacturing flaw that EDF proposed maintaining as-is.

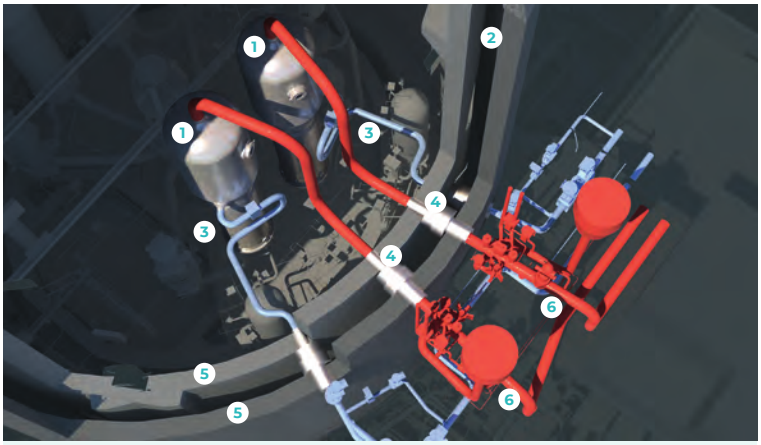
In December 2018, EDF sent ASN a file aiming to demonstrate that the quality of these eight welds is sufficient, enabling their breakage to be precluded with a high level of confidence. This demonstration is more particularly based on an in-depth characterisation of the welds material.

ASN's examination of the EDF file, with the support of IRSN, will continue in 2019. ASN will consult its Advisory Committee for Nuclear Pressure Equipment (GP ESPN) on 9 April 2019 concerning the approach proposed by EDF.

In addition, the identification of shortcomings in EDF's monitoring of its contractors led ASN to ask EDF to conduct a review of the quality of the Flamanville 3 EPR reactor equipment, extended to include a broader scope of equipment and subcontractors, while adapting the depth of the review to the specific implications concerned.

In brief

The welds on the main steam lines in the Flamanville EPR reactor are affected by design and construction deviations. In its letter of 2 October 2018, ASN considered that priority should be given to restoring the conformity of the welds and asked EDF to send it a file presenting its deviations processing approach. This file was examined by ASN, with the technical support of IRSN and their conclusions are presented to the GP ESPN meeting in April 2019.



1 Steam generators 2 Annulus 3 Feedwater Flow Control System
4 Penetrations 5 Double containment 6 Steam System (VVP)

Nuclear power plants

Fourth periodic safety review of the 900 MWe nuclear reactors

In the same way as any BNI, the nuclear reactors undergo an in-depth periodic safety review every 10 years, in order to check their level of safety and make any necessary improvements.

A review with major implications

The 34 EDF reactors with a power of 900 MWe were commissioned between 1977 and 1987 and the first ones are approaching their fourth periodic safety review. This is the context in which the conditions for the continued operation of these reactors will be defined.

This fourth periodic safety review comprises particular challenges:

- Some equipment is reaching its design 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 adopted 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 in the light of the new generation of reactors, such as the EPR, the design of which meets significantly reinforced safety requirements.

At the end of 2020, ASN will issue a position statement 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.

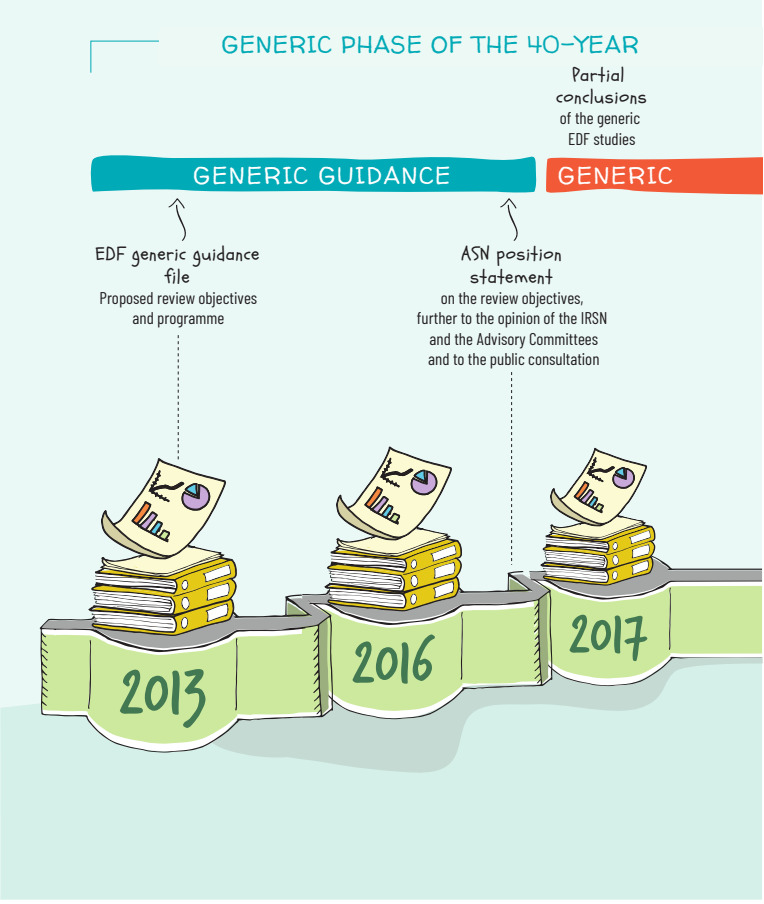
After examining the objectives proposed by EDF, with the support of IRSN, and following consultation of its Advisory Committees, ASN released a position statement on these objectives and issued additional requests in April 2016. EDF supplemented its programme of work and in 2018 presented ASN with the 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, ASN more particularly obtained the opinion of its Advisory Committees on the management of ageing and obsolescence and on the mechanical strength of the reactor pressure vessels.

It will again ask them for their opinion in 2019 and 2020 regarding:

- nuclear pressure equipment, more particularly the thermomechanical loads stressing the vessels;
- the accident studies in the safety case;
- the ability of the installations to withstand internal and external hazards;
- the probabilistic safety analyses;
- the management of accidents with core melt.

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. ASN will issue a position statement on the generic studies for this periodic safety review at the end of 2020.



ASN will issue its opinion on the continued operation of Tricastin NPP reactor in 2022.

In brief

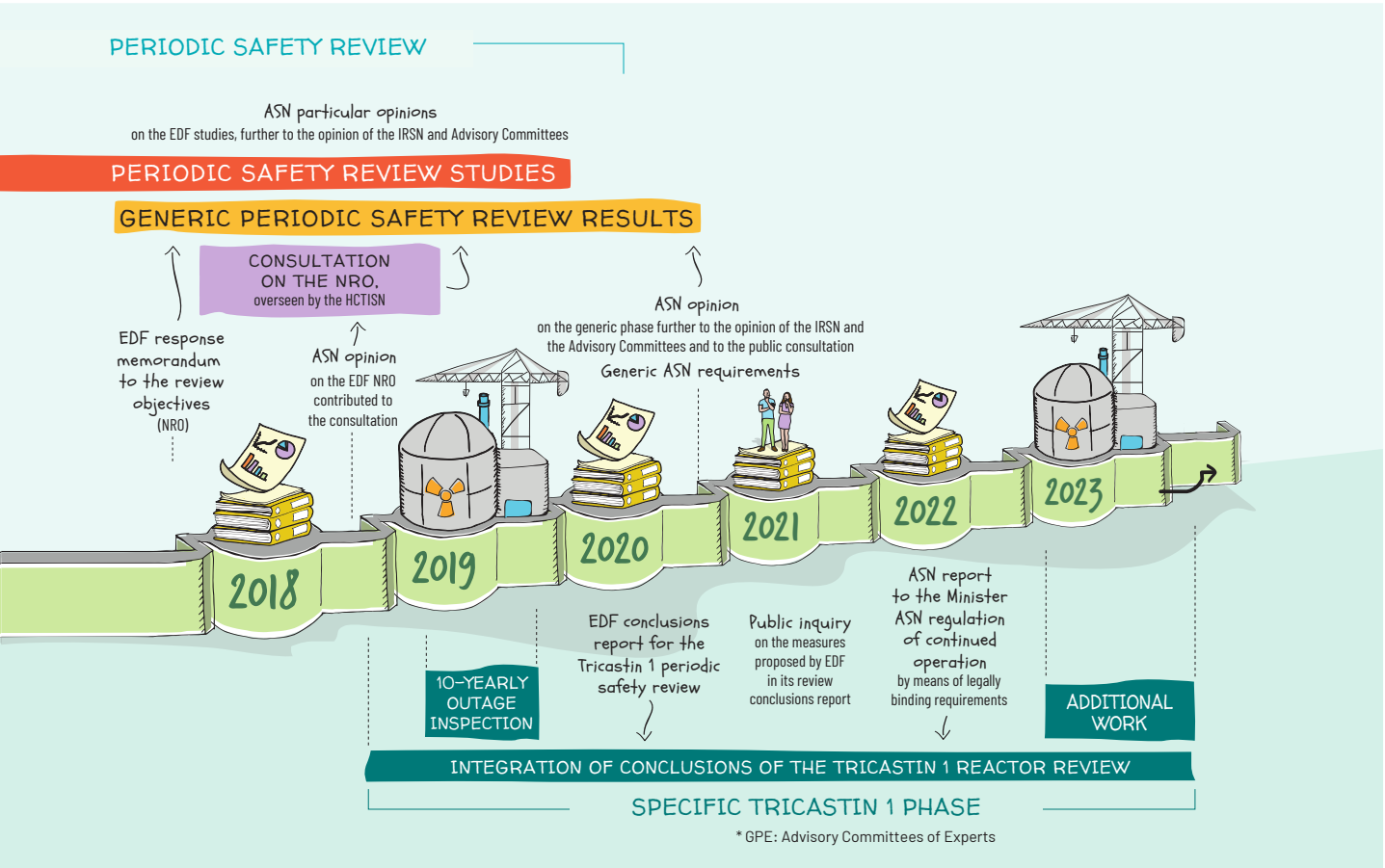
The periodic safety review has a two-fold objective:
- in-depth examination of the state of the facility, taking account of its ageing, in order to verify its compliance with the applicable baseline safety requirements;
- improve its safety level to take account of operating experience feedback and the technical progress made on the most recent reactors.

2019: the year of the first of the 4th ten-yearly outage inspections

In 2019, Tricastin NPP reactor 1 will undergo its fourth ten-yearly outage inspection, which is a major step in its fourth periodic safety review. During this outage, EDF will carry out a significant part of the required inspections and 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 report for this reactor, that will 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, 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. 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.



Nuclear safety and radiation protection

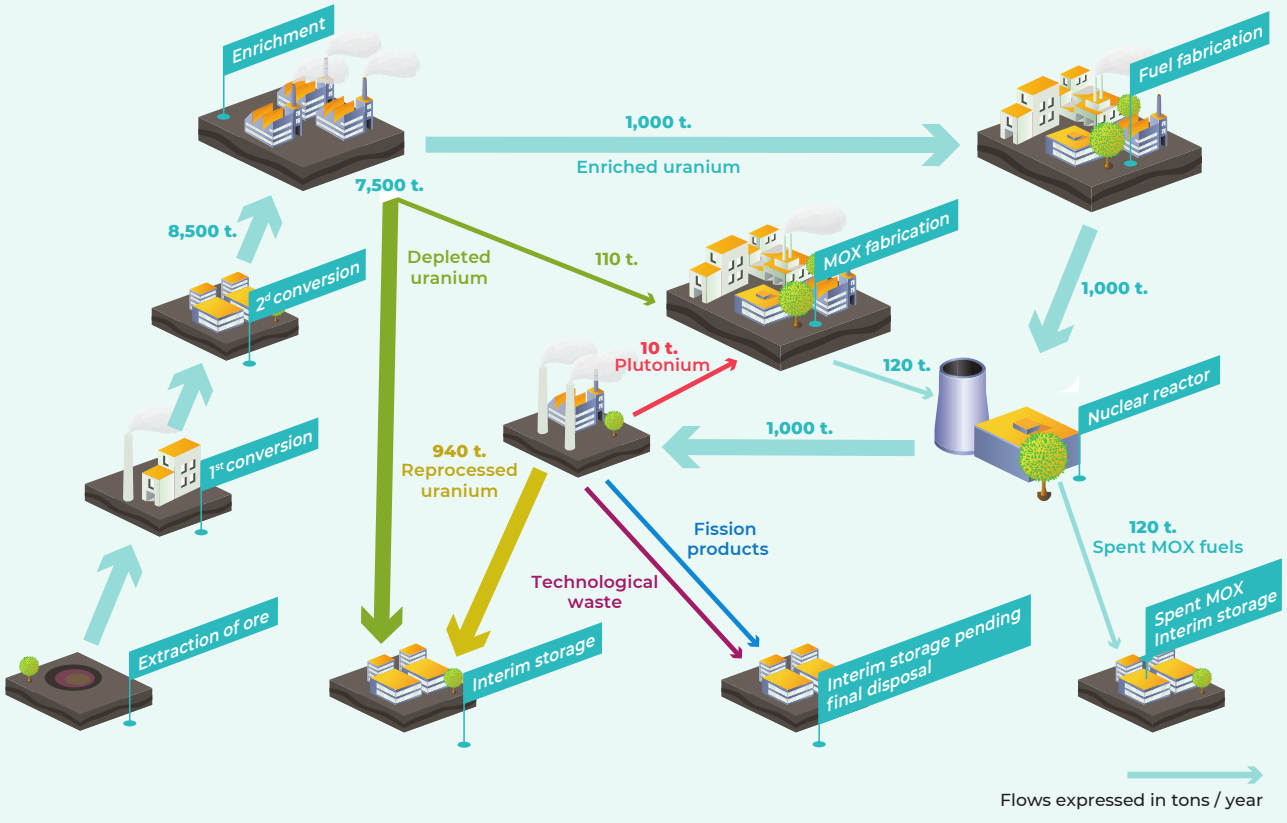
Nuclear fuel cycle consistency

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 nuclear reactors.

In 2015, ASN asked EDF to conduct an overall review of the "Cycle Impact" file by 2016. This update of the "Cycle Impact" file comprises a number of innovations with respect to the previous approaches initiated in 1999 and 2006:

- The study period, which habitually covered ten years, 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.

Fuel cycle diagram



From mining of uranium ore to the disposal of radioactive waste from spent fuels, ASN examines the “Cycle Impact” file supplied by the fuel cycle stakeholders.

In brief

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 examination of the “Cycle Impact” file was completed in October 2018.

In June 2016, EDF submitted the “Cycle Impact 2016” file covering the period 2016-2030. This file, which was 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 by 2040, on the basis of various energy mix evolution scenarios. After examination, ASN delivered its opinion on 18 October 2018.

It considers that the “Cycle Impact 2016” file provides a satisfactory presentation of the consequences of the various nuclear fuel cycle evolution 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 appear in particular that to avoid reaching the maximum capacity of existing storage facilities too quickly (nuclear reactor spent fuel pools and at La Hague), any reduction in production by reactors consuming MOX fuel must be accompanied by a reduction in that by reactors consuming fuel from Enriched Natural Uranium (ENU), so that all the spent ENU fuel is reprocessed.

The two parts of the equation are fuels and storage capacity.

In the longer term, it will be necessary either to have new storage capacities that are significantly greater than the current and planned volumes, or to be able to consume 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 asked the industrial players to start examining these two options without delay.

The Government is currently preparing the “Multi-annual Energy Plan” (MEP), which is updated every five years. The functioning of the nuclear fuel cycle could evolve according to the orientations thus defined in this plan. At the request of ASN, the industrial players will be required to study the consequences, in terms of nuclear safety and radiation protection, of the MEP on the nuclear fuel cycle and its consistency, at each MEP revision.

Oversight tool

National Radioactive Material and Waste Management Plan

Planning Act 2006-739 of 28 June 2006 on the sustainable management of radioactive material and waste, instituted the drafting of a National Radioactive material and waste Management Plan (PNGMDR) every three years.

The PNGMDR is prepared by the General Directorate for Energy and Climate (DGEC) at the Ministry responsible for Energy and by ASN, on the basis of the work done by a pluralistic working group more specifically comprising radioactive waste producers, licensees of management facilities for this waste, evaluation and control authorities and environmental protection associations.

In concrete terms, the PNGMDR gives a detailed inventory of radioactive material 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 prescriptions of the Environment Code and the studies to be conducted in the coming years, respectively. There are 83 of these studies, each one with a pilot and a completion deadline.

The same pluralistic approach to drafting will be adopted for the next edition of the PNGMDR, which will also be preceded by a public debate for the first time. 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 participation by the public. The CNDP decided to organise a public debate on the plan.

The debate, which will be held during the course of 2019, will be an opportunity to deliberate on a number of subjects with significant implications.

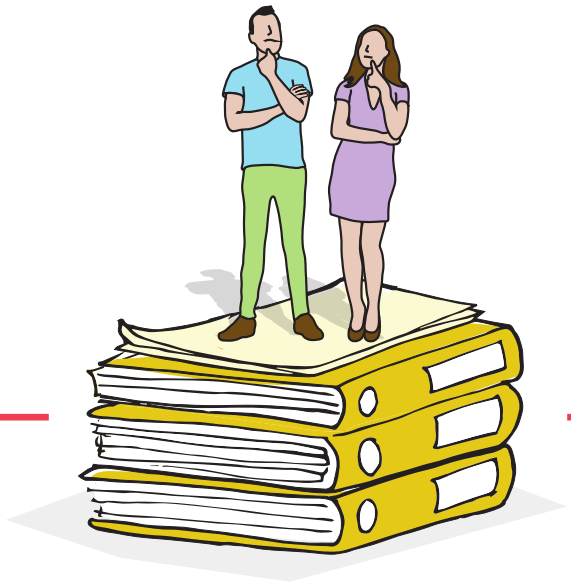
ASN and the DGEC, in cooperation with the particular public debates Commission, drafted a "project manager's report" which presents the main elements of the PNGMDR and identifies the main issues they propose submitting to the debate for the purpose of drafting the new plan. The contributions and thoughts expressed during the debate on the aspects of the PNGMDR which are not directly covered by the project manager's plan, will also be of use for drafting the next edition of the PNGMDR.

In brief

Since the first edition of the PNGMDR in 2007, there have been four successive plans. They have enabled progress to be made in structuring the radioactive material and waste management routes and strengthening the public policies which, in this field, contribute to the protection of human health, safety and the environment.

Classification of radioactive waste and corresponding management routes

<table>
<tr><th>CATEGORY</th><th>VERY SHORT LIVED WASTE</th><th colspan="2">SHORT-LIVED WASTE</th><th>LONG-LIVED WASTE</th></tr>
<tr><td>Very Low Level (VLL)</td><td rowspan="3">VSL
Management by radioactive decay</td><td colspan="2">VLL
Surface disposal (Industrial centre for collection, storage and disposal)</td><td></td></tr>
<tr><td>Low Level (LL)</td><td rowspan="2">LIL-SL
Surface disposal (Aube and Manche waste repositories)</td><td>LL-LL
Near-surface disposal being studied</td></tr>
<tr><td>Intermediate Level (IL)</td><td rowspan="2">IL-LL
Project for deep geological disposal (Cigéo project)</td></tr>
<tr><td>High Level (HL)</td><td>Not Applicable</td><td>HL</td></tr>
</table>



The issues of the next National Radioactive Material and Waste Management Plan identified in the project manager's report for the public debate

Numerous issues are covered by the PNGMDR and not all are developed in the project manager's report. For the purposes of the public debate, the project manager chose to develop five issues, on the basis of the ethical or strategic implications of certain management choices that could be adopted. For each of these five subjects, the project manager presents in its report the challenges and problems as it perceives them and the main characteristics of the management solutions which could be envisaged for the next edition of the PNGMDR, along with their significant impacts.

Managing radioactive material and preventing creating a burden on future generations

- Are the prospects for recycling radioactive material credible?
- How to assess this credibility, with what degree of confidence?
- What management choices should result from this analysis?
- How to mitigate the impacts of current choices on future generations?

Anticipating the evolution of spent fuel storage needs

- What additional technical measures could be used to reinforce the spent fuels storage strategy?
- How to optimise management of the risks and potential hazards linked to the operation of fuel cycle facilities?
- Given the intended reduction of nuclear energy in the electricity mix, on the basis of what scenarios should these additional storage needs be defined?

Very low level waste, a diversity of solutions to optimise its management

- Faced with the future large volumes of low toxicity waste in the coming decades, how should the current management methods for very low level waste be developed?

Low level long-lived waste, appropriate disposal facilities for the potential risks

- Faced with the difficulties being encountered with the development of a disposal centre for all these wastes, what options could supplement the ongoing projects?
- What shape could the new management guidelines take?

Defining the practical aspects of the pilot industrial phase for the *Cigéo* project and the reversibility of deep geological disposal

- In the 2016 Act, Parliament reaffirmed its wish to see the deep geological disposal project continue, in accordance with two principles, that is reversibility and the implementation of a pilot industrial phase prior to its actual commissioning.
- How to implement these two principles and address the expectations of civil society?
- How to involve civil society throughout the lifetime of the project?
- How to have civil society take part in the major decisions linked to the reversibility of the project (changes in energy policy, technological progress)?
- How to take decisions to close the disposal vaults?
- How to monitor and what objectives to set for the pilot industrial phase?

Regulatory news

2018 was marked by considerable activity on standards, more particularly concerning radiation protection, with the publication in June of three Decrees transposing Council Directive 2013/59/Euratom of 5 December 2013 setting Basic Standards for Health Protection against the dangers resulting from exposure to ionising radiation. In the field of Basic Nuclear Installations (BNI), ASN was closely involved in drafting a decree codifying the provisions applicable to BNIs, to the transport of radioactive substances and to nuclear transparency, which entailed extensive consultation with the stakeholders. Some international and national news should also be highlighted.

1 International news

• New IAEA regulations for the transport of radioactive materials – Special Safety Requirements N° SSR-6 – 2018 edition

The International Atomic Energy Agency (IAEA) revised the regulations for the transport of radioactive materials. The new 2018 edition of these regulations more specifically extends the list of Surface Contaminated Objects (SCO) to extremely voluminous solid objects such as BNI steam generators, so that they can be transported with a high level of safety. The new IAEA provisions are incorporated into the 2019 editions of the various international agreements for the various transport modes, such as the European Agreement on the international carriage of dangerous goods by Road (ADR).

The IAEA implementation guide for radioactive materials transport regulations, No. SSG-26, will be updated accordingly in 2019.

2 National news

2.1 Acts

• Act 2018-670 of 30 July 2018 concerning the protection of trade secrets, which transposes Directive (EU) 2016/943 of the European Parliament and the Council of 8 June 2016 on *the protection of undisclosed know-how and business information (trade secrets) against their unlawful acquisition, use and disclosure*, and its implementing Decree 2018-1126 of 11 December 2018 creating a new general system for the protection of trade secrets (Articles L. 151-1 to L. 154-1 of the new Code of Commerce).

"Trade secrets" enable companies to preserve the confidentiality of information which cannot benefit from protection under intellectual property law (patents, drawings and models, copyright), but which is nonetheless important in order to maintain their competitiveness.

The new system defines the information liable to be protected, illicit behaviours and the preventive measures that could be requested before the courts. It aims to provide companies with a degree of protection, notably with respect to their competitors.

The new provisions do not however constitute a radical change for ASN, in that it was already bound to respect "industrial and commercial secrecy" (the former terminology now replaced by trade secrets), a notion which was already present in the legislation specific to the communication of administrative documents and environmental information.

In addition to a change in terminology, also worth noting is:

- whistle-blowers are no longer bound by trade secrecy;
- the use of information covered by trade secrecy (in particular that obtained from a whistle-blower) is licit when it is intended for the protection of a legitimate interest recognised by European or national law.

• Act 2018-727 of 10 August 2018 on Building a State worthy of Societal Confidence ("ESSOC" Act) comprises measures with a direct effect on ASN.

The Act now requires that a copy of the report of a breach of the Environment Code be transmitted, unless otherwise stipulated by the Public Prosecutor, to the infringing party within at least five days and no later than ten days following transmission of the report to the Public Prosecutor.

In terms of environmental assessment, the Act now requires that when a project modification entails a case by case examination, the project manager shall refer to the administrative authority in charge of regulation and oversight (ASN for BNIs) so that this latter can, in place of the environmental Authority, determine whether or not the modification should or should not be subject to an environmental assessment. This concerns requests for significant modifications to BNIs liable to have notable negative impacts on the environment.

The "right to request an inspection and the enforceability of this inspection" could possibly be used by a BNI licensee, a party responsible for the transport of radioactive substances or for a nuclear activity, but this possibility will probably be restricted on nuclear matters, owing to the restrictions and limitations on its effects provided for by the Act.

Thus, anyone may ask to be the subject of an inspection as stipulated by the act or regulation *"except in the case of dishonesty on the part of the applicant, an inappropriate request or when the effect of the request is clearly to compromise the correct functioning of the service or place the administration in a situation whereby it is incapable of correctly carrying out its inspection programme"*. Even if the Act states that the express conclusions of this inspection may be enforceable on the administration, it also states that *"these express conclusions cease to be enforceable: 1° In the event of a change in the subsequent legal or actual situation such as to affect their validity; 2° When the administration carries out a further inspection giving rise to new express conclusions"*. In addition, the provisions on the enforceability of the inspection may not constitute an obstacle

to *"the application of the legislative or regulatory provisions directly protecting public health, the safety of individuals and property or the environment"*.

2.2 _ Decrees and Orders

2.2.1 _ Radiation protection

Three Decrees were published on 5 June 2018, more particularly transposing Council Directive 2013/59/Euratom of 5 December 2013 setting Basic Standards for Health Protection against the dangers resulting from exposure to ionising radiation. They more specifically modify the regulatory parts of the Defence, Environment, Public Health and Labour Codes, and thus supplement the regulatory framework of certain nuclear activities:

• Decree 2018-434 of 4 June 2018 implementing various nuclear provisions entirely modifies Chapter III of Part III of Book III of Part one of the Public Health Code (Articles R. 1333-1 to R. 1333-175). It comprises new measures reinforcing the general protection of the population, notably with regard to natural sources of ionising radiation, and of persons exposed for medical purposes. These new provisions transpose the provisions of the Directive of 5 December 2013 and create additional tools for reinforcing the effectiveness of the oversight of nuclear activities: the possibility of implementing land use restrictions on sites contaminated by radioactive substances and monitoring the protection of certain sources of ionising radiation (in particular those used in industry) against malicious acts. The main changes include those concerning:

- the administrative procedures covering the protection of sources against malicious acts ("source security");
- the new system applicable to small-scale nuclear activities (medical, veterinary, industrial and research applications), with the introduction of the registration system (simplified licensing) in addition to the existing notification and authorisation systems, thus reinforcing the graded approach according to the potential issues involved.

• Decree 2018-437 of 4 June 2018 concerning the protection of workers against the hazards of ionising radiation entirely modifies the provisions of Chapter 1 of Part V of Book IV of Part four of the Labour Code, which have been revised in full (Articles R. 4451-1 to R. 4451-135). The changes are not limited to the transposition of the new provisions of the Directive of 5 December 2013 but also propose a simplification of the existing provisions. More particularly, a grading of requirements more closely matching the risks run by the workers was adopted, along with closer harmonisation between the approach applicable to the ionising radiation risk and that adopted for the other occupational risks.

The main changes more specifically concern:

- regulatory limits: the limit for exposure of the lens of the eye is reduced to 20 mSv/year (from 150 mSv/year), although with a transitional implementation period of five years;
- the organisation of radiation protection; this is now based on the appointment of a "Radiation Protection Adviser" who, as chosen by the employer, may be either the Radiation Protection Expert/Officer, or a Certified Radiation Protection Organisation (OCR).

• Decree 2018-438 of 4 June 2018 concerning protection against the risks from ionising radiation to which certain workers are exposed, modifying the health and safety rules for the prevention of risks arising from naturally occurring or artificial ionising radiation applicable to pregnant women, women who have recently given birth, or nursing women, and young workers, more particularly with regard to the dose limit values and the information and training procedures. It specifies the working conditions in which staff holding a limited duration contract and temporary staff may not be employed, in order to take account of technological changes to the working equipment, notably that generating pulsed ionising radiation fields.

Radon

The Order of 27 June 2018 was also published, **determining the zones with radon potential in France.** This Order places municipalities in one of the three radon potential zones defined in Article R. 1333-29 of the Public Health Code, in which information, evaluation or measurement measures and radon exposure prevention measures specified in Articles L. 1333-22 of the Public Health Code, L. 125-5 of the Environment Code and L. 4451-1 of the Labour Code are taken by the parties concerned. This new municipality level map takes the place of the *département* level map which has been in place since 2004 (the list of the 31 priority *départements* is repealed).

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 to ensure that these waters comply with the regulation quality references and entail no risk to the health of consumers. ASN published opinion 2018-AV-0315 of 16 October 2018 concerning two draft orders which more particularly aim to create a shared approvals procedure for laboratories measuring radioactivity in the EDCH for the purposes of the health check. This approval, which is currently issued by the Ministry in charge of Health, will only be issued after obtaining an approval within the framework of the national environmental radioactivity monitoring network, issued by ASN (see point 2.3.3 – National environmental radioactivity Monitoring Network).

2.2.2 _ Basic Nuclear Installations (BNIs)

• 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 2015-992 of 17 August 2015, Ordinance 2016-128 of 10 February 2016 comprising various nuclear provisions and, with respect to ASN, by Act 2017-55 of 20 January 2017 concerning the general status of independent administrative Authorities and independent public Authorities, entails modifications to the regulatory provisions in force.

After the provisions concerning the BNI modification and decommissioning Systems and the rules concerning subcontracting brought about by Decree 2016-846 of 28 June 2016, other provisions concerning the Local Information Committees (CLIs), renewal of the ASN Commission, the ASN sanctions commission, third-party assessments and the transposition of the IED and Seveso Directives for BNIs are yet to be adopted.

Other provisions need to be modified to ensure good interfacing and interaction with new provisions which have been introduced since 2007, for example those concerning the environmental assessment, or following experience feedback, for example concerning the provisions surrounding a change in licensee.

On this occasion, the Minister responsible for Nuclear Safety decided to codify all the regulatory provisions in force (8 decrees). ASN was closely involved in producing this draft decree, which entailed extensive consultation with the stakeholders. After consulting the stakeholders and the public between September 2017 and January 2018, the High Council for the Prevention of Technological Risks – and then ASN – issued their opinions on 13 March and 21 June 2018 respectively.

The draft decree was referred to the Council of State at the end of November 2018 and was published on 16 March 2019 (Decree 2019-190 of 14 March 2019).

• The Order of 3 September 2018 modifying certain provisions applicable to nuclear pressure equipment and certain security accessories designed to protect it

Following the codification in the Environment Code of the provisions applicable to the in-service monitoring of nuclear pressure equipment, the Order of 3 September 2018 brought the various orders dealing with the in-service monitoring of this equipment into line with the Environment Code, while improving the way in which the two texts interface and interact. This modifying Order also clarified conformity assessment procedures and introduced a certain number of additional requirements based on experience feedback from application of the existing texts. Provisions more particularly concerning the accreditation of test laboratories or the conservation of material resulting from the manufacture of components were thus added.

2.2.3 _ Transport of radioactive substances

• Revision of the Order of 29 May 2009 concerning the carriage of dangerous goods by land (called the "TMD Order").

The Order of 29 May 2009 concerning the carriage of dangerous goods by land (known as the "TMD Order") covers the carriage by road, rail and river of dangerous goods, notably radioactive substances. It was modified by the Order of 11 December 2018 in order to take account of the changes to international and community regulations concerning the carriage of dangerous goods by road, which come into force on 1 January 2019. This revision also:

- incorporates new notification procedures on the ASN on-line services portal for events involving radioactive material transports on the public highway;
- specifies the contents of the radioactive materials transport incident and accident management plans mentioned in sections 1.4.1.1 and 1.4.1.2 of the European Agreement on the international carriage of dangerous goods by Road (ADR);
- clarifies the fact that the obligation to draw up a radiological protection programme mentioned in section 1.7.2 of the ADR applies to all companies involved in radioactive materials transport operations;
- specifies the procedures for use of the orange sign on conveyances corresponding to a single UN number which are not for "exclusive" utilisation.

2.3 _ ASN resolutions

2.3.1 _ 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.

• Draft resolutions in progress

In 2018, two draft resolutions concerning patient radiation protection were the subject of a public consultation. They concern:

- the diagnostic reference levels in medical imaging;
- continuing training of health professionals in patient radiation protection (modification of ASN resolution 2017-DC-0585 of 14 March 2017 concerning continuing training of professionals in the radiation protection of persons exposed to ionising radiation for medical purposes).

2.3.2 _ Transport of radioactive substances

• Revision of ASN resolution 2015-DC-0503 of 12 March 2015 relative to the notification system for companies transporting radioactive substances on French territory

The transposition into French law of Council Directive 2013/59/Euratom of 5 December 2013 led to a modification of the Public Health Code, with the various nuclear activities being split into the three notification, registration and authorisation administrative systems. Article R. 1333-146 of this Code refers to an ASN resolution to specify the characteristics of radioactive substances, the transport of which is covered by a particular system, the exemption conditions, the composition of the authorisation application file, the examination procedures, and the renewal, revocation and suspension conditions. In early January 2019, ASN consulted the public on the guidelines adopted for updating its resolution 2015-DC-0503 relative to the notification system for companies transporting radioactive substances on French territory. This update aims to introduce an authorisation system for the transport of sources with the highest safety and security implications.

2.3.3 _ The French National Network for environmental radioactivity Monitoring (RNM)

• ASN resolution 2018-DC-0648 of 16 October 2018 modifying ASN resolution 2008-DC-0099 of 29 April 2008 relative to the organisation of the National Network for environmental radioactivity Monitoring and setting out approval procedures for laboratories

ASN resolution 2008-DC-0099 of 29 April 2008, modified for the first time in 2015, sets out the organisation of the National Network for environmental radioactivity Monitoring (RNM) and the procedures for approval of laboratories by ASN.

This resolution was once again modified by ASN resolution 2018-DC-0648 of 16 October 2018, notably in order to introduce a new type of approval corresponding to the measurement of radon 222 in water. This revision allows alignment between the procedures for the approvals issued by ASN for the RNM and by the Directorate General for Health (DGS) for the health checks on waters intended for human consumption, respectively, which are based on common technical requirements: to obtain approval from the DGS, these laboratories must now first have obtained approval from ASN (see point 2.2.1 EDCH).

Pursuant to resolution 2008-DC-0099, ASN proceeded as follows:

- in resolution CODEP-DEU-2018-046580 of 26 September 2018, it appointed qualified persons for a period of five years, along with representatives of the approved laboratories, to sit on the environmental radioactivity monitoring laboratories approval Committee;
- in resolution CODEP-DEU-2018-046583 of 26 September 2018, it renewed the RNM steering Committee which sets the guidelines for the RNM. This Committee comprises representatives of all the network's stakeholders: ministerial departments, regional health agencies, representatives of nuclear licensee or association laboratories, members of the CLI, of IRSN, of ASN, etc.

2.4 _ ASN guides

• ASN Guide No. 29: Radiation protection in radioactive substances transport activities

The inspections carried out by ASN reveal that the risk of exposure to ionisation radiation is not adequately taken into account in the preventive measures relating to the transportation of radioactive substances. Yet some transport activities have significant radiation protection implications, particularly for the workers, owing to their close proximity to the packages. The annual dose for a driver transporting radiopharmaceuticals can thus reach 14 millisieverts per year (mSv/year), the maximum regulatory value being set at 20 mSv/year. ASN Guide No. 29 aims to help carriers meet their regulatory obligations relative to the radiation protection of workers and the general public. It highlights the relationships between the applicable texts, such as the Order of 29 May 2009 relative to the carriage of dangerous goods by land, and the Labour and Public Health Codes. The Guide includes the ASN recommendations regarding the minimum content of the radiological protection programme required by the regulations, along with concrete examples.

2.5 _ The professional guides approved by ASN

On the basis of Article R. 1333-69 of the Public Health Code, ASN resolution 2017-DC-0585 of 14 March 2017, on the continuing training of professionals in the radiation protection of persons exposed to ionising radiation for medical purposes, introduced an approval procedure for continuing professional training guides on patient radiation protection intended for health professionals.

In 2018, nine guides were approved:

- the continuing training guide for the radiation protection of persons exposed to ionising radiation for medical purposes intended for radiographers working in medical imaging (conventional radiology, computed tomography);
- the continuing training guide for the radiation protection of persons exposed to ionising radiation for medical purposes intended for paramedical professionals (radiographers, technicians and nurses) working in nuclear medicine;
- the continuing training guide for the radiation protection of persons exposed to ionising radiation for medical purposes intended for health professionals in the external radiotherapy and brachytherapy sectors, comprising the guide produced with the French Society of Oncological Radiotherapy (SFRO), the French Society of Medical Physics (SFPM) and the French Association of Paramedical Radiography Personnel (AFPPE);
- the continuing training guide for the radiation protection of persons exposed to ionising radiation for medical purposes intended for physicians qualified for radio-diagnosis and medical imaging;
- the continuing training guide for the radiation protection of persons exposed to ionising radiation for medical purposes intended for medical physicists working in medical imaging (conventional radiology, computed tomography, fluoroscopy-guided interventional practices);
- the continuing training guide for the radiation protection of persons exposed to ionising radiation for medical purposes intended for dentists;
- the continuing training guide for the radiation protection of persons exposed to ionising radiation for medical purposes intended for paramedical professionals working in nuclear medicine;
- the continuing training guide for the radiation protection of persons exposed to ionising radiation for medical purposes intended for preparation staff in hospital pharmacies;
- the continuing training guide for the radiation protection of persons exposed to ionising radiation for medical purposes intended for radio-pharmacists.

ASN has 11 regional divisions through which it carries out its regulatory responsibilities throughout metropolitan France and in the French overseas *départements* and collectivities. Several ASN regional divisions can be required to coordinate their work in a given administrative region. As at 31 December 2018, the ASN regional divisions totalled 226 employees, including 171 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. They check application within these installations of the regulations relative to nuclear safety and radiation protection, to pressure equipment and to Installations Classified for Protection of the Environment (ICPEs). They ensure the labour inspection in the nuclear power plants.

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 preparedness for these situations, they help prepare the emergency plans drawn up by the Prefects and take part in the periodic exercises.

The ASN regional divisions contribute to the public information duty. 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 concerning informing 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 NPPs operated by EDF:
  - Bugey (4 reactors of 900 MWe);
  - Saint-Alban/Saint-Maurice (2 reactors of 1,300 MWe);
  - Cruas-Meysse (4 reactors of 900 MWe);
  - Tricastin (4 reactors of 900 MWe);
- the nuclear fuel fabrication plants operated by Framatome in Romans-sur-Isère;
- the nuclear fuel cycle plants operated by Orano Cycle and its subsidiaries on the Tricastin industrial platform;
- the Operational Hot Unit at Tricastin (BCOT) operated by EDF;
- the High Flux Reactor operated by the Laue-Langevin Institute in Grenoble;
- the Activated waste packaging and storage facility (Iceda) under construction on the Bugey nuclear site and the Bugey Inter-Regional Warehouse (MIR) 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 irradiation facility in Dagneux;
- the nuclear fuel fabrication plant and pelletizing unit of SICN in Veurey-Voroize, waiting to be delicensed;
- the CEA (French Alternative Energies and Atomic Energy Commission) reactors and plants in Grenoble, decommissioned and waiting to be delicensed;
- the CERN international research centre located on the Swiss-French border;

see p. 200

- small-scale nuclear activities in the medical sector:
  - 22 external-beam radiotherapy departments;
  - 6 brachytherapy departments;
  - 23 nuclear medicine departments;
  - about 150 centres carrying out fluoroscopy-guided interventional procedures;
  - 120 computed tomography scanners;
  - some 10,000 medical and dental radiology devices;

see p. 230

- small-scale nuclear activities in the veterinary, industrial and research sectors:
  - one synchrotron;
  - 700 veterinary structures (practices or clinics);
  - about 30 industrial radiology agencies;
  - about 600 users of ionising radiation in the industrial sector;
  - about 100 research units;

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- activities linked to the transport of radioactive substances;
- 3 head offices and 8 agencies of approved bodies.

In 2018, ASN carried out 337 inspections in the Auvergne-Rhône-Alpes region, comprising 116 inspections in the Bugey, Saint-Alban/Saint-Maurice, Cruas-Meysse and Tricastin nuclear power plants, 102 inspections in plants and installations undergoing decommissioning, 109 inspections in small-scale nuclear activities and 10 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.

ASN drew up three violation reports in the exercise of its oversight duties.

ASN was notified of 31 significant events rated level 1 on the INES scale, of which 29 occurred in BNIs and 2 in small-scale nuclear activities. In the small-scale nuclear activities, 10 events concerning radiotherapy patients were rated level 1 on the ASN-SFRO scale and one was provisionally rated level 2.

Bugey Site

Bugey nuclear power plant

The Bugey NPP, situated in the municipality of Saint-Vulbas in the Ain *département*, 35 km east of Lyon and operated by EDF, comprises four pressurised water reactors, 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 accommodates one of the regional bases of the FARN (Nuclear Rapid Intervention Force), a special emergency response force created by EDF in 2011 following the Fukushima 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.

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

Reactors 2, 3, 4 and 5 in operation

ASN considers that the nuclear safety, radiation protection and environmental protection performance of the Bugey NPP is in line with its general assessment of EDF's performance. The NPP maintains a high level of proficiency in the area of operating and maintenance activities. ASN has nevertheless noted weaknesses in environmental protection and the control of fire-related risks.

With regard to nuclear safety, the performance of the Bugey NPP in the areas of reactor management and periodic tests in 2018 is satisfactory. The site must remain vigilant in its preparation and performance of routine operating tasks such as the manoeuvring of valves or installation configuring actions carried out from the control room.

With regard to maintenance, the 2018 workload was higher than in 2017, with three maintenance outages on reactors 4, 5 and 2. The performance of the Bugey NPP showed improvements and ASN notes that an effort has been made to limit the contingencies and technical events resulting from inadequate application of the procedures.

With regard to protection of the environment, ASN notes that the Bugey NPP must improve its prevention of risks of leakage in buried structures (pipes and conduits) carrying radioactive and/or chemical fluids. ASN nevertheless notes that the overall performance of the NPP is satisfactory with regard to regulatory compliance in its management of effluents and waste.

In the area of radiation protection, the performance of the Bugey NPP is mixed. Although the governance principles described in the organization are appropriate, they are not visibly applied in the field. In 2018, ASN noted a large number of deviations from requirements by workers (noncompliance with radiological zoning, noncompliance with radiological checks on leaving controlled areas, etc.)..

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.

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.

Nevertheless, the main decommissioning operations, such as removal of the waste stored in the reactor vessel and decommissioning of the vessel itself, have been postponed due to difficulties in accomplishing the operations to decommission the reactor vessel under water. A scenario of decommissioning «in air» is therefore now being studied. This change of strategy would result in the decommissioning of the Bugey 1 reactor being pushed back by several decades, meaning that the decommissioning deadline (2027) set by its decree would no longer be met. (see chapter 13).

In addition to this, EDF has carried out the Bugey 1 periodic safety review and submitted it to ASN in December 2018.

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, the production quality file, the start-up tests, waste management and the operating documents. EDF submitted its response to ASN's requests at the end of 2018.

The last finishing operations and the pre-commissioning tests were continued in 2018.

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 work site. ASN notes that the test programme is running significantly behind schedule. EDF now envisages commissioning the facility in the second half of 2019.

ASN has moreover continued its examination of the application file for approval of the packaging of Intermediate-Level Long-Lived Waste (ILW-LL) in «C1PGSP» packages in the Iceda facility, submitted by EDF in November 2015 and supplemented in May 2016 at the request of ASN. ASN has not been able to give its approval on the basis of the examination of the file as it currently stands. Further studies are 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 to integrate ASN's requests.

Inter-Regional Warehouse

The Inter-Regional Warehouse (MIR – BNI 02) operated by EDF at Bugey is a storage facility for fresh nuclear fuel intended for the nuclear power plant fleet in service.

The level of safety of MIR was satisfactory in 2018. The periodic safety review of the facility is in progress, as are the stress tests required by ASN in the wake of the Fukushima NPP accident. The facility has more specifically been modified to improve control of the risk of flooding.

Saint-Alban/Saint-Maurice nuclear power plant

The Saint Alban/Saint Maurice 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 pressurised water reactors commissioned in 1986 and 1987. Reactor 1 constitutes BNI 119 and reactor 2 BNI 120.

ASN considers that the radiation protection performance of the Saint-Alban/Saint-Maurice NPP stands out positively with respect to the general assessment of the EDF plants. With regard to nuclear safety and protection of the environment, the performance is in line with the general standard of the EDF plants.

ASN observes that the nuclear safety results for the Saint-Alban/Saint-Maurice NPP in 2018 are satisfactory. ASN notes in particular that the vigilance in fighting fire outbreaks paid off in 2018 and that EDF competently managed the regular outages of reactors 1 and 2, which were affected respectively by a technical problem on the control rod clusters and constraints associated with the rise in temperature of the river Rhône. ASN nevertheless observes that EDF must make progress in the configuring of systems.

Concerning maintenance work, the third ten-yearly outage of reactor 2 went smoothly on the whole, particularly with regard to the integration of modifications.

With regard to environmental protection, the organisation defined and implemented by EDF to meet the regulatory requirements concerning the monitoring of environmental discharges seems satisfactory on the whole. The site has made progress in waste management.

With regard to radiation protection, ASN notes that the operational results were satisfactory. This assessment was confirmed during the tightened inspections campaign conducted in the Rhône-Alpes region in 2018 on the theme of radiation protection.

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 pressurised water reactors of 900 MWe each. Reactors 1 and 2 constitute BNI 111 and reactors 3 and 4 constitute BNI 112.

ASN considers that the overall performance of the Cruas-Meysse NPP falls short of its general assessment of EDF performance.

In 2018, ASN noted shortcomings more particularly in the handling of deviations and in environmental protection. ASN therefore considers that EDF must rapidly put in place fundamental measures to restore, in the field, the required technical capacities to maintain the conformity of its installations with the equipment design, manufacturing, production and operating requirements.

As regards nuclear safety, ASN notes some improvements with respect to 2017. The Cruas-Meysse NPP is showing greater compliance with the operating technical specifications, with indicators that having been pointing upwards over the last five years. ASN thus notes a drop in the number of reactor trips and better management of the activities that involve placing system components in a given configuration such that the system and equipment meet operating, availability and safety targets. In late 2017, ASN issued a resolution requiring the Cruas-Meysse NPP to ensure tightened oversight of the operations performed on equipment ensuring the dependability of control of nuclear chain reactions. ASN notes that EDF has taken the subject duly in hand, notably by identifying difficulties in personnel training and shortcomings in the knowledge of certain equipment and in reactor management. A follow-up inspection showed that EDF had put in place a suitable organisation to meet the requirements of the ASN resolution. However, a significant event reported by EDF in September 2018 shows that EDF must continue its efforts and maintain its vigilance in this area.

The fire risk remains a subject of concern on the site. Despite a reduction in the number of fire outbreaks in 2018, ASN considers it absolutely vital for the NPP to improve its organisation in this respect.

Concerning reactor outages, ASN considers that the situation shows a mixed picture; EDF must improve the quality of reactor outage preparation by safeguarding its internal processes.

With regard to environmental protection, the summer of 2018 was marked by two cases of water table pollution, one by tritium, the other by hydrocarbons.

With regard to radiation protection, 2018 continues in line with the preceding years: collective dosimetry is controlled but there are difficulties in obtaining satisfactory levels of radiological cleanliness during reactor outages and deficiencies in the control of access to areas with high dosimetric risks.

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 harbours a large number of installations, with a nuclear power plant comprising four 900 MWe reactors, nuclear fuel cycle facilities, and the BCOT (Operational Hot Unit) which fulfils maintenance and storage functions. 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*.

Tricastin nuclear power plant

The Tricastin NPP comprises four 900 MWe pressurised water reactors: 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.

In 2016 and 2017, ASN obliged shutdowns of all or part of the facility, due firstly to the question of carbon segregation in the steam generators, and secondly to the deficiency in the earthquake resistance of the embankment protecting the Tricastin NPP against flooding. ASN observes that the management of these outages and the simultaneous restarting of the Tricastin reactors was a real challenge which EDF managed capably on the whole, with no noteworthy significant events.

With regard to nuclear safety, although the NPP's performance was satisfactory until the end of the summer, with areas showing progress (compliance with the operating technical specifications, the configuring of systems, processing alarms in the control room, etc.), ASN nevertheless noted weaknesses in operating quality in the autumn, with the reporting of twelve significant safety-related events in September and October 2018. ASN notes that the Tricastin NPP still has weaknesses in the area of periodic tests. With regard to maintenance, ASN notes that despite the busy industrial programme for 2018, the scheduled refuelling and maintenance outages were capably managed on the whole.

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. ASN notes persistent weaknesses in the radioactive effluent treatment systems and the question of liquid effluent containment. Waste management, can also be improved.

With regard to radiation protection, at the end of a tightened inspection ASN noted shortcomings in the management of contaminated workers, particularly when skin contaminations were concerned. ASN noted above all that this issue is not adequately followed-up in the NPP's integrated management system.

In June 2019, the Tricastin NPP reactor 1 will be the first in the French fleet of 900 MWe reactors operated by EDF to undergo its fourth 10-yearly outage, which is a stage of the 4th periodic safety review. ASN will be particularly attentive to this 10-yearly outage and will deploy a specific oversight plan.

Nuclear fuel cycle installations

The Tricastin fuel cycle installations mainly cover the upstream activities of the fuel cycle and, as of the end of 2018, they are 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 the BNI) for converting depleted UF_6 into U_3O_8;
- **the former Comurhex** facility (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 (BNIs 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 BNI (DBNI) which more particularly operates the nuclear materials storage areas, virtually all of which are for civil uses.

In the light of its on-site inspections carried out in 2018, ASN considers that the level of safety of the Orano Cycle facilities on the Tricastin site has improved, particularly thanks to the gradual shutdown of the oldest facilities, the commissioning of facilities with reassessed safety standards and the completion of the works stemming from the lessons learned from the Fukushima NPP accident.

The in-depth inspection conducted by ASN on the site in 2018, comprising in particular several exercises and in-situation scenarios, revealed the emergency management organisation and means – which are shared – to be adequate for emergency situation management, whatever the accident-stricken facility. ASN moreover considers that the presence of a local emergency response force, its organisation, the means at its disposal and the quality of its action constitute an asset in the emergency organisation of the Orano Cycle platform at Tricastin, given the chemical and nuclear accident risks involved in the operation of its facilities.

In the light of the other inspections carried out in 2018 on the platform and at site central management, ASN considers that Orano Cycle must improve the follow-up of its commitments made with ASN and monitor its service providers more closely. The radioactive substance transport operations, which are now organised centrally, are managed satisfactorily.

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 uranium from reprocessing is placed in storage on the Tricastin site. The W plant situated within the perimeter of BNI 155 can process the depleted UF_6 from the Georges Besse 2 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, 2018 saw the implementation of the commitments made further to the periodic safety review of the facility. The progress with these commitments and the organization put in place to track them regularly have been verified by ASN and found to be satisfactory.

After completing its tests, the new UF_6 emission unit (EM3) of the W plant was commissioned in mid-2018 and is now in the reliability-enhancement phase. This new unit provides better containment in the event of UF_6 leakage and better resistance to internal hazards (fire, explosion, etc.) and external hazards (earthquake). The old unit was shut down within the deadlines set by ASN (30 June 2018). The ASN resolution setting the requirements applicable to the W plant was modified in May 2018 to regulate operation of the EM3 unit.

More generally, the licensee must continue to improve operating rigour and more specifically the detection and management of deviations. ASN remains attentive to the maintaining of the required rigour in operating and maintenance actions, the management of detected anomalies and the effectiveness of the corrective actions put in place.

Putting in place a sole licensee

With a view to simplifying the legal organisation of the Areva Group, a process to merge the Areva subsidiaries present on the Tricastin site was initiated in 2012, so that Areva NC could become the sole licensee of all the site BNIs. This process was completed for the Comurhex BNI in 2013. The process to change the licensee from Socatri, Eurodif and *Société d'Enrichissement du Tricastin* (SET) was completed in 2018.
Orano Cycle, formerly Areva NC, is therefore now the sole licensee of all the cycle facilities on the site.

In addition, further to the waste management deficiencies detected in 2017, an unannounced inspection on this subject was carried out in March 2018. This inspection confirmed recurrent shortcomings in the implementation of the requirements relative to waste management. At the end of this latter inspection, ASN asked Orano Cycle to put in place a complementary plan, combined with inspection and monitoring measures, with the aim of lastingly reinforcing compliance with the rules for waste identification, management and storage. In 2019, ASN will check that this plan has been implemented and enables the required standard of conformity to be reached.

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 February 2014, Orano Cycle submitted a decommissioning file for BNI 105 (formerly Comurhex), which underwent a public inquiry in 2017 and its examination by ASN continued in 2018. The main issues associated with the decommissioning of BNI 105 are linked to the risks of dissemination of radioactive substances, exposure to ionising radiation and criticality, due to the residual uranium-bearing substances present in certain items of equipment.

Under the effect of the hot summer temperatures, two drums of uranium-bearing materials stored in this facility developed leaks, leading in the case of one drum to the dispersion of contamination outside the storage building, with no consequences outside the site. This event was rated level 1 on the INES scale. ASN has asked for the creation of a containment chamber to store the drums pending their repackaging, and the renovation of the floor surfaces to achieve a satisfactory level of containment. More generally ASN expects the licensee, in 2019, to reinforce the containment of its old facilities and the means dedicated to their monitoring.

The tests of the new production units of the Comurhex 2 project, grouping the facilities for converting uranium tetrafluoride (UF_4) into uranium hexafluoride (UF_6), continued in 2018 with the introduction of UF_4 into the plant systems in autumn. Orano Cycle had difficulties in validating the operation of certain equipment items due either to processes which turned out to be ill-suited or to construction defects.

The inspections carried out in 2018 showed that the validation processes prior to the commissioning of new facilities were satisfactory on the whole but should be applied with greater rigour. ASN also noted a lack of rigour in the first operating activities.

The licensee must apply greater rigour in the operation of its facilities, both old and new. It must also, as of 2019, improve the containment of the old facilities until the radioactive substances stored in them have been definitively removed.

Georges Besse I enrichment plant

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

After shutting down production at this plant in May 2012, the licensee – Eurodif production – carried out, from 2013 to 2016, the Eurodif «Prisme» process of «intensive rinsing operations followed by venting», which consisted in performing repeated rinsing of the gaseous diffusions 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. The examination of this file continued in 2018.

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

Further to the Eurodif plant final shutdown and decommissioning preparation operations, which have been under way since 2017, ASN authorised, in August 2018, entry of the shut down facilities into a monitored standby phase which is to last until the start of the first decommissioning operations, planned for 2028. ASN ascertained beforehand, essentially through various inspections, that the facilities were in a safe state. It verified more specifically the prior removal of the operational waste.

ASN will be attentive to the maintaining of rigour in facility monitoring and of a safety culture that is appropriate for the specific shutdown situation of the facilities.

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 areas (BNI 178).

Georges Besse II enrichment plant

The Georges Besse II plant (BNI 168), operated by *Société d'Enrichissement du Tricastin* (SET) until 2018, is 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 2018 was satisfactory. The technologies used in the facility enable high targets for safety, radiation protection and environmental protection to be achieved.

ASN had identified two subjects requiring particular attention in 2017: the fact that the water-presence detectors in the sampling plant ovens were not connected to the instrumentation & control system, an anomaly that was not detected during either the commissioning test or the periodic tests, and the process for assessing physical modifications to the facility, deemed insufficient during an inspection. In 2018 ASN verified that these subjects had been correctly addressed.

The licensee Orano Cycle has demonstrated vigilance with regard to minor deviations. It was thus capable of dealing competently, as soon as it was detected, with a significant safety event rated level 1 on the INES scale concerning insufficient UF_6 solidification times following the taking of liquid samples.

In 2019, the licensee must be particularly careful in defining the items and activities important to protection and their associated requirements in its subcontracted activity specifications. It must also ensure that the operating contingencies which are not covered by handling procedures form the subject of «hold points» involving the service responsible for safety.

Maintenance, effluent treatment and waste packaging facilities (formerly Socatri)

ASN considers that the level of operational safety of the Socatri facilities (BNI 138) was satisfactory in 2018.

Orano Cycle continued implementation of the significant safety improvements prescribed by ASN or for which it had made commitments further to the last periodic safety review of the facility. Nevertheless, improvements in fire-risk prevention are still required.

Alongside this, the licensee conducted tightened inspections of the retention structures in operation, as prescribed by ASN in April 2017. All the retention structures identified as noncompliant by these inspections have been rendered compliant.

Examination of the BNI substantial modification file, involving more specifically the creation of «Trident», a facility for processing the site's waste, was completed with Decree 2019-113 of 19 February 2019. The development work on this facility started in 2018, after receiving authorisation from ASN. Its commissioning will be subject to another ASN authorisation.

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 installation groups the uranium storage areas and the new emergency management premises of the Tricastin platform. ASN registered this installation in December 2016 and has ascertained, with the Defence Nuclear Safety Authority (ASND), the continuity of oversight of the nuclear safety of this installation. The installation baseline requirements are currently being upgraded to be in conformity with the regulatory texts applicable to BNIs.

The results of the ASN inspections conducted since the BNI was registered are satisfactory. Two deviations relative to the availability of communication means in the event of an emergency were noted and are currently being addressed.

In 2017, Orano Cycle filed an application with the Minister responsible for Nuclear Safety to integrate the storage areas currently situated in BNI 93 (Eurodif, Georges Besse I) – which are intended to remain in operation – into this BNI.

P35 facility

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

ASN registered this facility in January 2018 and has ascertained, with ASND, the continuity of oversight of the nuclear safety of these storage areas. The installation baseline requirements are currently being overhauled to ensure conformity with the regulatory texts applicable to BNIs.

The first inspection conducted by ASN in 2018 revealed no anomalies.

Alongside this, under the project to group together the Tricastin site storage areas within a single BNI – the Tricastin uranium-bearing material storage areas BNI, Areva – now called Orano Cycle – filed an application with the Minister responsible for Nuclear Safety in late 2017 to merge BNIs 178 and 179.

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 were commissioned in February 2018 following validation of the prior test results. Commissioning of the last bench, which will finalise the complete commissioning of the facility, is planned for 2019.

During its inspections ASN noted shortcomings in the traceability of proof of conformity of the facilities with the safety requirements and in the traceability of deviations. It thus revealed the fact that the fire hatches of the facility did not undergo a systematic verification of conformity during acceptance of the facility. At the request of ASN, a fire hatch verification campaign was carried out and the noncompliant hatches were rendered compliant in 2018.

ASN also considers that the licensee must improve the management of the waste storage areas and the associated traceability, the management of fire loads, the monitoring of service providers and the tracking of its personnel training courses.

New uranium storage facility project

In February 2015, Orano Cycle informed ASN that it wanted to create a new BNI intended for storage on the Tricastin site of uranium-bearing materials resulting from fuel reprocessing. Orano Cycle has undertaken actions to optimise the site's existing storage areas in order to push back the date they are filled to capacity from 2019 to 2021, and in November 2017 it filed an application for authorisation to create 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 continue in 2019.

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.

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

In 2018, the BCOT continued the cutting up of the used control rod guide tubes from the pressurised water reactors operated by EDF. The operations should be completed in 2020 at the latest.

The examination of the periodic safety review report led ASN to prescribe several improvement measures, particularly concerning worker radiation protection.

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 be now carried out on the Saint-Dizier maintenance base (Bamas). Transfer of the activities and the start of tooling disassembly began in 2018.

Romans-sur-Isère site

Framatome operates two basic nuclear installations on its Romans-sur-Isère site in the Drôme *département*, namely the research reactor fuel fabrication unit (BNI 63) and the pressurised water reactor 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 CERN.

Framatome nuclear fuel fabrication plants

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 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).

Framatome maintained its efforts with regard to rigour of operation in 2018, and implemented an ambitious works programme within its two facilities.

The site continued to increase its personnel numbers in the following areas in 2018: safety, project management, regulatory inspections and service provider monitoring.

During 2018, ASN checked the fulfilment of the commitments made following the periodic safety reviews of the two BNIs (BNIs 98 and 63), which involved additional safety studies or work to reinforce the buildings (fire-risk management, anti-seismic reinforcements, improved containment).

The improvement in safety management and operating rigour is confirmed. These improvements must nevertheless continue, notably through the systematic checking of activities. In effect, 4 events linked to prevention of the criticality risk were reported in 2018 and rated level 1 on the INES scale, and 3 of them gave rise to reactive inspections by ASN.

With regard to radiation protection, the situation has improved but further progress can be made in certain areas. The dosimetric risks nevertheless remain moderate in these facilities which do not use reprocessed uranium.

With regard to environmental protection, the site must further improve its control of the waste management routes, particularly with regard to the distinction between radioactive waste and conventional waste.

In view of the site's significant improvements in safety management, organisation and operating rigour, ASN decided in May 2018 to lift the tightened monitoring constraint which had been placed on the site in 2014.

The other industrial and research facilities

High Flux Reactor of the Laue-Langevin Institute

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

The HFR, 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 ha situated between the rivers Isère and Drac, just upstream of their confluence, near the CEA centre of Grenoble.

ASN considers the HFR safety management to be fairly satisfactory but it has observed deviations in the operating organization during inspections, which have led it to demand improvement measures in certain areas.

The works to set up «hardened safety core» safeguard systems to integrate the lessons learned from the Fukushima NPP accident were completed in the first half of 2018, which is positive.

The setting up of an Integrated Management System (IMS) for quality and safety that meets the requirements of the Order of 7 February 2012 continued in 2018. This system aims to improve the licensee's control of the activities and the state of the facilities.

ASN has noted in particular the ILL's substantial work on its new deviation management process. ASN expected the ILL to improve the tracking and performance of the inspections and periodic tests specified in the general operating rules, and it observed this in 2018. ASN nevertheless considers that the ILL must continue to put in place the other processes of its IMS. It must also associate deployment of this system with training and awareness-raising measures for its teams. Lastly, it must improve worker oversight and monitoring. ASN also expects improvements in the process for managing physical modifications to the facility, as the shortcomings it noted had led it, in February 2018, to serve formal notice on the ILL to comply with the regulations in effect on this subject.

Furthermore, during 2018 ASN observed shortcomings in the tracking of ILL commitments made in the context of the inspection follow-ups and the significant event reports. The effectiveness and the durability of the corrective actions defined in response to deviations, events or ASN findings, must be improved.

Lastly, ASN has asked the licensee to reinforce its organisation for controlling the fire risk. The licensee has set up an action plan.

Alongside this, ASN has conducted a preliminary analysis of the periodic safety review report submitted by the ILL in November 2017. ASN notes the work of the licensee, particularly on the conformity check of Equipment Important to the Protection of interests (EIP) with regard to safety and on the updating of the safety baseline requirements. Nonetheless, a number of shortcomings have been identified, especially regarding the analysis of conformity of the facility with the regulatory requirements, in particular for the hazard risks (fire, aircraft crash, etc.). ASN has therefore asked the licensee to supplement the file so that its examination can be continued.

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, prostheses) and polymerising plastic materials.

The facility displayed a satisfactory level of safety in 2018.

Ionisos must nevertheless improve its analyses of deviations and events, and the communication of information to ASN.

CERN accelerators and research centre (Geneva)

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.

Three joint inspections by the French and Swiss Authorities were held in 2018, focusing on the commissioning of the Medicis facility, the management of inter-site transport of radioactive substances and CERN's fire management organisation. These inspections found the practices on the whole to be satisfactory.

In 2018, ASN and the OFSP also finalised the examination of the safety files submitted by CERN to demonstrate the safety of the new facilities, particularly the Medicis facility designed to produce radioisotopes for medical research purposes.

Installations 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 the commencement of the second Superphénix decommissioning phase, which consists in opening the reactor pressure vessel to dismantle its internal components both *in situ* and in dedicated facilities constructed in the reactor building, by direct or remote manipulation, depending on the activation of the structures.

Following two failures of equipment important to the protection of the facilities, one of them rated a significant event of level 1 on the INES scale, EDF had difficulties in procuring certain items of equipment which had become obsolete. ASN has asked the licensee to establish an action plan for the management of obsolescence.

With regard to emergency situation management and further to ASN's discovery of functional deficiencies, the site reinforced its organisation in 2018. To test its effectiveness, ASN organised a further unannounced night-time exercise. This exercise showed the situation to be satisfactory. These improvements were confirmed during a significant event involving loss of the site electrical power sources which occurred on 14 December 2018 and was rated level 1 on the INES scale.

Lastly, further to deviations in the monitoring of subcontracted activities and the management of waste, observed by ASN during inspections in 2017, the licensee took measures in 2018 to clarify and reinforce the site's organisation in these areas.

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 those relating to the Effluents and solid Waste Treatment Station and decay storage (STED) (BNIs 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 marking, ASN will make delicensing of the STED dependent on the implementation of active institutional controls.

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) comprises two nuclear installations, BNIs 65 and 90. The fuel fabrication activities were definitively stopped in the early 2000's. The decommissioning operations were authorised by Decrees 2006-191 and 2006-190 of 15 February 2006, and the decommissioning work has now been completed.

The site nevertheless displays residual contamination of the soil and groundwater, the impact of which is compatible with the envisaged future use (industrial). ASN has therefore asked the licensee to submit, as a prerequisite to delicensing, an application for the implementation of active institutional controls designed to restrict the use of the soil and groundwater and to guarantee that the land usage remains compatible with the state of the site. 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. It will not be possible to declare this delicensing until these active institutional controls have been effectively put into place by the Prefect of the Isère *département*, following the examination procedure, which includes a public inquiry, in 2019. The Local Information Committee was also consulted about the institutional controls project and the delicencing file, and gave its opinion on them in December 2018.

Labour inspection in the nuclear power plants of the Auvergne-Rhône-Alpes region

Twenty eight labour inspections were carried out during 2018, along with twenty five days of presence in the region's nuclear power plants for meetings, discussions with employees and staff representatives, and participation at the meetings of the committees for health, safety and working conditions.
The inspections are divided between inspections conducted on the sites of maintenance work carried out during the reactor outages and thematic inspections (electrical risk, explosive atmosphere, asbestos risk). Lastly, inspections were also carried out further to serious workplace accidents.

Broadly speaking, what emerges from 2018 is:

- raised awareness and the implementation of an action plan to improve control of the risk associated with explosive atmospheres in the EDF facilities with the need to keep better track of the compliance of its facilities with the requirements of the labour code (electrical risk, ATEX explosion risk);
- the need for EDF to be more involved in the oversight of conformity of the collective protective means intended to limit contamination dispersion;
- the need, more generally, to continue the radiation protection efforts;
- the need for real-time updating of the work-related documents during the works so that the collective andindividual protection requirements are consistent with the states of the work site and the associated risks.

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:

see p. 200

- small-scale nuclear activities in the medical sector:
  - 8 external-beam radiotherapy departments;
  - 4 brachytherapy departments;
  - 14 nuclear medicine departments;
  - 36 centres performing fluoroscopy-guided interventional procedures;
  - 52 computed tomography scanners;
  - about 800 medical radiology devices;
  - about 2,000 dental radiology devices;

see p. 230

- small-scale nuclear activities in the veterinary, industrial and research sectors:
  - about 200 veterinary practices, 3 of them equipped with scanners;
  - about 400 industrial and research establishments, including 28 companies exercising an industrial radiography activity;
  - 162 users of devices for detecting lead in paint;
  - 2 accelerators;

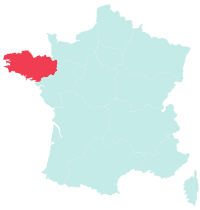
see p. 256

- activities linked to the transport of radioactive substances;
- approved laboratories and organisations:
  - 3 organisations approved for radiation protection controls, with 4 agencies;
  - 5 organisations approved for radon monitoring and 1 laboratory approved for measuring radioactivity in the environment.

In 2018, ASN carried out 53 inspections in the Bourgogne-Franche-Comté region in small-scale nuclear activities and 5 inspections relative to the transport of radioactive substances.

Among the significant events reported and analysed to draw lessons from them, 7 events concerning radiotherapy or brachytherapy patients were rated level 1 on the ASN-SFRO scale, while 2 events concerning the theft or loss of a radioactive source were rated level 1 on the INES scale.

ASN also devoted particular attention to the Framatome manufacturing plants situated in the Bourgogne-Franche-Comté region. The steps taken by ASN in this respect are described in chapter 10.



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, undergoing decommissioning;

see p. 200

- small-scale nuclear activities in the medical sector:
  - 8 external-beam radiotherapy departments;
  - 5 brachytherapy departments;
  - 11 nuclear medicine departments;
  - 37 centres performing fluoroscopy-guided interventional procedures;
  - 54 computed tomography scanners;
  - some 2,500 medical and dental radiology devices;

see p. 230

- small-scale nuclear activities in the veterinary, industrial and research sectors:
  - 1 cyclotron;
  - 20 industrial radiography companies;
  - about 450 licences for industrial and research equipment, including 325 users of devices to detect lead in paint;

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- activities linked to the transport of radioactive substances;
- approved laboratories and organisations:
  - 6 radiation protection technical control agencies;
  - 7 radon screening agencies;
  - 4 head offices of laboratories approved for taking environmental radioactivity measurements.

In 2018, ASN carried out 49 inspections, comprising 2 inspections in the Monts d'Arrée NPP undergoing decommissioning and 47 in small-scale nuclear activities including 2 relating to the transport of radioactive substances.

Among the 37 significant events reported and analysed to draw lessons from them, 12 events concerned radiotherapy patients and 6 of these were rated level 1 on the ASN-SFRO scale and 1 was rated level 2. One event concerning a brachytherapy patient was rated level 2 on the ASN-SFRO scale.

ASN drew up two violation reports in the exercise of its oversight duties.

The Brennilis NPP

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 part of the decommissioning operations, with the exception of decommissioning of 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;
- clean-out and demolition of the effluent treatment station.

These operations were to be completed before 28 July 2018.

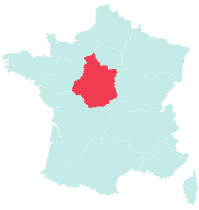
During 2018, EDF continued decommissioning of the Effluent Treatment Station (STE). The basement demolition work, which began in August 2016, was completed in early 2018 due to various work site contingencies. EDF then started the operations to remove the polluted soil situated beneath the STE, in accordance with the soil management plan approved by ASN in April 2018. The partial decommissioning operations were not yet completed on 28 July 2018.

Moreover, in accordance with the amending Decree of 16 November 2016, EDF submitted the complete decommissioning file for the reactor in July 2018. This file is currently being examined by ASN.

Alongside this, EDF finalised the worksite teardown operations for the reactor containment heat exchanger decommissioning site after the fire that occurred in September 2015. ASN considers that the licensee conducted this work in compliance with the safety and radiation protection requirements.

In 2018, the licensee also started arrangements and the work to render secure the reactor building with a view to preparing the operations to take samples from the reactor block. These sampling operations were subject to the prior consent of ASN through a resolution of 21 August 2017. EDF has submitted an application file which is currently being examined by ASN.

ASN considers that the licensee shows rigour and transparency in its handling of the malfunctions and deviations that occur on its site. The management of waste, particularly in the storage areas situated within the reactor containment, and compliance with regulatory requirements need to be improved.



Centre-Val de Loire region

The Orléans division regulates nuclear safety, radiation protection and the transport of radioactive substances in the 6 *départements* of the Centre-Val de Loire region.

THE INSTALLATIONS AND ACTIVITIES TO REGULATE COMPRISE:

- BNIs:
  - the Belleville-sur-Loire NPP (2 reactors of 1,300 MWe);
  - the Dampierre-en-Burly NPP (4 reactors of 900 MWe);
  - the Saint-Laurent-des-Eaux site: the NPP 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);

see p. 200

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

see p. 230

- 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.

In 2018, ASN carried out 145 nuclear safety and radiation protection inspections: 101 inspections of the nuclear installations of the EDF sites of Belleville-sur-Loire, Chinon, Dampierre-en-Burly and Saint-Laurent-des-Eaux, and 44 inspections in small-scale nuclear activities in the Centre-Val de Loire region.

ASN carried out 67 days of labour inspections in the nuclear power plants.

In 2018, 11 significant events rated level 1 on the INES scale were reported by the licensees of the EDF nuclear installations in the Centre-Val de Loire region, to which can be added 7 general events rated level 1 on the INES scale which concerned some of the region's NPPs. In small-scale nuclear activities, one event rated level 1 on the INES scale was reported in 2018, while 3 events concerning radiotherapy patients were rated level 1 on the ASN-SFRO scale.

ASN inspectors issued three violation reports 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 on the whole in line with the general assessment of EDF in the areas of radiation protection and the environment. The performance with regard to safety remains below average, despite the notable improvements made in 2018 and which remain to be consolidated.

In the area of safety, there are still numerous significant events resulting from a lack of rigour in operational control of the facility and ASN observes only slight progress in this respect, despite the alerts of the previous years. To give an example, EDF reported a significant event rated

level 1 on the INES scale due to late detection of a reactor control rod cluster position which was outside the limits set by the installation's safety baseline requirements. ASN nevertheless observed a distinct improvement in the general state of the installations and the detection of anomalies in 2018. It is nonetheless necessary to ensure that these changes in culture are integrated by all the departments and maintained over the long term. Consequently, ASN has decided to maintain the site under tightened surveillance. This situation is likely to change during 2019 depending on the robustness and durability of the actions put in place by the licensee to improve its operating management results. ASN shall specially monitor the improvement plan implemented by the licensee on this subject in 2019.

In the area of radiation protection, ASN underlines the significant efforts made by the site, even though control of the risk of contamination dispersion during reactor outage periods can be improved.

The environmental performance of the Belleville-sur-Loire NPP is comparable with the national average and can be further improved. ASN does however wish to underline the fact that significant improvement work was carried out in 2018, such as the reconditioning of several facilities which could have presented risks for the environment (including the demineralisation station).

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 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 the nuclear safety performance of the Dampierre-en-Burly NPP is on the whole in line with the general assessment of the EDF plants. This being said, its environmental and radiation protection performance are below the national average.

With regard to safety, the results are satisfactory, with a good level of involvement of the independent safety organisation. However, several significant events resulting from a lack of rigour in the management, operation and monitoring of the installations reveal shortcomings in the implementation of practices to enhance worker reliability. This has led the licensee to implement *ad hoc* corrective actions which ASN will monitor with particular attention in 2019. With regard to the maintenance of the installations, ASN considers that improvements can be made in service provider monitoring, spare parts management and the maintenance activities. An increase in the number of maintenance non-qualities on equipment important to safety was effectively observed in 2018. By way of example, EDF reported a significant event rated level 1 on the INES scale on account of late detection of a non-quality in maintenance work performed on the valve of a pipe passing through the reactor containment. Lastly, ASN considers that the site must further improve its management of fire-related risks.

With regard to radiation protection, the site's performance is still below the norm. The findings from ASN inspections and the increase in the number of significant radiation protection events reported in 2018 show that the radiation protection fundamentals are insufficiently taken into account on the worksites (radiological cleanliness, worksite surveillance, non-compliance with optimisation approach, etc.). However, since summer 2018 the licensee has become aware of its weaknesses in this area and has put in place a new action plan – more robust than the one presented in 2017 – to regain control in this area. This situation shall be specifically monitored by ASN in 2019.

With regard to the environment, in the light of the inspections carried out in 2018, ASN considers that the site must make further improvements. This is because although the gaseous and liquid effluent discharges remain within the maximum permitted values, ASN has observed numerous nonconformities, particularly concerning pollution control and prevention and waste management.

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 nuclear power plant 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 Gas-Cooled Reactors designated Chinon A1, A2 and A3, are currently being decommissioned. The site also accommodates the AMI (Irradiated Materials Facility), 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 NPP

Reactors B1, B2, B3 and B4 in operation

ASN considers that the safety and environmental protection performance of the Chinon NPP on the whole is in line with ASN's general assessment of EDF, and that the radiation protection performance is above the national average.

ASN considers that the site is maintaining a satisfactory level with regard to nuclear safety. It underlines improvements in the overall upkeep of the worksites and the completeness of the documents examined during various inspections. Progress is required in the preparation of the risk analyses and in the performance of the system configuring and periodic test activities, which have been the cause of several significant events. Furthermore, the NPP's organisation for detecting deviations and justifying their remediation time frames is not sufficiently robust and must be improved. Lastly, the site must improve its management of the risks relating to fire, explosion and lightning in order to ensure the conformity of its installations with the associated regulations.

The radiation protection performance of the Chinon site is satisfactory, as witnessed by good results in terms of dosimetry and radiological cleanliness. The radiation protection rules are generally well integrated at the preparation stage and during the performance of work in controlled areas, despite the detection of a few deviations.

Although comparable with the national average, the environmental performance of the Chinon site can be improved on the whole. Although the maximum discharge values for gaseous and liquid effluents are respected and the number of environment-related significant events is low, numerous regulatory deviations concerning catering for the legionella and amoeba risks and waste management were noted.

Reactors A1, A2 and A3 undergoing decommissioning

The graphite-moderated Gas-Cooled Reactor (GCR) series comprises six reactors, including the Chinon A1, A2 and A3. These first-generation reactors used natural uranium as the fuel and graphite as the moderator. They 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 since 1986. Chinon A2 D is also partially decommissioned and houses Groupe 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 is currently being examined by ASN (see chapter 13).

The operations to decommission the exchangers (first step in decommissioning of the facility) on the Chinon A3 reactor began several years ago. After an interruption of several months due to the presence of asbestos, decommissioning of the heat exchangers of the south premises of Chinon A3 was completed in June 2018. Regarding decommissioning of the heat exchangers of the north premises, the parts containing asbestos had to be cleaned before starting the operations in 2018.

ASN considers that the level of safety of the Chinon nuclear installations undergoing decommissioning (Chinon A1, A2 and A3) is generally satisfactory. The inspections carried out in 2018 revealed satisfactory control of reactor containment and compliance with EDF's commitments concerning nuclear waste management. Significant improvements have been made in waste monitoring and management. The removal of a large quantity of waste packages resulting from the decommissioning operations is a positive point in this respect.

Nuclear fuel cycle installations

Inter-Regional fresh fuel Warehouse

Commissioned in 1978, the Chinon Inter-Regional 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.

After making several additional information requests between 2015 and 2017, ASN notified EDF in 2018 of the admissibility of the periodic safety review report submitted in 2015 and will continue its examination in 2019.

The facility was emptied of all the fuel assemblies in 2018 to allow the replacement of the handling crane and the «removal» of the levelling slab. With a view to performance of this work, ASN authorised the downgrading of areas of potential nuclear waste production on the facility into conventional waste areas, and the temporary modification of the general operating rules.

Research facilities undergoing decommissioning

Irradiated Materials Facility

The Irradiated Material Facility (AMI), which was declared and commissioned in 1964, is situated on the Chinon nuclear site and operated by EDF. This 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 decommissioning of the facility in view, the activities in the AMI are now essentially monitoring and decommissioning preparation operations. The year 2018 was chiefly taken 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 inspection in the AMI irradiated materials facility - June 2018

The decommissioning file underwent a public inquiry and consultations in 2017. Based on this, ASN continued its examination and drew up a draft decommissioning decree.

ASN considers that the management of waste treatment operations and the monitoring of outside contractors are satisfactory. 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 gas-cooled nuclear reactors, 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 NPP

Reactors B1 and B2 in operation

ASN considers that the performance of the Saint-Laurent-des-Eaux NPP is on the whole in line with the general assessment of EDF in the areas of safety, environment and radiation protection.

With regard to nuclear safety, ASN considers that the site has regressed with respect to the previous years. ASN nevertheless underlines the good general upkeep of the worksites, the satisfactory condition of the components and equipment of the inspected systems, and a high-quality independent safety organisation. This being said, shortcomings in operating rigour and operational control management of the facilities were observed in 2018. Numerous events highlight, for example, deficiencies in the management of operating contingencies and poor monitoring of procedures. The NPP's organisation for characterising deviations and justifying their remediation time frames is not sufficiently robust and must be improved, as must experience feedback management.

Generally speaking, Saint-Laurent-des-Eaux shows satisfactory radiation protection performance, although it came down in 2018. Despite the involvement of the personnel responsible for radiation protection, the traceability and monitoring of dosimetry optimisation actions on high-risk work sites can in particular be improved. Several significant radiation protection events moreover reveal failures of workers to comply with requirements.

The site's organisation to meet the regulatory requirements with regard to the environment can be further improved in a number of aspects. The dedicated department demonstrates resolve to make improvements and progress, supported by an active independent environment organisation. Good practices are observed during the inspections on the various themes addressed. Nevertheless, deficiencies in deviation detection have again been observed in this area. In 2019, ASN will ensure that the site works actively on the reviews of the conformity of its facilities with the regulatory framework.

Reactors A1 and A2 undergoing decommissioning

The former Saint-Laurent-des-Eaux NPP constitutes a Basic Nuclear Installation comprising two «integrated» Gas-Cooled Reactors, Saint-Laurent-des-Eaux reactors A1 and A2. Their final shutdown was pronounced 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).

Pending decommissioning of the reactor pressure vessels, other operations are performed outside the pressure vessel or to prepare for its decommissioning. Some worksites presenting a risk of contamination by alpha radionuclides (emptying tanks, characterising sludge, removing the source term from the Saint-Laurent-des-Eaux A2 pool) had been suspended in 2016 following the discovery of confirmed cases of internal contamination of personnel working on these sites. In 2017, EDF initiated an operating rigour plan which stepped up worker training and monitoring. The worksites were resumed in 2017. ASN has checked the measures defined in the plan and observed improvements in the management of the worksites involving an «alpha» contamination risk.

The liquid and solid waste removal operations continued as part of the decommissioning of the Saint-Laurent-des-Eaux A reactors. Research is still in progress to create a new legacy waste characterisation chamber and to define a storage solution to bring together «legacy waste with projected disposal route» and «legacy waste without disposal routes».

ASN considers that the level of safety of the Saint-Laurent-des-Eaux A reactors is satisfactory. To give an example, the organisation of the aids put in place to monitor waste management and the periodic checks of the installations are satisfactory.

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 (Low-Level Long-Lived Waste - LLW-LL) coming from the operation of Saint-Laurent-des-Eaux A Gas-Cooled Reactors. 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

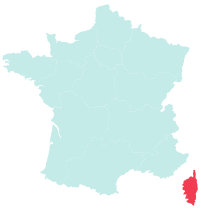
of the silos, the activity of the water table, and monitoring the condition of civil engineering structures). These actions are on the whole carried out satisfactorily.

In the context of its new decommissioning strategy for the GCR, EDF has announced 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 presented the progress of the silo emptying and storage facility studies to ASN in 2018. Complementary studies are in progress to consolidate the scenario and find technical optimisations. EDF plans submitting, at the end of 2020, the application file for authorisation to create a new storage BNI, and the decommissioning file which will take into account the operations to empty, clean-out and demolish the existing silos.

Labour inspection in the nuclear power plants of the Centre-Val de Loire region.

Specific inspections were conducted within the four NPPs of the Centre-Val de Loire region on the themes of fire and personnel evacuation and sheltering in the event of incidents or accidents. These inspections served to check, among other things, compliance with the obligations associated with the utilisation of work places on account of the fire risk. Fire remains a subject of concern that is constantly on the nuclear power plants' agenda, and for which ASN expects significant improvements.



Corse
Collectivity

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

THE INSTALLATIONS AND ACTIVITIES TO REGULATE COMPRISE:

see p. 200

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

see p. 230

- small-scale nuclear activities in the veterinary, industrial and research sectors:
  - some 40 veterinary surgeons using diagnostic radiology devices;
  - about 40 industrial and research establishments, including 25 users of devices for detecting lead in paint;

see p. 256

- activities linked to the transport of radioactive substances.

ASN carried out 4 inspections in Corse in 2018: 1 in the medical sector, 1 in the industrial sector and 2 in the transport of radioactive substances.

Overseas *départements* and regions

The regulation of radiation protection and the transport of radioactive substances in the 6 overseas *départements* and regions (Guadeloupe, Martinique, Guyane, La Réunion, Mayotte, Saint-Pierre-et-Miquelon) is ensured by the Paris division.

The Paris division also acts as expert to the competent authorities of Nouvelle-Calédonie and French Polynésie.

THE INSTALLATIONS AND ACTIVITIES TO REGULATE COMPRISE:

see p. 200

- small-scale nuclear activities in the medical sector:
  - 4 external-beam radiotherapy departments;
  - 3 brachytherapy departments;
  - 4 nuclear medicine departments;
  - 26 centres performing fluoroscopy-guided interventional procedures;
  - about 35 centres in possession of at least one Computed Tomography (CT) scanner;
  - about 100 medical radiology centres;
  - about 1,000 dental radiology devices;

see p. 230

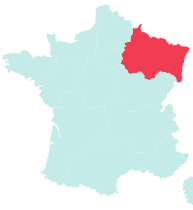
- small-scale nuclear activities in the veterinary, industrial and research sectors:
  - more than 70 users of veterinary radiology devices;
  - 2 industrial radiography companies using gamma radiography devices;
  - 1 cyclotron;

see p. 256

- activities linked to the transport of radioactive substances.

23 inspections were carried out in the small-scale nuclear activities sector in the French Overseas *départements* and regions in 2018. Two on-site inspection campaigns were carried out by the ASN Paris Division.

One event concerning radiotherapy patients was rated level 1 on the ASN-SFRO scale in 2018.



Grand Est region

The Châlons-en-Champagne and Strasbourg divisions are jointly responsible for regulating nuclear safety, radiation protection and the transport of radioactive substances in the 10 *départements* of the Grand Est region.

THE INSTALLATIONS AND ACTIVITIES TO REGULATE COMPRISE:

- BNIs:
  - the Cattenom NPP (4 reactors of 1,300 MWe);
  - the Chooz B NPP (2 reactors of 1,450 MWe);
  - the Chooz A NPP (currently being decommissioned);
  - the Fessenheim NPP (2 reactors of 900 MWe);
  - 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;

see p. 200

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

see p. 230

- small-scale nuclear activities in the veterinary, industrial and research sectors:
  - about 85 veterinary clinics;
  - about 500 licensed industrial activities, with more than half of the licenses being for possession of devices to detect lead in paint;
  - about 50 research laboratories situated mainly in the universities of the region;

see p. 256

- activities linked to the transport of radioactive substances;
- 5 head offices of organisations approved in radiation protection.

In 2018, ASN conducted 181 inspections, of which 71 were in the NPPs, 5 in radioactive waste disposal facilities, 87 in the small-scale nuclear activities sector, 11 in the transport of radioactive substances and 7 concerning approved organisations or approved laboratories.

ASN also carried out 17 days of labour inspections in the NPPs.

During 2018, 16 significant events reported by nuclear installation licensees in the Grand Est region were rated level 1 on the INES scale. In the small-scale nuclear activities sector, 4 significant events were rated level 1 on the ASN-SFRO, and 5 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.

The site comprises four pressurised water reactors each with a unit power of 1,300 MWe, commissioned between 1986 and 1991 and producing each year about 37 TWh, that is to say 7% of EDF's national electricity production. Reactors 1, 2, 3 and 4 constitute BNIs 124, 125, 126 and 137 respectively.

ASN considers that the performance of the Cattenom site with regard to nuclear safety, radiation protection and protection of the environment is in line with the general assessment of the EDF plants, with an improvement in

radiation protection but a persistent shortfall in maintenance and operating operations.

The year 2018 was thus marked by several events associated with maintenance non-qualities, leading to unscheduled shutdowns or replacements of parts. Some of these events are linked to modifications made in 2016 during the third 10-yearly outage of reactor 1, highlighting some one-off shortcomings in their integration; others confirm the need to reinforce the verification of the technical actions of the operators or the monitoring of service providers. Nevertheless, the site's ability to manage incidental events, once clearly identified, remains satisfactory.

An action plan to improve the way operating activities are carried out was put in place in late 2017. ASN notes a reduction in the number of events caused by a lack of vigilance, but considers that the action plan has not yet brought adequate results in the preparation and deployment phases, where control and rigour can be improved.

ASN considers that the efforts undertaken to achieve conformity in environmental aspects must be extended to a reinforcement of the environmental protection culture, to better prevent accidental spillages, inspection equipment downtimes and the crossing of pre-alarm thresholds.

The finely-tuned coordination of the biocide treatments of the cooling towers in 2018 enabled the chemical and micro-organism discharge values to be kept within permissible limits, but the need to perform treatments, including during cold periods – which is a local particularity – could necessitate the adaptation of the prescriptive framework governing discharges.

Lastly, the positive dynamics in radiation protection management observed in 2017 were confirmed in 2018 in a context of more sustained activity: the efforts made with regard to radiological cleanliness and dosimetric optimisation must be continued.

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 comprises 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 two reactors each with a power rating of 1,450 MWe (BNIs 139 and 144) commissioned in 2000.

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 improvements in reactor operation but considers that the required level of rigour has not yet been reached; the licensee must not reduce its efforts in this area. The significant events, which remain numerous, also underline shortcomings in activity preparation and operator training. The quality of the operational documentation and its updating is moreover considered a weak point for the operational control and maintenance activities alike. In this latter respect, care must be taken to ensure that equipment modifications or changes in maintenance requirements are duly integrated.

With regard to radiation protection, ASN considers the site's performance satisfactory on the whole. Dosimetry and radiological cleanliness were well managed during the reactor outages. The site must nevertheless maintain its vigilance to ensure compliance with the basic radiation protection actions.

Lastly, ASN considers that the sites organisation for environmental protection is satisfactory on the whole. Certain events nevertheless revealed uncontrolled discharges of cooling fluids and occasional failures in equipment involved in the monitoring of liquid and gaseous discharges.

Reactor A undergoing decommissioning

The decommissioning work on the reactor A pressure vessel continued in 2018, including in particular the commissioning of the packaging facility for waste resulting from the underwater cutting up of the reactor pressure vessel and the cutting up of its closure head.

The decommissioning work on the equipment still present in the nuclear auxiliaries cavern bunkers was interrupted during the year. This work, chiefly carried out by remote operation, nevertheless involves manual interventions which were poorly evaluated in the initial work file and necessitated reviewing of the radiation protection measures.

With regard to the environment and nuclear safety, ASN considers that the decommissioning operations have been carried out satisfactorily.

No event occurred in the area of radiation protection in 2018. The licensee must nevertheless remain vigilant with regard to the risk of contamination by alpha particles in the monitoring of its service providers.

Fessenheim nuclear power plant

The Fessenheim NPP comprises two pressurised water reactors, each with a power rating of 900 MWe, which produce the equivalent of the electricity consumption of the Alsace region (about 12 TWh per year). It is situated 1.5 km from the German border and about 30 km from Switzerland. The two reactors, which constitute BNI 75, were commissioned in 1977.

ASN considers that the nuclear safety performance of the Fessenheim site, as in the previous years, stands out positively with respect to the average for the nuclear fleet. The site remains at good level for environmental protection. Lastly, with regard to radiation protection, the site is in line with the general assessment of the EDF plants.

The operating safety of the reactors remained highly satisfactory in 2018. The return of reactor 2 to service after lifting the test certificate of its steam generator went well and did not lead to a drop in the performance of the site with respect to 2017, whereas only one reactor was operated that year. The licensee must however improve its preparation for work operations and the periodic tests.

The volume of maintenance work was very low in 2018 as there was no scheduled reactor outage, but the effort to maintain the facilities in good condition remains visible. Particular attention shall be paid to the implementation of the maintenance programmes and maintaining the facilities in good condition in 2019 in view of the future final shutdown of the site (see box). It should be noted that this uncertain context has had no impacts at present, from ASN's viewpoint, on the social climate and the involvement of the personnel.

The number of significant events relating to the environment remains low, confirming the overall positive judgement expressed by ASN in the preceding years. Nevertheless, the fact that the two events reported were detected during the preparation or performance of ASN inspections calls for a reinforcement of the site's ability to detect deviations, particularly concerning the auxiliary equipment items which are outside the scope of the periodic tests and preventive maintenance programmes.

Lastly, in a context of a low maintenance workload, no major radiation protection events occurred in 2018.

Prospect of final shutdown of the Fessenheim site

Following the announcement of further delays in the Flamanville EPR construction worksite, the shutting down of the Fessenheim NPP, initially planned for the end of 2018 was pushed back to 2019, then to 2020, leading to the scheduling of two new refuelling and maintenance outages in 2019.

The principle of decorrelating the shutdown of the Fessenheim NPP and commissioning of the Flamanville EPR, in accordance with the Government's demand, and EDF's confirmation that there is no prospect of operating reactors 1 and 2 beyond their fourth periodic safety reviews, which reach their respective terms in September 2020 and August 2022, now set an operating limit on the reactors.

ASN has noted these factors and in late 2018 started the updating of the prescriptions applicable to the site, particular regarding the «hardened safety core» provisions defined further to the lessons learned from the Fukushima NPP accident (see chapter 10), in order to adapt them to the particular case of a site that is shut down and waiting for decommissioning.

ASN nevertheless observes that at the end of 2018 the site still has no firm industrial schedule for its end of operation and has not yet been the subject of a final shutdown notification in accordance with the procedure provided for in Article L. 593-26 of the Environment Code.

ASN considers that the persistent uncertainty in this file, already marked by numerous schedule changes, is unsatisfactory, and it also notes that it particularly affects the life of the site in several respects:

- the rescheduling of the periodic maintenance operations for equipment items whose withdrawal from service had been planned, then postponed, necessitates a particular effort for planning and the examination of arrangements that might possibly be necessary, particularly those that require a technical assessment or an authorisation;
- the preparation of the decommissioning file and of those pre-decommissioning operations which can be started as soon as production stops, cannot remain subject to the vagaries of an unstable schedule. ASN nevertheless observes that the site has already started to remove the spent fuel assemblies in order to achieve a situation presenting the lowest possible risk as early as possible;
- the social climate of the site and the employees' commitment, which have been satisfactory until now, must be safeguarded. This implies in particular having a clear schedule for the reduction in personnel numbers concomitantly with the shutdown, and individual visibility of personnel transfers.

ASN reminds EDF that is must declare final shutdown of the reactors as soon as possible in order to best prepare their decommissioning. EDF has sent ASN a preliminary guideline notice for the fourth periodic safety review of the Fessenheim NPP with a view to final shutdown, and a preliminary decommissioning plan. The final shutdown notification shall be accompanied by an updated decommissioning plan; the decommissioning file must be transmitted no later than two years after the notification.

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 pressurised water reactors, each of 1,300 MWe, commissioned in 1987 and 1988. Reactor 1 constitutes BNI 139 and reactor 2 BNI 140.

ASN considers that the radiation protection performance of the Nogent-sur-Seine site is on the whole in line with the general assessment of EDF, while its performance in nuclear safety and radiation protection is below average.

With regard to nuclear safety, ASN considers that operating rigour has regressed, particularly on account of deficiencies in the preparation of operating activities.

As far as maintenance is concerned, ASN considers that the progress in the work monitoring is insufficient, particularly when implementing equipment modifications. ASN also notes shortcomings in the analysis of the fitness of equipment to be returned to service following the maintenance operations. Progress is also expected in the integration of the regulatory requirements regarding prevention of the fire risk.

With regard to radiation protection, ASN considers that the site has undertaken to correct the malfunctions observed in the preceding years. More specifically, significant improvements have been made in the preparation of maintenance worksites involving radiological risks and the organisation for dealing with contaminated personnel. Vigilance must moreover be maintained in the detection and processing of deviations in this area.

Regarding environmental protection, ASN considers that the site must further improve its performance, particularly in the internal management of effluents, which reveals shortcomings in the environmental culture of the workers or in the implementation of the procedures. ASN has observed progress in the management of conventional waste but remains attentive to compliance with the regulatory provisions concerning the management of radioactive waste.

Soulaines-Dhuys waste disposal centre

Commissioned in January 1992, the Aube radioactive waste repository (CSA) took over from the Manche disposal centre which ceased its activities in July 1994, and benefited from the experience acquired with the Manche centre. This disposal facility, which constitutes BNI 149, has a capacity of one million cubic metres of Low and Intermediate Level Short-Lived Waste (LL/ILW-SL). The operations authorised in the facility include waste packaging either by injection of mortar into metal chambers of 5 or 10 m^3, or by compaction in 200L drums. At the end of 2018, the volume of waste in the repository totalled some 335,175 m^3, that is to say about 33.5% 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, in line with the previous years, that the CSA is operated under satisfactory conditions of safety and radiation protection.

Labour inspection in the nuclear power plants of the Grand Est region

ASN performed 9 inspections and took part in 7 meetings or surveys on the four sites and continued its oversight actions in the area of occupational safety, particularly during reactor outages.
The management of occupational safety remains broadly satisfactory on all the sites. ASN nevertheless observes, as in the preceding years, some shortcomings in the application of prevention measures and performance of risk analyses by the licensee and its service providers. On the subject more specifically of the electrical risk, ASN has again, in the course of specific inspections, observed shortcomings in the meeting of regulatory obligations.
On the Cattenom site, strict occupational safety management has been observed, with only a few isolated deviations being noted. Reinforcement of prevention of the asbestos risk, the need for which was highlighted by a few minor events, is covered by a dedicated organisation to limit the risk of accidental exposure.
On the Fessenheim site, some cases of exceeding maximum permitted daily working times, which can form the subject of a waiver for safety reasons, underline the need to adopt a suitable organisation to limit their occurrence and duration.

ASN inspectors at the Aube waste repository (CSA) – December 2018

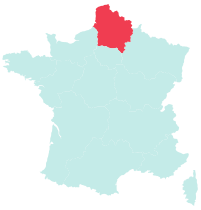
In 2018, ASN authorised the partial commissioning of the package inspection facility which gives the CSA more effective means of checking the quality of the received packages. Complete commissioning of this facility, planned for early 2019, will require another authorisation.

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 2018.

Deep geological waste repository project

After examining the safety options file for the *Cigéo* deep geological waste repository (see chapter 14), ASN issued its opinion on 11 January 2018.

Alongside this, ASN considers that the scientific experiments and work conducted by Andra in the underground laboratory at Bure continued in 2018 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:

- BNIs:
  - the Gravelines NPP (6 reactors of 900 MWe) operated by EDF;
  - Somanu (*Société de maintenance nucléaire*) operated by Framatome in Maubeuge (Nord *département*) - classified BNI until 28 May 2018, then ICPE;

see p. 200

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

see p. 230

- small-scale nuclear activities in the veterinary, industrial and research sectors:
  - 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, 19 companies using gamma ray densitometers and 280 users of devices for detecting lead in paint;
  - 340 veterinary surgeries or clinics practising diagnostic radiology;

see p. 256

- activities linked to the transport of radioactive substances;
- organisations approved by ASN:
  - 4 agencies of approved organisations in the area of small-scale nuclear activities.

In 2018, ASN's carried out 111 inspections in the Hauts-de-France region, of which 21 were in the Gravelines NPP, 85 in small-scale nuclear activities and 5 in the transport of radioactive substances.

ASN also carried out 12 labour inspection operations in the Gravelines NPP.

During 2018, 5 significant events rated level 1 on the INES scale were notified by the Gravelines NPP.

In small-scale nuclear activities, 4 events were rated level 1 on the INES scale, while 9 events concerning radiotherapy and brachytherapy treatments were rated level 1 on the ASN-SFRO scale and 1 concerning radiotherapy treatment was rated level 2 on the ASN-SFRO scale.

ASN drew up one violation report in the exercise of its oversight duties.

Gravelines nuclear power plant

The Gravelines NPP, operated by EDF, is located in the Nord *département* on the shores of the North Sea, 21 km east of Calais and 15 km west of Dunkerque. The site is situated 30 km from Belgium and 60 km from the United Kingdom. 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 nuclear safety and radiation protection performance of the Gravelines NPP is in line with its general assessment of EDF performance. Improvements in operating rigour were observed in 2018.

With regard to nuclear safety, the Gravelines NPP made progress in 2018 in the areas of reactor control and compliance with procedures. The site must nevertheless remain vigilant with regard to system configuring and enhancing the reliability of practices.

Concerning maintenance, 2018 saw the performance of its third 10-yearly outage of reactor 6 (the last reactor on the site to undergo this outage). Alongside this, the condition of certain facilities (particularly the pumping stations which display recurrent corrosion problems) and more generally the condition of the premises need to be improved. The involvement of all the members of personnel is necessary to detect and report deviations.

With regard to environmental protection, ASN considers that the performance of the Gravelines NPP is below the average for the EDF plants; it must in particular ensure better control of the site's wastewater treatment. In 2018, ASN adapted the prescriptions relative to the conditions of sampling and discharging of effluents from the Gravelines NPP into the environment, more specifically to allow the performance of pumping tests in the groundwater table before installing the ultimate water back-up system.

With regard to radiation protection, ASN continues to note shortcomings in the access control of some areas presenting risks of radiological exposure. Progress is also expected in the detection and handling of deviations in this area.

In the area of transport, the Gravelines NPP must be attentive to compliance with package tie-down rules during on-site transport operations.

The key event in 2018 relating to ASN inspections on this site was an in-depth inspection conducted from 14 to 18 May by a team of ten inspectors from all over France and coordinated by the ASN Inspector-in-Chief. This inspection was attended by two observers from the Belgian nuclear regulator (AFCN and BelV) and three members of the Gravelines CLI, in addition to the participating technical experts from IRSN. A film of this inspection can be viewed on *asn.fr*.

In-depth inspection by ASN at the Gravelines NPP – May 2018.

The *Société de maintenance nucléaire* in Maubeuge

Société de maintenance nucléaire (Somanu) is situated in the industrial zone of Grévaux-les-Guides in the locality of Maubeuge in the Nord *département*. The facility ensures the repair, maintenance and expert assessment of equipment and activities stemming primarily from nuclear reactors, excluding fuel elements. Somanu constituted BNI 143.

After reviewing the quantities of radioactive substances handled by Somanu, the Ministry for Ecological and Inclusive Transition and ASN have acknowledged that the BNI now comes under the system of Installations Classified for Protection of the Environment (ICPE) and is consequently now outside the scope of ASN oversight.

Labour inspection in the Gravelines nuclear power plant

Twelve labour inspection operations were carried out in the Gravelines NPP during 2018. The inspections were divided between inspections conducted on the maintenance worksites, carried out during the reactor outages, and thematic inspections (work at height, electrical conformity, lifting). Meetings were also organised with senior management, employes and personnel representatives.
With regard to health and safety, ASN remains attentive to the training of operators working at height and to the precautions to be taken when lifting loads. Unlike 2017, there were no serious work accidents.

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 basic nuclear installations of this region.

THE INSTALLATIONS AND ACTIVITIES TO REGULATE COMPRISE:

- Basic Nuclear Installations regulated by the Orléans division:
  - the CEA Saclay centre, including in particular the experimental reactors Osiris and Orphée;
  - the UPRA (Artificial Radionuclide Production Plant) operated by CIS bio international in Saclay;
  - the CEA Fontenay-aux-Roses centre;

see p. 200

- small-scale nuclear activities in the medical sector regulated by the Paris division:
  - 26 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 centres;
  - about 8,000 dental radiology devices;

see p. 230

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

see p. 256

- activities linked to the transport of radioactive substances;
- organisations approved by ASN:
  - 12 organisations approved for radiation protection controls.

ASN carried out 202 inspections in the Île-de-France region in 2018, of which 42 were in the field of nuclear safety, 151 in small-scale nuclear activities and 9 in the transport of radioactive substances.

Four Safety-related Significant Events (ESS) notified in Île-de-France and concerning BNIs were rated level 1 on the INES scale. In the small-scale nuclear activities, 3 Significant Events relating to Radiation protection (ESR) were rated level 1 on the INES scale, while 10 events concerning radiotherapy patients were rated level 1 on the ASN-SFRO scale.

ASN drew up two violation in the exercise of its oversight duties.

Saclay site

CEA Saclay Centre

The Saclay centre, covering an area of 223 hectares, is located about 20 km south-west of Paris, in the Essonne *département*. Some 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 of the French NPPs and their safety. Eight BNIs are located in this centre. It also houses an office of the French national institute for nuclear science and technology (training institute) and

two industrial firms: Technicatome, which designs nuclear reactors for naval propulsion, and CIS bio international, 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 megawatts thermal (MWth). It was primarily intended for technological irradiation of structural materials and fuels for various power reactor technologies. Another of its functions was to produce radionuclides for medical uses.

Its critical mock-up, the ISIS reactor with a power of 700 kWth, is essentially used for training purposes today. These two reactors, which constitute BNI 40, were authorised by a Decree dated 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. CEA intends to continue with operation of the ISIS reactor until March 2019. In October 2018, the CEA submitted its decommissioning file for complete installation – the Osiris reactor and the ISIS reactor.

Since the Osiris reactor was shut down, the operations to remove the radioactive substances and hazardous materials and the decommissioning preparation operations are under way, with an organisation that is adapted to this new reactor status. Spent fuel removals continued in 2018, and two major decommissioning preparation operations were authorised by ASN resolutions. Improvements in the fire protection of the installation are moreover currently being implemented.

The inspections carried out by ASN in 2018 found the management of radioactive sources and the monitoring of outside contractors to be satisfactory. Management of the decommissioning preparation operations was also found to be satisfactory, but schedule slippages were observed. Alongside this, the deadlines for updating the baseline requirements must be better respected so that the rules applicable to the facility reflect its actual condition.

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 a 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 are 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 is intended for the performance of non-destructive test on certain components.

The CEA has scheduled shutdown of the Orphée reactor for the end of 2019. The decommissioning file, expected before the end of 2019, shall be examined by ASN.

ASN considers that the level of safety of the Orphée reactor is on the whole satisfactory. The licensee's organisation in other respects is appropriate. The commitments made by the licensee are correctly implemented, particularly those further to the last periodic safety review.

The rigour of operation of the cooling towers must nevertheless be improved. Similarly, ASN has observed a number of deviations in radiation protection, particularly concerning the placarding of radiological zoning and contamination control measures.

Spent Fuel Testing Laboratory (LECI) – CEA Centre

The LECI was built and commissioned in November 1959. The CEA declared it as a basic nuclear installation on 8 January 1968. An extension was authorised in 2000. The LECI (BNI 50) 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 a 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. ASN shall be particularly attentive to compliance with the assigned deadlines for the reinforcement work to ensure the earthquake resistance of the building 625 (end of 1st quarter 2021).

The inspections carried out in 2018 revealed operation of the facility to be satisfactory. More specifically, radiation protection and criticality were found to be well managed.

Nevertheless, ASN notes an increase in the number of incident notifications in 2018 and shall be attentive to the lessons learned from them.

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 that of exposure to ionising radiation due to the presence of very high-level sealed sources.

In 2017 and 2018, CEA carried out modifications on the facility to eliminate the common mode failure risk on the cabled Pagure and Vulcain channels, and improved control of access to the Poséidon and Pagure bunkers. ASN examined the management of these modifications during an inspection in 2018, and found it to be satisfactory.

Alongside this, ASN considers that the BNI 77 is operated satisfactorily with regard to radiation protection, particularly as regards worker dosimetric monitoring. The organisation for the in-service monitoring of pressure equipment, however, must be improved.

Solid waste and liquid effluent treatment facilities

The CEA operates diverse facilities: laboratories associated with fuel cycle research as well research reactors. 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 Decree of 14 June 1971. Managed by the CEA, this facility processes, packages and stores the high, intermediate and low-level waste from the Saclay centre installations. It also stores legacy materials and waste (spent fuels, sealed sources, scintillating liquids, ion-exchange resins, technological waste, etc.) pending disposal.

For several years now the CEA has been having difficulties in meeting the requirements set by ASN and the commitments it made following the periodic safety review of 2009 or the inspection follow-ups.

In 2017, in view of the delays in the removal from storage operations, the CEA requested a change in the deadlines prescribed in ASN resolution 2010-DC-0194 of 22 July 2010, particularly the pushing back of facility final shutdown deadline to 31 December 2022 so that the BNI can continue to be used for the management of radioactive waste from the Saclay BNIs. ASN will be attentive to the justification for the new time frames requested for completion of the removal from storage operations. It will more particularly set the conditions for continued operation of the facility further to the examination of the periodic safety review (for which the report was submitted in 2017), which is conducted constistently with the examination of the decommissioning file transmitted in 2015 and supplemented in 2017.

In the light of the inspections carried out in 2018, ASN considers that the level of safety of the facility is acceptable. The removal from storage operations are proceeding under suitably safe conditions, despite the divergences from schedule. The year was nevertheless marked by several significant events concerning loss of integrity of drums of waste, reflecting the need to better control their storage conditions.

Lastly, and more broadly, in view of the scheduled final shutdown and decommissioning of BNI 72, ASN shall be attentive to the proposed organisation and the means committed by the CEA for the future treatment of the solid waste from the Saclay site..

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 installation is dedicated to the treatment of radioactive liquid effluents. The CEA was authorised by a Decree of 8 January 2004 to create an extension in the BNI, called «Stella», for the purpose of treating and packaging low-level aqueous effluents from the Saclay centre. These effluents are concentrated by evaporation then immobilised in a cementitious matrix in order to produce packages acceptable by Andra's 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 made progress since the early stages in defining its packaging solution for all the effluents from the installation. Thus, in June 2018, Andra authorised the packaging of these concentrates in accordance with the 12H package approval. The CEA must now ask ASN for authorisation to manufacture these packages.

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. ASN considers that the CEA must clarify its management strategy for the liquid effluents produced on the Saclay site, particularly regarding the future of premises 97 and the management of the effluents produced by BNI 35 itself.

In addition, the Decree of 8 January 2004 authorising the creation of Stella also stipulated that the CEA must remove the legacy waste stored in the eight MA500 tanks and the HA4 tank of BNI 35 within ten years. Due to the technical difficulties encountered in the recovery and packaging of this waste, the CEA was unable to meet the various prescribed deadlines and requested a deadline extension. As at the end of 2018, tank HA4 and 7 of the MA500 are empty. The operations to prepare for the emptying of the last MA500 tank have begun.

The CEA has scheduled several legacy effluent recovery operations and submittal of the associated files in 2019.

In view of the inspections performed in 2018, ASN underlines the proficiency of monitoring of barrier integrity and of operational management for accidents. Furthermore, the licensee rapidly found an alternative solution to remedy the unavailability of the facility's boiler pending its replacement at the end of 2018.

The emergency organisation and means, however, can be improved, and the fire risks study carried out for the periodic safety review must be supplemented.

Facilities undergoing decommissioning at the CEA Saclay centre

The decommissioning operations performed on the Saclay site concern two finally shut down BNIs (BNIs 18 and 49) and three BNIs in operation (BNIs 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 ICPEs – Installations Classified for Protection of the Environment (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.

More generally, the CEA's decommissioning and waste management strategy is subject to examination by ASN (see chapter 13).

Ulysse reactor – CEA Centre

Ulysse was the first French university reactor. The installation, which constitutes BNI 18, underwent final shutdown in 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 installation presents limited safety risks.

Further to the authorisation granted by ASN in early 2017, cutting up of the reactor block concrete block – the last step of the nuclear worksites – began in July 2017. The first phase of cutting up the «conventional» part of the reactor block was completed in April 2018. The second phase corresponding to cutting up of the «nuclear» part is in progress and will end in early 2019, before the final clean-out step.

The removal of about one hundred concrete blocks resulting from the first cutting-up phase is planned for the first half of 2019. ASN will ensure beforehand that the planned clean-out criteria have been satisfied.

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.

The decommissioning of the TOTEM shielded chain in cell No. 10, and the clean-out of cell Nos. 11 and 15 continued in 2018.

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 in the operations to be carried out. The licensee must therefore draw up a decommissioning decree modification file. ASN will be attentive to the justification of the deadline and the conditions of safety of the future operations.

ASN considers that the level of safety of BNI 49 undergoing decommissioning must be improved. 2018 was marked by significant events associated with the fire risk. For example, CEA reported one event rated level 1 on the INES scale for malfunctions of the automatic fire detection system which led the licensee to suspend the work in progress in the premises concerned.

The inspections of the facility confirmed improvements in the management of the waste storage areas. ASN nevertheless notes deficiencies in the monitoring of operations performed by outside contractors, and in the management of deviations and tracking of the performance of inspections and periodic tests. ASN shall be attentive to the performance of corrective actions in these areas..

Artificial Radionuclide Production Plant

UPRA (Artificial Radionuclide Production Plant) – BNI 29 – 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 2000s, this subsidiary was bought up by several companies specialising in nuclear medicine. In 2017, the parent company of CIS bio international acquired Mallinckrodt Nuclear Medecine 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. Another role of BNI 29 until the end of 2019 is also to retrieve disused sealed radioactive sources which were used for radiotherapy and industrial irradiation.

ASN considers that the safety performance of CIS bio international must still be significantly improved. It is true that ASN noted the licensee's efforts in 2018 to make its organisation and its operating processes more efficient, but the results are still insufficient.

As in the preceding years, the large number of significant events, the causes of which always include organisational and human deficiencies, reflects a poor culture of operating safety and reveals a lack of commitment of management to take organisational and human factors properly into account. Compliance with the requirements of the operating rules and the monitoring of activities must be improved, particularly

Assessment of the CEA Saclay centre

The CEA centres of Saclay and Fontenay-aux-Roses were grouped together in a single centre (CEA Paris-Saclay) in 2017. A new organisation was also implemented in 2017 in order to improve the management of the decommissioning projects, with the creation of the Department of facilities undergoing clean-out and decommissioning. During the period of consolidation of these new organisations, ASN has been vigilant with regard to the maintained control of safety and radiation protection in the Saclay BNIs. ASN considers that safety of operation of the CEA Saclay centre's BNIs is satisfactory. The organisation of transport movements, which represent large quantities of highly diverse types of packages and contents, is also efficient.
The CEA nevertheless still has difficulties in fulfilling technical requirements within the deadlines set by ASN. The decommissioning and legacy waste recovery and packaging operations are falling behind schedule. ASN considers that the progress of the decommissioning projects is one of the major safety challenges for the shut down installations and that the management of the waste from the decommissioning operations is crucial for the smooth running of the decommissioning programmes.
The inspections conducted by ASN in 2018 have shown the CEA's need for increased vigilance in the management of the fire risk within the BNIs. This concerns equally well the demonstration of control of the risks as the performance of periodic checks that guarantee correct operation of the equipment involved in fire protection.
The revising of the On-site Emergency Plan (PUI) was still not finished in 2018. Its updating will provide a renewed estimate of the risk that the Saclay nuclear installations represent given the risk reduction resulting from the shutdown of the Osiris reactor. On completion of the examination and approval of the On-site Emergency Plan, ASN will be able to assess the possibility of setting up buildings open to the public in large numbers near the CEA site.
Further to the Fukushima NPP accident, ASN had initiated stress tests on the nuclear installations. More particularly, the CEA's emergency management means were examined for the Saclay centre. In 2015 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. Faced with the confirmed lateness in the deployment of the new emergency management buildings, the compensatory measures proposed by the CEA will have to be operational rapidly.
A national emergency exercise was organised in December 2018. Its purpose was to test the emergency response mechanisms planned by the public authorities and the licensee should an accident occur in a BNI. This exercise was held over two days. The first day focusing primarily on «nuclear safety» was organised around an accident scenario which was unknown to the participants and concerned BNI 101 (Orphée reactor) and led to the mobilisation of the emergency organisation (departmental operations centre of the Essone *département* Prefect's Office, the IRSN emergency technical centre, strategic management and command post of the CEA Saclay centre and the CEA emergency coordination centre). ASN considers that this exercise identified several weaknesses in the CEA's emergency organisation which will have to be corrected.
The second day, in which «civil protection» was the prime focus, enabled the Essonne Prefect's office, with the support of the regional players, to prepare the implementation of population protection measures.

the management of inspections and periodic tests, the handling of deviations and the tracking of maintenance operations. To give an example, CIS bio international reported a significant event rated level 1 on the INES scale for deficiencies in the management and traceability of inspections and periodic tests.

ASN also observed that, in view of the delays that have built up in recent years and despite the efforts made since the end of 2016, the licensee had difficulty in complying with the requirements resulting from the previous periodic safety review. By ASN resolution 2018-DC-0628 of 15 March 2018, ASN gave CIS bio international formal notice to comply with the unfulfilled requirements, setting deadlines of mid-2018 and end of 2018. ASN checked compliance with these new deadlines in inspections.

Alongside this, the application of new regulatory requirements is not adequately anticipated. This has more specifically led ASN to give CIS bio international, through resolution2018-DC-0629 of 15 March 2018, formal notice to draw up a waste management study and establish corresponding general operating rules that are in conformity with resolution 2015-DC-0508.

Lastly, complementary studies concerning the consequences of accident situations are currently being examined. The risks created by the installation shall be significantly reduced in the medium term. This reduction will be due to the stopping of the activity associated with disused high-level sealed sources and the production of iodine-131-based radiopharmaceuticals. These changes in operation, for which the deadline is the end of 2019, will be examined during the examination of the periodic safety review report submitted in the 2nd half of 2018.

More broadly speaking, ASN expects a lasting turnaround of CIS bio international. Operating rigour, the safety culture, the oversight of operations, the cross-functionality of the organisation, and compliance with the baseline requirements of the facility and ASN resolutions must all be improved.

CEA's Fontenay-aux-Roses centre

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.

More generally, the CEA's decommissioning and waste management strategy is subject to examination by ASN (see chapter 13).

Procédé and Support installations
– CEA Centre

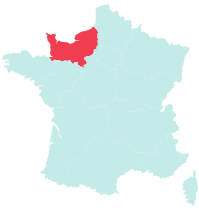
The decommissioning of these two installations which constitute BNI 165 and 166 respectively, was authorised by two Decrees of 30 June 2006. The initially planned duration for the decommissioning operations was about ten years. The CEA informed ASN that, due to strong presumptions of radioactive contamination beneath one of the buildings, to unforeseen difficulties and to a change in the overall decommissioning strategy of the CEA's civil centres, the decommissioning operations would extend beyond 2030, and in June 2015 it filed an application to change the prescribed decommissioning time frames.

ASN deemed that the first versions of these files were not admissible. In accordance with its commitments of 2017, in the 1st quarter of 2018 the CEA sent the new version of the files aiming to extend the decommissioning authorisation for the nuclear installations of the Fontenay-aux-Roses centre.

2018 witnessed slippages in the performance of the studies, in project scheduling and in the decommissioning operations schedule. Thus, the complements to the on-site emergency plan expected in 2017 were not submitted to ASN until the end of 2018 and will be examined in 2019.

Assessment of the CEA Fontenay-aux-Roses centre

ASN observes that the CEA once again has numerous difficulties in meeting the deadlines of projects that are fundamental for safety. ASN expects an improvement in the quality of the studies submitted by the CEA, which must be self-sufficient and include more detailed analyses.
Control of the fire risk remains a major issue. ASN registered improvements in 2018; the CEA provided elements demonstrating control of the fire risk at the end of the year.
Alongside this, equipment qualification compliance and discharge monitoring are satisfactory, but meeting commitments and control of containment must still be improved. Likewise, there is room for improvement in the detection of deviations and the monitoring of service providers. ASN never-theless notes the responsiveness of the personnel and good organisation of the various themes inspected, especially waste management.



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:

- BNIs:
  - the NPPs of Flamanville (2 reactors of 1,300 MWe), Paluel (4 reactors of 1,300 MWe) and Penly (2 reactors of 1,300 MWe) operated by EDF;
  - the Flamanville 3 EPR reactor construction site;
  - the Orano Cycle spent nuclear fuel reprocessing plant at La Hague;
  - the Andra Manche repository;
  - the Ganil (National Large Heavy Ion Accelerator) in Caen;

see p. 200

- small-scale nuclear activities in the veterinary, industrial and research sectors:
  - 8 external-beam radiotherapy departments (21 devices);
  - 1 proton therapy department;
  - 3 brachytherapy departments;
  - 11 nuclear medicine departments;
  - 35 centres performing fluoroscopy-guided interventional procedures;
  - 66 computed tomography scanners;
  - some 2,100 medical and dental radiology devices;

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- small-scale nuclear activities in the veterinary, industrial and research sectors:
  - about 450 industrial and research establishments, including 18 companies exercising an industrial radiography activity;
  - 1 cyclotron;
  - about 21 laboratories situated mainly in the universities of the region;
  - 10 companies using gamma ray densitometers;
  - 150 users of devices for detecting lead in paint;
  - about 260 veterinary surgeries or clinics practising diagnostic radiology;

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

In 2018, ASN carried out 203 inspections in Normandie, comprising 62 inspections in the Nuclear Power Plants (NPP) of Flamanville, Paluel and Penly, 20 inspections on the construction site of the Flamanville 3 EPR reactor, 67 inspections on fuel cycle facilities, research facilities and facilities undergoing decommissioning, 46 inspections in small-scale nuclear activities and 8 in the transport of radioactive substances.

In addition to this, 46 days of labour inspection were carried out on the NPP sites and the Flamanville 3 worksite.

During 2018, 14 significant events rated level 1 on the INES scale were notified to ASN. In addition, 7 events rated level 1 on the ASN-SFRO scale were notified by the heads of radiotherapy departments in the Normandie region.

ASN drew up two violation reports in the exercise of its 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 with regard to nuclear safety, radiation protection and environmental protection is, on the whole, in line with the general assessment of EDF plant performance.

ASN nevertheless noted diverse shortcomings during its reactor outage inspection in 2018, which tend to indicate that safety management needs to be stepped up for outage monitoring. ASN considers that the quality of the authorisation application files must also be improved and their transmission better anticipated.

With regard to the 10-yearly outage of reactor 1, ASN considers that the preparation and tracking of the works and maintenance operations must be significantly improved. ASN considers that the licensee must also improve the monitoring of the reactor restarting process which enables it to ensure compliance with the safety baseline requirements. Lastly, ASN considers that the internal checks of the activities performed must be improved.

With regard to reactor operation and management, ASN considers that the site's performance is satisfactory on the whole, but the efforts made in the analysis of the periodic tests must be continued.

With regard to radiation protection, ASN considers that the organisation in place is satisfactory when the reactors are in operation. During the reactor outages, however, the management of access to limited-stay areas and the monitoring of limited-term contract or temporary personnel must be improved, as must the control of contaminated equipment storage conditions.

With regard to environmental protection, ASN considers that the organisation in place for the management of discharges and waste is satisfactory. The management of waste during reactor outages must however be further improved.

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 FARN, the special Nuclear Rapid Intervention Force created by EDF in 2011 further to the Fukushima 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 and radiation protection is on the whole in line with the general assessment of EDF, and that its environmental protection performance is even more satisfactory.

With regard to reactor operation and management, ASN considers that the site's performance is satisfactory on the whole, even if the periodic tests must be scheduled with greater rigour, particularly during reactor outages. ASN considers that the management of fire detection inhibitions and the quality of the risk analyses during interventions must be improved. Lastly, ASN considers it necessary to continue improving the rigour in the preparation and monitoring of maintenance activities.

With regard to reactor 2, the 10-yearly outage which began in May 2015 ended in July 2018. ASN considers that the repair operations on the equipment impacted by the fall of the steam generator in 2016 were carried out satisfactorily. Reactor 2 is the first of the 1,300 MWe plant series on which EDF has replaced the steam generators. ASN considers that the requalification operations, which include the main primary system hydrostatic test, were carried out satisfactorily. Lastly, during restarting of the reactor after a shutdown of more than three years, ASN checked that the various material difficulties had been resolved.

As for reactor 3, ASN considers that its outage went well on the whole, even though it lasted longer than planned due to an unexpected finding in the reactor vessel head. ASN also notes that the development of corrosion on the equipment located outside the buildings needs to be better taken into account.

With regard to radiation protection, ASN considers that the organisation in place is satisfactory when the reactors are in operation. During reactor outages however, the management of entries into controlled areas and control of the contamination risk must be improved. Several significant events reflect a lack of radiation protection culture in some of the workers.

With regard to environmental protection, ASN considers that the organisation in place for the management of discharges and waste is satisfactory. The site made a significant effort in 2018 to improve the leak-tightness of its cooling units. The management of radioactive waste stored in the dedicated building, however, must be further improved.

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, radiation protection and environmental protection is, on the whole, in line with the general assessment of EDF plant performance. The licensee must nevertheless continue the efforts made in 2018 in safety management, particularly as regards the management of deviations.

With regard to operation and reactor management, ASN considers that the site's performance is satisfactory on the whole. ASN considers that particular attention must be paid to the preparation of operational management activities in order to reinforce the rigour during work on the equipment and during the periodic tests. The management of operational control procedures called out in the phases

ASN inspection at the Penly NPP on the earthquake theme – May 2017

of operational management of incidents or accidents must also be improved.

With regard to the refuelling outages of the two reactors, which were marked by technical contingencies necessitating prolonged repairs, ASN considers that the Penly NPP must improve work preparation and the verification and monitoring of maintenance activities.

In the area of radiation protection, ASN considers that continued improvement of the organisation in place is necessary. The way radiation exposure risks are taken into consideration is found to be highly variable, and ASN still detects numerous deviations during its worksite inspections. The licensee must also continue its ongoing efforts to improve the knowledge and radiological risk awareness of outside contractor personnel.

With regard to environmental protection, ASN considers that the organisation in place for the management of discharges and waste is satisfactory; the licensee made significant waste removal efforts in 2018. ASN also notes an increase in the number of failures of measuring equipment involved in monitoring discharges and the environment.

Flamanville 3 EPR reactor construction worksite

Following issuing of the creation authorisation Decree 2007-534 of 10 April 2007 and of the building permit, construction work on the Flamanville 3 reactor began in September 2007.

The electromechanical installation activities continued in 2018 with, among other things, the hydrostatic test of the nuclear steam supply system main primary system, continuation of assembly of the main secondary and auxiliary systems, modifications to the instrumentation and control of the installation and cable-pulling and electrical connection operations. Important starting test phases were carried out, including in particular the cold tests, the functional tests with reactor vessel open and the continuation of the hot test preliminary tests. ASN conducted a specific inspection of these operations and also checked the measures taken with regard to protection of the environment and preparation for reactor operation.

ASN considers that the organisation put in place for the start-up tests was on the whole satisfactory in 2018. Nevertheless, despite the improvements in EDF's organisation for the start-up tests, continued significant efforts must be made to achieve the prerequisite defined for the performance of the start-up tests and the associated supporting documents to prove the representativeness of these tests. ASN will continue its oversight action on these themes in 2019, particularly in the preparation for operation, the start-up tests and bringing the main secondary systems into compliance.

ASN inspected EDF's organisation for protection of the environment on the worksite, notably the management of the buried waste discovered on the site in 2017 and the integration of the new requirements associated with application of ASN resolutions 2018-DC-0639 and 2018-DC-0640 of 19 July 2018. ASN noted numerous events concerning the environment during 2018, demonstrating insufficient consideration of the risks for the environment when performing the start-up tests.

ASN continues its inspection of the organisation implemented by the teams responsible for future operation of the Flamanville 3 reactor, particularly concerning the preparation for operational control of the installation, control of the fire risk and protection of the environment. ASN considers that substantial work remains to be accomplished in this respect. In view of EDF's current schedule, ASN should conduct an in-depth inspection of this organisation in 2019.

Labour inspection in the nuclear power plants of the Normandie region

ASN conducted oversight actions concerning the conditions of health and safety during maintenance and construction operations and the management of subcontracting in the nuclear power plants.
ASN more specifically examined the conditions of occurrence of several workplace accidents, including one electric shock incident and the several-day isolation of a person who suffered a serious malaise. Inspections were carried out on several NPPs to check the compliance work on fuel handling machines in the reactor buildings and the taking into account of the explosion risk.

The electromechanical assembly operations continued in 2018 and were marked by two major points relating to the main steam pipes:

- continuation of the examination of the deviations relative to the failure to take into account the specific requirements of the break preclusion procedure prior to the manufacture and assembly of these equipment items;
- the discovery of welding defects not detected during the end-of-manufacture inspections.

These points form the subject of an in-depth examination by ASN, which is based on several inspections carried out in 2018 supporting the analysis of the root causes of the detected deviations and the verification of the implementation of appropriate corrective actions to repair the incriminated welds. In view of the significant shortcomings in EDF's monitoring of outside contractors, ASN has asked for a quality review to be performed on the equipment of the Flamanville EPR reactor. In addition to this, the procedure proposed by EDF for dealing with the anomalies detected in the welds of the main pipes of the steam systems is currently being examined. ASN will give its opinion on the acceptability of this procedure in 2019.

ASN ensures the labour inspection missions on the Flamanville 3 worksite. In 2018, ASN checked that outside contractors working on the site complied with the provisions relative to labour law. Observation of the applicable safety rules was checked regularly. ASN also responded to requests coming directly from employees, performed investigations further to workplace accidents and examined or co-examined requests for waivers to provisions of the labour regulations. Lastly, ASN conducted several oversight operations concerning the regulatory provisions governing the transnational secondment of workers.

Manche waste Disposal Facility

The Manche waste Disposal Facility (CSM), which entered service in 1969, was the first radioactive waste repository operated in France. 527,225 m^3 of waste packages are emplaced in it. The CSM stopped accepting waste in July 1994.

In application of Decree 2016-846 of 28 June 2016, the CSM, which is managed by Andra, is considered to be in the decommissioning phase (operations prior to its closure) until installation of the long-term cover has been finished. An ASN resolution shall specify the date of closure of the repository (entry into monitoring and surveillance phase) and the minimum duration of the CSM monitoring and surveillance phase.

ASN considers that the state and the operation of the facilities are satisfactory. Andra must nevertheless continue its efforts to reinforce the stability of the cover and to eliminate the residual infiltrations of water into the repository at the edge of the membrane. More specifically, at the end of 2017, after examining the safety review guidance file, ASN formulated demands concerning the justification of the technical principles of deployment of the long-term cover and of the CSM memory system, and the updating of the impact study.

ASN considers that the organisation defined and implemented on the site to control the operations prior to closure of the facility, and to preserve the condition of the systems, equipment and buildings, is satisfactory. The licensee must nevertheless show greater rigour in the technical oversight of the activities.

National Large Heavy Ion Accelerator

The Ganil (National Large Heavy Ion Accelerator) economic interest group was authorised in 1980 to create an accelerator in Caen (BNI 113). This research facility produces, accelerates and distributes ion beams with various energy levels to study the structure of the atom. The 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 the Ganil.

In 2017, the Ganil requested a change in the deadlines of six of the ten requirements of ASN resolution 2015-DC-0512 of 11 June 2015 relative to its first periodic safety review. Examination of this request continued in 2018. Alongside this, ASN noted that the studies and certain compliance work associated with the fire-detection and fire-fighting systems had been started. The licensee must ensure that this work is carried out in compliance with the regulations in effect.

"Exotic nuclei" are nuclei which do not exist naturally on Earth. They are created artificially in the Ganil for nuclear physics experiments on the origins and structure of matter. In order to be able to produce exotic nuclei, the Ganil was authorised in 2012 to build phase 1 of the Spiral 2 project. ASN issued the partial commissioning authorisation for this project at the end of 2014. During the examination of the complete commissioning authorisation application, ASN asked the licensee for additional information, which it provided and enabled the examination to continue.

The Ganil must continue its efforts in the monitoring of the compliance work and procedures relating to worker radiation protection, in the tracking of its commitments and ASN requests and requirements, and more generally in the updating of its integrated management system. The Ganil must also adapt its organisation in view of the commissioning of phase 1 of the Spiral 2 project.

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.

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.

Operations carried out in the plant

The reprocessing plants comprise several industrial units, each intended for a particular operation (see chapter 11). 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.

The effluents and waste generated by the operation of the plants

The fission products and other transuranic elements resulting from reprocessing are concentrated, vitrified and packaged in Standard Vitrified Waste Packages (CSD-V). The pieces of assembly cladding are compacted and packaged in Standard Compacted Waste Packages (CSD-C). These reprocessing operations, which are detailed in chapter 11, involve chemical and mechanical processes which produce gaseous and liquid effluents and solid waste.

Oversight of the La Hague plants

On-site transport

Application of the general operating rules specific to the on-site transport of hazardous radioactive and non-radioactive substances is now operational on the La Hague site. The licensee has applied for an extension to the end-of-2018 deadline for the improvements in the transport systems demanded by ASN in its resolution of 3 May 2016, due to difficulties in implementing these improvements. This extension application is currently being examined by ASN.

Tracking the compliance notice concerning the Nuclear Pressure Equipment (NPE)

The La Hague site plants contain various nuclear pressure equipment items which can present a high risk for safety. The design, manufacture and maintenance of nuclear pressure equipment is governed by a specific regulation, the ESPN (French acronym for NPE) Order. Through ASN resolution 2015-DC-0510 of 26 May 2015, ASN gave the licensee formal notice to comply with the regulatory obligations for periodic inspection of the NPE in service. This compliance notice resolution contains deadlines extending over the period from 31 January 2016 to 31 July 2018.

For the 54 NPE items concerned by the compliance notice, the licensee has either carried out the required regulatory actions or submitted an equipment downgrading or shutdown notification, or applied for authorisation to waive the regulatory provisions by producing the necessary technical justifications. Their examination has led ASN to issue resolutions to authorise the waivers and set compensatory measures to guarantee a level of safety at least equivalent to that resulting from full accomplishment of the common law measures. In the light of these elements, ASN notified the licensee on 7 September 2018 that the provisions of its compliance resolution 2015-DC-0510 were satisfied

Additional requirements further to the stress tests

In 2018, ASN continued its inspections concerning the implementation of physical and organisational measures associated with the stress tests carried out further to the Fukushima Daicchi accident. In particular, the provisions relative to the emergency situation management premises prescribed by ASN resolution 2015-DC-0483 of 8 January 2015 were put in place within the required time frame. ASN will be particularly attentive in 2019 to the measures for managing the accident situations feared for legacy waste storage areas.

Examination of the safety review reports

In the context of the periodic safety review of BNI 117, ASN has verified the conformity check carried out by the licensee, and in particular the aspect concerning the ageing of the facilities. ASN notes that the methodological procedure adopted by the licensee for this periodic safety review is ambitious and rigorous. However, random sampling checks of its implementation have revealed deficiencies in traceability between the various steps of the method used for

the review and the conformity check. This weakness results in an insufficient level of control of the action plan and could be prejudicial to its implementation over the long term.

ASN analysed the admissibility of the periodic safety review report for BNI 118 submitted by Orano Cycle in November 2017. It considered it generally satisfactory with regard to the requirements of the Environment Code, but nevertheless requested additional information concerning the conformity check of the activities important to protection, and the examination of the protection measures with respect to fire, the tornado hazard, and the dimensioning of the emergency management resources. The safety review report is currently being examined.

Management of the condition of the evaporation concentration containers

ASN continued to verify 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 exceeding that considered in their design.

The regular assessments of the results of the monitoring actions on these equipment items and of the regulatory inspections carried out by the licensee and communicated to ASN show that the thickness of evaporator 4120-23 in the T2 facility, identified as being the most affected by corrosion, is close to the minimum required thickness. Given the corrosion

The installations at La Hague

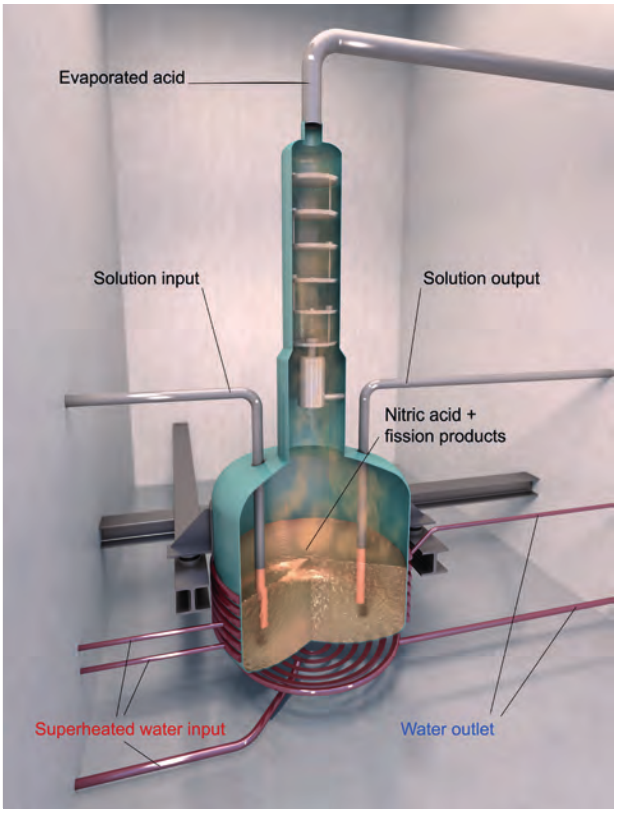
Shut down installations undergoing decommissioning:

- **BNI 80: Oxide High Activity facility (HAO)**
  - HAO/North: Facility for underwater unloading and spent fuel storage
  - HAO/South: Facility for shearing and dissolving of spent fuel elements
- **BNI 33: UP2-400 facility, first reprocessing unit**
  - HA/DE: Facility for separation of uranium and plutonium from fission products
  - HAPF/SPF (1 to 3): Facility for fission product concentration and storage
  - MAU: Facility for uranium and plutonium separation, uranium purification and storage in the form of uranyl nitrate
  - MAPu: Facility for purification, conversion to oxide and initial packaging of plutonium oxide
  - LCC: Central product quality control laboratory
  - ACR: Resins packaging facility
- **BNI 38: STE2 facility: Collection, treatment of effluents and storage of precipitation sludge, and AT1 facility, prototype installation currently being decommissioned**
- **BNI 47: ELAN II B facility, CEA research installation currently being decommissioned**

Installations in operation:

- **BNI 116: UP3-A plant**
  - T0: Facility for dry unloading of spent fuel elements
  - D and E pools: Pools for storage of spent fuel elements
  - T1: Facility for shearing of fuel elements, dissolving and clarification of solutions obtained
  - T2: Facility for separation of uranium, plutonium and fission products, and concentration/ storage of fission product solutions
  - T3/T5: Facilities for purification and storage of uranyl nitrate
  - T4: Facility for purification, conversion to oxide and packaging of plutonium
  - T7: Facility for vitrification of fission products
  - BSI: Facility for plutonium oxide storage
  - BC: Plant control room, reagent distribution facility and process control laboratories
  - ACC: Hull and end-piece compaction facilities
  - AD2: Technological waste packaging facility
  - ADT: Waste transit area
  - EDS: Solid waste storage area
  - D/E EDS: Storage/removal from storage of solid waste
  - ECC: Facilities for storage and recovery of technological waste and packaged structures
  - E/EV South-east: vitrified residues storage facility
  - E/EV/LH and E/EV/LH 2: Extension of vitrified residues storage capacity
- **BNI 117: UP2-800 facility**
  - NPH: Facility for underwater unloading and storage of spent fuel elements in pool
  - C pool: Pool for storage of spent fuel elements
  - R1: Fuel elements shearing, dissolving and resulting solutions clarification facility (including the URP: Plutonium Re-dissolution Facility)
  - R2: Uranium, plutonium and fission product separation, and fission product solution concentration facility (including the UCD: alpha waste centralised processing unit)
  - R4: Facility for purification, conversion to oxide and initial packaging of plutonium oxide
  - SPF (4, 5, 6): Facilities for storage of fission products
  - BST1: Facility for secondary packaging and storage of plutonium oxide
  - R7: Facility for vitrification of fission products
  - AML - AMEC: Packaging reception and maintenance facilities
- **BNI 118: STE3 facility: Effluent recovery and treatment and storage of bituminised waste packages**
  - D/E EB: Storage of alpha waste
  - MDS/B: mineralisation of solvent waste

Diagram of an evaporator and details of the half-tubes of the heating circuit



kinetics, this could lead the licensee to stop its operation around 2020.

Evaporator monitoring will remain a subject of particular attention for ASN until the new evaporators replacing the current ones are put into service.

In November 2016, ASN gave an opinion on the safety options presented by the licensee for new fission product evaporators. In November 2017, it authorised construction of the civil engineering structures of the new buildings that are to house the evaporators, and it inspected the construction worksites in 2018. ASN considers the monitoring of the service providers to be satisfactory. Orano Cycle must submit the application for authorisation to use these new evaporators to ASN in 2019.

La Hague Orano Cycle reprocessing plants undergoing decommissioning

UP2-400 irradiated fuel reprocessing plant

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 the 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). The ongoing operations in the four BNIs concern the retrieval and packaging of legacy waste and decommissioning.

Retrieval and packaging of legacy waste

Unlike the direct on-line packaging of the waste generated by the new UP2-800 and UP3-A plants at La Hague, most of the waste generated by the first UP2-400 plant was stored in bulk without permanent packaging. The operations to retrieve this waste are technically delicate and necessitate substantial means. They present major safety and radiation risks, which ASN monitors with particular attention.

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

Over the years, retrieval of this waste has fallen considerably behind the initial schedule and continued to do so in recent years. ASN considers that any pushing back of deadlines must be justified by Orano Cycle and accompanied by compensatory measures that enable the risk to be reduced to the lowest level possible, because the buildings in which this legacy waste is stored are ageing and do not meet current safety standards. ASN considers in particular that Orano Cycle must retrieve the legacy waste produced by operation of the UP2-400 facility as quickly as possible, and more specifically the sludges stored in the STE2 silos, the waste from the HAO and 130 silos, and continue the processing of the fission product solutions stored in the SPF2 unit.

ASN has regulated all the legacy waste retrieval and packaging programmes at La Hague through prescriptions stipulated in resolution 2014-DC-0472 of 9 December 2014. This resolution defines priorities in terms of the safety of the legacy waste retrieval and packaging operations and sets milestones for each of the programmes concerned.

STE2

The scenario presented in 2010 concerning the retrieval and packaging of STE2 sludges is divided into three steps:
- retrieval of sludges stored in silos in STE2 (BNI 38);
- transfer and processing, initially by drying and compacting, in STE3 (BNI 118);
- packaging of the resulting pellets in «C5» packages for deep geological disposal.

Schematic diagram of retrieval and packaging of the waste from Silo 130

ASN authorised the first phase of work to retrieve the sludges from STE2 in 2015. During 2017, Orano Cycle submitted additional information relating to the first phase of the work and an authorisation application concerning the process for retrieving the sludges from STE2 and transferring them to STE3. This file is currently being examined.

The creation authorisation decree for the STE3 effluents treatment station was modified by the Decree of 29 January 2016 to allow the installation of the STE2 sludges treatment process.

Orano Cycle, however, has informed ASN that the process adopted for treating the sludges in STE3 could lead to difficulties in equipment operation and maintenance. It has also presented the alternative centrifuge treatment scenario that it intends implementing, which will lead to the production of drums for interim storage in the existing dedicated facility. Orano Cycle plans submitting a safety options file in 2019. The currently prescribed regulatory deadline for starting retrieval of the sludges will not be met.

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 only ensured 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 storing and packaging operations. ASN had set 1 July 2016 as the start date for all the waste retrieval operations. In the light of the justifications provided by Orano Cycle concerning the technical difficulties encountered, ASN pushed back the operations start date to 30 April 2018. Orano Cycle, however, did not meet this new regulatory deadline, even though the ventilation system of the retrieval and packaging facilities was actively connected in 2018 and the tests important to safety prior to entry of the facilities into active service were also started in 2018. After noting during an inspection that waste retrieval had effectively not yet started in April 2018, and taking account of the new technical and organisational difficulties encountered during the tests, ASN asked Orano Cycle to propose a realistic deadline for starting waste retrieval, explicitly defining the margins on the critical path and the margins for residual risks, with justifications. The examination of the authorisation applications concerning the first retrieval phases continued in 2018.

The old fission product solutions stored in the SPF2 unit of the UP2-400 plant

The licensee has chosen cold crucible vitrification for the packaging of the fission products resulting from the reprocessing of fuels from the Gas-Cooled Reactor series and containing molybdenum (UMo FP) in particular. The package thus produced is a Standard UMo Vitrified Waste Package (CSD-U).

Operational application of cold crucible vitrification was authorised by resolution of 20 June 2011. Unforeseeable problems were encountered during its development and implementation. Consequently, Orano Cycle was unable to meet the end-of-retrieval deadline set at 31 December 2017 by ASN resolution of 26 June 2012 and asked for this deadline to be pushed back until the end of 2019, on the basis of the CSD-U package production rate in 2018. This application is currently being reviewed by ASN.

The nuclear safety issues associated with Silo 130

Silo 130 was designed and built in compliance with the nuclear safety requirements in force in the 1960's. The structure of the Silo 130 civil engineering is today weakened by ageing and by the fire of 1981. Furthermore, the waste, which was initially stored dry, is now submerged in a large volume of water resulting from the extinguishing of the 1981 fire. The water is therefore in direct contact with the waste and can contribute to the corrosion of the carbon steel lining, which today is the sole containment barrier.
One of the major risks therefore concerns the dispersion of radioactive substances into the environment (infiltration of the contaminated water into the water table).
Another factor that can compromise the safety of Silo 130 is linked to the nature of the substances present in the waste, such as magnesium, which is pyrophoric. Hydrogen, a highly inflammable gas, can also be produced by the phenomena of radiolysis or corrosion (presence of water). These elements contribute to the fire and explosion risks.

Final shutdown and decommissioning operations

HAO facility

BNI 80 carried out the first stages of the reprocessing of spent nuclear fuels: reception, storage then shearing and dissolution. The dissolution solutions produced in BNI 80 were then transferred to the UP2-400 industrial plant in which the subsequent reprocessing operations took place.

BNI 80 comprises:
- HAO North, spent fuel unloading and storage site;
- HAO South, in which the shearing and dissolution operations were carried out;
- the «filtration» building, which accommodates the filtration system for the pool of the HAO South facility;
- the HAO silo, in which are stored the hulls and end-pieces (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 SOC (Organised Storage of Hulls) comprising three pools in which the drums containing the hulls and end-pieces are stored.

Decommissioning of the HAO facility was authorised by Decree of 31 July 2009. Orano Cycle encountered difficulties during the operations prior to decommissioning of cells 904 and 906 (difficulties in particular in achieving a radiological level in cell 906 compatible with semi-remote decommissioning operations, which led it to revise its decommissioning scenario. The new scenario will be presented to ASN in 2019.

The waste retrieval and packaging project currently under way in the HAO silo and the SOC, represents the first hold point in the decommissioning of the facility. Orano Cycle has expressed its difficulties in meeting the prescribed deadlines for retrieval of the waste contained in the HAO silo and the SOC. Pushing back the deadlines will make it necessary to modify the Decree of 31 July 2009. In 2018, the licensee continued the construction of the cell for the waste retrieved from the silo, and in late November 2018 it installed all the large equipment items.

Alongside this, BNI 80 had undergone a periodic safety review. Further to the examination of this review, ASN set additional requirements in a resolution of 4 January 2018.

UP2-400 plant, STE2 effluent treatment station and ÉLAN IIB facility

In July 2015, Orano Cycle submitted complete decommissioning files for BNIs 33 and 38. It also submitted the safety review reports for BNIs 33, 38 and 47. The examination of the reviews, conducted jointly with that of the decommissioning files, serves among other things to ascertain that the ageing management provisions are compatible with the decommissioning strategy envisaged by the licensee, in particular with the projected duration of the decommissioning project as a whole. The licensee must carry out additional studies of the earthquake resistance of the LCC (Central quality Control Laboratory). In 2018, Orano Cycle submitted updates to the decommissioning files for BNIs 33 And 38. The licensee continued carrying out the decommissioning operations authorised by the Decrees of 2013, notably in BNI 33. The decommissioning of BNI 33 is progressing satisfactorily, while that of BNI 38 is encountering difficulties, essentially due to the uncertainties about the radiological and chemical content of the cells. As far as BNI 47 is concerned, the results of the additional characterisations, prerequisites for the decommissioning operations, led Orano Cycle to start revising the decommissioning scenario, which will be presented to ASN in 2019. ASN nevertheless notes that Orano Cycle is endeavouring to establish action plans to control the schedule drifts.

Assessment of the La Hague site

ASN considers the results of Orano Cycle's activity at the La Hague site to be fairly satisfactory in the area of nuclear safety and satisfactory on the whole for worker radiation protection and environmental protection. ASN nevertheless notes that the licensee must improve the points developed below, particularly the management of maintenance and the periodic checks and the tracking of action plans.

Several inspections and events highlighted shortcomings in the periodic checks required by the General Operating Rules (RGE). ASN more specifically noted periodic checks that were not performed, and difficulties in demonstrating satisfactory training of the workers responsible for these checks.

In early 2018, the licensee subcontracted maintenance technical services, all trades combined, to an outside company for each of the three operational units of the plants in operation. These new contracts, called «multi-technique contracts», group together varied services which are themselves subcontracted in whole or in part. The ASN inspections showed that there were major implications in terms of skills and knowledge of the facilities for the chosen contractors.

Furthermore, the licensee must improve the robustness of its preventive maintenance policy for Equipment Important to Protection (EIP) and the control of its implementation. The preventive maintenance of the EIPs helps ensure the durability of their qualification, in the same way as the periodic checks and tests.

With regard to the monitoring of outside contractors, the licensee must reinforce its method of preparing the monitoring plans, taking into account the risks associated with subcontracted operations, and improve the skills and qualification of its monitoring personnel and their embracing of the specific provisions of the Order of 7 February 2012. These actions are all the more important given the implementation of these multi-technique contracts which require monitoring methods that are suited to the grouping of services.

ASN considers that Orano Cycle must continue the actions undertaken to improve the monitoring and managing of deviations and the associated lessons learned. Orano Cycle must better characterise the deviations, reduce their processing times, deepen the analysis of causes to develop preventive measures which are sometimes neglected in favour of curative actions. The actions plans drawn up further to the lessons learned from deviations or events reported to ASN must be implemented with greater rigour. ASN has observed delays in the implementation of actions associated with the control of handling operations.

ASN has noted lines for improvement with regard to the integration of Organisational and Human Factors (OHF) in the processes relating to organisational modifications and safety, implementation of the associated baseline requirements of the Orano group and decompartmentalisation of the departments in which the site's skills are situated. Orano Cycle must develop its resources and the professionalization of its network of OHF representatives in order to improve its abilities to assess early warning signs, deviations and events, and to deepen the analysis of the root and organisational causes of malfunctions. Orano Cycle must also ensure that the skills specific to this subject are better integrated in the preparation and monitoring of organisational changes.

During inspections on the fire theme, the inspectors noted problems with accessibility of buildings for the fire-fighting teams due to the presence of several major worksites and a lack of upkeep of certain secondary access points. Such situations can cause additional delays in response team interventions. On the other hand, progress was noted in compliance with the places specifically reserved for the emergency means, guaranteeing deployment of the response teams as close as possible to where they are needed.

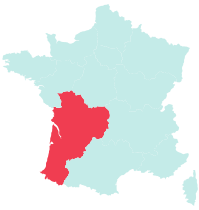
With regard to the periodic checks of the emergency means, ASN notes a widespread drift in the annual inspections of the site's fire extinguishers, indicating shortcomings in the licensee's organisation for tracking these checks.

Lastly, ASN carried out unannounced emergency situation simulations and finds that Orano Cycle must improve the coordination between its measures to control the fire risk and the measures to physically protect the nuclear materials.

In the context of the review of the analysis of risks associated with hazardous substances conducted by Orano Cycle in early 2018, ASN conducted an inspection to check *in situ* the operational nature of the safety barriers described by the licensee. ASN considers that significant improvements must be made regarding the prevention of major accidents involving hazardous substances. ASN has asked the licensee to significantly improve the non-radiological-risk culture of its teams and its means for checking risk prevention measures. The licensee must also carry out an in-depth assessment of the measures taken to prevent explosion risks and to protect the installations.

With regard to worker radiation protection, the organisation defined and implemented on the La Hague site and the results obtained are found to be satisfactory on the whole. Random sampling checks have nevertheless revealed deficiencies in cordoning off radiological zones, lateness in performing measuring instrument calibration checks and a lack of rigour in the updating of the radiation protection grids defining the radiological zoning of the installations (traceability of changes in the radiological zoning of the rooms). Furthermore, ASN has noted the increase in subcontracting of the radiation protection activity and the emergence of difficulties in recruiting and ramping up the skills of the service providers, points that will receive particular attention in 2019.

With regard to control of impacts and discharges, the organisation defined and implemented on the La Hague site and the results obtained are found to be satisfactory. ASN considers that Orano Cycle must be attentive to the rigour of management of the waste storage areas and continue its efforts to control the risks associated with the management of waste collection and packaging points.



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:

- BNIs:
  - the Blayais NPP (4 reactors of 900 MWe);
  - the Civaux NPP (2 reactors of 1,450 MWe);

see p. 200

- small-scale nuclear activities in the medical sector:
  - 19 external-beam radiotherapy departments;
  - 6 brachytherapy departments;
  - 24 nuclear medicine departments;
  - 91 centres performing fluoroscopy-guided interventional procedures;
  - 90 computed tomography scanners;
  - some 6,000 medical and dental radiology devices;

see p. 230

- small-scale nuclear activities in the veterinary, industrial and research sectors:
  - 679 industrial and research establishments, including 46 companies exercising an industrial radiography activity;
  - 1 cyclotron particle accelerator;
  - 67 laboratories situated mainly in the universities of the region;
  - 19 companies using gamma ray densitometers and 352 users of devices for detecting lead in paint;
  - 475 veterinary surgeries or clinics practising diagnostic radiology;

see p. 256

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

In 2018, ASN carried out 141 inspections in the Nouvelle-Aquitaine region, comprising 45 inspections in the Blayais and Civaux NPPs, 80 inspections in the small-scale nuclear activity sector, 6 inspections in the area of radioactive substance transport and 10 inspections of approved organisations and laboratories.

ASN also carried out 21 days of labour inspection at the Blayais NPP and 11 days at the Civaux NPP.

During 2018, 10 significant events rated level 1 on the INES scale were notified by the NPP licensees in the Nouvelle-Aquitaine region. In small-scale nuclear activities, 8 events concerning radiotherapy patients were rated level 1 on the ASN-SFRO scale and 1 was rated level 2.

Blayais nuclear power plant

Situated in the Gironde *département*, 50 km north of Bordeaux, the Blayais site accommodates the NPP 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 with respect to its general assessment of EDF performance:
- is on the whole comparable with regard to nuclear safety;
- stands out positively with regard to radiation protection;
- is below average with regard to environmental protection.

With regard to safety, ASN notes that the reactor refuelling and maintenance outages went well. ASN nevertheless observes that the site has persistent difficulties in planning, preparing and performing the periodic tests required by the general operating rules. As in the preceding years, the quality

of the operational documentation constitutes a weak point for the smooth running of these tests, which introduces a risk of noncompliance with the procedures. Deficiencies in technical control and operational communication were also observed on several occasions.

As far as occupational radiation protection is concerned, ASN observes a significant drop in the number of significant event notifications compared with the preceding years. ASN notes that the licensee has met its targets with regard to collective dosimetry and radiological cleanliness of worksites. ASN does nevertheless note a few situations that reveal a lack of radiation protection culture in some workers and a lack of rigour in the management of radioactive sources.

With regard to protection of the environment, the licensee has identified the probable origin of the legacy presence of tritium in the captive water table situated beneath the power plant. The presence of tritium is in all likelihood due to leaks in the floors of the nuclear auxiliaries buildings of reactors 3 and 4. It nevertheless has no impact outside the site. ASN considers that the continuation of investigations and the implementation of repairs must be a priority for the site in 2019. ASN notes the substantial efforts made by the licensee to improve the management of its radioactive waste in accordance with the applicable rules, which the inspectors had found deficient early in the year.

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.

ASN considers that the radiation protection and environmental protection performance of the Civaux NPP are on the whole in line with its general assessment of EDF performance, but that its nuclear safety performance falls short of this general assessment.

In the area of safety, ASN notes that during the maintenance outages of reactors 1 and 2 the licensee evidenced numerous shortcomings in the preparation, planning and performance of maintenance operations on equipment important for safety. These difficulties led to maintenance non-qualities, which the site has since corrected. ASN considers that the quality of maintenance has deteriorated with respect to the preceding years. EDF has not sufficiently learned the lessons from the maintenance outage of 2017. With regard to the operating activities, ASN considers that reactor operational management is on the whole carried out with rigour, but the site must still make further efforts in this area.

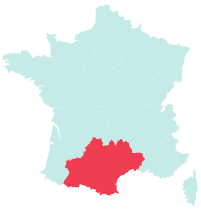
ASN considers that radiation protection must be taken into greater consideration in work preparation. ASN considers that the licensee must improve the optimisation of radiation doses received by the workers and improve the management of worker access to certain regulated areas in order to limit the risk of exposure to ionising radiation. It notes that radioactive sources are managed with rigour.

In the area of environmental protection, ASN considers that the licensee must improve its management strategy for accidental spillages of hazardous products on the site to prevent their transfer into the environment. It also considers that the licensee must improve its management of the microbiological risk and of radioactive waste on its facilities.

Labour inspection in the nuclear power plants of the Nouvelle-Aquitaine region

A tightened inspection at the Blayais NPP revealed a lack of command of the European regulations relative to the chemical risk. ASN will assess the measures taken by the licensee during 2019.
Specific investigations were carried out following workplace accidents and in response to specific requests concerning employees of outside companies. A tooling verification request was made on this occasion.

At the Civaux NPP, the labour inspectors made observations concerning compliance with the volumes of fresh air supplied in confined spaces, which led the licensee to postpone certain maintenance operations. A tightened inspection highlighted a lack of command of the European regulations relative to the chemical risk. ASN will assess the measures taken by the licensee during 2019. The labour inspectors noted that the inspection perimeter and the follow-up to observations made by an accredited organisation during the regulatory checks had to be improved, particularly in the electrical area. A request to have the electrical systems verified was made at the end of this inspection. Lastly, specific investigations were carried out following workplace accidents and in response to specific requests concerning employees of outside companies.



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:

- BNIs:
  - 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 Ecrin facility for storing 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;
  - 20 nuclear medicine departments;
  - 101 centres performing fluoroscopy-guided interventional procedures;
  - 118 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 500 industrial and research establishments, including 26 companies exercising an industrial radiography activity;
  - 4 cyclotron particle accelerators;
  - 79 laboratories situated mainly in the universities of the region;
  - about 300 users of devices for detecting lead in paint;
  - about 450 veterinary surgeries or clinics practising diagnostic radiology;

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- activities linked to the transport of radioactive substances;
- activities linked to the transport of radioactive substances;
  - 3 head offices of laboratories approved for taking environmental radioactivity measurements;
  - 7 head offices of organisations approved for radiation protection controls.

In 2018, ASN carried out 124 inspections in the Occitanie region, comprising 40 inspections in BNIs, 68 inspections in small-scale nuclear activities, 8 in the transport of radioactive substances and 8 concerning organisations and laboratories approved by ASN.

ASN also carried out 12 days of labour inspection at the Golfech NPP.

During 2018, seven significant events rated level 1 on the INES scale were reported by nuclear installation licensees. In small-scale nuclear activities, 2 significant events rated level 1 on the INES scale were reported to ASN. Four events involving radiotherapy patients were rated level 4 on the ASN-SFRO scale.

ASN also drew up one violation report against a medical centre.

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 and radiation protection performance of the Golfech NPP are on the whole in line with its general assessment of EDF performance, but that its nuclear safety performance falls short of this general assessment.

Labour inspection in the Golfech nuclear power plant

With regard to labour inspection, the inspectors noted in 2018 that the inspection perimeter and the follow-up of the observations made by an accredited organisation during regulatory checks concerning the handling cranes in particular needed to be improved.
A tightened inspection highlighted a lack of command of the European regulations relative to the chemical risk. ASN will assess the measures taken by the licensee during 2019.

In the area of nuclear safety, ASN observes that the quality of operational control has deteriorated with respect to the preceding years, resulting in the reporting of numerous significant events for safety, 4 of which are rated level 1 on the INES scale. ASN notes that the staffing of the team in charge of operational control of reactor 2 was at the absolute minimum required on several occasions during the scheduled outage and that the conditions for ensuring serenity in the control room were deteriorated on both reactors. The scheduled outage of reactor 2 went well on the whole. The licensee took account of the lessons learned from the shutdowns of 2017. ASN nevertheless considers that the improvements in activity preparation must continue. Lastly, ASN considers that the Golfech licensee must continue to improve its capacity to detect, analyse and process the deviations affecting its installations.

With regard to environmental protection, ASN notes that the site must improve its management of hazardous substances, particularly the identification of substances and knowledge of their toxicity for the environment and for humans. ASN nevertheless underlines the site's progress in management of the microbiological risk and of waste.

With regard to occupational radiation protection, ASN notes deficiencies in the preparation and conducting of activities involving serious radiation risks. The site has persistent difficulties in meeting the dosimetric targets it sets itself.

Marcoule platform

The Marcoule nuclear platform is situated to the west of Orange in the Gard *département*. Its 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 MOX fuel, 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 CEA Marcoule centre accommodates three civil installations: the Atalante laboratories (BNI 148), the Phénix reactor (BNI 71) and the Diadem storage facility (BNI 177).

Atalante facility – CEA Centre

The main purpose of the Atalante facility (BNI 148), created in the 1980s, is to conduct research and development on the recycling of nuclear fuel, the management of ultimate waste and 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. In 2018, ASN asked the CEA for additional information concerning in particular the protection of the facility against external hazards (lightning and flooding), control of the risk of loss of electrical power, and the methodology for radiological and chemical characterisation of the soils. The CEA provided additional information in 2018 and this is currently being examined.

ASN considers that the level of safety of Atalante is on the whole satisfactory. Shortcomings have nevertheless been noted in the provisions for monitoring outside contractors, particularly those performing periodic checks and tests on the facility. ASN moreover carried out a reactive inspection following an incident that occurred on 19 December 2018 involving the shattering of a bottle containing a radioactive liquid while being handled in a glove box, resulting in the injury of the worker performing the operation.

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 broad phases of its decommissioning are governed by Decree 2016-739 of 2 June 2016. ASN resolution 2016-DC-0564 of 7 July 2016 prescribes various decommissioning milestones and operations for the CEA.

The licensee is currently conducting actions to meet the ASN requirements and to fulfil 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 on the whole satisfactory. Removal of irradiated fuels and the first decommissioning activities (removal of equipment, etc.) continued in 2018 under suitably safe conditions, but at a slower rate than planned as far as fuel removal is concerned. The

construction of the NOAH facility and the putting in place of the equipment that will be used to treat the sodium from Phénix and other CEA installations, also progressed in 2018. The commissioning file for this facility is to be received in 2019. Management of the modifications to the facility must moreover be improved.

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)

At the end of 2018, the CEA Informed ASN that certain construction operations were being put on hold for budgetary reasons.

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 considers that the CEA must rapidly resume the operations necessary for its commissioning.

Assessment of the CEA Marcoule centre

ASN considers that the level of nuclear safety and radiation protection of the CEA Marcoule centre is on the whole satisfactory. Regarding environmental protection, the centre's piezometers are currently being brought into conformity with the Order of 11 September 2003.
ASN considers that the management of on-site transport operations at the Marcoule centre is relatively satisfactory. Management of the on-site transport baseline rules must nevertheless be improved.
In the context of the stress tests carried out further to the Fukushima Daiichi accident, CEA Marcoule 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.

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.

The licensee submitted its periodic safety review guidance file for the installation in 2018. The licensee had moreover taken all the necessary measures to meet its commitments and the requirements of ASN resolution 2014-DC-0440 of 15 July 2014, further to its previous periodic safety review.

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 low-level events observed over the last two years concerning noncompliance with the rules of entry into and exit from specially identified areas within the plant, as much for personnel radiation protection as for safe management of radioactive waste, have come slightly down in number.

The major radiation risks in the plant are addressed with rigour, the licensee having undertaken in particular to conduct work over the long term to achieve significant dosimetric improvements as part of the work environment optimisation rendered necessary by the ageing of the plant.

The criticality risk, which is a major factor in this type of installations, suitably addressed by the licensee. With regard to this risk, low-level events did nevertheless occur in 2018, notably during maintenance operations in which operators have to work on the automated lines (referred to as «manual-slaved» control mode). Orano Cycle also informed ASN on 13 April 2018 of noncompliance with a criticality risk management rule prior to the introduction of a new motor into one of the glove boxes of the pelletizing facility. This event was rated level 1 on the INES scale because it concerned noncompliance with a safety-criticality rule.

With regard to the lessons learned from the Fukushima Daiichi accident, ASN is monitoring continuation of the construction of the new earthquake-resistant emergency command post.

Centraco plant

The Centraco plant, which constitutes BNI 160, was created in 1996 and is operated by Socodéi, a subsidiary of EDF. The purpose of the Centraco plant is to sort, decontaminate, reuse, treat and package – particularly by reducing their volume – waste and effluents with low levels of radioactivity. The waste resulting from the plant's processes is then routed to Andra's CSA repository.

The facility comprises:
- a melting unit melting a maximum of 3,500 tonnes of metallic waste per year;
- an incineration unit incinerating a maximum of 3,000 tonnes of solid waste and 2,000 tonnes of liquid waste per year;
- and interim storage areas.

The incineration and waste melting units functioned under suitably safe conditions without yet reaching their maximum processing capacity. The technical shutdown of the incineration unit for preventive maintenance was extended in anticipation of the preventive replacement of a ventilation filter in the last containment barrier.

Through its resolution 2014-DC-0446 of July 2014, ASN had prescribed additional analyses concerning the aircraft crash, lightning and earthquake hazards. These analyses were submitted to ASN in 2018 and are currently being examined.

ASN considers that the level of nuclear safety and radiation protection in the Centraco plant is on the whole satisfactory. ASN considers that the significant events reported by the licensee are dealt with competently.

The management of on-site transport operations within the Centraco plant is satisfactory. Improvements are nevertheless expected in the on-site transport rules and their oversight, particularly with regard to the formalising of requirements specific to on-site transport which do not stem from the conventional rules governing transport on the public highway.

Gammatec ioniser

The Gammatec ioniser, which constitutes 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 sanitising (disinfecting) or sterilising materials 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 remains satisfactory. The methods of managing deviations must nevertheless be better formalised in the integrated management system of the facility.

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.

Marcoule platform environmental protection

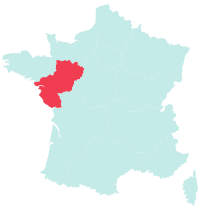
The management of waste and transfers of effluents from the civil installations, and monitoring of the environment are governed by ASN resolutions of 1 March 2016 setting out the requirements relative to the limits and conditions of liquid and gaseous effluent discharges from the Melox, Ata-lante, Centraco and Gammatec facilities. ASN considers this management and monitoring to be satisfactory. In the context of decommissioning of the Phénix reactor, a similar draft resolution for the Phénix reactor was made available for consultation by the public, the Local Information Committee, the licensee and the Departmental Council for the environment and health and technological risks in 2018, and is currently being finalised. In appli-cation of these resolutions, the Marcoule site licensees must update the site's environmental impact study (which dates from 2012) by the end of 2019.

The entire Malvesi plant is subject to the system governing Seveso high-threshold ICPEs (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 thirty years with a volume of waste not exceeding 400,000 m^3 and total radiological activity of less than 120 terabecquerels.

The Écrin facility was commissioned by ASN resolution 2018-DC-0645 of 12 October 2018. This authorisation now enables the licensee to start the work defined in the authorisation decree, more specifically the creation of a vault to the south of basin B2 in which the materials removed from basins B5 and B6 can be stored. Once all these works are completed, a bituminous cover shall be put in place of the basins of the BNI. These works, which will span several years, should start in 2019.

Furthermore, in the French National Radioactive Material and Waste Management Plan (PNGMD), 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.



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:

- BNIs:
  - the Ionisos irradiator in Sablé-sur-Sarthe;
  - the Ionisos irradiator in Pouzauges;

see p. 200

- small-scale nuclear activities in the medical sector:
  - 6 external-beam radiotherapy departments;
  - 4 brachytherapy units;
  - 11 nuclear medicine departments;
  - 40 centres performing fluoroscopy-guided interventional procedures;
  - 52 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;
  - 34 industrial radiography companies, including 7 gamma radiography contractors;
  - about 400 licences for industrial and research equipment, including 220 users of devices to detect lead in paint;

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- activities linked to the transport of radioactive substances;
- 5 radiation protection technical control agencies:
  - 1 radon screening agency;
  - 1 head office of laboratories approved for taking environmental radioactivity measurements.

In 2018, ASN carried out 54 inspections in small-scale nuclear activities and 4 inspections relative to the transport of radioactive substances.

Among the 24 significant events reported and analysed to draw lessons from them, 3 events concerned radiotherapy patients, one of which was rated level 1 on the ASN-SFRO scale, another level 2.

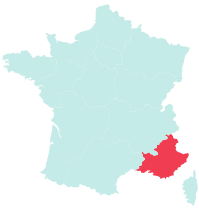
Ionisos irradiator

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 ionise (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 basin for underwater storage containing the radioactive sources and 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 2018.



Provence Alpes-Côte d'Azur region

The Marseille division regulates nuclear safety, radiation protection and the transport of nuclear substances in the 6 *départements* of the Provence-Alpes-Côte d'Azur (PACA) region.

THE INSTALLATIONS AND ACTIVITIES TO REGULATE COMPRISE:

- BNIs:
  - the CEA Cadarache research Centre which counts 21 civil BNI's, including the Jules Horowitz Reactor currently under construction;
  - the ITER installation construction site, adjacent to the CEA Cadarache centre;
  - the Gammaster industrial ioniser;

see p. 200

- 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;
  - 103 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 400 industrial and research establishments, including 21 companies exercising an industrial radiography activity;
  - 3 cyclotron particle accelerators;
  - 144 laboratories situated mainly in the universities of the region;
  - about 300 users of devices for detecting lead in paint;
  - 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;
  - 4 organisations approved for radiation protection controls.

In 2018, ASN carried out 107 inspections in the PACA region, comprising 45 inspections in BNIs, 53 inspections in small-scale nuclear activities, 6 in the transport of radioactive substances and 3 concerning organisations and laboratories approved by ASN.

During 2018, three significant events rated level 1 on the INES scale were reported by nuclear installation licensees. In small-scale nuclear activities, 2 significant events rated level 1 on the INES scale were reported to ASN. Five events involving radiotherapy patients were rated level 1 on the ASN-SFRO scale.

ASN drew up one violation report in the exercise of its oversight duties.

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 Effluent Treatment Station (STE, BNI 37-B);

- the Plutonium technology facility (ATPu, BNI 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.

Ten installations at the Cadarache centre are in final shutdown status and either preparing or have started their decommissioning (7 of them have submitted or are going to submit their decommissioning file while 3 of them have received a decommissioning decree), 10 installations are in operation and one installation 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. It is noteworthy that 10 reports were submitted in 2017. In the examination of these reports, ASN is particularly attentive to the robustness of the action plans proposed and deployed. 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 CEA was authorised by a Decree of 17 April 1980 to use 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. The CEA has requested the pushing back of the ASN requirement that the facility be completely emptied of the stored radioactive substances before the end of 2018, and the compensatory conditions are currently being examined by ASN. Final shutdown of the facility is planned for the end of 2023 and the decommissioning file is to be received by the end of 2019.

The Cascad facility, authorised by a Decree of September 1989 modifying the Pégase facility and operated since 1990, is dedicated to the dry storage of spent fuel in wells. Unlike Pégase, for which ASN has prescribed removal of the stored substances as early as possible, the standard of safety of Cascad is satisfactory.

ASN opinion on the safety of the facility in 2018 is generally positive. The CEA must nevertheless clarify the schedule for certain removal operations concerning the radioactive substances currently stored in the Pégase pool.

Cabri research reactor

– CEA Centre

The Cabri reactor (BNI 24), created on 27 May 1964, is used for experimental programmes aiming at acquiring a deeper understanding of nuclear fuel behaviour 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.

The year 2018 saw the first active tests of the CIP experimental programme (Cabri International Program) in the pressurised water loop of the renovated installation, which was authorised by ASN on 30 January 2018.

ASN considers that the level of safety 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 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. In addition, the last sodium-containing waste was transferred at the end of 2018 to the Phénix installation (BNI 71) on the Marcoule site.

The decommissioning file for BNI 25 was submitted by the licensee at the end of 2014 and supplemented in 2016. It underwent a public inquiry from 5 June to 6 July 2018. ASN is continuing the examination of this file.

ASN considers that the level of safety of the Rapsodie in 2018 is satisfactory.

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 of the perimeters of these two BNIs.

At present, the STD is the CEA's only civil BNI licensed for the packaging of LL/ILW-LL radioactive waste, called «low dose» and «intermediate dose» waste, before it is stored in the Cedra facility (BNI 164) pending transfer to a deep geological repository. The continued operation 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, the completion of which is planned for 2012. In the meantime, compensatory measures concerning the limiting of the quantities of radioactive substances in the facility and fire protection in particular, are applied.

The licensee reported one event rated level 1 on the INES scale concerning the fall of a package of intermediate-level waste in the facility on 25 October 2017. This fall was not detected and treated as a deviation from the installation's operating rules until July 2018. ASN conducted a reactive inspection concerning this event and noted firstly the fact the lack of any communication to ASN – for a period of 8 months – of information concerning what was a significant event, and secondly the fact that the report on the experience feedback on the suction-cup pick-up systems (used to handle these packages) transmitted by the licensee in response to a previous request of ASN, was particularly incomplete and did not mention the fall of the package in question.

ASN considers that the safety culture, the operating rigour, the control of subcontracted operations and the licensee's relations with its service providers on this facility must be significantly improved.

Active Effluents Treatment Station

– CEA Centre

The STE installation (BNI 37-B) has been shut down since 1 January 2014. Submission of the decommissioning file was prescribed for December 2019, in view in particular of the complexity of the installation and the time necessary for characterisation of the soils and the equipment before starting decommissioning.

ASN considers that the level of safety of BNI 37-B in 2018 is on the whole satisfactory. Nevertheless, the characterisation of the soils has revealed legacy radioactive markings which formed the subject of several significant event notifications during 2018. ASN remains particularly attentive to the way the CEA handles this new information concerning the state of the soils and the conduits, particularly in its management of storm water, due to the contamination of certain surfaces over which the storm water runs.

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 (PWR) using 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.

The removal of the waste and materials from the facilities has proceeded satisfactorily. Alongside this, the takeover of the facilities by the CEA, the installation licensee since 1 January 2017 following the transfer of responsibility from Orano, is now satisfactory.

ASN considers that the level of safety and radiation protection of the facilities in 2018 is on the whole satisfactory. The monitoring of the fire loads must nevertheless be improved to ensure adequate protection against the fire risk.

Masurca research reactor

– CEA Centre

The Masurca reactor (BNI 39), whose construction was authorised by 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 not been functioning since 2007.

The CEA submitted the report of the periodic safety review of the installation in April 2015, the examination of which ended in March 2018 with the ASN Chairman's resolution CODEP-CLG-2018-019352 of 12 March 2018 which regulates the continued operation of the installation. Final shutdown of the installation was declared by the CEA on 31 December 2018.

The situation of the Masurca reactor in terms of nuclear safety and radiation protection in 2018 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 kWe) critical mock-ups, used for neutron studies, in particular to evaluate the absorption of gamma rays or neutrons by materials.

The ÉOLE reactor (BNI 42), whose construction was authorised by the Decree of 23 June 1965, was mainly intended for neutron studies of moderated arrays, in particular those of Pressurised Water Reactors (PWR) and Boiling Water Reactors (BWR). The Minerve reactor (BNI 95), whose transfer from the Fontenay-aux-Roses studies centre to the Cadarache studies centre was authorised by 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.

The CEA submitted the decommissioning file for these installations in July 2018, and ASN is currently examining it. Pending decommissioning, operations in preparation for decommissioning, such as the removal of radioactive and hazardous substances, took place in 2018.

ASN considers that the level of nuclear safety and radiation protection of the ÉOLE and Minerve in 2018 is on the whole satisfactory. In September 2018, the licensee reported a significant event that occurred during the transport of radioactive substances between the two installations, rated level 1 on the INES scale due to noncompliance with two on-site transport rules.

The enriched Uranium Processing Facilities (ATUe) – CEA Centre

From 1963 to 1995, the ATUe (BNI 52) converted 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 true radiological condition of the installation; ASN has made several requests for additional information in this respect, and the modification request is still being examined.

In 2018, ASN authorised the CEA to proceed with the treatment of the radiologically marked soils situated within the perimeter of the installation.

ASN considers that the decommissioning of the ATUe is conducted in a relatively satisfactory manner.

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.

High-activity laboratory LECA-STAR
– CEA Centre

The Active Fuel Examination Laboratory (LECA) 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 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. Nevertheless, its resistance to an earthquake of the «Safe Shutdown Earthquake» (SSE) level is not guaranteed today, and the CEA must propose ASN an acceptable strategy for the future of this facility. 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, and it is currently examining them.

ASN considers that the safety of BNI 55 was maintained at a satisfactory level in 2018. ASN notes a good level of involvement of senior management in the safety issues. Nonetheless, ASN remains attentive to ensuring that social, organisational and human factors are properly taken into account in the operation of the facility. The licensee reported a significant event rated level 1 on the INES scale, for under-estimation of the mass of fissile material contained in two fuel cladding samples transferred from CEA Cadarache to CEA Saclay.

Solid Radioactive Waste Storage Area
– CEA Centre

BNI 56, declared in January 1968 for the disposal of waste, is used for interim storage of 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 has been in progress for several years, and the CEA submitted the decommissioning file for the installation to ASN in June 2018.

ASN notes the lateness in the projects for retrieval and packaging of the waste stored in this facility. On account

of the safety and radiation risks, the retrieval solutions are technically complex to design and implement. The CEA must improve its project management.

ASN considers that the safety management of BNI 56 has significantly progressed over the last few years and has reached a satisfactory level. With regard to environmental protection, over and beyond the monitoring of the water table under the BNI, which is adequately ensured by the licensee, ASN remains attentive to the compliance work on the storm water management system, given the operating history and the radiological marking of certain areas of the facility.

Phébus research reactor

– CEA Centre

The Phébus reactor (BNI 92) is a pool experimental reactor with a power rating of 38 MWth 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 ASN is currently examining it, along with its periodic safety review report submitted in 2017. The initial schedule for removal of spent fuel elements, authorised in 2017, could not be met in 2018 due to the unavailability of the receiving facility (located on the CEA Marcoule site). ASN points out that decommissioning is governed by compliance with this milestone.

ASN's assessment of the Phébus installation is satisfactory on the whole for 2018. The formalisation of the methods of monitoring outside contractors must nevertheless be improved.

Laboratory for Research and Experimental Fabrication of Advanced nuclear Fuels (Lefca)

– CEA Centre

Commissioned in 1983, the Lefca (BNI 123), is a laboratory designed for conducting studies on plutonium, uranium, actinides and their compounds. The Lefca carries out studies aimed at understanding the behaviour of these materials in the reactor and at various stages in the fuel cycle. It also conducts research in the treatment, stabilisation and reconditioning of these materials. In 2018, the Lefca finalised the transfer of part of its research and development activities to the Atalante laboratories (BNI 148) of Marcoule.

ASN inspection in the Cedra facility – October 2018

The groundwater drainage system for preventing the risk of liquefaction of the soils in the event of an earthquake, the installation of which is required by ASN resolution 2010-DC-0173 of 5 January 2010, was put into service in January 2018. In addition, renovation work on the nuclear ventilation of the facility, made necessary due to the obsolescence of the controlling programmable controllers, is in progress and closely monitored by ASN.

Technical requirements have been laid down to govern continued operation of the installation through ASN Chairman's resolution CODEP-CLG-2018-034301 of 5 July 2018. Furthermore, at the end of 2018 the licensee declared that final shutdown of the installation would be effective no later than 31 December 2023.

Finally, ASN considers that the level of safety of the installation is on the whole satisfactory.

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 operation of Chicade is on the whole satisfactory. The licensee reported several significant events relating to diffuse discharges of tritium to ASN in 2018, and ASN remains particularly attentive to the resolving of these diffuse discharges over the long term. The CEA must also learn the lessons from equipment failures, which are the cause of other significant events.

Cedra storage facility

– CEA Centre

Since 2006 the Cedra facility (BNI 164) processes ILW-LL waste and stores «low and medium dose» waste packages pending the creation of appropriate disposal routes.

The CEA submitted the facility's periodic safety review report to ASN in November 2017. ASN is currently examining this file, with particular attention to its exhaustiveness and the defining of the acceptance criteria applicable to the stored packages.

ASN considers that, after several years marked by failures to comply with the package acceptance and storage specifications, the management of the packages and the safety of the package reception, handling, storage and monitoring operations have improved and now reached a standard that is on the whole satisfactory. The CEA must nevertheless ensure the reliability of its suction-cup pick-up systems, which have caused significant events in this facility and others in recent years.

Assessment of the CEA Cadarache centre

ASN considers that the level of nuclear safety of the CEA Cadarache centre in 2018 is relatively satisfactory. ASN does however still note persistent disparities between the facilities of the centre, and had to use its enforcement powers further to the fall of a package in BNI 37-A, an event rated level 1 on the INES scale.
With regard to operation of the BNIs, ASN maintains its overall positive assessment of 2017 regarding the management of skills and training, compliance with the operating baseline requirements and, more broadly, the radiation protection measures taken by the centre's senior management. The management of nuclear safety is on the whole satisfactory, but the sharing of experience feedback and lessons learned between facilities must be improved. The results concerning the monitoring of service providers and subcontractors are mixed. The interfaces between the nuclear licensee and its service providers must be improved, particularly for the support facilities. In this respect, it would be beneficial to extend the good practices observed in some of the facilities of the centre to all them.
ASN considers moreover that the CEA must continue its efforts concerning protection against the fire risk, particularly in its control of the fire loads present in the facilities, the management of the periodic checks and tests, and compliance with the waste storage rules. Lastly, it was noted that only three facilities had a suitable lightning protection system. A compliance programme has been started.
ASN will be attentive to the correct performance of the work identified in the periodic safety reviews.
For the CEA, ASN observes that several projects concerning the renovation of facilities or the construction of new facilities were subsequently redefined or abandoned for budgetary reasons. In some cases, ASN may have to restrict the operating conditions, or even ask for the shutdown of certain old facilities.
The ASN resolutions of 11 July 2017 regulating discharges , transfers of effluents and monitoring of the environment of the civil installations of the Cadarache centre, referenced 2017-DC-0596 and 2017-DC-0597, are currently being deployed by the CEA which must finalise its assessment which aims at proving the conformity of the installations with these resolutions. The management of storm water before discharge must be improved in some of the older facilities.
With regard to the on-site transport of radioactive substances at the Cadarache centre, the licensee on the whole complies with its baseline requirements. The traceability of the checks carried out during these operations and the monitoring of service providers when this activity is subcontracted must nevertheless be improved.
The CEA must also revise is emergency situation management provisions to meet the requirements of ASN resolution 2017-DC-0592 of 13 June 2017. The main improvements expected concern the emergency management agreements made with the outside organisations, the emergency exercises, the teaching and training of the personnel involved in emergency management and turning lessons learned to good account.
With regard to the lessons learned from the Fukushima NPP accident, the CEA has entirely reviewed its draft project for an emergency centre that is resistance to extreme hazards due to project management difficulties, and has submitted a request to ASN for its entry into service to be pushed back. ASN thus modified the date initially prescribed for the commissioning of an operational emergency management centre that is robust to extreme hazards by resolution 2019-DC-0661 of 31 January 2019. ASN underlines that the compensatory measures proposed by the CEA pending the availability of an emergency centre that can withstand extreme hazards must be rapidly operational.
Major milestones were crossed in 2018 in the activities of decommissioning and retrieval and packaging of legacy radioactive waste and nuclear materials, notably with the completion of emptying of pools P1 and P2 of the storage area (BNI 56), and the completion of removal of the sodium-containing objects still present in the Rapsodie facility (BNI 25). ASN notes moreover that the waste and fuel removal milestones are correctly followed.

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. The removal of the material stored in the MCMF, which ended in December 2017, has lowered the activity levels in the facility. In 2018, the CEA submitted a file relating to the application for authorisation to commission new glove boxes, and it is currently being examined.

The safety of the facility is satisfactory. The CEA must nevertheless guarantee the maintaining of skills, in view of the significant personnel changes in the facility.

Effluent advanced management and processing facility (Agate) – CEA Centre

The Agate facility (BNI 171), commissioned in 2014 to replace BNI 37-B undergoing decommissioning, uses an evaporation process to concentrate radioactive liquid effluents containing mainly beta and gamma emitting radionuclides.

The Agate facility evaporator could not be used from 1 August 2017 to 8 October 2018 because deposits were discovered on the internal walls of the tank during its periodic inspection, causing interruption of the inspection. The CEA removed these deposits and put the evaporator back into service in 2018. This fortuitous discovery highlighted the need for the CEA to have buffer storage capacities for radioactive effluents in the facility and in the facilities that produce the effluents, the volumes of which increase significantly during periods when the evaporator is out of service.

ASN considers that the level of 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 on the Cadarache since 2009, is a pressurised-water technological irradiation reactor designed to study the behaviour of materials under irradiation and of power reactor fuels. It will also allow the production of artificial radionuclides intended for nuclear medicine. Its power is limited to 100 MWth.

The construction work on the RJH installation continued in 2018, notably with the continuation of installation of the lining on the pools of the «reactor» and «nuclear annex» buildings, and the installation of the hot cell doors. In addition to this, the manufacture of the large equipment off the site is still in progress.

ASN considers that the CEA manages the RJH construction worksite satisfactorily. Management and correction of deviations are carried out with rigour and efficiency.

ASN is examining the CEA's request, addressed to the Minister responsible for nuclear safety, to push back by four years the planned facility commissioning deadline due to delays in the construction work. In 2019, the licensee must clarify its overall commissioning strategy for the facility.

ITER

The ITER installation (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 s). This international project enjoys financial support from China, South Korea, India, Japan, Russia, the European Union and the United States, who make in-kind contributions by providing equipment for the project.

Owing to the delays in project progress and in some of the R&D work necessary for its design, ASN – through its resolution 2017-DC-0601 of 24 August 2017 – has regulated the new strategy for progressive commissioning of the installation through until 2035. The construction of the site's buildings continued in 2018, as did the manufacture of the equipment necessary for production of the first plasma, planned for 2025.

During 2018, ASN also took a favourable stance with regard to the licensee's planned modifications to the system for limiting the pressure in the vacuum chamber and the cooling system, which are major safety systems. The license must nevertheless submit additional safety studies and analyses focusing on the impact of these modifications and report on the progress of its action plan for controlling the hydrogen and dust explosion risk.

The inspections of the ITER Organisation carried out by ASN conclude that the safety requirements have been satisfactorily taken into account by the entire chain of outside contractors, as from the installation design stage. Improvements have been noted for the work packages under the responsibility of the European agency. The detection and processing of safety deviations must nevertheless be improved, paying attention to the quality of the analysis of causes. In effect, noncompliance with a defined requirement concerning a minimum wall thickness, which was not detected by the licensee or the chain of outside contractors, was revealed during an ASN inspection in December 2018.

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 (disinfecting) or sterilising materials or improving their performance. 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 standard of safety of Gammaster in 2018 remains satisfactory. The licensee must nevertheless continue its efforts regarding the management of maintenance operations.

UN 2917
RADIOACTIVE MATERIAL
TYPE B(M) PACKAGE NON-FISSILE
UN 2917, RADIOACTIVE MATERIAL,
TYPE B(M) PACKAGE, 7
RADIOACTIVE III
CONTENTS Co-60
ACTIVITY 13.7716 TBq
1.7
TRANSPORT INDEX
7

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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 comprising a risk of human exposure to ionising radiation related to the use either of an artificial source, whether substances or devices, or of a natural source, whether natural radioactive substances or materials containing natural radionuclides*". These nuclear activities include those carried out in Basic Nuclear Installations (BNI) and during the transport of radioactive substances, as well as in the medical, veterinary, industrial and research fields.

The various principles with which the nuclear activities must comply, particularly those of nuclear safety and radiation protection, are set out in chapter 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 State of knowledge of the hazards and risks associated with ionising radiation

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

1.1 Biological and health effects

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

When not repaired by the cells themselves, this damage can lead 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 leukemia, broncho-pulmonary cancers (owing to radon inhalation) and jawbone sarcomas. Outside the professional area, the monitoring for more than sixty years of a cohort of about 85,000 people irradiated at Hiroshima and Nagasaki 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 which, as a result of the radioactive iodine released, caused in the areas near the accident an excess in the incidence of thyroid cancers in young people exposed during their childhood. The consequences of the Fukushima Daiichi accident on the health of the neighbouring populations are not yet sufficiently known and analysed to draw epidemiological lessons from them.

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

The internationally established public health objectives related to radiation protection aim to prevent the appearance of

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

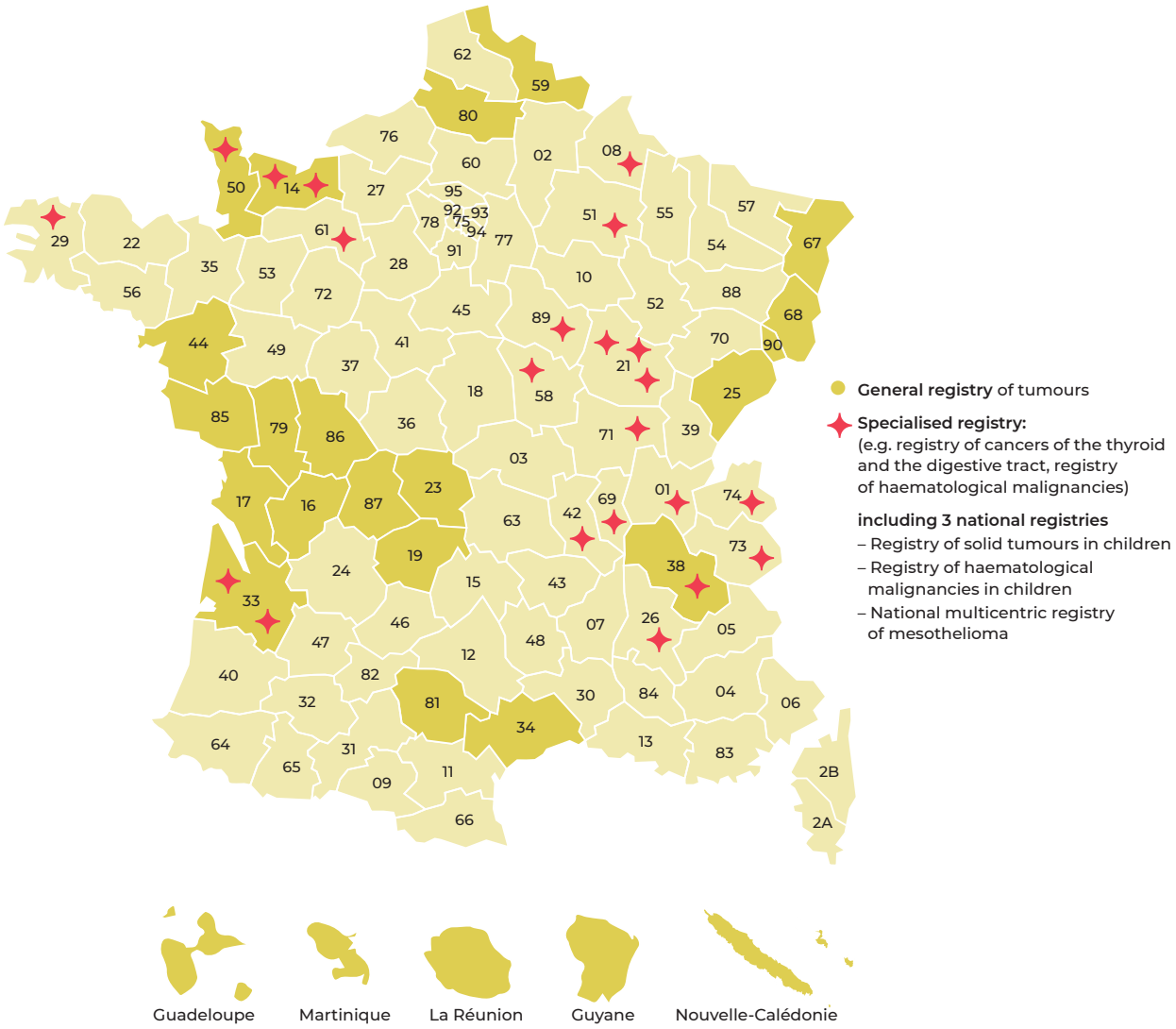
1.2 — Evolution of risks linked to ionising radiation

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 PMSI (Medicalised Programme for Information Systems) 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* 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 in the context primarily 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.

French cancer registries (2018)



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 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 radiological 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 ICPR publication 103).

The evaluation of the risk of lung cancer due to radon[1] is based on a large number of epidemiological studies conducted directly in the home in France and on an international scale. These studies have revealed a linear relationship, even at low exposure levels (200 Bq/m^3) over a period of 20 to 30 years. The World Health Organisation (WHO) has made a synthesis of the studies and recommends maximum annual exposure levels of between 100 and 300 Bq/m^3 for the general public. ICRP publication 115 compared the risks of lung cancer observed through studies on uranium miners with those observed in the overall population and concluded that there was a very good correlation between the risks observed in these two conditions of exposure to radon. The ICRP recommendations consolidate those issued by the WHO which considers that 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 French national public health agency (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 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.

The recommendations of the International Commission on Radiological Protection (ICRP)

In 2007, the ICRP published new recommendations for the calculation of effective and equivalent doses (publication 103). Since then, the ICRP has been updating the values of the effective dose coefficients for internal and external exposure taking these latest recommendations into account. Its last 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 asked the Advisory Committee for Radiation Protection in Industrial and Research Applications of Ionising Radiation and for the Environment (GPRADE) to identify to the difficulties that could arise from application of the new ICRP coefficients (publication 137 - 2017). The GPRADE report is expected in 2019.

(*) Order of 1 September 2003 defining the methods for calculating effective doses and equivalent doses resulting from human exposure to ionising radiation.

1. *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.*

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.

1.3.1 _ Radiosensitivity

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

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.

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

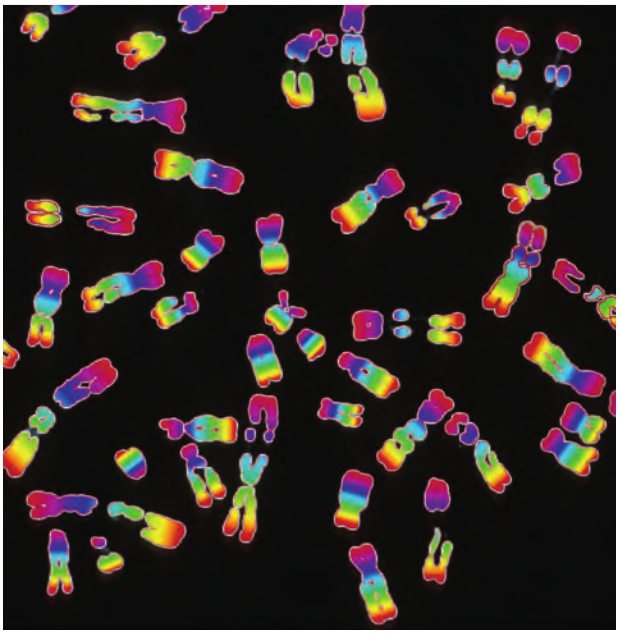
Several advances were made in 2018 concerning the variability of individual responses to ionising radiation:
- a growing number of publications on this subject, focusing as much on the clinical aspects in which this variability is seen, such as complications in radiotherapy due to increased radiosensitivity or the early appearance of cancers due to increased radiosensivity of the early appearance of cancers due to increased radiosusceptibility, as on the subjacent cellular and tissular mechanisms;
- the holding of an international seminar dedicated to the subject by the European research group MELODI in Malta in May 2018, the work of which is currently being published;
- the creation in October 2018 by the ICRP of a working group (TG111) dedicated to this subject with the aim of producing radiation protection recommendations based on acquired knowledge.

The individual response to ionising radiation is thus gradually being recognised as an important subject of research and application in radiobiology and radiation protection.

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.



Pairs of chromosomes have characteristic bands of colouring (Inserm)

• Dose, dose rate and duration of exposure

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

• 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).

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 a cell develops with a particular combination of DNA lesions that enables it to escape from the usual control of cellular division, and that it takes about ten to one hundred DNA lesions (mutations, breaks, etc.) at critical points to pass through these stages. All the agents capable of damaging cellular DNA (tobacco, alcohol, various chemical substances, ionising radiation, high temperature, other environmental factors, notably nutritional and free radicals of normal cellular metabolism, etc.) contribute to cellular 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 nanosieverts per hour (nSv/h) to 100 nSv/h.

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

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

The doses due to internal exposure of natural origin vary according to the quantities of radionuclides of the uranium and thorium families incorporated through the food chain, which depend on each individual's eating habits. According to IRSN (Institute of Radiation Protection and Nuclear Safety, 2015), the average dose per individual would be about 0.32 mSv per year. The average concentration of potassium-40 in the organism represents about 55 Bq per kilogram body mass, resulting in an average effective dose of about 0.18 mSv per year.

Waters intended for human consumption, in particular groundwater and mineral waters, become charged in natural radionuclides 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 (2 litres/inhabitant/day) may reach several tens or hundreds of microsieverts (µSv).

Radon exhalation potential in metropolitan France (source: IRSN)

— Bounds of 31 priority *départements* for radon monitoring
▪ Areas of the potential for radon exhalation

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 (see map below). 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 (BRGM). Based on this, a finer classification, by locality, was published by Interministerial Order of 27 June 2018.

Ultimately, the new obligation placed on dosimetry laboratories to communicate the dosimeter results to IRSN should enhance knowledge of radon exposure in France (see the *3rd National Plan 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.

Considering the average time spent inside the home (which itself attenuates the ionic component of cosmic radiation), the average individual effective dose in a locality at sea level in France is 0.27 mSv per year, whereas it could exceed 1.1 mSv per year in a mountain locality situated at an elevation of about 2,800 metres. The average annual effective dose per individual in France is 0.32 mSv. It is lower than the global average value of 0.38 mSv per year published by UNSCEAR.

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

2.2 _ Ionising radiation arising from human activities

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

2.2.1 _ Basic Nuclear Installations

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. Basic Nuclear Installations (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.

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 2018 figures in an appendix to this report.

• Accident prevention and nuclear safety

The fundamental internationally adopted principle underpinning the specific organisational system and regulations applicable to nuclear safety is that of the responsibility of the licensee (see chapter 2). The public authorities ensure that this responsibility is fully assumed, in compliance with the regulatory requirements. As regards the prevention of risks for workers, BNI licensees are required to implement all necessary means to protect workers against the hazards of ionising radiation. They must more particularly ensure compliance with the general rules applicable to all workers exposed to ionising radiation (work organisation, accident prevention, medical monitoring of workers, including those from outside contractors, etc.).

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 consists of the means of response implemented in the event of an incident or accident.

2.2.3 _ Small-scale nuclear activities

Ionising radiation, whether emitted by radionuclides or generated by electrical equipment, is used in many areas, including medicine (radiology, radiotherapy, nuclear medicine 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 is radioactive. The three fundamental principles on which strict radioactive waste management is based are the accountability of the waste producer, the traceability of the waste and public information.

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

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

2.2.5 _ Management of contaminated sites

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

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

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.

Examples include:
- 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.

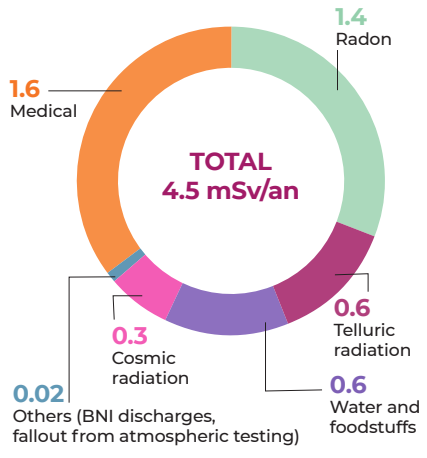
3 ___ Monitoring of exposure to ionising radiation

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 (see Diagram 1) per person per year, but this exposure is subject to wide individual variability, particularly depending on the place of residence and the number of radiological examinations received (source: IRSN 2015); the average annual individual effective dose can thus vary by a factor of up to 5 depending on the *département*. Diagram 1 represents an estimate of the respective contributions of the various sources of exposure to ionising radiation for the French population.

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

Diagram 1



Source: IRSN 2015.
* This diagram does not integrate the data published in ICRP 167 of January 2018.

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 exposure of persons liable to be exposed to ionising radiation, particularly those working in BNIs or in small-scale nuclear facilities, has been in place for several decades. This system is primarily based on the mandatory wearing of a passive dosimeter by workers liable to be exposed and it is used to check compliance with the regulation limits applicable to workers. These limits concern the total exposure (since 2003, the annual limit expressed in terms of effective dose has been 20 mSv for 12 consecutive months), obtained by adding the dose due to external exposure to that resulting from any internal contamination; other limits, called equivalent dose limits, are defined for the external exposure of certain parts of the body such as the hands and the lens of the eye (see "References" heading on *asn.fr*).

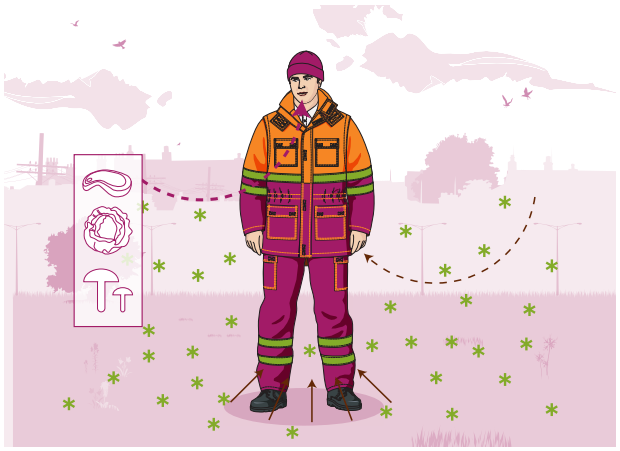
The recorded data allow the identification of the cumulative exposure dose for a given period (month or quarter) for each person working in nuclear facilities, including workers from subcontractor companies. They are grouped together in Siseri (Ionizing radiation exposure monitoring information system) managed by IRSN and are published annually. The monitoring system does not at present include worker exposure to radon.

The results of worker exposure to ionising radiation presented below are taken from the IRSN 2017 assessment of occupational exposure to ionising radiation in France. From the methodological aspect, the IRSN assessment for 2017 introduces a significant change. This is because the 2017 assessment of external exposure has been drawn up exclusively using data recorded in Siseri, whereas in the previous years it was established by aggregating the annual syntheses requested of the dosimetry organisations. Consequently, the 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 2017, a breakdown of the populations monitored, the collective dose

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

(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 (close to 58%), only accounts for about 18% of the collective dose; on the other hand, the nuclear industry however, which represents about 20% of the headcount, accounts for more than 70% of the collective dose. The industrial sector, which represents 4% of the headcount, accounts for 5% of the collective dose.

Table 3 shows that the total number of workers monitored by passive external dosimetry has increased by 1% since 2015.

In 2017, the collective dose reached 53.5 man-Sv, a value that is about 20% lower than in 2016. This reduction is linked essentially to a drop in activity in the nuclear sector. The volume of maintenance activities at EDF in particular is lower than it was in 2016.

The number of monitored workers whose annual effective dose exceeded 20 mSv has been stable since 2015 (1 to 2 exceedances per year); two cases exceeding the effective annual dose were observed in 2017 (an effective dose of 40.7 mSv for a worker in the non-destructive testing sector and an effective dose of 43.7 mSv for a medical worker) (see Diagram 2).

With regard to the dosimetry of the extremities (fingers and wrist), 27,949 workers were monitored in 2017 (i.e. 8% of the total number of persons monitored). Out of all the persons monitored, there were four cases where the 500 mSv regulatory equivalent dose limit at the extremities was exceeded, all in the interventional radiology sector (the exceedances are situated between 510 mSv and 1,270 mSv).

For the second year running, data relative to monitoring of the lens of the eye are available. Two thousand five hundred and five people were subject to monitoring of lens of the eye exposure. The maximum dose recorded is 44.1 mSv and concerns the area of medical applications. This value should be compared with the new regulatory dose limit for the lens of the eye: cumulative value of 100 mSv over five years, without exceeding 50 mSv in a given year (20 mSv/year as from 2023).

The results of dosimetric monitoring of worker external exposure in 2017 published by IRSN in June 2018 show on the whole that the prevention system introduced in facilities where sources of ionising radiation are used is effective, because for 96% of the population monitored, the annual dose remained lower than 1 mSv (effective annual dose limit for the public as a result of nuclear activities). Exceeding the regulatory limit values remains exceptional.

Monitoring of external exposure of nuclear workers (year 2017)

Table 1

	NUMBER OF PERSONS MONITORED	COLLECTIVE DOSE (MAN.SV*)	INDIVIDUAL DOSE > 20 MSV
Reactors and energy production (EDF)	24,961	5.73	0
Fuel cycle; decommissioning	12,579	3.65	0
Transport	800	0.07	0
Logistics and maintenance (contractors)	29,794	26.56	0
Effluent, waste	608	0.07	0
Others	6,313	1.05	0
Total civil nuclear	75,055	37.13	0

(Source: *Occupational exposure to ionising radiation in France - IRSN results*, June 2018)
* 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.

Monitoring of external exposure of workers in small-scale nuclear activities (year 2017)

Table 2

	NUMBER OF PERSONS MONITORED	COLLECTIVE DOSE (MAN.SV*)	INDIVIDUAL DOSE > 20 MSV
Medicine	154,264	8.07	1
Dental	35,506	1.41	0
Veterinary	19,151	0.33	0
Industry	14,426	2.64	1
Research	12,117	0.28	0
Others	40,837	1.95	0

(Source: *Occupational exposure to ionising radiation in France - IRSN results*, June 2018)
* Man-Sv: Unit of quantity of collective dose.

Development of number of persons monitored in all sectors and of the collective dose from 2015 to 2017(*)

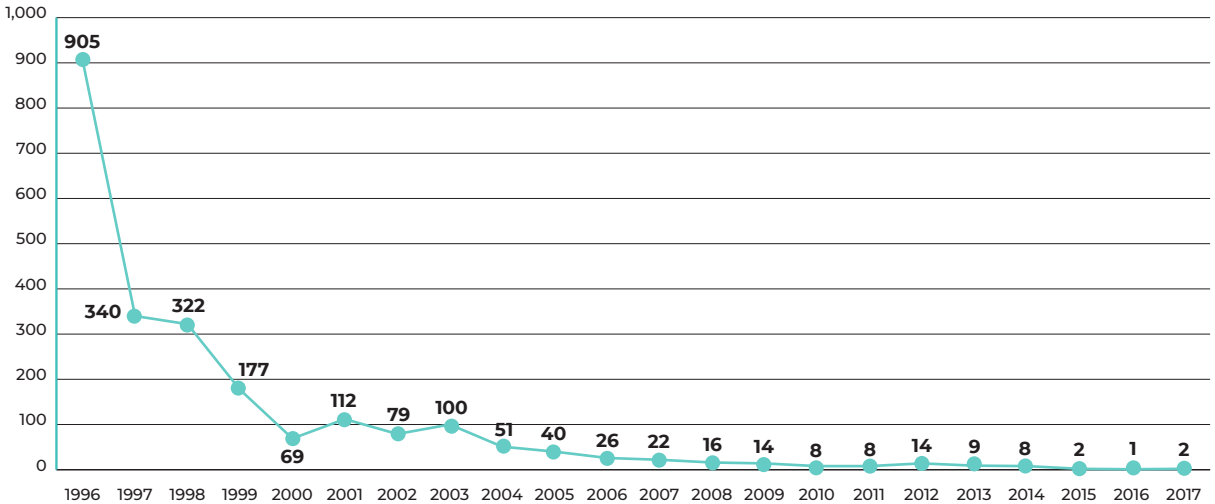
Table 3

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

(Source: *Occupational exposure to ionising radiation in France - IRSN results*, June 2018)
* For comparison purposes, the results for 2015 and 2016 have been retroactively reassessed applying the new methodological approach.

Evolution of number of workers monitored, with an annual effective dose in excess of 20 mSv from 1996 to 2017

Diagram 2



Source: IRSN

Results of dosimetry monitoring of worker external exposure to ionising radiation (natural radioactivity excluded) in 2017
(Source: Occupational exposure to ionising radiation in France - IRSN results, June 2018*)*

- Total population monitored: 360,694 workers
- Monitored population for whom the dose remained below the detection threshold: 285,856 workers, or more than 79%
- Monitored population for whom the dose remained between the detection threshold and 1 mSv: 61,927 workers, or about 17%
- Monitored population for whom the dose remained between 1 mSv and 20 mSv: 12,911 workers, or more than 3.6%
- Monitored population for whom the annual effective dose exceeded 20 mSv: 2 workers
- Monitored population for whom the annual effective dose to the extremities exceeded 500 mSv: 4 workers
- Collective dose (sum of individual doses): 53.5 man-Sv
- Annual average individual dose in the population which recorded a dose higher than the detection threshold: 0.72 mSv

Results of internal exposure monitoring (natural radioactivity excluded) in 2017

- Number of routine examinations carried out: 243,871 (of which less than 0.7% were considered positive)
- Population for which a dose estimation was made: 439 workers
- Number of special monitoring examinations or verifications performed: 9,159 (of which 12% were above the detection threshold)
- Population having recorded a committed effective dose exceeding 1 mSv: 3 workers

Results of cosmic radiation exposure monitoring in 2017 (civil aviation)

- Collective dose for 22,600 flight crew members: 46.9 man-Sv
- Annual average individual dose: 2.1 mSv

Results of monitoring of exposure to natural radionuclides of the uranium and thorium decay chains in 2017

- External exposure:
  - collective dose for 1,425 workers: 61 man-mSv
  - annual average individual dose in the population which recorded a dose higher than the detection threshold: 0.22 mSv
- Internal exposure:
  - collective dose for 375 workers: 76 man-mSv
  - annual average individual dose in the population which recorded a dose higher than the detection threshold: 0.60 mSv

To conclude, as in the preceding years, the results for the doses received by the workers in 2017 remained stable, with the annual dose received remaining below 1 mSv for about 96% of the workers liable to be exposed, and two cases exceeding the annual limit dose of 20 mSv. Monitoring of exposure of the lens of the eye with, for this tissue, compliance with the new limit, constitutes the main objective of radiation protection in the immediate years and more specifically in the area of fluoroscopy-guided interventional medical practices.

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

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

The results of 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 2017. Only one study was produced in 2017 (coal-fired power station sector). The estimated doses are all below 0.05 mSv/year.

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 (system put in place by the DGAC - General Directorate for Civil Aviation, IRSN, the Paris Observatory and the French Institute for Polar Research Paul-Emile Victor (*sievert-system.com*), has been changed. It is IRSN that calculates the individual doses avec 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 2017, SievertPN had sent Siseri all the flight crew doses for ten airlines having subscribed to the system, giving a total of 22,600 flight crew members monitored by this system. In 2017, 19% of the individual doses were below 1 mSv and 81% of the individual annual doses were between 1 mSv and 5 mSv. The maximum permitted individual annual dose is 5.5 mSv.

3.2 _ Doses received by the population

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

The automated monitoring networks managed nationwide by IRSN (*Téléray*, *Hydrotéléray* and *Téléhydro* networks) offer real-time monitoring of environmental radioactivity and can highlight any abnormal variation. In the case of an accident or incident leading to the release of radioactive substances, these measurement networks would play an essential role by providing data to back the decisions to be taken by the

authorities and by notifying the population. In a normal situation, they contribute to the evaluation of the impact of BNIs (see chapter 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 per year) cannot be controlled directly. However, for BNIs, there is detailed accounting of radioactive effluent discharges and radiological monitoring of the environment is implemented around the installations. On the basis of the data collected, the dosimetric impact of these discharges on the populations in the immediate vicinity of the installations is then calculated using models simulating transfers to the environment. The dosimetric impacts vary, according to the type of installation and the lifestyles of the reference groups chosen, from a few microsieverts to several tens of microsieverts per year.

There are no known estimates for nuclear activities other than 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 (Ukraine), can make a marginal contribution to population exposure. Thus the average individual effective dose currently being received in metropolitan France as a result of fall-out from the Chernobyl accident is estimated at between 0.01 mSv and 0.03 mSv/year (IRSN 2001). That due to the fall-out from atmospheric testing was estimated in 1980 at about 0.02 mSv. Given a decay factor of about 2 in 10 years, current doses are estimated at well below 0.01 mSv per year (IRSN, 2015). With regard to the fall-out in France from the Fukushima Daiichi accident (Japan), the results published for France by IRSN in 2011 show the presence of radioactive iodine at very low levels, resulting in very much lower doses for the populations than those estimated for the Chernobyl accident, and having negligible impact.

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

• Exposure due to natural radioactivity in drinking water

The results of the monitoring of the radiological quality of the tap water distributed to consumers carried out by the regional health agencies between 2008 and 2009 (DGS/ASN/IRSN report published in 2011) showed that 99.83% of the population receives tap water whose quality complies at all times with the total indicative dose of 0.1mSv/year set by the regulations. This basically satisfactory assessment also applies to the radiological quality of the bottled water produced in France (DGS/ASN/IRSN report published in 2013).

As from 2019, measurement of the radon content of tap water and bottled water will be 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

Since 1999, it is compulsory to take periodic radon measurements in places open to the public, especially in educational institutions and healthcare and social institutions, due to the risk of lung cancer attributable to prolonged exposure to radon. Since August 2008, this compulsory monitoring has been extended to workplaces located in the priority geographical areas.

On the basis of the results communicated by the ASN-accredited organisations for the 2017/2018 campaign, more than 95% of the screenings were carried out in educational institutions and healthcare and medical-social institutions (48% and 46% of screenings respectively). The radon activity concentration is lower than the action threshold of 400 Bq/m^3 in 79% of educational institutions and 87% of the healthcare and medical-social institutions screened.

For the institutions in which the radon activity concentration exceeds 400 Bq/m^3, simple remediation measures or works must be carried out to lower the radon activity concentration to below this threshold. This threshold was reduced in June 2018 to 300 Bq/m^3. Nearly 50% of the post-work inspections carried out by the ASN-accredited organizations confirmed that the radon activity concentration had been brought below the 400 Bq/m^3 threshold.

The results of the inspections in places open to the public are not appropriate for precisely assessing the doses linked to exposure of the general public due to the fact that exposure in the home accounts for the largest part of the doses received during one's lifetime.

Informing and heightening the awareness of the public and the main actors concerned by the radon risk (regional authorities, employers, etc.) are therefore essential and are now entered as a top strategic priority in the 3rd National Plan for Radon Risk Management. This national plan for the 2016-2019 period is coordinated by ASN. It was published in January 2017.

In this new plan, the strategy of informing and raising awareness is based on the new legislative measures adopted in 2016. Prominent among these is the obligation to inform real estate buyers and tenants of the health risks associated with radon in the home.

Deployment of the 3rd National Plan for Radon Risk Management 2016-2019, which accompanies the updating of the regulations in this area (see the "References" heading on *asn.fr*) and the publication in June 2018 of the new mapping of localities considered as priorities with regard to the radon risk, should allow an increase in communication towards the public in order to heighten awareness of this risk. In consultation with the public administrations concerned Regional Health Agencies (ARS), Regional Directorate for the Environment, Planning and Housing (Dreal), Regional Directorate for Enterprises, Competition, Consumption, Labour and Employment (Direccte)), the regional divisions of ASN are committed to taking part in the information actions and performing inspections, particularly in buildings open to the public.

ASN regional divisions playing a front-of-stage role in the prevention of the radon risk in the regions

In the exercise of its mission to monitor radon concentrations in buildings open to the public, ASN conducted three inspections of the largest managers of teaching institutions in the Bourgogne-Franche-Comté region. These inspections (of the departmental councils of the Nièvre and Saône-et-Loire *départements*, which manage 30 and 51 junior secondary schools respectively, and the town of Autun, which manages 7 primary schools) confirmed that the demands made by ASN in 2016 had been taken into account and that all the schools had undergone radon screening. Remediation measures are in progress in 10% of the schools of the region, where the radon concentration was higher than the threshold for regulatory action.

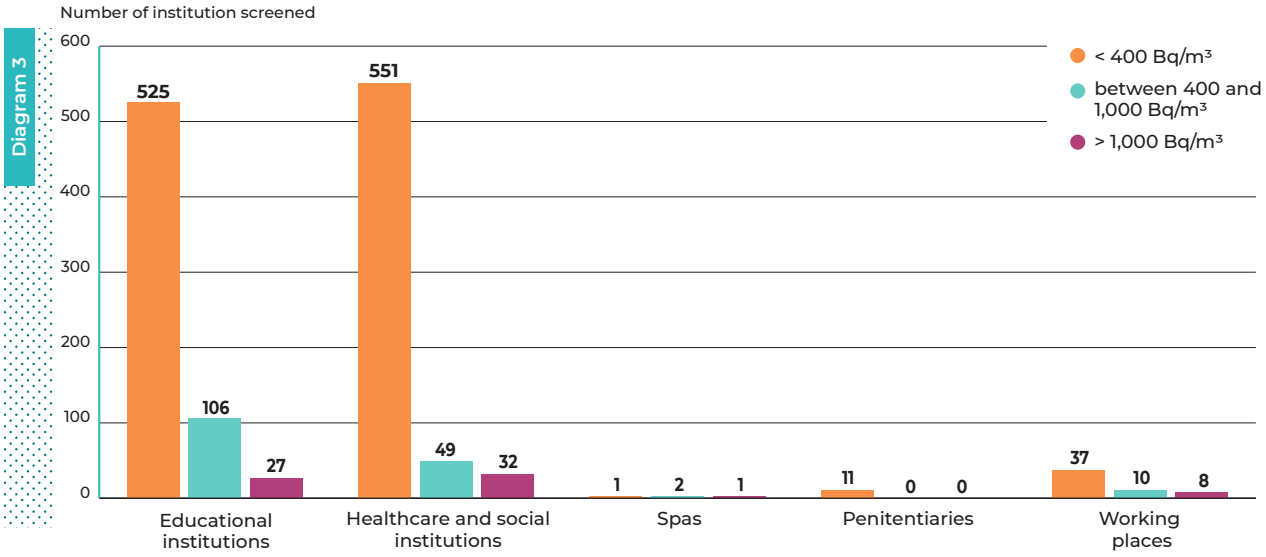
In the Auvergne-Rhône-Alpes region, the ASN Lyon division exercised its oversight in the buildings open to the public in 8 *départements* with priority status for management of the radon risk: the result of the remote survey initiated in 2014 with the 80 largest municipalities of the region responsible for public schools led ASN to chase up more than 10 municipalities in which the radon management situation was unsatisfactory (no screening, failure to take remedial action in excess radon situations, no new measurements taken to check the effectiveness of remedial work, etc.). In the PACA and Occitanie regions, two inspections were conducted in the departmental councils of the Hautes-Alpes and Lozère *départements*.

ASN also focused its actions on informing the stakeholders and the public. Along with the public administrations (Dreal, ARS, Cerema) and partner organisations (trade associations, local authorities, etc.), it draws the attention of elected officials, building trade professionals, employers, managers of buildings open to the public, and the public at large, to the radon risk and the changes in regulations. This is the case in the Bourgogne-Franche-Comté region, where ASN, since 2011, has participated in the actions of the partners of the “pluralistic radon initiative”, which aims at raising the awareness of regional authorities, building trade professionals and private individuals to the risks induced by exposure to radon. Since 2016, the Dijon division of ASN has also been participating in the Franco-Swiss “Jurad-Bat” project, which aims at establishing, in 2019, a cross-border computer platform to foster integration of the radon issue in the training of building trade professionals. In Bourgogne-Franche-Comté in 2018, ASN, the Regional Health Agency (ARS) and Regional Directorate for the Environment, Development and Housing (Dreal) jointly set up a Regional Guidance Committee for Radon Risk Management (Comor) to analyse the experience feedback from the various initiatives and use it to draw up a coordinated action plan for the entire region.

In the Grand Est region, in collaboration with the ARS and ATMO – an accredited air quality monitoring association, ASN took part in an information seminar for local elected officials which was held on 16 May 2018 in Holtzwihr (Haut-Rhin). Some 30 mayors attended the seminar. This gave ASN the opportunity to present the new obligations incumbent on local authorities following the transposition of Directive 2013/59 Euratom into French law. An information session was also held at the spas of Niederbronn-les Bains and Morsbronn-les-Bains (Bas-Rhin *département*) on 27 July 2018 with the ARS, as the management of the two spas had decided to assess the radon risk at the work stations situated in the basement.

Lastly, in the Pays de la Loire region, in which between 65% and 80% of the municipalities in the *départements* of Loire-Atlantique, Maine-et-Loire, Mayenne and Vendée are situated in areas with high radon potential, the ASN Nantes division participated in the first “Radon morning” held on 6 November 2018, which was attended by more than 80 representatives of local authorities, teaching institutions, health and social facilities, associations and design offices. The aim of this event, which formed part of the 3rd Regional Plan for Health and the Environment (PRSE3), was to present the new regulatory obligations with regard to the radon risk in buildings open to the public. The new obligations with regard to labour law were also presented. Lastly, this event provided the opportunity to set out the new obligations in the areas of real estate (information to buyers and tenants) and to encourage the local authorities to conduct radon measurement campaigns in private homes in order to raise awareness in the general public.

Distribution of radon activity concentrations by type of institution screened (in %), 2017/2018 campaign



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

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.

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

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

ASN's second plan of action, 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 address several areas, including human resources and training, quality and safety of professional practices, and equipment.

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

Table 4

IMAGING METHOD	PROCEDURES		COLLECTIVE EFFECTIVE DOSE	
	NUMBER	%	mSv	%
Conventional radiology (dentistry excluded)	44,175,500	54.0	18,069,200	17.7
Dental radiology	27,616,000	33.8	165,700	0.2
Computed Tomography	8,484,000	10.4	72,838,900	71.2
Diagnostic interventional radiology	377,000	0.5	3,196,400	3.1
Nuclear medicine	1,103,000	1.3	7,928,300	7.8
Total	81,755,500	100.0	102,198,500	100.0

Source: IRSN 2014

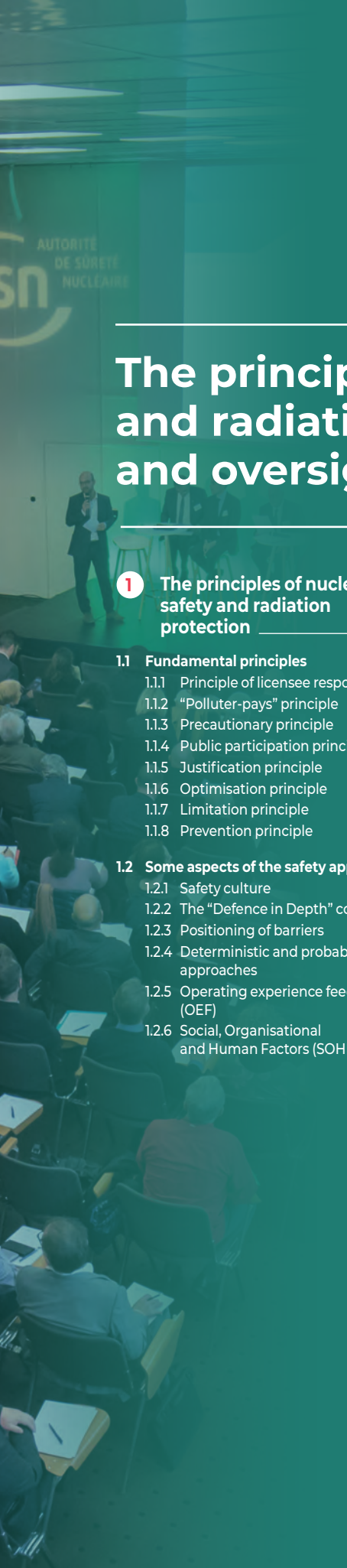
Particular attention is required in order to control and reduce the doses linked to medical imaging, more specifically when alternative techniques can be used for a same given indication, because the multiplication of the most heavily irradiating examinations for the same person could lead to a final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

Managing the doses of ionising radiation delivered to persons during a medical examination remains a priority for ASN. A second plan of action, which extends the previous one (2011-2017), drawn up in collaboration with the stakeholders (institutional and professional), was published in July 2018. A new IRSN assessment of how doses delivered to patients are evolving is expected in 2019.

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. Following the recommendations of this opinion, at the end of 2017 ASN set up a pluralistic and multi-disciplinary working group coordinated by IRSN to produce a methodological guide for assessing the impact of ionising radiation on the flora and fauna. The draft guide is to be submitted to ASN in the first quarter of 2020.



02

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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 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), which established the international framework for the oversight of nuclear safety and radiation protection.

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

1.1.1 – Principle of licensee responsibility

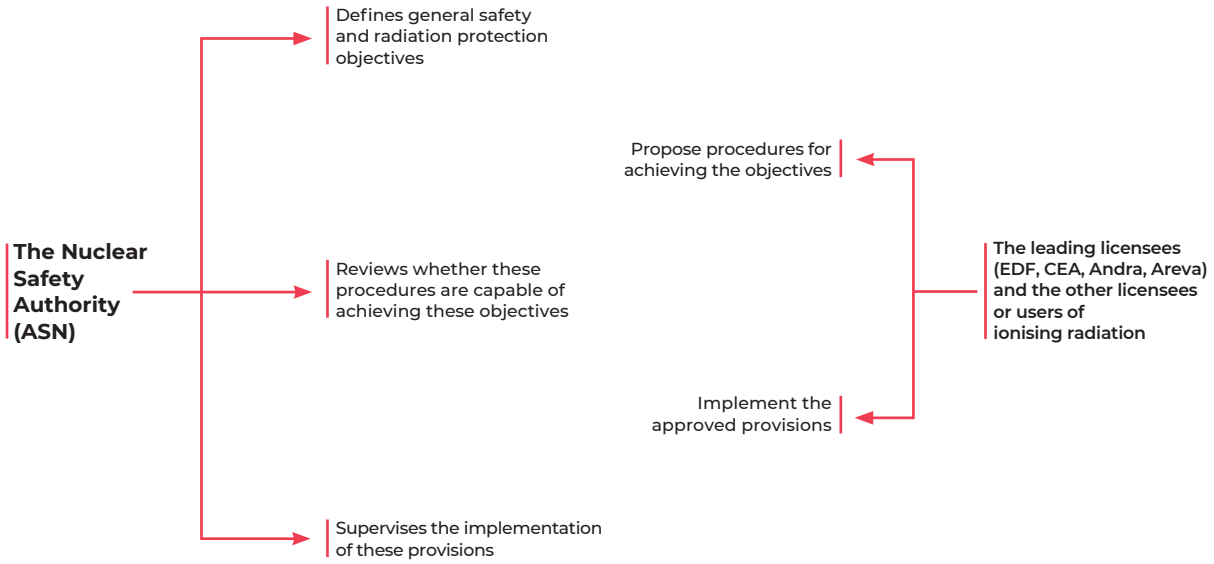
This principle, defined in Article 9 of the Convention on Nuclear Safety, is the first of IAEA's fundamental safety principles. It stipulates that responsibility for the safety of nuclear activities entailing risks lies with those who undertake or perform them.

It applies directly to all nuclear activities.

1.1.2 – "Polluter-pays" principle

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

Responsibility of licensees and responsibility of ASN



1.1.3 _ Precautionary principle

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

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

1.1.4 _ Public participation principle

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

The fundamental safety principles

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

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

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

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

1.1.8 _ 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), an international nuclear safety consultative group reporting to the General Director 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:

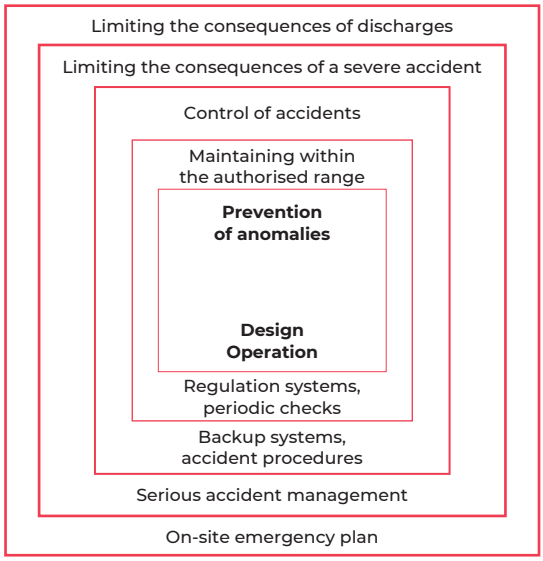
• Level 1: Prevention of abnormal operation and system failures

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.

The 5 levels of "Defence in Depth"



• Level 3: Control of accidents without core meltdown

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

Such accidents are generally studied with pessimistic hypotheses, that is to say the various parameters governing this accident are assumed to be as unfavourable as possible. In addition, the single failure criterion is applied, in other words we postulate that in the accident situation and in addition to the accident, there will be the most prejudicial failure of one of the components used to manage this situation. As a result of this, the systems 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 Probabilistic Safety Assessments (PSA) consist in establishing event trees for each "initiating event" leading to the activation of a safeguard system (level 3 of defence in depth), defined by the failure (or the success) of the actions provided for in the reactor management procedures and the failure (or correct operation) of the reactor. The probability of each sequence is then calculated based on statistics on the reliability of systems and on the rate of success of actions (including data on "human reliability"). Similar sequences of events that correspond to the same initiating event are grouped into families, making it possible to determine the contribution of each family to the probability of reactor core meltdown.

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

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

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

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

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

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

1.2.5 _ Operating Experience Feedback (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). A first goal of OEF is to understand, and thus ensure progress in technological understanding and knowledge of actual operating practices, so that whenever pertinent, a fresh look can be taken at the design (technical and documentary). As OEF is a collective process, a second goal is to share the resulting knowledge on the basis of the date of detection and recording of the anomaly, the lessons learned from it and how it was rectified. A third goal of OEF is to act on working organisations and processes, on working practices (both individual and collective) and on the performance of the technical system.

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

1.2.6 _ Social, Organisational and Human Factors (SOHF)

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

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

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

The working environment for instance concerns the heat, sound or light environment of the workstation, as well as the accessibility of the premises.

The variability in worker characteristics (vigilance varies with the time of day, the level of expertise varies according to the seniority in the position) and in the situations encountered (unexpected failure, social tension) explains that 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 the licensee define and implement an Integrated Management System (IMS) designed to ensure that the safety, radiation protection and environmental protection requirements are systematically taken into account in all decisions concerning the facility. The IMS specifies the steps taken with regard to all types of organisation and resources, in particular those adopted to manage important activities. ASN thus asks the licensee to set up an IMS able to maintain and continuously improve safety, notably through the development of a safety culture.

2 — The stakeholders

The organisation of the regulation and 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 Member State *"shall establish or designate a regulatory body entrusted with the implementation of the legislative and regulatory framework referred to in Article 7, and provided with adequate authority, competence and financial and human resources to fulfil its assigned responsibilities."* 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 OPECST (Parliamentary Office for the Evaluation of Scientific and Technological Choices) and to the parliamentary commissions concerned.

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

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

The exchanges between ASN and elected officials are presented in more detail in chapter 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, within the General Directorate for Risk Prevention at the Ministry for Ecological and Solidarity-Based Transition, is in particular tasked – in collaboration with ASN – with proposing Government policy on nuclear safety and radiation protection, except for defence-related activities and installations and the radiation protection of workers against ionising radiations.

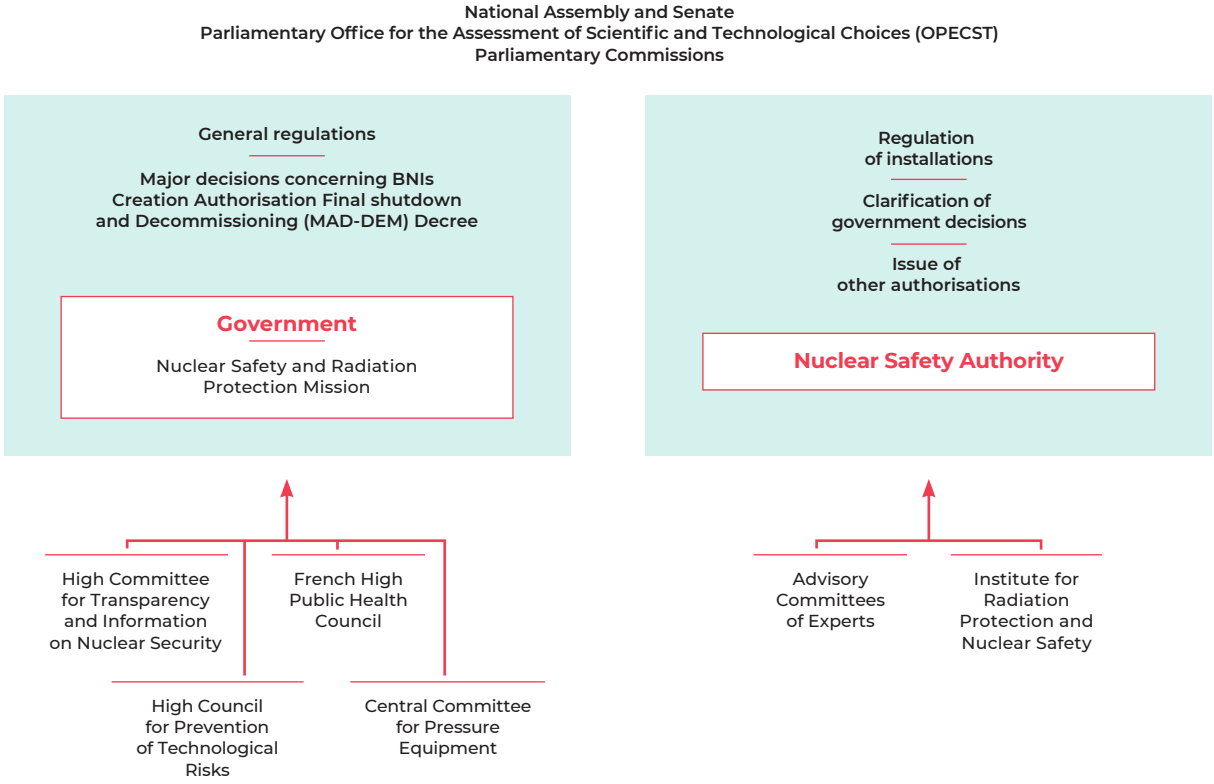
• Defence and Security High Official (HFDS)

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

This responsibility lies with the Minister for Ecological and Solidarity-based Transition, with the support of the HFDS and more specifically its Nuclear Security Department. The HFDS thus acts as the nuclear security Authority, by drafting regulations, issuing authorisations and conducting inspections in this field, with the support of IRSN.

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

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 transparency within its fields of competence.

ASN is governed by a Commission comprising five commissioners, including the ASN Chairman. They are appointed for a six-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 *Official Journal*.

• Authorisation

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

Some of these ASN resolutions require approval by the Minister responsible for Nuclear Safety.

ASN issues the licenses, carries out registration and receives the notifications provided for in the Public Health Code concerning small-scale nuclear activities and issues licenses or approvals for radioactive substances transport operations. The ASN resolutions and opinions defined by its Commission are published in its *Official Bulletin* on its website (*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 will be 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.

• Research monitoring

The quality of ASN's resolutions and decisions relies primarily on robust technical expertise which, in turn, requires the best and most up-to-date knowledge. In this field, the 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. *"ASN keeps track of national and international research and development work on nuclear safety and radiation protection. It formulates any proposals or recommendations concerning research needs in nuclear safety and radiation protection. These proposals and recommendations are communicated to the Ministers and to the public stakeholders exercising the research duties concerned so that they can be taken into account in the orientations and the definition of the research and development programmes of interest for safety"* (Article L. 592-31-1 of the Environment Code).

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

ASN takes part in IRSN's steering committee on research and draws on the expertise of a Scientific Committee to examine its proposed orientations concerning the research work to be conducted or taken further in the fields of nuclear safety and radiation protection. In a resolution dated 6 July 2018, the ASN Commission appointed for a four year-term the nine members of the Scientific Committee, selected for their expertise in the field of research. 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. The renewed Scientific Committee met for the first time on 9 November 2018.

On the basis of the work of the Scientific Committee, ASN issued a first opinion in April 2012 underlining the importance of research for ASN and identifying the first research topics to be taken further in the fields of nuclear safety and radiation protection, regarding social, organisational and human factors, radiobiology, ageing of PWR metal materials and non-destructive examinations.

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

A third opinion was issued on 4 May 2018 on research topics to 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.

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

The Fukushima Daiichi 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 Call for Projects. This call for projects enabled twenty-three projects to be carried out between 2013 and 2018. The year 2019 will be devoted to releasing the results obtained under this call for projects. Some of them also received continued funding as of 2019 for a period of two to three years, depending on the project.

Within the framework of the support given to Andra by the General Commissariat for Major Investments for research into nuclear waste, Andra decided in December 2014 to issue a Call for Projects entitled *"Optimisation of Decommissioning Radioactive Waste Management"*. This enabled fifteen research projects to be launched in this field.

2.3.2 _ Organisation

• ASN Commission

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

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

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

In 2018, the ASN Commission met 73 times. It issued 20 opinions and 39 decisions.

• ASN head office departments

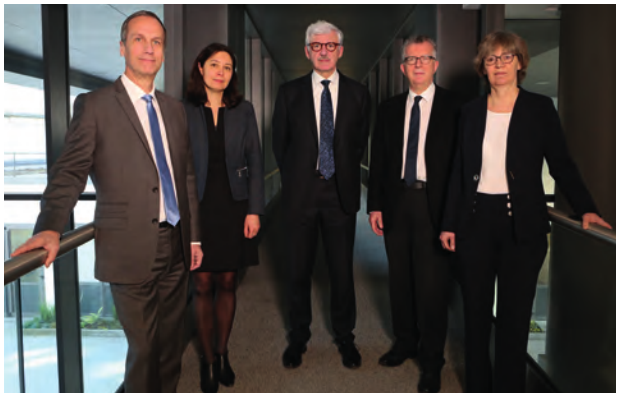
The ASN head office departments comprise an Executive Committee, an Office of Administration, a Management and Expertise Office and eight departments covering specific themes.

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

The 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

The Commission



From left to right: **Jean-Luc Lachaume, Lydie Évrard, Bernard Doroszczuk, Philippe Chaumet-Riffaud and Sylvie Cadet-Mercier**

The Executive Committee

From left to right: **Daniel Delalande, Olivier Gupta, Bastien Poubeau, Anne-Cécile Rigail and Julien Collet (Christophe Quintin, not in photo)**

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 three offices: "Public Information", "Publications and Multimedia" 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 comprises two offices: "Expertise and Research" and "Coordination and Quality".
- 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

The members of the management committee

From left to right: **Céline Acharian, Fabien Feron, Olivia Lahaye, Alain Rivière, Simon Liu, Jean-Luc Godet, Christophe Kassiotis, Frédéric Joureau, Brigitte Rouède and Rémy Catteau (Julien Husse, not in photo)**

The regional division heads

From left to right and from top to bottom: **Marc Champion, Alexandre Houlé, Jean-Michel Ferat, Pierre Siefridt, Hermine Durand, Aubert Le Brozec, Vincent Bogard, Hélène Heron, Pierre Bois, Rémy Zmyslony and Caroline Coutout**

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.

2.3.3 _ Operation

• Human resources

As at 31 December 2018, the total ASN workforce stood at 516, divided between the head office departments (289 staff members), the regional divisions (226 staff members) and various international organisations (1 staff member).

This workforce can be further broken down as follows:
- 434 tenured or contract staff members;
- 82 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.

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

Subsequent to this request, six additional staff positions were granted by the Government and Parliament, under the "2018-2020 three-year plan".

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

• Skills management

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

Management of 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.

The Regional representatives

From left to right: **Jérôme Goellner, Christophe Chassande, Alice-Anne Médard, Laurent Tapadinhas, Annick Bonneville, Patrick Berg, Corinne Tourasse and Hervé Vanlaer (Françoise Noars and Jean-Pierre Lestoille, not in photo)**

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 2018, 49 ASN nuclear safety and radiation protection inspectors were senior inspectors, or nearly 14.5% of the 339 ASN staff members holding at least one accreditation.

In 2018, nearly 4,635 days of training were provided to ASN staff through 238 sessions forming part of 125 different courses.

• 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 2018, the ASN Social Dialogue Committee (SDC) met on five occasions, including two extraordinary sessions, to discuss various subjects: the on-call duty system, the time charter and the use of teleworking and roaming work, the reorganisation of the ASN support and transverse departments, the ASN internal regulations and their appendices (charter of ethics and analysis and assessment charter), the pricing policy for the administrative canteen, the professional elections (obligation to ensure a balanced male/female representation within the personnel social dialogue bodies), the travel charter, preliminary administrative inquiries, the social audit, the training audit, or implementation of the budget.

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 2018.

The debates and discussions with the personnel representatives also covered the following topics:

- the actions fostered by the CHSCT, more particularly monitoring the Prevention of Psychosocial Risks (RPS) and the operating audit of the RPS unit;
- annual audit of the general health, safety and working conditions situation at ASN;
- coordination of the network of prevention assistants;
- the occupational health/safety inspector's visit to the head office premises;
- the visits by the CHSCT delegation to the Châlons-en-Champagne and Strasbourg divisions.

In consultation with the member of the CHSCT and with the assistance of the network of prevention assistants, the administration continued its actions to improve the prevention of occupational risks and launched its campaign to update the consolidated Occupational Risks Assessment Document (DUERP).

For its part, the Joint Consultative Commission, with competence for contractual staff, met twice in 2018. In addition to the procedure to give tenure to contractual staff set out in Decree 2016-1085 of 3 August 2016 and which expired at the end of 2018, the debates mainly concerned the procedures for hiring and employing contractual staff at ASN and their career development and mobility projects.

It should be noted that regarding the actions decided on by the CCP, the administration organised a first meeting in June 2018, bringing together all the contractual staff assigned to ASN. This meeting should become a regular occurrence.

Finally, in the same way as the rest of the civil service, ASN organised professional elections on 6 December, to renew the representatives of the SDC and the CCP. These elections were marked by a turn-out of just under 75% for the SDC and just over 70% for the CCP.

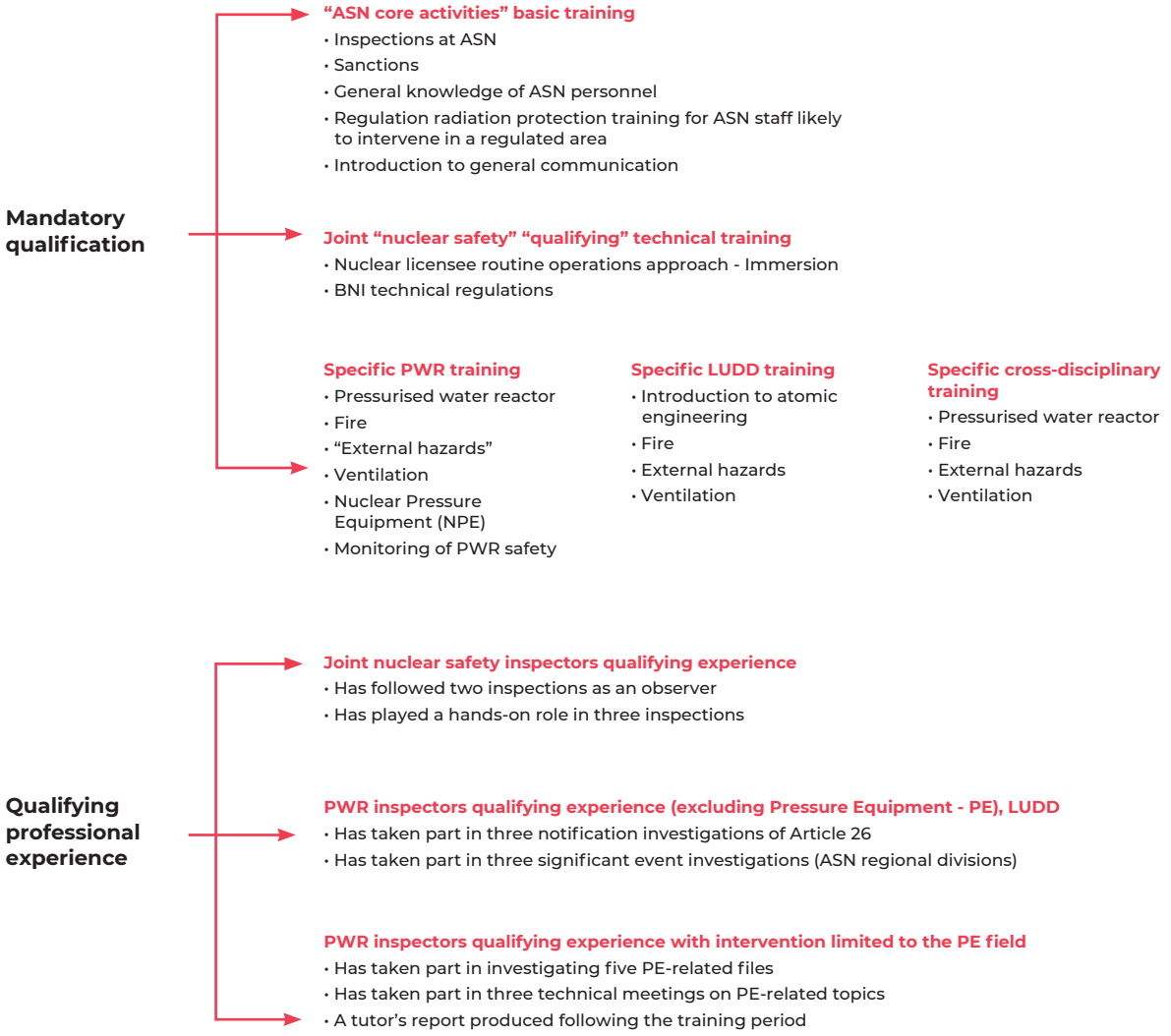
• Professional ethics

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 GPMED (Advisory Committee for Radiation Protection for Medical and Forensic Applications of Ionising Radiation). 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 65 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 (DG), the Deputy Director Generals, the Secretary 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).

"Nuclear safety" inspector training programme, Pressurised Water Reactor (PWR), Laboratories, Plants, Decommissioning and Waste (LUDD) and cross-disciplinary qualification



- "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): the decision defining ASN positions subject to the declaration of interests in this respect will be adopted jointly with the new internal rules of procedure.
- Management by the ASN Director General of his financial instruments in conditions which 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.

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

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 5 April 2018, ASN notes that the increase in its human resources by two FTE for 2018 clearly shows the Government's attentiveness to the resources devoted to the oversight of nuclear safety, at a time of unprecedented challenges. However, as the events which occurred during the year confirmed its analysis of the needs for the "2018-2020 three-year period", ASN maintains its request for hiring of

13 FTE for the years 2019 and 2020. For 2019, ASN obtained the creation of two staff positions.

• ASN management tools

The Multi-year Strategic Plan

The Multi-year Strategic Plan (PSP), produced under the authority of the ASN Commission, develops ASN's strategic lines for a period of several years. It is presented annually in an operational orientation document that sets the year's priorities for ASN, and which is in turn adapted by each entity into an annual action plan that is subject to periodic monitoring. This three-level approach is an essential part of ASN's organisation and management.

The PSP for the 2018-2020 period comprises the following five strategic points:

- reinforce implementation of a graded and efficient approach to our regulation and oversight;
- improve the running of technical assessments;
- reinforce the efficiency of our actions in the field;
- consolidate our operation to the benefit of regulation and oversight;
- promote the French and European safety approach on the international stage.

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

The ASN internal management system

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

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

Quality management system

To guarantee and improve the quality and effectiveness of its actions, ASN defines and implements a quality management system inspired by the International Standard Organisation (ISO) and IAEA international standards. This system is based on:

- an organisation manual containing organisation notes and procedures, defining the rules to be applied for each task;
- internal and external audits to check rigorous application of the system's requirements;
- listening to the stakeholders;
- performance indicators for monitoring the effectiveness of action taken;
- a periodic review of the system, to foster continuous improvement.

Internal communication

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

2.4 _ The consultative and discussion bodies

2.4.1 _ The High Committee for Transparency and Information on Nuclear Security

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

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

The HCTISN's activities in 2018 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 PE takes the place of the Central Committee for Pressure Equipment (CCAP). The role of this sub-committee is to examine non-regulatory decisions falling within this scope of competence.

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

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

2.4.4 _ 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 General Council of the *département*, comprise various categories of members: representatives of *département* General Councils, of the municipal councils or representative bodies of the groups of communities and the Regional Councils concerned, members of Parliament elected in the *département*, representatives of environmental protection associations, economic interests and representative trade union and medical profession union organisations, and qualified personalities.

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

ASN international audits (IRRS missions)

IAEA's IRRS (Integrated Regulatory Review Service) 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 the result of 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 will be the case in Germany and United Kingdom in 2019.

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 2018, IRSN's overall workforce stood at 1,700 employees, of which 430 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, Nuclear Pressure Equipment (NPE), reactors, transport, laboratories and plants, medical radiation protection, radiation protection in non-medical sectors and the environment, respectively.

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

On 2 October 2018, ASN renewed the composition of the following five Advisory Committees for a period of four years, their mandates having expired:

- the Advisory Committee for Nuclear Reactors (GPR);
- the Advisory Committee for Laboratories and Plants (GPU);
- the Advisory Committee for Waste (GPD);
- the Advisory Committee for Transport (GPT);
- the Advisory Committee for Nuclear Pressure Equipment (GPESPN).

In total, just over half the experts appointed are new members.

A new Advisory Committee was set up to for Decommissioning Activities (GPDEM), to deal with the growing challenges of the decommissioning of nuclear facilities, which are distinct from those concerning the operation of facilities in service or the management of nuclear waste. Its members were appointed for a four-year term by decision of the General Director dated 30 October 2018.

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

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.

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

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 Waste (GPD)

The Advisory Committee for Waste (GPD) is chaired by Pierre Bérest and comprises 38 experts appointed for their competence in the nuclear, geological and mining fields. In 2018, an information meeting and three plenary meetings jointly with the "laboratories and plants" GPU were held. Members of the GPT and GPRADE were involved in these joint meetings.

• Advisory Committee for Nuclear Pressure Equipment (GPESPN)

Since 2009, the GPESPN has replaced the Standing Nuclear Section (SPN) of the 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. It held three plenary meetings in 2018.

• Advisory Committee for Radiation Protection in Medical and Forensic Applications of Ionising Radiation (GPMED)
Chaired by Bernard Aubert, the GPMED comprises 36 experts appointed for their competence in the field of radiation protection of health professionals, the general public and patients and for medical and forensic applications of ionising radiation. The composition of the GPMED was renewed on 16 December 2016. It held one plenary meeting in 2018.

• Advisory Committee for Radiation Protection for Industrial and Research Applications of Ionising Radiation and in the Environment (GPRADE)
Chaired by Jean-Paul Samain, the GPRADE comprises 34 experts appointed for their competence in the fields of radiation protection of workers (other than health professionals) and the public, for industrial and research applications using ionising radiation and for exposure to ionising radiation of natural origin, and protection of the environment. The composition of the GPRADE was renewed on 16 December 2016. It held two plenary meetings in 2018.

• Advisory Committee for Nuclear Reactors (GPR)
The Advisory Committee for Nuclear Reactors is chaired by Philippe Saint Raymond and comprises 36 experts appointed for their competence in the field of nuclear reactors. In 2018, it held four plenary meetings and visited the Flamanville EPR prior to examining its commissioning file.

• 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 one plenary meeting in 2018.

• Advisory Committee for Laboratories and Plants (GPU)
The Advisory Committee for Laboratories and Plants 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 2018, it held five plenary meetings, including three jointly with the GPD, and visited two BNIs before examining their file during a meeting.

• Advisory Committee for "Decommissioning" (GPDEM)
Chaired by Henri Legrand, the GPDEM comprises 34 experts appointed for their competence in the field of BNI decommissioning. The GPDEM was created by a decision of the ASN Director General on 30 October 2018 and has held its first meeting.

2.5.3 _ The ASN's other technical support organisations

To diversify its expertise and benefit from other particular skills, ASN committed credits of €0.15 million in 2018.

The framework agreement implemented in 2013 with expert analysis and assessment organisations, in order to stimulate the use of diversified expertise, came to an end in 2018. In 2019, ASN will examine the benefits to be gained from continuing with this type of framework agreement.

In 2018, ASN more particularly continued or initiated collaborations with a group of several organisations approved for nuclear pressure equipment, for an analysis of the regulatory and standards reference system concerning the evaluation of the conformity of certain equipment items.

2.6 _ The pluralistic working groups

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

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

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

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

The work of the PNGMDR WG is presented in greater detail in chapter 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 (Steering Committee responsible for Post-Accident Management). This committee, headed by ASN, has representatives from the ministerial departments concerned, the health agencies, associations, the CLI, and IRSN.

The work of the Codirpa is presented in greater detail in chapter 4.

2.6.3 _ The other pluralistic working groups

Considering that it was necessary to move forward with regard to the reflections and work being done on the contribution of humans and organisations to the safety of nuclear facilities, ASN therefore decided in 2012 to set up the Steering Committee for Social, Organisational and Human Factors (COFSOH). The purpose of the COFSOH is on the one hand to allow exchanges between stakeholders on such a difficult subject as social, organisational and human factors and, on the other, to draft documents proposing common positions by the various members of the COFSOH on a given subject, 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 coordinates the national committee in charge of the third national radon risks plan for the period 2016-2019, which met twice in 2018 (see chapter 1). Within this framework, ASN more particularly launched a working group in 2018 to deal with the drafting of an information and awareness-raising strategy targeting the audiences concerned.

Advisory Committee meetings and visits in 2018

Table 1

GPE	MAIN TOPIC	DATE
GPR	Examination of EPR safety options dossier – new model	10 and 11 January
GPR	Examination of level 1 (PSA 1) and 2 (PSA 2) probabilistic safety assessments for the 1450 MWe nuclear power reactors (N4 plant series) in preparation for their second periodic review	1st February
GPU/GPD	Periodic safety review of the Aube repository – BNI 149	8 February
GPESPN	Demonstration of in-service performance of steam generator n° 335 of the Fessenheim NPP reactor 2.	27 February
GPESPN	Management of ageing as part of the 4th periodic safety review of the 900 MWe reactors	15 March
GPR	Management of ageing of systems, structures and components as part of the 4th periodic safety review of the 900 MWe reactors	21 and 22 March
GPRADE	Information on the transposition of directive 2013/59/Euratom – Management of contaminated wastes after atmospheric releases – Involvement by the GPRADE and other Advisory Committees	27 March
GPMED	Order of 22 September 2006 relative to dosimetry information in reports for medical procedures using ionising radiation Presentation of two reports to the SFPM	27 March
GPD/GPU	Orano (Areva) decommissioning and waste management strategy	11 and 12 April
GPU	Nuclear fuel cycle in France – Examination of the "2016 Cycle impact" dossier transmitted by EDF	25 May
GPR	Inspection of Flamanville 3 EPR	30 May
GPU/GPD	CEA decommissioning and waste and materials management strategy	27 and 28 June
GPR	Commissioning of the Flamanville 3 EPR	4 and 5 July
GPRADE	Information on the texts implementing Decrees 2018-437 and 2018-434 of 4 June 2018 – Changes to Codirpa doctrine – The working group concerning radon exposure in the workplace	5 October
GPD	Kick-off and information meeting on the topic of earthquakes and the Cigeo project	25 October
GPT	DN30 package model approval application	8 November
GPU	Inspection of La Hague BNI 117	13 November
GPESPN	In-service performance of the core zone of the 900 MWe reactor pressure vessels for the 10-year period following their fourth ten-yearly outage inspection	20 and 21 November
GPU	Periodic safety review of BNI 117 – UP2 800 in the Orano Cycle facility at La Hague (1st meeting on the R2 facility (except the UCD unit) and on the SPF4, SPF5 and SPF6 facilities	4 December
GPU	Examination of safety dossier for the EDF centralised storage pool	20 December

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 AFSSAPS alongside other new responsibilities. Its key role is to offer patients equitable access to innovation and to guarantee the safety of health products throughout their life cycle, from initial testing through to monitoring after receiving marketing authorisation.

The Agency and its activities are presented on its website: *ansm.sante.fr*. The ASN-ANSM convention was renewed on 2 September 2013.

2.7.2 _ French National Authority for Health

The French National Authority for Health (HAS), an independent administrative Authority created by the French Government in 2004, is tasked primarily with maintaining an equitable health system and with improving patient care. The Authority and its activities are presented on its website *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 periodically 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.

Breakdown of licensee contributions

Table 2

LICENSEE	AMOUNT FOR 2018 (MILLIONS OF EUROS)			
	BNI TAX	ADDITIONAL TAXES WASTE AND DISPOSAL	SPECIAL ANDRA CONTRIBUTION	CONTRIBUTION ON BEHALF OF IRSN
EDF	544.61	96.67	115.92	48.42
Orano-Framatome	14.89	6.20	7.44	6.3
CEA	5.60	18.34	25.30	6.93
Andra	5.41	3.30	-	0.40
Others	5.11	1.67	-	0.71
Total	**575.62**	**126.18**	**148.66**	**62.76***

* 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 2018, the ASN budget amounted to €84.45 million in payment credits. It comprised €45.89 million in ASN payroll credits and €38.56 million in operating credits for the ASN central services and its eleven regional divisions.

The total IRSN budget for 2018 amounted for its part to €213.70 million, of which €84.3 million were devoted to the provision of technical support for ASN. IRSN credits for ASN technical support are covered in part (€41.6 million) by a subsidy from the State's general budget allocated to IRSN and included in action 11 "Research in the field of risks" of programme 190 "Research in the fields of energy and sustainable development and spatial planning", of the interministerial "Research and higher education" mission. The rest (€42.70 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. Each year, ASN is consulted by the Government concerning the corresponding part of the State subsidy to IRSN and the amount of the annual contribution due from the BNI licensees.

In total, in 2018, the State's budget for transparency and the regulation of nuclear safety and radiation protection in France amounted to €298.15 million.

As shown in the Table 3, these credits are split between five programmes (181, 217, 333, 218 and 190) to which must be added the annual contribution on behalf of IRSN.

To put this into perspective, the amount of the BNI Tax, paid to the general State budget, amounted in 2018 to €575.62 million.

This complex funding structure is detrimental to the overall clarity of the cost of regulation. It moreover leads to difficulties in terms of budgetary preparation, arbitration and implementation.

Budget structure of the credits allocated to transparency and the regulation of nuclear safety and radiation protection in France (January 2019)

Table 3

MISSION	PROGRAMME	ACTION	NATURE	BUDGET RESOURCES				REVENUE
				INITIAL BUDGET ACT 2018 AE (€M)	INITIAL BUDGET ACT 2018 CP (€M)	INITIAL BUDGET ACT 2019 AE (€M)	INITIAL BUDGET ACT 2019 CP (€M)	BNI TAX 2018 (€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)	45.89	45.89	46.45	46.45	
			Operating and intervention spending	12.64	17.64	12.53	17.53	
			Total	**58.53**	**63.53**	**58.98**	**63.98**	
		Action 1: Prevention of technological risks and pollution	Operation of the HCTISN (High Committee for Transparency and Information on Nuclear Security)	0.15	0.15	0.15	0.15	
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	14.50	14.50	14.50	14.50	
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	6.27	6.27	6.27	6.27	
			Sub-total	**79.45**	**84.45**	**79.90**	**84.90**	
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	41.60	41.60	41.36	41.36	
		Sub-action 11-2 (3 others areas): French Institute for Radiation Protection and Nuclear Safety	-	129.40	129.40	130.27	130.27	
Annual contribution to IRSN instituted by Article 96 of Act 2010-1658 of 29 December 2010			-	42.70	42.70	42.70	42.70	
			Sub-total	**213.70**	**213.70**	**214.33**	**214.33**	**575.62**
GRAND TOTAL				**293.15**	**298.15**	**294.23**	**299.23**	
Grand total without IRSN contribution				**250.45**	**255.45**	**251.53**	**256.53**	**575.62**

BNI Tax, additional waste taxes, additional disposal tax, special Andra contribution and contribution to IRSN

Pursuant to the Environment Code, the ASN Chairman is responsible for assessing and ordering payment of the BNI tax, introduced under Article 43 of the 2000 Budget Act (Act 99-1172 of 30 December 1999). The revenue generated by this tax, the amount of which is set yearly by Parliament, came to €575.62 million in 2018. The proceeds go to the central State budget.

Furthermore, for nuclear reactors and spent nuclear fuel reprocessing plants, Act 2006-739 of 28 June 2006 creates three additional "research", "support" and "technological dissemination" taxes. The revenue from these taxes is allocated to funding economic development measures and research into underground disposal and storage by Andra. The revenue from these taxes represented €126.18 million in 2018, of which €3.30 million were paid in 2018 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 2018.

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 €62.76 million in 2018.

4 Outlook

In 2019, ASN will continue to implement the 2018-2020 multi-year strategic plan, notably with reinforced implementation of a graded and efficient approach to its regulation, improved oversight of technical investigations and consolidation of its actions in the field.

In terms of internal operations, ASN will continue with efforts to improve efficiency across its activities and will improve the management of its resources 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.

When preparing its resolutions, ASN relies on the opinions and recommendations of eight Advisory Committees of Experts (GPE). ASN intends to continue to reinforce the guarantees of independence of the expertise on which it relies, and transparency in the process of drafting its regulations and decisions.

In the coming years, ASN will maintain strong ties – while retaining its full independence – with the other stakeholders involved in the oversight and information duties, in the field of nuclear safety and radiation protection. ASN will in particular promote the involvement of the stakeholders in pluralistic working groups.

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03

Regulation of nuclear activities and exposure to ionising radiation

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CHAPTER 03

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 in 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.

In 2018, ASN implemented its new oversight strategy, notably by focusing this on the actions that produce the greatest benefit for the protection of people and the environment. 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.

ASN definition of essential inspection points

For each activity considered to be a priority in the small-scale nuclear field, ASN has defined essential inspection points. They are systematically verified during the course of an inspection. Each of them was defined with a specification of what is to be inspected and how, such as the documents to be consulted prior to the inspection, interviews or direct observations, more particularly to ensure the greatest possible consistency nationwide.

For example:

- 16 points are to be checked during industrial radiography inspections on worksites, including regulatory compliance of signage;
- 18 points are to be checked during inspections of fluoroscopy-guided interventional practices, with the most important ones concerning radiation protection of the professionals concerned.

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 to 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 BNIs;
- the manufacturers and users of Nuclear Pressure Equipment (NPE) used in the BNIs;
- those in charge of radioactive substances transport;
- those in charge of activities entailing a risk of exposure of individuals and workers to ionising radiation;
- those in charge of implementing ionising radiation exposure monitoring measures;
- the nuclear licensees, their suppliers, contractors or sub-contractors when they carry out activities important for the protection of persons and the environment outside the perimeter of the BNIs.

In this chapter, these persons or entities are called the "licensees".

ASN also 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. It uses the experience feedback from 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 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"*. 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, 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 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 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 (see chapter 10).

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 (6.7 Full-Time Equivalent – FTE) in the field has increased since 2009, particularly during reactor outages, with inspection visits, advisory roles at the meetings of the Committee for Health, Safety and Working Conditions (CHSCT) and the Inter-company Committee on Safety and Working Conditions (CIESCT), as well as 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.

Methods of ASN regulation of the various radiation protection players

Table 1

	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 et 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
Bodies approved for radiation protection inspections	• 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 inspections

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 (Art. R. 4226-14), or more generally for work equipment (Art. 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 approved organisation) and periodic verifications (by the radiation protection advisor). The Order specified in Article R. 4451-51 determines the procedures and, as applicable, the frequency of the verifications, as well as the contents of the corresponding verification reports.

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 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 2017, the Organisations Approved for Radiation Protection inspections (OARP) carried out 72,550 inspections, for which the breakdown per type of source and per field is given in Table 2.

The external inspection reports performed in each facility by the OARP are at the disposal of and examined by ASN personnel on the occasion of:
- licence renewals or modifications requiring ASN authorisation;
- inspections.

Examination of these reports on the one hand makes it possible to check that the 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. It thus approves laboratories for the monitoring of:
- environmental radioactivity (see point 4.3);
- worker dosimetry (see chapter 1).

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 2018;
- the organisations responsible for certifying the conformity of packagings designed to contain 0.1 kg or more of 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 2018.

As at 31 December 2018, the following are approved by ASN:
- 41 organisations tasked with radiation protection checks; 11 approvals or approval renewals were delivered in 2018;
- 58 organisations tasked with measuring radon activity concentration in buildings. Nine of these organisations can also carry out measurements in cavities and underground structures, while 6 are approved to identify sources and means of radon ingress into buildings. In 2018, ASN issued 41 new approvals or approval renewals;

Number of radiation protection inspections performed in 2017 by organisations approved for radiation protection inspections

Table 2

	MEDICAL	VETERINARY	RESEARCH / TEACHING	INDUSTRY OUTSIDE BNIS	BNI	TOTAL
Sealed sources	1,363	12	3,636	13,256	17,478	35,745
Unsealed sources	669	4	2,580	1,274	8,566	13,093
Mobile electrical generators of ionising radiation	3,365	257	67	947	12	4,648
Fixed electrical generators of ionising radiation	8,478	938	744	5,214	189	15,563
Particle accelerators	496	1	108	147	17	769
Dental	2,732					2,732
Total	17,103	1,212	7,135	20,838	26,262	72,550

- 14 organisations tasked with the monitoring of worker internal dosimetry, 7 for external monitoring and 2 for monitoring exposure associated with natural radioactivity (one for internal exposure and one for external exposure). In 2018, ASN issued 6 new approvals or approval renewals;
- 5 organisations tasked with NPE inspections;
- 3 organisations qualified for Nuclear Pressure Equipment (NPE) and Simple Pressure Vessels (RPS) within the perimeter of BNIs (in-service monitoring);
- 19 inspection departments qualified for in-service monitoring of NPE and RPS within the perimeter of NPPs;
- 62 laboratories for environmental radioactivity measurements covering 880 approvals, of which 129 are approvals or approval renewals delivered during 2018.

ASN gives the General Directorate for Health (DGS) an opinion on the approval of the laboratories analysing radioactivity in water intended for human consumption.

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 relevant activities (work, transport operation). They may also concern the head office departments or design and engineering departments at the major licensees, the workshops or engineering offices of the subcontractors, the construction sites, plants or workshops manufacturing the various safety-related components.

ASN uses various types of inspections:
- standard inspections;
- reinforced inspections, which consist in conducting an in-depth examination of a targeted topic by a larger team of inspectors than for a routine inspection;
- in-depth inspections, which take place over several days, concern a number of topics and involve about ten or so inspectors. Their purpose is to carry out detailed examinations and they are overseen by senior inspectors;
- inspections with sampling and measurements. With regard to both discharges and the environment of the facilities, these are designed to check samples that are independent of those taken by the licensee;
- event-based inspections carried out further to a particularly significant event;
- worksite inspections, ensuring a significant ASN presence on the sites on the occasion of reactor outages or particular work, especially in the construction or decommissioning phases;
- inspection campaigns, grouping inspections performed on a large numbers of similar installations, following a predetermined template.

Labour inspectorate work in the NPPs entails various types of interventions[1] which more particularly involves:
- checking application of the Labour Code by EDF and outside contractors in the NPPs (verification operations that include inspections);
- participation in the meetings of the CHSCT, the Social and Economic Committee (CSE) and the Joint Contractors Committee on Safety and Working Conditions (CIESCT) (EPR worksite);
- 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 5.2).

Some inspections are carried out with the support of an IRSN representative specialised in the facility checked or the topic of the inspection.

• ASN inspectors

ASN has inspectors designated and accredited by its Chairman, in accordance with the conditions defined by Decree 2007-831 of 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.

1. *The intervention is the unit representative of the activity traditionally used by the labour inspectorate.*

ASN definition of its inspection priorities

In order to take account, on the one hand, of health and environmental issues, licensee safety and radiation protection performance and, on the other, of the large number of activities for which it has oversight, ASN regularly identifies and reassesses its inspection priorities. It conducts regular oversight of subjects entailing potential risks, which are systematically examined on a yearly basis, and also identifies topical subjects requiring more particular attention in any given year. For example, in 2018, the inspections focused on the following topics or activities:

- management of category 2 and 3 deviations in BNIs;
- management of subcontracted activities in the NPPs;
- cross-checking of waste studies updated in 2017 for the NPPs;
- the quality and inspection of retentions in the NPPs;
- shipments of radioactive substances by the radiopharmaceutical producers;
- transport operations performed by the nuclear medicine departments;
- fluoroscopy-guided interventional medical practices;
- the detection and prevention of radon risks;
- industrial radiography.

The search for fraud is also among the priorities, mainly through the definition of inspection methods concerning this topic.

To identify these activities and these topics, ASN relies on current scientific and technical know-how and considers the information collected by itself and by IRSN: inspection results, frequency and nature of incidents, major modifications to facilities, examination of dossiers, feedback of information concerning the dose received by the workers and information about checks by the approved organisations. It adapts its priorities to take account of significant events occurring in France or around the world.

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.

Table 3 presents the headcount of inspectors, which stood at 318 on 31 December 2018. 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 54% of the ASN inspectors. The 147 inspectors assigned to the departments take part in ASN inspections within their field of competence; they represent 46% of the inspector headcount and carried out 17% of inspections in 2018, 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. The inspection work carried out by the ASN inspectors is not adequately reflected simply by the number of inspections performed, but more by the number of inspection days (a day spent on an inspection by one inspector represents 1 inspector.day).

In 2018, the ASN inspectors carried out a total of 1,813 inspections, representing 4,178 inspection days in the field, broken down as shown in Table 4.

• 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.

Breakdown of inspectors per inspection domain (as at 31 December 2018)

Table 3

INSPECTOR CATEGORIES	DEPARTMENTS	DIVISIONS	TOTAL
Nuclear safety inspector (BNI)	112	109	221
of which nuclear safety inspector (transport)	12	26	38
Radiation protection inspector	40	110	150
Labour inspector	2	12	14
Number of inspectors all domains	147	171	318

Number of inspection days per field

Table 4

BASIC NUCLEAR INSTALLATION (BNI) (EXCLUDING PRESSURE EQUIPMENT)	PRESSURE EQUIPMENT	TRANSPORT OF RADIOACTIVE SUBSTANCES	SMALL-SCALE NUCLEAR ACTIVITIES	APPROVED ORGANISATIONS AND LABORATORIES	TOTAL
1,891	231	205	1,665	186	4,178

Number of organisations approved for measuring radon levels

Table 5

	APPROVAL UNTIL 15TH SEPTEMBER 2019	APPROVAL UNTIL 15TH SEPTEMBER 2020	APPROVAL UNTIL 15TH SEPTEMBER 2021	APPROVAL UNTIL 15TH SEPTEMBER 2022	APPROVAL UNTIL 15TH SEPTEMBER 2023
Level 1 option A*	5	8	15	11	3
Level 1 option B**	0	0	1	3	1
Level 2***	0	1	3	1	1

* Workplaces and premises open to the public for all building types.
** Workplaces, cavities and underground structures (except buildings).
*** Represents complementary investigations.

• Information relative to the inspections

ASN informs the public of the follow-up to the inspections by posting the inspection follow-up letters on-line at *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

In 2018, 2,122 inspector.days were devoted to inspecting BNIs and PE, broken down into 748 inspections, about 20% of which were unannounced.

This inspection work is broken down into 1,150 inspector.days in the NPPs (370 inspections), 741 inspector.days in the other BNIs (286 inspections), in other words mainly fuel cycle facilities, research facilities and installations being decommissioned, along with 231 for pressure equipment (92 inspections).

Two in-depth inspections were performed in 2018:
- in the Gravelines NPP on the topic of safety management, more specifically compliance with maintenance and operating documentation;
- on the facilities operated by Orano on the Tricastin site, on the topic of emergency preparedness and response.

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

205 inspector.days were devoted by ASN to inspecting transport activities, comprising 117 inspections, of which 26% 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 2018, 1,665 inspector.days were devoted to inspections in small-scale nuclear activities, broken down into 842 inspections, of which 10% 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.

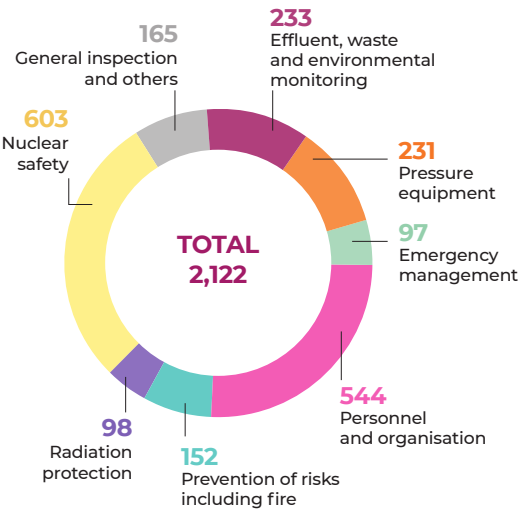
In 2018, 186 inspector.days were devoted to inspecting approved organisations and laboratories, comprising 106 inspections, of which 48% were unannounced.

3.1.7 _ Checks on exposure to Radon and Naturally Occurring Radioactive Materials (NORM)

ASN also monitors radiation protection in premises where exposure of individuals to natural ionising radiation can be enhanced owing to the underlying geological context (radon in premises open to the public) or the characteristics of the materials used in the industrial processes (non-nuclear industries).

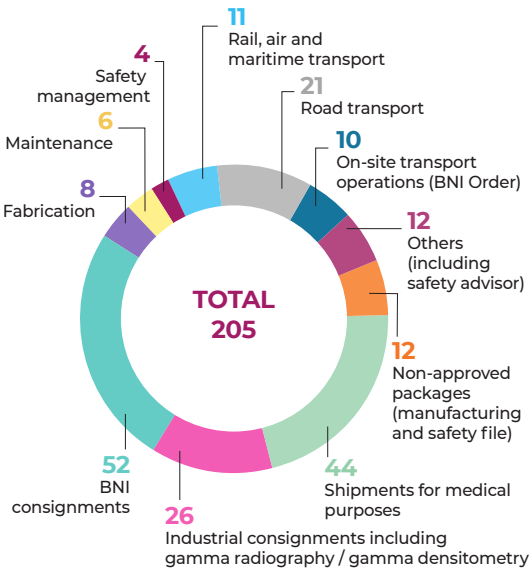
Breakdown of inspection days in the BNIs by topic in 2018*

Graph 1



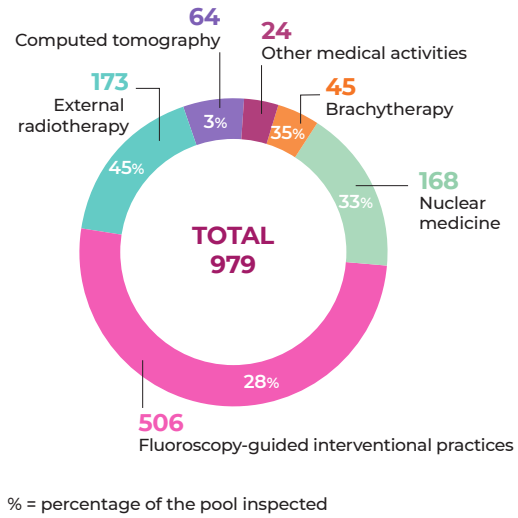
Breakdown of inspection days in the transport of radioactive substances by topic in 2018*

Graph 2



Breakdown of inspection days in the medical field by nature of activity in 2018*

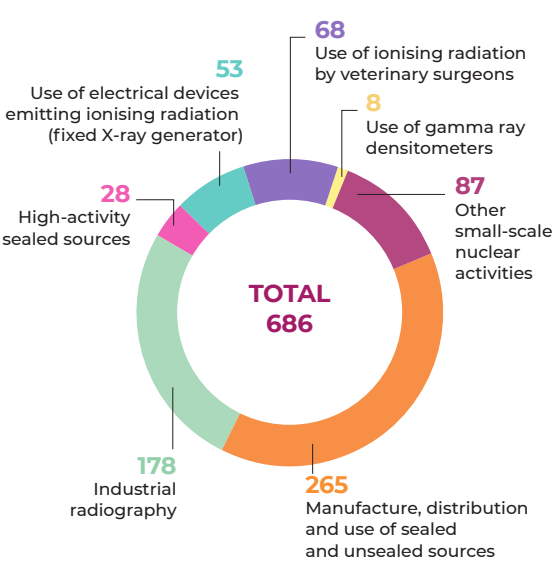
Graph 3



% = percentage of the pool inspected

Breakdown of inspection days in small-scale nuclear industrial and veterinary activities by nature of activity in 2018*

Graph 4



* Inspection day figures rounded off.

• Monitoring exposure to radon

Article R. 1333-15 of the Public Health Code and Article R. 4451-136 of the Labour Code provide for the radon activity concentration to be measured either by IRSN or by ASN approved organisations.

These measurements are to be taken between 15 September of a given year and 30 April of the following year.

For the 2017-2018 measurement campaign, the number of approved organisations is indicated in Table 5.

• Monitoring exposure to natural ionising radiation in non-nuclear industries

The Order of 25 May 2005 defined the list of professional activities (ore or rare earth processing industries, spas and facilities treating groundwater for human consumption) requiring monitoring of human exposure to natural ionising radiation. In these activities, the materials used contain natural radionuclides likely to generate doses that are significant from the radiation protection standpoint.

• Monitoring natural radioactivity in water intended for human consumption

Monitoring the natural radioactivity in water intended for human consumption is the role of the ARS. The procedures

for these checks take account of the recommendations issued by ASN and are taken up in the DGS Circular of 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.

At the design and construction stage, ASN – aided by its technical support organisation – assesses the safety analysis reports describing and justifying the design principles, equipment and system design calculations, utilisation rules and test procedures, and quality organisation provisions implemented by the prime contractor and its suppliers. It also analyses the facility's environmental impact assessment. ASN regulates and oversees the construction and manufacture of structures and equipment, in particular that of the main primary system and the main secondary systems of pressurised water reactors. In accordance with the same principles, it checks the packages intended for the transport of radioactive substances.

Once the nuclear facility has been commissioned, following ASN authorisation, all changes to the facility or its operation made by the licensee that could affect security, public health and safety, or the protection of the environment, are notified to ASN or submitted to it for authorisation. Moreover, the licensee must perform periodic safety reviews to update the assessment of the facility, taking into account any changes in techniques and regulations, and experience feedback. The conclusions of these reviews are submitted by the licensee to ASN, which can issue new binding requirements for continued operation.

• The other files submitted by BNI licensees

There is a considerable volume of files on specific topics such as fire protection, PWR fuel management strategies, relations with contractors, and so on.

The licensee also periodically submits activity reports and summary reports on water intake, liquid and gaseous discharges and the waste produced.

3.2.2 _ Review of the applications required by the Public Health Code

ASN is responsible for reviewing applications to possess and use ionising radiation sources in the medical and industrial sectors. ASN also deals with the specified procedures for the acquisition, distribution, import, export, transfer, recovery and disposal of radioactive sources. It in particular relies on the inspection reports from the approved organisations and the reports on the steps taken to remedy nonconformities detected during these inspections.

In addition to the 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 as system.

Based on thirty years of experience, ASN felt that it would be useful to transpose this approach, which was initially limited to nuclear safety, to radiation protection and protection of the environment. ASN thus drafted three guides defining the principles and reiterating the obligations binding on the licensees with regard to notification of incidents and accidents:

- 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 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 INES scale (International Nuclear and Radiological Event Scale) of the significant events which have occurred in a nuclear facility are not on their own indicators of the facility's level of safety. On the one hand, a given rating level is an over-simplification and is unable to reflect the complexity of an event and, on the other, the number of events listed depends on the level of notification compliance. The trend in the number of events does not therefore reflect any real trend in the safety level of the facility concerned.

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.

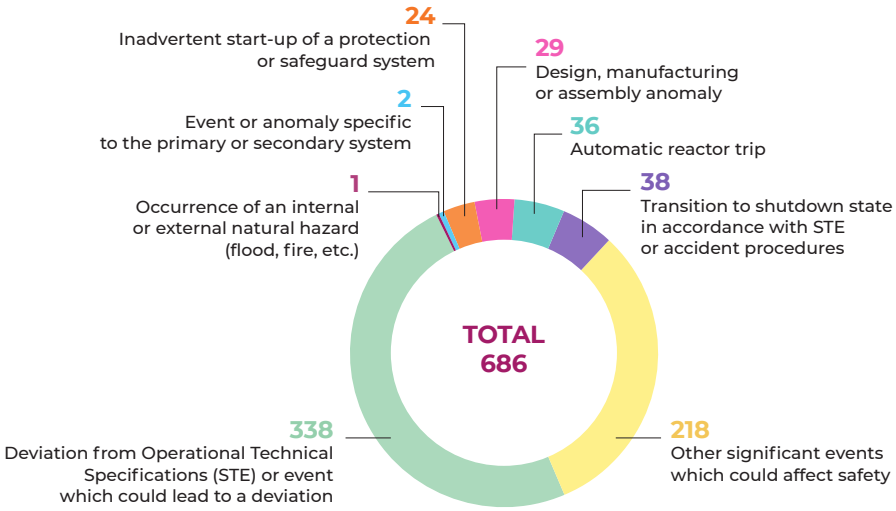
Operating experience feedback comprises the events which occur in France and abroad in nuclear facilities or in those presenting non-radiological hazards, if it is pertinent to take them into account in order to reinforce nuclear safety or radiation protection.

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.

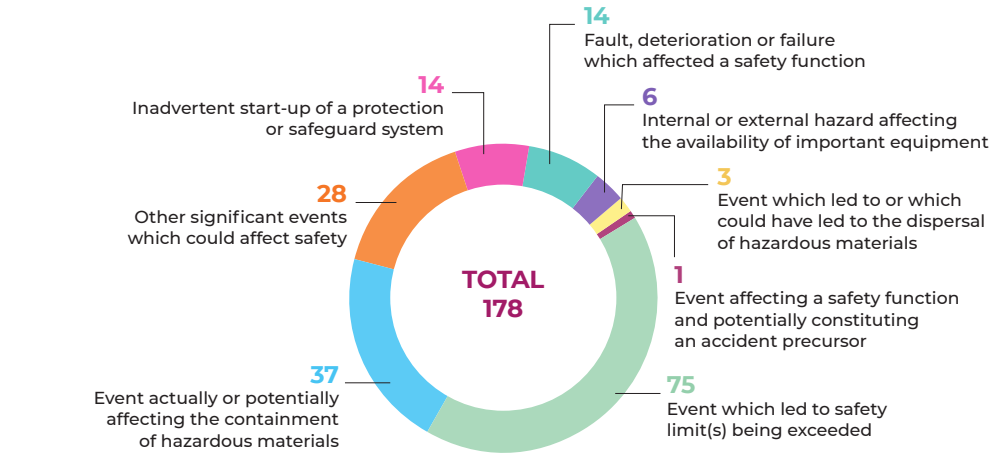
Events involving safety in NPPs, notified in 2018

Graph 5



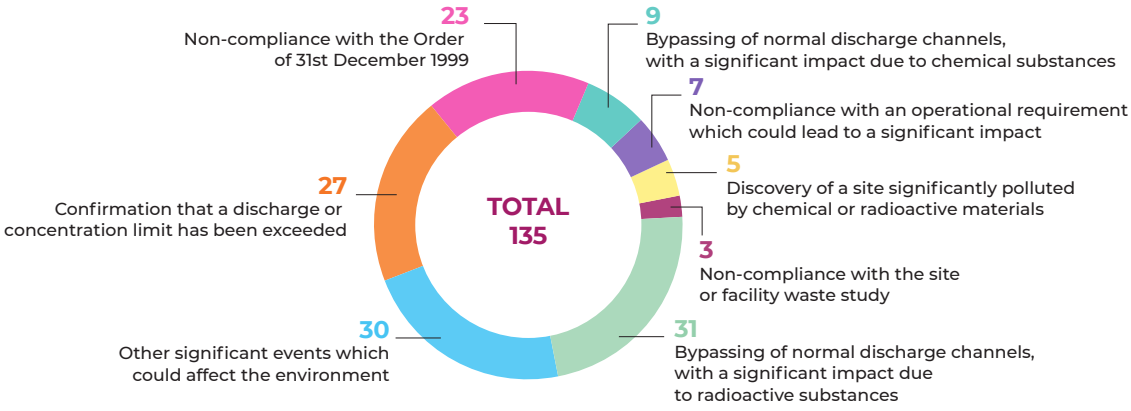
Events involving safety in BNIs other than NPPs notified in 2018

Graph 6



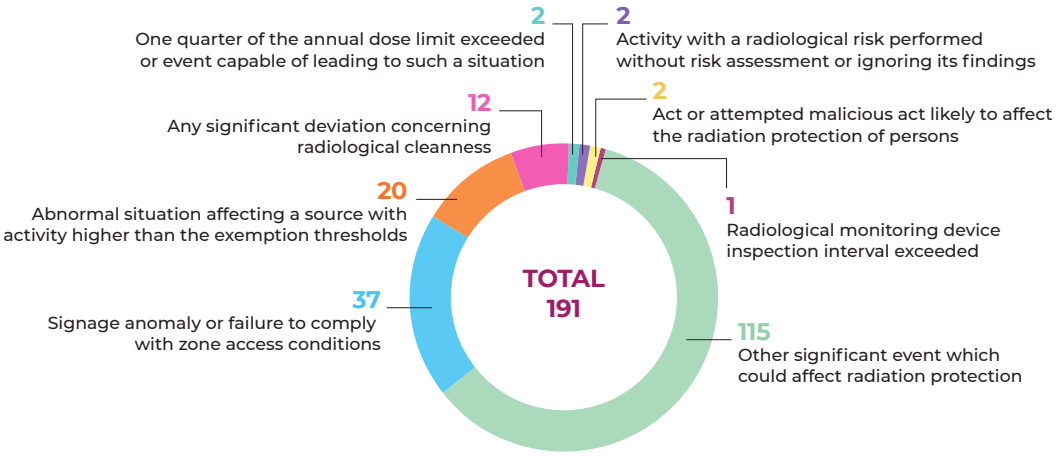
Significant environment-related events in BNIs notified in 2018

Graph 7



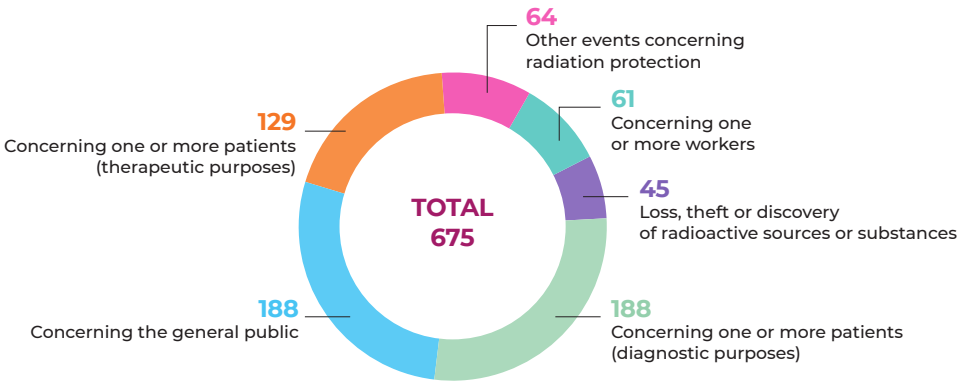
Events involving radiation protection in BNIs notified in 2018

Graph 8



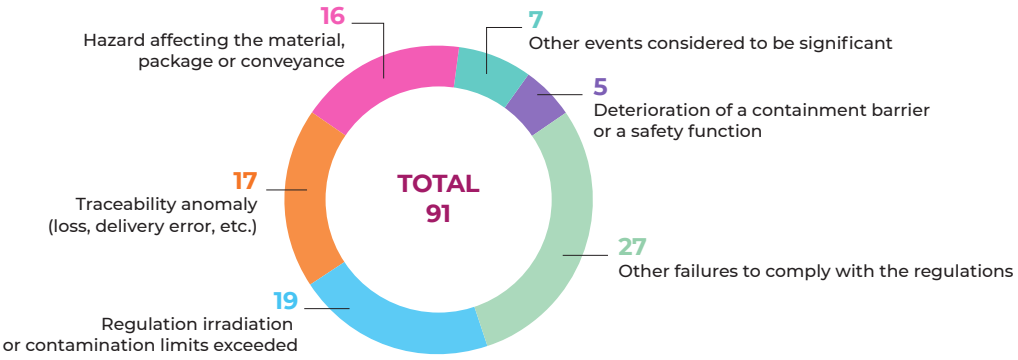
Events involving radiation protection (other than BNIs and RMT) notified in 2018

Graph 9



Events involving the transport of radioactive substances notified in 2018

Graph 10



Rating of significant events on the INES scale between 2013 and 2018

Table 6

		2013	2014	2015	2016	2017	2018
Basic Nuclear Installations (BNIs)	Level 0	905	872	848	847	949	989
	Level 1	103	99	89	101	87	103
	Level 2	2	0	1	0	4	0
	Level 3 and +	0	0	0	0	0	0
	Total BNI	**1,010**	**971**	**938**	**948**	**1,040**	**1,092**
Small-scale nuclear activities (medical and industrial)	Level 0	130	157	126	111	144	143
	Level 1	22	34	25	30	36	22
	Level 2	2	4	2	0	3	0
	Level 3 and +	0	0	0	0	0	0
	Total NPx	**154**	**195**	**153**	**141**	**183**	**165**
Transport of radioactive substances	Level 0	50	60	56	59	64	88
	Level 1	1	3	9	5	2	3
	Level 2	0	0	1	0	0	0
	Level 3 and +	0	0	0	0	0	0
	Total TSR	**51**	**63**	**66**	**64**	**66**	**91**
	Total	**1,215**	**1,229**	**1,157**	**1,153**	**1,289**	**1,348**

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 2018, 1,956 significant events were reported to ASN:
- 1,190 significant events concerning nuclear safety, radiation protection and the environment in BNIs; 1,092 of these events were rated on the INES scale (989 events rated level 0 and 103 events rated level 1). Of these events, 26 significant events were rated as "generic events", in other words concerning several reactors, of which 5 were rated level 1 on the INES scale;
- 91 significant events concerning the transport of radioactive substances, including 3 level 1 events on the INES scale;
- 675 significant events concerning radiation protection in small-scale nuclear activities, including 165 rated on the INES scale (of which 22 were level 1 events).

In 2018, none of the events reports to ASN was rated above level 1 on the INES scale, whether in the field of BNIs, small-scale nuclear activities, or the transport of radioactive substances.

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 2018, differentiating between them according to the various notification criteria for each field of activity.

3.4 _ Heightening the awareness of professionals and cooperating with the other administrations

Regulation is supplemented by awareness programmes designed to ensure familiarity with the regulations and their application in practical terms appropriate to the various professions. ASN aims to encourage and support initiatives by the professional organisations that implement this approach by issuing best practice and professional information guides.

Awareness-raising also involves joint actions with other administrations and organisations which oversee the same facilities, but with different prerogatives. One could here mention the labour inspectorate, the medical devices inspectorate work by the ANSM, the medical activities inspectorate work entrusted to the technical services of the Ministry of Health, or the oversight of small-scale nuclear activities at the Ministry of Defence entrusted to the Armed Forces General Inspectorate, jointly with ASN.

3.5 _ Information about ASN's regulatory activity

ASN attaches importance to coordinating government departments and informs the other departments concerned of its inspection programme, the follow-up to its inspections, the penalties imposed on the licensees and any significant events.

To ensure that its inspection work is transparent, ASN informs the public by placing the following on its website *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 pressurised water nuclear reactors. 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 requirements regulating discharges stipulate the minimum checks that the licensee is required to carry out. The monitoring focuses on the liquid and gaseous effluents (monitoring of the activity of discharges, characterisation of certain effluents prior to discharge, etc.) and on the environment around the facility (checks during discharge, samples of air, water, milk, grass, etc.). The results of this monitoring are recorded in registers transmitted to ASN every month.

The BNI licensees also regularly transmit a certain number of discharge samples to an independent laboratory for additional analysis. The results of these "cross-checks" are sent to ASN. This programme of cross-checks defined by ASN is a way of ensuring that the accuracy of the laboratory measurements is maintained over time.

• 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[3] Micro-pollutant Plan designed to preserve the quality of water and biodiversity, presented by the Minister for Ecology in September 2016, aims to protect surface waters, groundwaters, biota, sediments and waters intended for human consumption from all molecules liable to pollute the water resources, more particularly those previously identified during campaigns to Search for Hazardous Substances in Water (RSDE). This plan aims to meet the good water quality objectives set by the framework directive on water and contributes to those of the framework strategy directive for the marine environment, by limiting the input of pollutants into the marine environment from water courses.

For NPPs, the RSDE campaigns reached the conclusion that copper and zinc discharges in particular needed to be monitored. Under the Micro-pollutants Plan, the ASN actions initiated in 2017 comprise three parts:

- monitor the effective implementation of the action plan proposed by EDF to reduce discharges of copper and zinc (gradual replacement of the brass condenser tubes with stainless steel or titanium tubes);
- monitor the discharge trends for these substances;
- if necessary revise the individual requirements applicable to NPPs, setting emission limits for these molecules.

In 2018, ASN began work to revise the resolutions regulating effluent discharges and water intake for the Dampierre-en-Burly and Belleville-sur-Loire NPPs. This modification includes a revision of the copper and zinc emission limit values. EDF thus sent ASN an update of the impact assessments for these NPPs and a study presenting the combined impact of the four Belleville-sur-Loire, Dampierre-en-Burly, Saint-Laurent-des-Eaux and Chinon NPPs on the Loire Valley as a whole. These studies are currently being examined by ASN and will be the subject of a public consultation in 2019.

• 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 2016 relative to control of the detrimental effects and the impact of Basic Nuclear Installations 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.

3. A micro-pollutant can be defined as being an undesirable substance that can be detected in the environment in very small concentrations (microgram per litre or even nanogram per litre). Its presence is due, at least in part, to human activity (Industrial processes, agricultural practices or day to day activities) and it may, at these very small concentrations, create negative effects on living organisms owing to its toxicity, its persistence and its bioaccumulation.

ASN in-depth inspection at the Gravelines NPP – May 2018.

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 below) 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 final report plus recommendations will be published in 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 Basic Nuclear Installations on health and the environment). The result must be compared with the annual dose limit for the public (1 mSv/year) defined in Article R. 1333-11 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.

In practice, only traces of artificial radioactivity are detectable in the vicinity of the nuclear facilities; most measurements taken during routine surveillance are below the decision threshold or reflect the natural radioactivity. As these measurements cannot be used for dose estimations, models for the transfer of radioactivity to humans must be used, on the basis of measurements of discharges from the installation. These models are specific to each licensee. They are detailed in the installation's impact assessment. During its assessment, ASN verifies that these models are conservative, in order to ensure that the impact assessments will in no case be underestimated.

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).

Radiological impact of BNIs since 2012 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).

Table 7

LICENSEE/SITE	REFERENCE GROUP MOST EXPOSED IN 2017	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)					
			2012	2013	2014	2015	2016	2017
Andra / CSA	CD24	2.1	1.10^{-5}	1.10^{-6}	2.10^{-6}	2.10^{-6}	2.10^{-6}	2.10^{-6}
Andra's Manche repository	Hameau de La Fosse	2.5	4.10^{-4}	3.10^{-4}	3.10^{-4}	2.10^{-4}	2.10^{-4}	2.10^{-4}
Framatome Romans	Ferme Riffard	0.2	6.10^{-4}	5.10^{-4}	3.10^{-4}	3.10^{-4}	3.10^{-4}	2.10^{-5}
Orano Cycle / La Hague	Digulleville	2.8	9.10^{-3}	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}	3.10^{-4}	2.10^{-4}	2.10^{-4}
CEA / Cadarache [b]	Saint-Paul-lez-Durance	5	2.10^{-3}	2.10^{-3}	2.10^{-3}	1.10^{-3}	$<2.10^{-3}$	$<2.10^{-3}$
CEA / Fontenay-aux-Roses [b]	Achères	30	3.10^{-5}	3.10^{-5}	1.10^{-4}	2.10^{-4}	$<2.10^{-4}$	$<2.10^{-4}$
CEA / Grenoble [c]	-	-	2.10^{-8}	5.10^{-9}	(c)	(c)	(c)	(c)
CEA / Marcoule [b] (Atalante, Centraco, Phénix, Melox, CIS bio)	Codolet	2	2.10^{-4}	2.10^{-4}	2.10^{-3}	2.10^{-5}	$<2.10^{-3}$	$<2.10^{-3}$
CEA / Saclay [b]	Le Christ de Saclay	1	1.10^{-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	8.10^{-4}	7.10^{-4}	4.10^{-4}	5.10^{-4}	4.10^{-4}	3.10^{-4}
EDF / Blayais	Braud et Saint-Louis	2.5	2.10^{-4}	2.10^{-3}	6.10^{-4}	5.10^{-4}	5.10^{-4}	4.10^{-4}
EDF / Bugey	Vernas	1.8	6.10^{-4}	4.10^{-4}	2.10^{-4}	2.10^{-4}	9.10^{-5}	2.10^{-4}
EDF / Cattenom	Koenigsmacker	4.8	3.10^{-3}	5.10^{-3}	8.10^{-3}	7.10^{-3}	9.10^{-3}	8.10^{-3}
EDF / Chinon	La Chapelle-sur-Loire	1.6	5.10^{-4}	3.10^{-4}	2.10^{-4}	2.10^{-4}	2.10^{-4}	2.10^{-4}
EDF / Chooz	Chooz	1.5	9.10^{-4}	2.10^{-3}	7.10^{-4}	6.10^{-4}	6.10^{-4}	4.10^{-4}
EDF / Civaux	Valdivienne	1.9	9.10^{-4}	2.10^{-3}	8.10^{-4}	9.10^{-4}	2.10^{-3}	8.10^{-4}
EDF / Creys-Malville	Creys-Mépieu	0.95	7.10^{-4}	2.10^{-4}	2.10^{-4}	2.10^{-6}	3.10^{-4}	1.10^{-4}
EDF / Cruas-Meysse	Savasse	2.4	4.10^{-4}	4.10^{-4}	2.10^{-4}	2.10^{-4}	2.10^{-4}	4.10^{-4}
EDF / Dampierre-en-Burly	Lion-en-Sulias	1.6	1.10^{-3}	9.10^{-4}	4.10^{-4}	5.10^{-4}	5.10^{-4}	5.10^{-4}
EDF / Fessenheim	Nambshein	3.5	1.10^{-4}	1.10^{-4}	4.10^{-5}	4.10^{-5}	3.10^{-5}	2.10^{-5}
EDF / Flamanville	Flamanville	0.8	6.10^{-4}	7.10^{-4}	5.10^{-4}	2.10^{-4}	2.10^{-4}	2.10^{-4}
EDF / Golfech	Golfech	1	7.10^{-4}	6.10^{-4}	2.10^{-4}	3.10^{-4}	3.10^{-4}	2.10^{-4}
EDF / Gravelines	Gravelines	1.8	4.10^{-4}	6.10^{-4}	8.10^{-4}	4.10^{-4}	4.10^{-4}	5.10^{-4}
EDF / Nogent-sur-Seine	Saint-Nicolas-la-Chapelle	2.3	6.10^{-4}	1.10^{-3}	5.10^{-4}	4.10^{-4}	7.10^{-4}	5.10^{-4}
EDF / Paluel	Saint-Sylvain	1.4	5.10^{-4}	9.10^{-4}	9.10^{-4}	4.10^{-4}	3.10^{-4}	3.10^{-4}
EDF / Penly	Biville-sur-Mer	2.8	6.10^{-4}	7.10^{-4}	4.10^{-4}	4.10^{-4}	4.10^{-4}	5.10^{-4}
EDF / Saint-Alban/ Saint-Maurice	Saint-Pierre-de-Bœuf	2.3	4.10^{-4}	4.10^{-4}	2.10^{-4}	2.10^{-4}	3.10^{-4}	2.10^{-4}
EDF / Saint-Laurent-des-Eaux	Saint-Laurent-Nouan	2.3	2.10^{-4}	2.10^{-4}	2.10^{-4}	1.10^{-4}	1.10^{-4}	1.10^{-4}
EDF / Tricastin	Bollène	1.3	7.10^{-4}	5.10^{-4}	2.10^{-4}	2.10^{-4}	2.10^{-4}	2.10^{-4}
Ganil / Caen	IUT	0.6	$<3.10^{-3}$	$<2.10^{-3}$	$<2.10^{-3}$	$<2.10^{-3}$	$<2.10^{-3}$	8.10^{-3}
ILL / Grenoble	Fontaine (gaseous discharges) and Saint-Égrève (liquids)	1 et 1.4	1.10^{-4}	2.10^{-4}	3.10^{-4}	2.10^{-4}	2.10^{-4}	5.10^{-5}

(a) Until 2008, for installations operated by EDF, only "adult" figures were calculated. From 2010 to 2012, the dose of the most exposed reference group of each site for the two age classes (adult or infant) is mentioned. As of 2013, the dose of the reference group is provided for three age classes (adult, child, infant) for all the BNIs. The dose value indicated is the harshest value in the age classes.

(b) For the Cadarache, Saclay, Fontenay-aux-Roses and Marcoule sites, the dose estimates entered in the table are the sum of the dose estimates transmitted by CEA. As these estimates comprise at least one term of less than 0.01 microsieverts, the values indicated are preceded by the "less than (<)" sign.

(c) As the site has no longer had radioactive discharges since 2014, the radiological impact caused by radioactive discharges has been and continues to be nil since 2014.

In addition to the impact assessments produced on the basis of discharges from the facilities, the licensees are required to carry out environmental radioactivity monitoring programmes (water, air, earth, milk, grass, agricultural produce, etc.), more specifically to verify compliance with the hypotheses of the impact assessment and to monitor changes in the radioactivity in the various compartments of the environment around the facilities (see point 4.1.1).

An estimation of the doses from BNIs is presented in Table 7. For each site and per year, this table gives the estimated effective doses received by the most exposed reference population groups.

The estimated doses from BNIs for a given year are determined on the basis of the accounted discharges from each installation for the year in question. This assessment takes account of the discharges through the identified outlets (stack, discharge pipe to river or seawater). It also includes diffuse emissions and sources of radiological exposure to the ionising radiation present in the facilities. These elements are the "source term".

The estimate is made in relation to one or more identified reference groups. These are uniform groups of people (adults, infants, children) receiving the highest average dose out of the entire population exposed to a given installation, following realistic scenarios (taking into account the distance from the site, meteorological data, etc.). All of these parameters, specific to each site, explain most of the differences observed between sites and from one year to another.

For each of the nuclear sites presented, the radiological impact remains far below, or at most represents 1% of the limit for the public (1 mSv per year). Therefore in France, the discharges produced by the nuclear industry have an extremely small radiological impact.

4.1.3 _ Monitoring imposed by the European Union

Article 35 of the EURATOM Treaty requires that the Member States establish the facilities needed to carry out continuous monitoring of the level of radioactivity in the air, water and soil and to ensure compliance with the basic standards of health protection for the general public and workers against the hazards of ionising radiation. All Member States, whether or not they have nuclear facilities, are therefore required to implement environmental monitoring arrangements throughout their territory.

Article 35 also states that the European Commission may access the monitoring facilities to verify their operation and their effectiveness. During its verifications, the European Commission gives an opinion on the means implemented by the member states to monitor radioactive discharges into the environment and the levels of radioactivity in the environment around nuclear sites and over the national territory. It gives its assessment of the monitoring equipment and methodologies used and of the organisational setup.

Since 1994, the Commission has carried out the following 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 (see box).

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 CLI, of IRSN, of ASN, etc. ASN resolution CODEP-DEU-2018-046583 of 26 September 2018 renewed the composition of the RNM steering committee.

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;

Environmental monitoring: Verification technical visit by the European Commission under Article 35 of the EURATOM Treaty in May 2018 on the La Hague site

A verification technical visit by the European Commission under Article 35 of the EURATOM Treaty took place from 29 to 31 May 2018 on the La Hague reprocessing plant site.

The programme of the visit comprised various presentations, more particularly concerning the regulation of liquid and gaseous discharges from the Orano La Hague facility, the programmes for monitoring the environment around the site implemented by the licensee and by IRSN respectively, the National environmental radioactivity Monitoring Network (RNM) and ASN approval of the environmental radioactivity measurement laboratories. These presentations were supplemented by visits to the La Hague site and its environs (laboratories dedicated to environmental monitoring, to monitoring effluents and dosimetry measurements, response vehicles, sampling stations, environmental monitoring station in the village of Digulleville, monitoring station operated by IRSN in Omonville-la-Petite and IRSN laboratory in Cherbourg-Octeville).

Following the visit, the Commission's representatives declared themselves to be highly satisfied with all the presentations and the visits. They underlined the pertinence and exhaustiveness of the monitoring programme implemented and welcomed the fact that all the environmental radioactivity measurement results obtained by the RNM were made available to the public.

The technical report of this visit, drafted by the members of the Commission, is currently being finalised and will be published on the European Commission's website. The conclusions of this report indicate that the environmental monitoring arrangements, in both normal and emergency situations, are adequate and comply with the regulatory requirements.

- ensures there are no facility malfunctions, including by analysing the ground water and checking licensees' compliance with the regulations;
- contributes to transparency and information of the public by transmitting monitoring data to the RNM.

4.2.3 _ 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 8 gives examples of the monitoring performed by the licensee of an NPP and of a research centre or plant.

When several facilities (whether or not BNIs) are present on the same site, joint monitoring of all these installations is possible, as has been the case, for example, on the Cadarache and Tricastin sites since 2006.

These monitoring principles are supplemented in the individual requirements applicable to the facilities by monitoring measures specific to the risks inherent in the industrial processes they use.

Each year, in addition to sending ASN the monitoring results required by the regulations, the licensees transmit nearly 120,000 measurements to the national network for environmental radioactivity monitoring.

4.2.4 _ 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 km around BNIs;
  - the *Hydrotéléray* network (monitoring of the main watercourses downstream of all nuclear facilities and before they cross national boundaries);
- continuous sampling networks with laboratory measurement, for example the atmospheric aerosols radioactivity monitoring network;
- processing and measurement in a laboratory of samples taken from the various compartments of the environment, whether or not close to facilities liable to discharge radionuclides.

Every year, IRSN takes more than 25,000 samples in all compartments of the environment (excluding the remote-measurement networks).

The radioactivity levels measured in France are stable and situated at very low levels, generally at the detection sensitivity threshold of the measuring instruments. The artificial radioactivity detected in the environment results essentially from fallout from the atmospheric tests of nuclear weapons carried out in the 1960s, and from the Chernobyl accident. Traces of artificial radioactivity associated with discharges can sometimes be detected near installations. To this can be added

Example of radiological monitoring of the environment around BNIs

Table 8

ENVIRONMENT MONITORED OR TYPE OF INSPECTION	CATTENOM NPP (RESOLUTION 2014-DC-0415 OF 16 JANUARY 2014)	AREVA 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 spectrometry α 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.

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 report on 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 _ Measurement quality

Articles R.1333-25 and R.1333-26 of the Public Health Code require the creation of a National Monitoring Network (RNM) and a procedure to have the radioactivity measurement laboratories approved by ASN. The RNM working methods are defined by the above-mentioned ASN resolution of 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, about fifty types of measurements are covered by approvals. There are just as many corresponding Inter-Laboratory comparison Tests (ILT). These tests are organised by IRSN in a 5-year cycle, which corresponds to the maximum approval validity period.

4.3.1 _ Laboratory approval procedure

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 Inter-laboratory Comparison Test (ILT);
- review of it by ASN;
- review of the application files – which are made anonymous - by a pluralistic approval commission which delivers an opinion on them.

The laboratories are approved by ASN resolution, published in its *Official Bulletin*. The list of approved laboratories is updated every six months.

The above-mentioned ASN resolution of 29 April 2008 was modified by ASN resolution 2018-DC-0648 of 16 October 2018, more specifically in order to introduce a new type of approval for measuring radon 222 in water. This revision aligns the procedures for the approvals issued by ASN for the RNM and by the Directorate General for Health (DGS) for the health oversight on waters intended for human consumption, respectively, which are based on common technical requirements: to obtain approval from the DGS, these laboratories must now first have obtained approval from ASN.

4.3.2 _ The approval commission

The approval commission is tasked with ensuring that the measurement laboratories have the organisational and technical competence to provide the RNM with high-quality measurement results.

The commission is authorised to propose approval, rejection, revocation or suspension of approval to ASN. It issues a decision on the basis of an application file submitted by the candidate laboratory and its results in the inter-laboratory comparison tests organised by IRSN. It meets every six months.

The commission, chaired by ASN, comprises qualified persons and representatives of the State services, laboratories, standardising authorities and IRSN. ASN resolution CODEP-DEU-2018-046580 of 26 September 2018, appointing candidates to the environmental radioactivity measurement laboratories approval commission, renewed the mandates of the commission's members for a further five years.

4.3.3 _ Approval conditions

Laboratories seeking approval must set up an organisation meeting the requirements of standard NF EN ISO/IEC 17025 concerning the general requirements for the competence of calibration and test laboratories.

In order to demonstrate their technical competence, they must take part in Inter-laboratory Comparison Tests (ILTs) organised by IRSN. The ILT programme, which now operates on a five-yearly basis, is updated annually (see Table 9). 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 defines the assessment 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 2018, IRSN organised six ILTs. Since 2003, 76 ILTs have been carried out, covering nearly 58 types of approval. The most numerous approved laboratories (53) 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. 30 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.).

Lessons learned by ASN about the organisation of ILTs and the results of these tests

From 2003 to 2018, IRSN organised 76 ILTs. Laboratory participation in the ILTs is in response both to the requirement set out by standard NF EN ISO/CEI 17025 specifying the general requirements concerning the competence of calibration and testing laboratories and to the regulation which requires that laboratories present the results obtained in the ILTs in support of their approval applications.

Since the first ILTs organised in 2003, ASN and IRSN have observed progress among the population of approved laboratories: over time, the laboratories have on the whole obtained more satisfactory results in the ILTs, which means a relative drop in the number of corroboration tests to be organised and in the number of approvals issued for trial periods.

ASN therefore considers that IRSN's organisation of the inter-laboratory comparison tests is an efficient, robust and proven system which fully meets its objective of assessing the quality and reliability of the measurements taken by the various participating laboratories. It helps promote an improvement in the competence of the laboratories and ensures that their performance is maintained over time, inorder to guarantee the quality of the environmental radioactivity measurement results made available to the public on the RNM *mesure-radioactivite.fr* website.

In 2018, ASN issued 129 approvals or approval renewals. As at 1 January 2019, the total number of approved laboratories stood at 62, 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*.

5 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.

5.1 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:

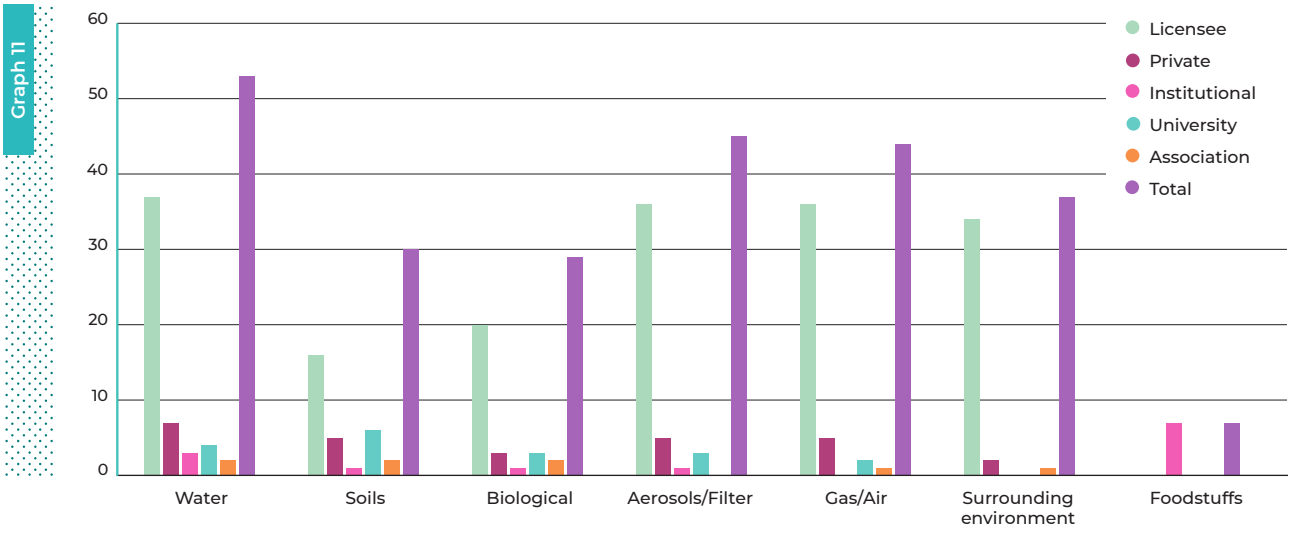
- actions that are impartial, justified and appropriate to the level of risk presented by the situation concerned. Their scale is proportionate to the health and environmental risks associated with the deviation identified and also take account of factors relating to the licensee (past history, behaviour, 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.

Breakdown of the number of approved laboratories for a given environmental matrix as at 1 January 2019

Graph 11



Approval chart and forecast five-year Inter-Laboratory Test (ILT) programme

Table 9

CODE	RADIOACTIVE MEASUREMENTS CATEGORY	TYPE 1			TYPE 2		TYPE 3		TYPE 4		TYPE 5		TYPE 6		TYPE 7						
		SEA WATER	WATER		SOIL AND SEDIMENT MATRICES		BIOLOGICAL MATRICES		AEROSOLS ON FILTER		GAS AIR		AMBIENT MEDIUM (SOIL/AIR)		FOODSTUFFS FOR HEALTH INSPECTION					
.. -01	Emitting radionuclides γ > 100 keV			1_01		2_01		3_01		4_01		5_01		-	L	S	L	S	L	7_01
.. -02	Emitting radionuclides γ < 100 keV			1_02		2_02		3_02		4_02		5_02		-	L	S	L	S	L	7_02
.. -03	Total alpha			1_03		-		-		4_03		-		-						
.. -04	Total beta			1_04		-		-		4_04		-		-						
.. -05	^{3}H			1_05		2_05		3_05		-		Cf.1_05 5_05		-						
.. -06	^{14}C			1_06		2_06		3_06		-		5_06		-						
.. -07	^{90}Sr/^{90}Y			1_07		2_07		3_07		4_07		-		-						
.. -08	Other pure beta emitters (^{63}Ni...)		^{99}Tc	1_08	^{99}Tc	2_08	^{99}Tc	3_08	^{99} Tc	4_08		-		-						
.. -09	U Isotopes			1_09		2_09		3_09		4_09		-		-						
.. -10	Th Isotopes			1_10		2_10		3_10		4_10		-		-						
.. -11	^{226}Ra + desc.			1_11		2_11		3_11		-		^{222}Rn 5_11		-						
.. -12	^{228}Ra + desc.			1_12		2_12		3_12		-		^{220}Rn 5_12		-						
.. –13	Pu, Am, (Cm, Np) Isotopes			1_13		2_13		3_13		4_13		-		-						
.. –14	Halogenated gases			-		-		-		-		5_14		-						
.. –15	Noble gases			^{222}Rn 1_15		-		-		-	^{85}Kr	5_15		-						
.. –16	Ambient gamma dosimetry			-		-		-		-		-		6_16						
.. –17	Total uranium			1_17		2_17		3_17		4_17		-		-						

1st half year 2019 / 2nd half year 2019 — 1st half year 2020 / 2nd half year 2020 — 1st half year 2021 / 2nd half year 2021 — 1st half year 2022 / 2nd half year 2022 — 1st half year 2023 / 2nd half year 2023 — L: Liquid — S: Solid

The boxes in the approval chart for which an ILT is scheduled correspond to the matrix/measurement type pairings for which regulation monitoring is imposed on at least one licensee.

In addition to ASN's administrative actions, reports can be drafted by the inspector and sent to the Public Prosecutor's Office.

5.2 — An appropriate policy of enforcement and sanctions

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 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 will be within the competence of the future ASN Sanctions Commission, which will be set up once the implementing provisions of the Ordinance have been adopted and have come into force (Decree by Council of State).

Number of infringement reports transmitted by the ASN inspectors between 2013 and 2018

Table 10

	2013	2014	2015	2016	2017	2018
Report excluding labour inspection in the nuclear power plants	26	15	14	7	13*	14
Labour inspection report in the nuclear power plants	10	9	3	1	5	2

* The 2017 Report was completed subsequent to the publication of the *ASN Report on the State of Nuclear Safety and Radiation Protection in France in 2017*.

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 five infringements (fine), in the field of nuclear safety, are stipulated by Decree 2007-1557 of 2 November 2007 relative to BNIs and to the nuclear oversight of the transport of radioactive substances, for the infringements detailed in its Article 56, as well as in the field of radiation protection, by Decree 2018-434 of 4 June 2018 containing various nuclear provisions (Art. R. 1337-14-2 to 5 of the Public Health Code), more particularly with regard to non-compliance with significant event notification requirements and to the administrative system (transmission of the title application file, compliance with general requirements, information concerning a change of 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.

5.3 _ 2018 results concerning enforcement and sanctions

As a result of infringements observed, the ASN inspectors (nuclear safety inspectors, for BNIs, the transport of radioactive substances or nuclear pressure equipment, labour inspectors and radiation protection inspectors) transmitted twelve infringement reports to the public prosecutor's offices, two of which concerned labour inspections in the NPPs.

ASN served formal notice to BNI licensees on five occasions.

With regard to labour inspection, an administrative fine was imposed by the Normandy Regional Directorate for Competition Policy, Consumer Affairs, Labour and Employment (Direccte).

Table 10 shows the number of reports issued by the ASN inspectors since 2013.

6 Outlook

The goal of ASN's multi-year strategic plan is to reinforce the effectiveness of its actions in the field, notably by reinforcing the ability of the inspectors to detect deviations and by developing new inspection practices. Steps have been taken in this direction at the initiative of the ASN chief inspector.

ASN also won a call for expressions of interest launched by the investing in the future programme, to trial artificial intelligence in public services. ASN's project, called Siance – French acronym for System of artificial intelligence for nuclear regulation and assessment – will aim to utilise the data mined from more than 21,000 ASN inspection follow-up letters, to help the inspectors in their work. It more particularly aims to be able to automatically detect early warning signs and statistical trends by analysing inspection follow-up letters and to produce guidelines for the future inspection programmes with improved targeting of topics or items to be inspected. This tool will be developed in 2019 with the support of the Interministerial Directorate for Digital and Information System affairs.

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Radiological emergency and post-accident situations

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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, 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. The doctrine published in November 2012 concerning the emergency phase exit, transitional and long-term periods, will be updated in 2019. The guidelines of this update were validated at the end of 2018.

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.

ASN took part in drafting the *Major Nuclear or Radiological Accident National Response Plan*, which was published by the Government in February 2014. The Plan incorporates the lessons learned from the Fukushima Daiichi accident and the post-accident doctrine drawn up by the Codirpa. 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.

In the vicinity of the facility, the Off-site Emergency Plan (PPI) is established by the Prefect of the *département* concerned pursuant to Articles L.741-6, R.741-8 et seq. of the Domestic Security Code, "*to protect the populations, property and the environment, and to cope with the specific risks associated with the existence of structures and facilities whose perimeter is localised and fixed. The PPI implements the orientations of civil protection policy in terms of mobilisation of resources, information, alert, exercises and training*". These Articles also stipulate the characteristics of the facilities or structures for which the Prefect is required to define a PPI.

The PPI specifies the initial actions to be taken to protect the general public, the roles of the various services concerned, the systems for giving the alert, and the human and material resources likely to be engaged in order to protect the general public.

The PPI falls within the framework of the Disaster and Emergency Response Organisation (Orsec) civil protection response organisation which describes the protective measures implemented by the public authorities in large-scale emergencies. Therefore, beyond the application perimeter of the PPI, the *département* or zone Orsec plan is activated.

The On-site Emergency Plan (PUI), prepared by the licensee, is designed to restore the plant to a controlled and stable condition and mitigate the consequences of an 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. Pursuant to Decree 2007-1557 of 2 November 2007 concerning BNIs and the regulation of the nuclear safety of the transport of radioactive substances, the PUI is one of the items to be included in the file sent to ASN by the licensee for commissioning of its facility. The obligations of the licensee relative to the preparation for and management of emergency situations are defined in Title VII of the Order of 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.

Pursuant to the international regulations on the carriage of dangerous goods, those involved in the carriage of dangerous goods must take steps appropriate to the nature and scale of the foreseeable hazards, in order to avoid damage or, as applicable, to mitigate the effects. These steps are described in a management plan for events linked to the transport of radioactive substances. The content of these plans is defined in ASN Guide No. 17.

To deal with the possibility of a radioactive substances transport accident, each *département* Prefect must include in their implementation of the national response plan a part devoted to this type of accident, the Orsec TMR (Transport of Radioactive Materials) plan. Faced with the diversity of possible types of transport operations, this part of the plan defines the criteria and simple measures enabling the first respondents (Departmental Fire and Emergency Service (SDIS) and law enforcement services in particular) to initiate the first reflex response measures to protect the general public and sound the alert, based on their findings on the site of the accident.

1.1.3 _ The response to other radiological emergency situations

Apart from incidents or accidents affecting nuclear installations or a radioactive substances transport operation, radiological emergency situations can also occur:
- during performance of a nuclear activity, for medical, research or industrial purposes;
- in the event of intentional or inadvertent dispersal of radioactive substances into the environment;
- if radioactive sources are discovered in places where they are not supposed to be.

In such cases, intervention is necessary to limit the risk of human exposure to ionising radiation. Together with the Ministries and 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 _ ASN role in the examination and monitoring of emergency plans and the drafting of contingency plans

• Examination of emergency plans for nuclear facilities or activities

ASN reviews the On-site Emergency Plans as part of the procedure to authorise the commissioning of BNIs or the possession and utilisation of high-level sealed sources (Article R.1333-33 of the Public Health Code), as well as the management plans for events linked to radioactive substances transports and their updates.

• Participation in drafting the Contingency Plans

Contingency Plans, such as the PPI, identify the general public protection measures to mitigate the health and environmental consequences of any accident. The Prefect decides whether or not to deploy these measures on the basis of the predicted dose that would be received by the population in the event of the accident.

Pursuant to the Domestic Security Code, the Prefect is responsible for drafting and approving the PPI. ASN provides assistance by analysing the technical data to be provided by the licensees, in particular the nature and scope of the consequences of an accident, with the help of its technical support organisation, IRSN.

The PPI currently makes it possible to plan the public authorities' response in the first hours of the accident in order to protect the population living within a 10 km radius around the affected reactor (this distance is to be raised to 20 km). On 3 October 2016, the Ministry for the Interior published an instruction concerning the response to a major nuclear or radiological accident: Changes in national doctrine for the drafting or modification of PPIs around NPPs operated by EDF. In 2017, it published a guide intended for the offices of the Prefects in order to implement this instruction by updating the PPIs for the NPPs to take account of the changes, in particular the preparation for "immediate" evacuation within a 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.

"Emergency management" in-depth inspection at Tricastin

The team for this in-depth inspection, which concerned the topic of emergency situations management, comprised about ten inspectors from around France, the ASN Chief inspector and an inspector from the Defence Nuclear Safety Authority (ASND).

The first half-day was devoted to the general organisation of the site in terms of emergency management and a number of specific functions. On the second day, the inspectors turned up at the site entrance in the middle of the night for a large-scale unannounced exercise entailing activation of the On-site Emergency Plan (PUI) (but also, for certain licensees, the PPI "reflex" phase).

The simulation was a means of testing both the quality of the site's operational response and the quality of its emergency organisation.

The rest of the inspection concerned the various facilities on the vast Tricastin site, with each team of inspectors carrying out theoretical or practical simulations.

This inspection found that, despite certain weaknesses identified in the field and the need for clarification in the sharing of responsibilities in the local "Strategic Management Command Post", which has subsequently been done through the transition to the single licensee, the site is considered to be able to manage an accident leading to the activation of the PUI on a facility. The inspection also demonstrated the benefits to be gained from performing inspections with field exercises to make ASN's examination of the provisions of the on-site emergency plans more robust and no doubt faster.

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. PPI revision work started in 2018 enables the municipalities concerned by the extension of these plans to be defined.

ASN also assists the Ministry of the Interior's General Directorate for Civil Security and Emergency Management (DGSCGC) with a view to supplementing the PPIs concerning aspects relating to post-accident management (see point 1.5).

1.2 _ Controlling urban development around nuclear sites

The aim of controlling urban development is to limit the consequences of an accident for the population and property. Since 1987, this type of approach has been implemented around non-nuclear industrial facilities and it has been reinforced since the AZF facility accident that occurred in Toulouse in 2001. Act 2006-686 of 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 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.

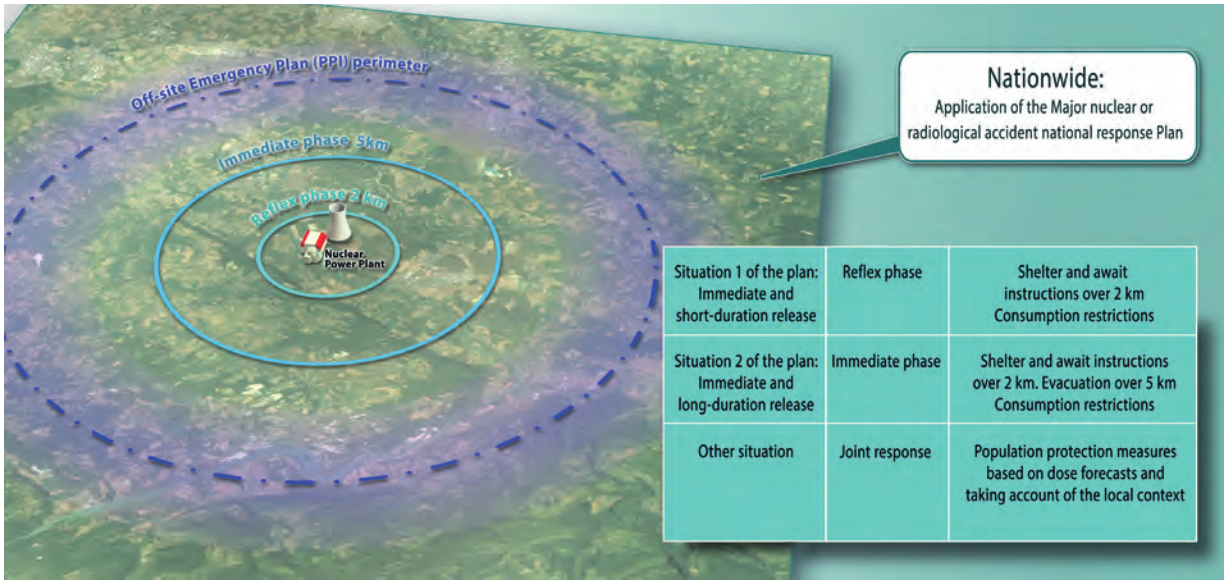
The current approach to controlling activities around nuclear facilities exclusively concerns those subject to a PPI and primarily aims to preserve the operational nature of the contingency plans, in particular for sheltering and evacuation, limiting the population numbers concerned whenever possible. It focuses on the PPI "reflex" zones, determined by the Circular of 10 March 2000 revising the Off-site Emergency Plans for BNIs, the pertinence of which was confirmed by the instruction of 3 October 2016. In these "reflex" zones», immediate steps to protect the population are taken in the event of a rapidly developing accident.

A Circular from the Ministry responsible for the Environment of 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.

Major nuclear or radiological accident national response plan

Diagram 1



1.3 _ Organising a collective response

The response by the public authorities to a major nuclear or radiological accident is determined by a number of texts concerning nuclear safety, radiation protection, public order and civil protection, as well as by the emergency plans.

Act 2004-811 of 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).

Thus, at the national level, ASN is actively involved in interministerial work on nuclear emergency management.

Following the Fukushima Daiichi accident, considerable thought was given nationally and internationally to consolidating and, as applicable, improving the response organisation of the public authorities. Indeed, this accident showed that it was necessary to improve preparation for the occurrence of a multi-faceted accident (natural disaster, accident affecting several facilities simultaneously). The response organisations thus put into place must be robust and capable of managing a large-scale emergency over a long period of time. Better advance planning must be carried out for work done under ionising radiation and, in order to provide effective support for the country affected, international relations must be improved.

1.3.1 _ Local response organisation

In an emergency situation, several parties have the authority to take decisions:

- The licensee of the affected nuclear facilities deploys the response organisation and the resources defined in its PUI (see point 1.1.1).
- ASN has a duty to monitor the licensee's actions in terms of nuclear safety and radiation protection. In an emergency situation, 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. More specifically through its regional division, ASN assists the Prefect in managing the situation.
- The Prefect of the defence and security zone is responsible for coordinating reinforcements and the support needed by the Prefect of the *département*, for ensuring 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 passing on information and heightening population awareness, more particularly during iodine tablet distribution campaigns.

1.3.2 _ National response organisation

In a radiological emergency situation, each 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).

1.4 _ Protecting the population

The steps to protect the populations during the emergency phase, as well as the initial actions as part of the post-accident phase, aim to protect the population from exposure to ionising radiation and to any chemical and toxic substances that may be present in the releases. These measures are mentioned in the PPIs.

1.4.1 _ General protective actions

In the event of a major nuclear or radiological accident, a number of measures can be envisaged by the Prefect in order to protect the population:
- Sheltering and awaiting instructions: the individuals concerned, alerted by a siren, take shelter at home or in a building, with all openings closed, and wait for instructions from the Prefect broadcast by 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.

The Prefect may also take measures to ban the consumption of foodstuffs liable to have been contaminated by radioactive substances as of the emergency phase (before the facility has been restored to a controlled and stable state).

The predicted doses are generally calculated over a maximum period of 24 hours for a one year old child (age at which sensitivity to ionising radiation is highest) exposed to the releases.

In the event of the release of radioactive substances into the environment, measures are decided on to prepare for management of the post-accident phase. They are based on the definition of area zoning to be implemented as of the end of the releases on exiting the emergency phase and including:
- a Population Protection Zone (ZPP) within which action is required to reduce both the exposure of the populations to ambient radioactivity and the consumption of contaminated food, as far as is reasonably possible (for example a ban on consumption of produce from the garden, restriction on access to wooded areas, ventilation and cleaning of homes, etc.);
- a Heightened Territorial Surveillance Zone (ZST), which is larger and which is more concerned with the economic management of the area, within which specific surveillance of foodstuffs and agricultural produce will be set up;
- if necessary, an evacuation perimeter is created within the ZPP, defined according to the ambient radioactivity (external exposure); the residents must be evacuated for a varying length of time depending on the level of exposure in their environment.

Transposition of the "BSS" Directive: case of emergency situations

The European "BSS" Directive of 5 December was transposed through the publication of Decree 2018-434 containing various nuclear-related provisions, Decree 2018-437 relative to the protection of workers against the risks of ionising radiation and Decree 2018-438 of 4 June 2018 relative to protection against the risks of ionising radiation to which certain workers are exposed.

"Reference levels" were introduced by the Ordinance of 10 February 2016. They are mainly used in the case of radiological emergency and post-accident situations and constitute a "baseline" for the optimisation approach. For emergency situations, the value chosen is 100 mSv/year effective dose received during the radiological emergency situation for exposure of the population (R. 1333-82). The corresponding "baseline values" are as follows:
- 50 mSv effective dose: evacuation decision;
- 10 mSv effective dose: sheltering;
- 50 mSv effective dose: distribution of iodine tablets.

These doses are calculated for the duration of the releases.

The provisions concerning the health and safety of workers intervening in a radiological emergency situation are transferred in full to the Labour Code (R. 4451-96 to R.4451-110), in order to allow harmonised implementation of the provisions applicable to workers intervening in a radiological emergency situation, whether on the site of the accident, within the perimeter of the facility, or outside in the areas in which special measures have been taken to protect the populations.

Two groups of responders in an emergency situation have been defined. The responders are assigned:
- to the first group, when the effective dose from occupational exposure is liable to exceed 20 mSv during the radiological emergency situation;
- to the second group when they are not in the first group and the effective dose is liable to exceed 1 mSv during the radiological emergency situation.

The reference level in a radiological emergency exposure situation is 100 mSv for the effective dose liable to be received by a worker intervening in such a situation and is 500 mSv in an exceptional situation (to save lives, prevent serious radiation-induced health effects or prevent the onset of catastrophic situations).

1.4.2 _ The provision of iodine tablets

Administering stable iodine tablets is a means of saturating the thyroid gland and protecting against the carcinogenic effects of radioactive iodines.

The Circular of 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.

The licensee is responsible for the safety of its facilities. This Circular requires that the licensee finance the public information campaigns within the perimeter of the PPI and carry out permanent preventive distribution of the stable iodine tablets, free of charge, through the network of pharmacies.

In 2018, ASN worked together with the Ministries for the Interior, for Health and for National Education, with the professional societies of Pharmacists and Physicians, the Anccli, IRSN and EDF on the future national campaign for the distribution of iodine tables to the populations living in the zone covered by PPIs, within a radius of between 10 and 20 km around the NPPs.

Outside the zone covered by a PPI, tablets are stockpiled to cover the rest of the country. In this respect, the Ministries for Health and for the Interior decided to create stocks of iodine tablets, positioned and managed by *Santé Publique France* (more particularly including the Health Emergency Preparedness and Response Organisation). Each Prefect organises the procedures for distribution to the population in their *département*, relying in particular on the mayors for this.

This arrangement is described in a Circular of 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 major nuclear or radiological accident national response plan.

1.4.3 _ Care and treatment of exposed persons

In the event of a radiological emergency situation, a significant number of people could be contaminated by radionuclides. These persons shall be cared for by the emergency response teams duly trained and equipped for this type of operation.

Circular 800/SGDSN/PSE/PPS of 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.

2016 national iodine tablet distribution campaign

1.5 _ Understanding the long-term consequences

The post-accident phase concerns the handling over a period of time of the consequences of long-term contamination of the environment by radioactive substances following a nuclear accident. It covers the handling of consequences that are varied (economic, health, environmental and social), by their nature complex and that need to be dealt with in the short, medium or even long term, with a view to returning to a situation considered to be acceptable.

The conditions for reimbursement for the damage resulting from a nuclear accident are currently covered by Act 68-943 of 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.

The Codirpa is currently continuing with work to take account of the lessons learned from the post-accident management carried out in Japan following the Fukushima Daiichi disaster, but also experience feedback from emergency exercises.

A new Working Group (WG) was set up in 2018 to determine the guidelines for the revision of the Codirpa doctrine and, more particularly, the introduction of measures in the field to validate the modelled zoning areas. It supplements the other WGs on the management of waste in a post-accident situation, the management of manufactured products, the management of water and marine environments and provides some answers to questions from the health professionals to whom those concerned by an accident would turn.

2 Organising for action in an emergency and post-accident situation

The emergency and contingency plans require intervention by many players, whose respective roles and duties must be clearly identified, as must the way they interact, to ensure correct coordination. The organisation of each of the players involved in the State's response to a radiological emergency situation, and the way they interact, are essential to the correct management of this type of situation. The roles and organisation of ASN in an emergency situation are thus precisely defined. Coordination with the international authorities is also essential, both bilaterally and internationally.

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.

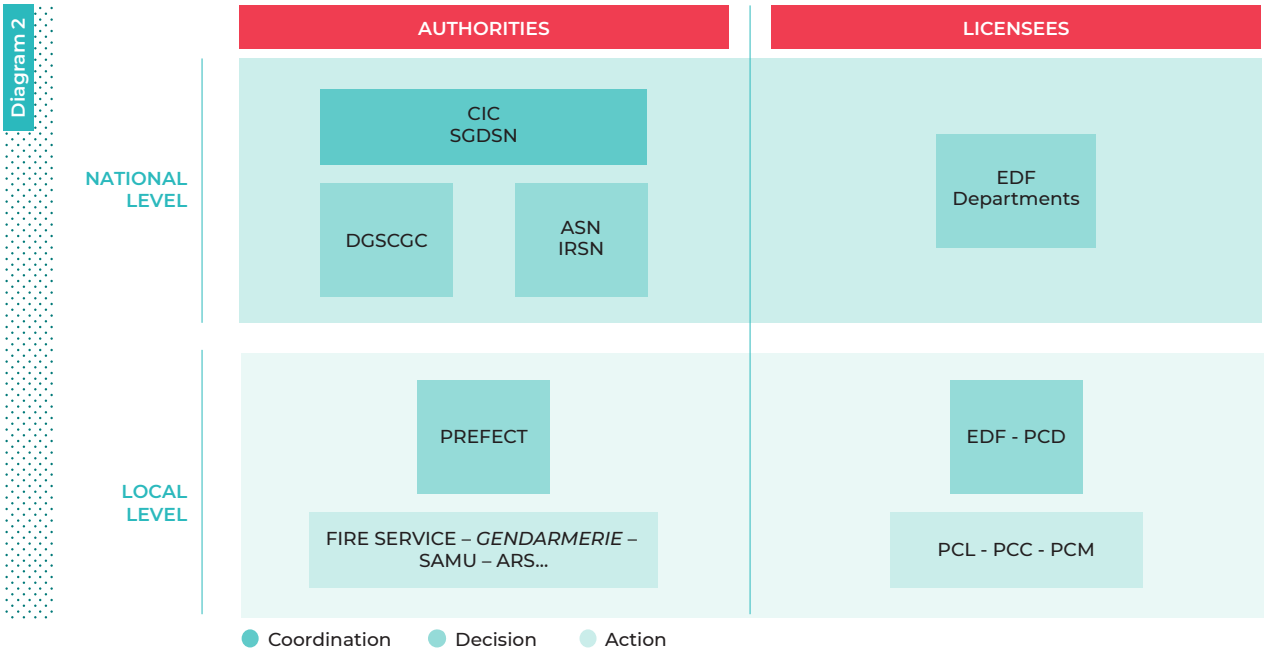
• Circulation of information

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.

Emergency response organisation in an accident situation affecting a nuclear reactor operated by EDF

Diagram 2



CIC: French Inter-ministerial Crisis Committee
SGDSN: General Secretariat for Defence and National Security
DGSCGC: General Directorate for Civil Protection and Crisis management (Ministry of the Interior)
ARS: Regional Health Agency
PCD: Command and Decision Post
PCL: Local Command Post
PCC: Supervision Command Post
PCM: Resources Command Post

• 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 of ASN

• Organising the response to accidents occurring in BNIs

The ASN emergency response organisation set up to deal with a nuclear accident in a BNI more specifically comprises:

- the participation of ASN staff in the various units of the CIC;
- at the national level, an Emergency Centre in Montrouge, consisting of three Command Posts (PC):
  - a "Strategy" Command Post, consisting of the ASN Commission, which, in an emergency situation could be called on to issue resolutions and impose requirements on the licensee of the installation concerned;
  - a Technical Command Post (PCT) in constant contact with its technical support organisation, IRSN, and with the ASN Commission. Its role is to advise the Prefect, who acts as the director of contingency operations;
  - a Communication Command Post (PCC), located close to the Technical Command Post. The ASN Chairman or his/her representative acts as spokesperson, a role which is distinct from that of the head of the Technical Command Post.

This Emergency Centre is regularly tested during national emergency exercises and is activated for actual incidents or accidents. At the local level, ASN representatives visit the *département* and zone Prefects to help them with their decisions and their communication actions. ASN inspectors may also go to the site affected; others take part in emergency management at the headquarters of the regional division involved.

Experience feedback from the Fukushima Daiichi accident also leads ASN to envisage sending one of its representatives, if necessary, to the French embassy of a country in which an accident occurred.

In 2018, the national Emergency Centre was activated 11 times, for two real situations and nine national exercises, one of which concerned a national defence nuclear facility, jointly with the Defence Nuclear Safety Authority (ASND).

The real situations concerned:

- In the early afternoon of 5 February 2018, a fire broke out in the Onet Technologies Nuclear Decommissioning – OTND plant in Pierrelatte, where low-level waste is stored and processed. The On-site Operations Plan (POI) for this Installation Classified for Protection of the Environment (ICPE) was triggered and ASN activated its Emergency Centre in order to support the Regional Directorate for the Environment, Planning and Housing (Dreal) and the office of the Prefect. The fire was rapidly extinguished and the smoke remained contained, as the facility is equipped with very high efficiency filters. The measurements taken by the automatic monitors as well as on samples taken from the site environment in the following days confirmed that no releases outside the facility had taken place. The Lyon regional division took part in the inspection of the site organised by the Dreal in the days following the incident.
- On 17 July 2018, at 22 h, a fire on a transformer of Nogent-sur-Seine NPP reactor 2, which was shut down for maintenance with core unloaded, led to the loss of the off-site power supply. The only diesel generating set available then provided the facilities with electricity, notably the pool cooling systems. EDF set up an appropriate organisation and alerted the ASN on-call team which was mobilised both nationally and locally for real-time monitoring of the event, together with its technical support organisation, IRSN. The incident ended several hours later, with off-site electrical power being restored.

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 DGSCGC, the Interministerial Emergency Management Operations Centre (COGIC), *Météo-France* and the ministerial operational monitoring and alert Centre of the Ministry for Ecological and Solidarity-based Transition.

The severity of the situation is evaluated by the various parties, who if necessary decide to activate their emergency management centres to manage the situation.

The deployment of an on-call duty system in 2018 reinforced the robustness and the mobilisation and intervention reactivity of the ASN staff.

Diagram 3 summarises the role of ASN in a radiological emergency situation. This functional diagram illustrates the importance of the ASN representative to the Prefect, who relays and explains the recommendations coming from the ASN Emergency Centre.

Table 1 shows the positions of the public authorities (Government, ASN and technical experts) and the licensees in a radiological emergency situation. These players each operate in their respective fields of competence with regard to assessment, decision-making, intervention and communication, for which regular audio-conferences are held. The exchanges between the players lead to decisions and orientations concerning the safety of the facility and the protection of the general public. Similarly, relations between the communication units and the spokespersons of the emergency centres ensure that the public and media are given coherent information.

Positions of the various players in a radiological emergency situation

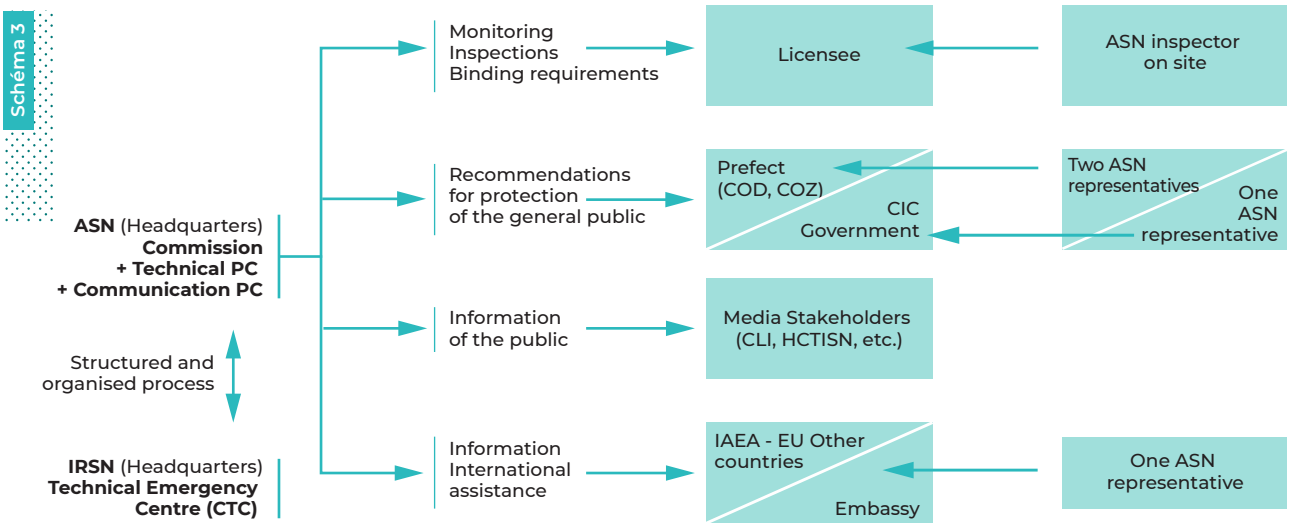
Table 1

	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

The role of ASN in a nuclear emergency situation

Schéma 3



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

• Organising a response to any other radiological emergency situation

A radiological emergency toll-free telephone number (0 800 804 135) enables ASN to receive calls 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 seriousness of the event, ASN may decide to activate its Emergency Centre in Montrouge. If not, only the ASN local level (regional division concerned) intervenes to perform its Prefect support and communication duties, if necessary calling on the expertise of the national departments. In order to enhance the graduated nature of the ASN response and organisation in the event of an emergency, for situations not warranting activation of the Emergency Centre, the system has been adapted for the creation of a national level support unit to assist the regional division concerned. The format and duties of this unit are tailored to each situation.

Once the public authorities have been alerted, the response generally consists of four main phases: care for the individuals involved, confirmation of the radiological nature of the event, securing the zone and reducing the emission and, finally, clean-up.

The Prefect or the mayor coordinates the intervention response teams, and decides on the protective measures to be taken, on the basis of the plans they have drawn up (Orsec for the Prefects, Local Safeguard Plans for the mayors). At the local level, the Prefects and the mayors can also call on the Mobile Radiological Intervention Units (CMIR) of the fire and emergency services.

In these situations, responsibility for the decision and for implementing protective measures lies with:

- the head of the establishment carrying out a nuclear activity (hospital, research laboratory, etc.) who implements the On-site Emergency Plan specified in Article L. 1333-6 of the Public Health Code (if the risks inherent to the installation so justify) or the owner of the site with regard to the safety of the persons on the site;
- the mayor or Prefect concerning public safety in the domain accessible to the public (in particular in the case of a radioactive substances transport incident).

Deployment of the ASN on-call team

In January 2018, ASN set up its 24/7 on-call system. This system aims to reinforce the robustness of ASN's organisation enabling it to deal with alerts, events and emergencies within its fields of competence. It constitutes the first level of the ASN emergency organisation, which also provides for the general alert and mobilisation of staff to activate the various units in the Emergency Centre and carry out various local missions (support for the Prefect, on-site liaison, etc.).

The ASN on-call team comprises 15 members distributed among the head-office departments and the regional divisions, who carry out this mission for seven consecutive days.

For the first year of operation of this system, ASN set up a monitoring committee which met twice, in April and October 2018, in order to review the deployment of the system and make recommendations. The system deployed is proving satisfactory and the identified areas for improvement primarily concern staff training, the "reflex" sheets and the operation of the dedicated equipment.

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 2018, concerning BNIs and the transport of radioactive substances. This programme, announced to the Prefects in the Interministerial Instruction of 20 December 2017, took account of the lessons learned from the Fukushima Daiichi NPP accident and the emergency exercises performed in 2017.

Generally speaking, these exercises enable the highest-level decision-making circles to be tested, along with the ability of the leading players to communicate, sometimes with simulated media pressure on them.

Table 2 describes the key characteristics of the national exercises conducted in 2018.

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 2018, 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 2017.

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, an exercise run by the ASND was organised during the course of 2018, in accordance with the Interministerial Instruction on nuclear and radiological emergency exercises. ASN activated its Emergency Centre to support the ASND in accordance with the agreement signed by both Authorities on 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.

National civil nuclear and radiological emergency exercises conducted in 2018

Table 2

NUCLEAR SITE	DATE OF THE EXERCISE	MAIN CHARACTERISTICS
FBFC, Framatome (Romans-sur-Isère)	1 February	Chemical and radiological risks Decision-making process, media pressure
Golfech nuclear power plant	27 March	Decision-making process
Saint-Laurent-des-Eaux nuclear power plant	11 April	Decision-making process, media pressure
Atalante and Melox (Marcoule)	5 June	Consequences for 2 BNIs with 2 different licensees Media pressure, Decision-making process
Fessenheim nuclear power plant	12 June	Decision-making process, international workshop
ILL (Grenoble)	2 October	Decision-making process, media pressure
Airbase (Istres)	6 November	Interfacing with ASND Support with radiation protection and post-accident aspects
Nogent-sur-Seine nuclear power plant	20 November	Decision-making process, media pressure
CEA Saclay Centre	18 December	Decision-making process, media pressure

The experience acquired during these many exercises enables ASN personnel to respond more effectively in real emergency situations.

3.2 _ Assessing with a view to improvement

Evaluation meetings are organised immediately after each exercise in each emergency centre and at ASN a few weeks after the exercise. ASN, along with the other players, endeavours to identify best practices and the areas for improvement brought to light during these exercises.

These assessment meetings enable the players to share their experience through a participative approach. They more specifically revealed:

- the importance of having scenarios that were as realistic as possible, in real meteorological conditions and that were technically complex enough to be able to provide useful experience feedback;
- the importance of communication in an emergency situation, in particular to inform the public and foreign authorities as rapidly as possible and avoid the spread of rumours liable to hamper good emergency management, in France and in other countries;
- the importance of providing the decision-makers with a clear view of the radiological consequences in the form of maps: the tool called Criter developed by IRSN gives a representation of the results of environmental radioactivity measurements.

In 2018, ASN also brought all the players together to review best practices to improve the response organisation as a whole. In the light of the lessons learned from the emergency exercises and actual emergency situations, ASN decided to study the possibility of adapting the activation of its emergency organisation to the situation actually encountered and the information sharing procedures. In addition, in order to improve the emergency organisation activation time, ASN will define criteria for triggering of the general alert by ASN when it becomes aware of an emergency situation and the licensee of the site concerned is late in triggering the alert.

Helicopter with external lateral baskets carrying detectors for the ULYSSE mobile gamma spectrometry measurement system developed by IRSN

4 Outlook

In accordance with the nuclear emergency duties entrusted to it by the Environment Code, ASN makes an active contribution to the review process currently being carried out by the public authorities following the Fukushima Daiichi accident, with the aim of improving the national radiological emergency organisation.

ASN is thus taking part in the work to implement the Major Nuclear or Radiological Accident National Response Plan and more particularly supports the Ministry for the Interior and the offices of the Prefects. This regional implementation will continue to be tested in 2019 during exercises, in particular in those *départements* in which there is no BNI.

Following the Government's September 2016 adoption of the principle of extending the radius of the PPI perimeter around NPPs from 10 to 20 km, the preparation for immediate evacuation out to 5 km and the pre-distribution of stable iodine tablets out to 20 km, ASN will in 2019 contribute to continuation of the PPI update work done by the offices of the Prefects and to the new population information and iodine tablets distribution campaign for inhabitants in the zone between 10 and 20 km from the NPPs.

In 2019, ASN will continue to be actively involved in the continued work on the roadmap for the Major Nuclear or Radiological Accident National Response Plan, in particular the work coordinated by the Ministry of the Interior with regard to the PPI perimeters for BNIs other than NPPs. It will also initiate the revision of the post-accident doctrine through the work of the Codirpa in accordance with the guidelines validated at the end of 2018.

In 2019, in order to prepare the offices of the Prefects for implementation of population protection or post-accident measures, a number of exercises will, as in 2018, be extended with a phase focused on civil security objectives (in particular the preparation for immediate evacuation within a 5 km radius around the NPPs) or workshops on the post-accident phase.

Finally, in 2019, ASN will be publishing a guide concerning reference documents regarding preparedness for and management of emergency situations, including the PUI, following on from the approval of ASN resolution 2017-DC-0592 of 13 June 2017 concerning the obligations of BNI licensees regarding preparedness for and management of emergency situations.

At this stage, it is possible to identify the initial results of the implementation of the French system for the response to a major nuclear or radiological accident. This system, described above, is robust, but could be perfected and several areas for improvement have been identified:

- One should bear in mind the specific nature of a nuclear emergency; it does not stop with technical management of the event, at the moment the installation is made safe, nor the safeguard of persons. The public authorities must take account of the implications of low doses over a long period of time, along with the psychosocial effects. The work done by the Codirpa to update the 2012 doctrine is helping to ensure that this is taken into account on the appropriate scale.
- It is clear that the correct means of involving the populations concerned in the exercises has not yet been found, with priority being given to preventing disruption of economic activity and avoiding risks for the population. Efforts must be continued with the aim of achieving greater involvement of the populations in the preparation phases.
- Although ASN regularly holds completely unannounced simulations with licensees, it is relatively rare for unannounced exercises to be carried out with the involvement of the public authorities. An exercise of this type is planned for 2019. For its part, ASN has this year started to conduct unannounced simulations with its on-call team, further enhancing the professionalism of its staff.
- Finally, management of a real emergency would necessarily involve the CIC. This national committee is only activated once every three years for a nuclear-related exercise and the next one on this scale could be held in 2019. Means of enabling this CIC to be simulated must be sought in order to make the decision-making circuit more realistic during the other national exercises. Experiments along these lines will be carried out in 2019 by the Ministry of the Interior.

Les nouveaux outils d'information et de concertation - Les nouveaux outils d'information et de concertation - Les nouveaux outils d'information et de concertation -

05

Informing the public and other audiences

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Informing the public and other audiences

At ASN, the French nuclear safety Authority, informing the public and other audiences is at the centre of its activities. The Acts of 2006 on Transparency and Security in the Nuclear Field[1] and 2015 on Energy Transition for Green Growth[2] entrusted ASN with the mission of making a statement on the state of nuclear safety and radiation protection in France. Consequently, throughout the year ASN informs the citizens, the media, the institutional and professional audiences of the situation of the Basic Nuclear Installations (BNI) and small-scale nuclear activities with respect to the safety and radiation protection requirements. It presents its regulatory and oversight activity and the actions it takes in this respect, and widely disseminates its resolutions and position statements, explaining them where necessary. After each inspection, ASN publishes an "inspection follow-up letter" which sets out its findings and the recommendations for the licensee: more than 21,000 follow-up letters can thus be consulted on line. 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 stake-holders 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 2018, to foster informing of the public at large, ASN shot a film showing the behind-the-scenes aspects of a 5-day inspection at the Gravelines Nuclear Power Plant (NPP). It also published a brochure setting out the issues of the 4th periodic safety review, aimed at the audiences of the Local Information Committees (CLIs) involved in the consultations on the continued operation of the oldest NPPs.

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 60,000 visitors per month on average, the *asn.fr* website is at the heart of the system for informing the public and other 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 (primacy of the image, simplified diagrams, computer graphics and illustrations). New educational content is also regularly put on line.

ASN takes care to translate into English the majority of the information notices, press releases, publications and content concerning major issues. These publications in English support ASN's work in the 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 4,500 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 4.2 million pages of the site were viewed in 2018.

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* now has a dedicated page for whistle-blowers in particular, proposing a secure form for reporting suspect situations.

1. *Act 2006-686 of 13 June 2006 relative to Transparency and Security in the Nuclear Field (TSN Act).*
2. *Act 2015-992 of 17 August 2015 relative to Energy Transition for Green Growth (TECV Act).*

Information and iodine tablet distribution campaigns

Every five years or so, an information and iodine tablet distribution campaign targets the populations living in the vicinity of nuclear power plants over the entire zone covered by the off-site emergency plans (PPI*). 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.

2018 saw the preparatory work for the information and iodine tablet distribution campaign in the zones situated between 10 and 20 km from the nuclear installations: this campaign, which is to start in mid-2019, will take into account of recent extension of the PPI areas. 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, CLI members, IRSN, EDF, etc. ASN will, on the strength its experience, assist the Ministry of the Interior in this procedure.

(*) PPI: French acronym meaning "Off-site Emergency Plan": 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.

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, including when it is delivered by other players.

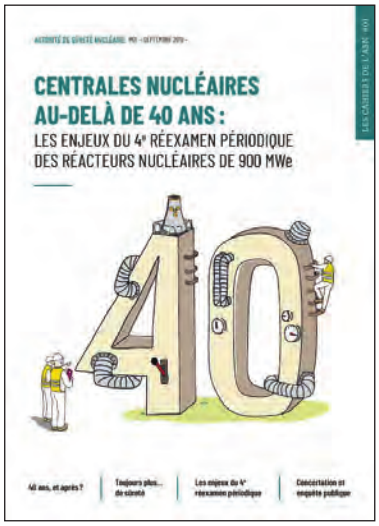
ASN news is followed and passed on by more than 9,000 subscribers on Twitter, nearly 8,500 on LinkedIn and nearly 3,500 on Facebook.

1.1.3 _ The ASN/IRSN exhibition

As part of their duty to inform the public, ASN and 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: an exhibition of about 80 display boards, educational booklets and a resources website. 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, the content of the ASN-IRSN exhibition was reorganised and referenced on line to make it readily accessible and reusable. A specific website shall be provided for the public in 2019.



The *"Les cahiers de l'ASN"* magazine # 1: Nuclear power plants beyond 40 years

1.1.4 _ The ASN Information Centre

Any citizen can address requests for information to ASN, either on-line (at the address info@asn.fr), by letter or by telephone. Each year, the on-line 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 in improving the safety of BNIs. Over the last few years it has thus undertaken a major overhaul of the technical and general regulations applicable to BNIs, while always being attentive to the clarity and completeness of the information delivered to the public concerning these regulations. The 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 one hundred issues of *Contrôle* magazine can still be consulted on *asn.fr*. The *Les cahiers de l'ASN* booklets provide a wide public with plain-language information on the ongoing issues and decision-making processes (e.g.: "Nuclear power plants beyond 40 years: the stakes of the 4th periodic safety reviews 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 2018, ASN published Guide No. 29 on "Radiation Protection in Radioactive Substance Transport Activities", and a sheet reiterating the "minimum technical design rules[3] for work premises in which X-ray emitting devices are used".

• 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 on-line formalities where necessary.

1.2.2 _ Radiation protection: a portal for notifying significant events

The notification of significant events is a key factor in reinforcing the safety and radiation protection culture. Since May 2017, all significant events concerning radiation protection have to be notified *via* ASN's on-line services portal: *teleservices.asn.fr*. The possibility of notifying incidents on line, which has been operational since 2015 for radiotherapy, is now available for all medical applications that use ionising radiation: nuclear medicine, interventional and fluoroscopy-guided practices, computed tomography and conventional and dental radiology.

New forms were created in 2018 to facilitate notification of the possession and utilisation of X-ray generators in the medical and industrial sectors. Significant transport events (excluding on basic nuclear installation sites) can now also be reported on line.

1.2.3 _ A bulletin and regular meetings to share good practices

ASN publishes the twice-yearly bulletin *Patient safety – Paving the way for progress*, co-signed by the SFRO (French Society for Radiation Oncology), the SFPM (French Society for Medical Physics), the AFPPE (the French Association of Radiographers), and the AFQSR (French Association for Quality and Safety in Radiotherapy). Sent to 180 radiotherapy centres in France, the bulletin highlights the progress and experience-sharing approach initiated by the radiotherapy centres to enhance treatment safety. An issue No. 12 on the analysis of the risks of vertebra identification errors in imaging was published in 2018.

ASN participates very regularly in the congresses of the French Association of Radiographers (AFPPE), the French Radiology Days (JFR) and the days of the French Society for Radiation Protection (SFRP) devoted to Radiation Protection Expert-Officers ("PCR" days). In 2018, ASN attended the JFR and the PCR days to present the main regulatory provisions of radiation protection applicable in medical and dental radiology.

ASN was also behind the initiative of national and regional thematic professional seminars (four professional seminars held in Paris, Marseille and Lyon, were organised by the ASN divisions in 2018). These events provide the opportunity to interchange with specialised audiences, to enhance knowledge of the regulations (regulatory sheets 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 2018, 15 regional conferences were held between the end of May and mid-July. ASN was thus able to reply directly to about one hundred media representatives, resulting in wide dissemination of the information (more than 150 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.

Interview with P. F. Chevet, ASN Chairman, at the presentation of the ASN Annual Report – April 2018

3. *Technical rules relating to ASN decision 2017-DC-0591 of 13 June 2017.*

The subjects at the core of media attention

The following subjects were broadly addressed in 2018: the safety situation of the Fessenheim NPP, the commissioning schedule for the EPR, and the *Cigéo* safety options file. With the announcing of the broad lines for multi-year energy programming, the issues of decommissioning, ageing and continued operation of the NPPs have been the subject of numerous exchanges with French and foreign media.
The journalists specialised in nuclear issues asked for information concerning the situation of the investigations in the Creusot Forge files (detection of falsification), and the state of progress of the post-Fukushima work. Information requests concerning the optimisation of doses in the medical sector were also received, albeit to a lesser exent.
Many articles on the change of the ASN chair were also published.

Presentation to the OPECST of the ASN *Report on the State of Nuclear Safety and Radiation Protection in France* – April 2018

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 each year 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.

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 on subjects relating to nuclear safety and radiation protection.

In 2018, ASN made itself available for the work of the board of inquiry on the safety and security of nuclear power plants chaired by Paul Christophe, member of the National Assembly, for which the report was presented in July by its rapporteur, Barbara Pompili, member of the National Assembly. The ASN regional divisions responded to the requests of the Departmental Councils or the CESER[4] 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 2018, ASN actively participated in the International Symposium on Communicating Nuclear or Radiological Emergencies to the Public organised by the IAEA, and assisted its Vietnamese counterpart - the Vietnam Agency for Radiation and Nuclear Safety – on the questions of transparency, communicating to the general public and emergency communication.

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[5]. 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).

4. *CESER: Regional Economic Social and Environmental Council.*
5. *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[6]. 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 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 mitigate these risks.

This right to information on the risks also concerns those responsible for the transport of radioactive substances when the quantities involved exceed the thresholds set by law.

• The Commission for Access to Administrative Documents (CADA)

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.

2.2 — Information given to people living in the vicinity of basic nuclear installations

The 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.

In 2018 and 2019, the radius of the zone around nuclear installations in which the resident populations will receive regular information on the state of safety of the installations and instructions to follow in the event of an emergency, will be extended from 10 km to 20 km. This extension of the zone covered by the "Off-site Emergency Plan" (PPI) aims to align French practices with European practices with regard to risk prevention. The population basins concerned by the information on the nuclear sites are significantly larger: 2018 was a year of collective reflection (Ministries of the Interior, Health, National Education, healthcare professionals, ASN, CLIs, IRSN, etc.) on the means to implement to succeed in this scaling up.

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 2018, 111 draft resolutions, opinions and guides were thus subject to public consultation.

2.3.1 — Public consultation on draft ASN regulations

Article L. 123-19 of the Environment Code provides for a procedure of consultation of the public *via* the Internet on draft regulatory texts having an impact on the environment.

ASN has decided to apply this widely. Consequently, all draft ASN regulations concerning BNIs, including those relating to nuclear pressure equipment, are considered as having an impact on the environment and are therefore subject to public participation. The same approach is applied for the ASN regulations relative to the transport of radioactive substances.

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.

Four consultations held in 2018 concerned draft ASN regulations.

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.

6. *See Article L. 121-15 of the Environment Code.*

2.3.2 _ Public consultation on draft ASN licensing decisions

The ASN licensing decisions[7] on nuclear safety and radiation protection can form the subject of several public consultation procedures which are presented below.

• Disclosure of the files by the licensee

Before setting up the general procedure for consultation, a procedure for file disclosure by the licensee was instituted for any project to modify a BNI or its operating conditions that could lead to a significant increase in its water intakes or environmental discharges (while being of insufficient scale to warrant a public inquiry procedure). Two files were made available to the public on *asn.fr* in 2018.

• The public inquiry

In application of the Environment Code, the BNI creation authorisation and decommissioning applications form the subject of a public inquiry[8]. 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[9] on line 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 but can be consulted throughout the inquiry period under the conditions set by the order governing the inquiry.

On 2018, a public inquiry was held for the decommissioning of the Rapsodie reactor in Saint-Paul-lez-Durance.

• Disclosure of drafts on *asn.fr*

The ASN licensing decisions which are not subject to public inquiry and which could have a significant effect on the environment are disclosed for consultation on the Internet. These are mainly individual requirements applicable to BNIs, the authorisation to commission a BNI or the delicensing of a decommissioned BNI, as well as authorisations for small-scale nuclear activities that could have a significant impact on the environment.

During 2018, 45 consultations concerned ASN licensing decisions relative to basic nuclear installations and 60 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 other actors in the area of information

2.4.1 _ High Committee for Transparency and Information on Nuclear Security (HCTISN)

The HCTISN, created by the TSN Act, is a body that informs, discusses and debates on nuclear activities, their safety and their impact on health and the environment.

The HCTISN 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 on line at *hctisn.fr*.

In 2018, the HCTISN made public a report on the "presentation of the French 'Fuel Cycle' in 2018", and an interim report setting out the first reflections on the management of Very-Low-Level (VLL) waste. In 2018, with the assistance of ASN, IRSN, EDF and Anccli (the National Association of Local Information Committees and Commissions), it set up the consultation on the continued operation of the 900 MWe reactors. At the end of the year, Christine Noiville was appointed chair of the High Committee[10], succeeding from Marie-Pierre Comets.

7. *ASN licensing decision: decision which applies to a licensee for a given installation.*
8. *In application of the provisions of Article L.123-12 of the Environment Code.*
9. *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.*
10. *By Decree dated 3 December published in the* Official Journal *of 5 December 2018.*

High Committee for Transparency and Information on Nuclear Security

The HCTISN comprises 40 members appointed by decree for six years. They include:

- two members of the National Assembly appointed by the National Assembly and two members of the Senate appointed by the Senate;
- six representatives of the CLIs;
- six representatives of environmental protection associations and approved health system users associations;
- six representatives of persons in charge of nuclear activities;
- six representatives of representative employee labour organisations;
- six "qualified personalities" chosen for their scientific, technical, economic or social competence, or for their information and communication expertise, including one appointed by the Government, three appointed by OPECST, one by the Academy of Science and one by the Academy of Moral and Political Sciences;
- the ASN Chairman, an IRSN representative and 4 representatives of the ministries concerned;
- the chair of the HCTISN is appointed by the Prime Minister from among Members of Parliament, members of the CLIs or qualified public figures.

The latest news concerning the HCTISN can be found on its website at *hctisn.fr*.

2.4.2 _ Institute of Radiation Protection and Nuclear Safety (IRSN)

IRSN implements a policy of information and communication that is consistent with the objectives agreement signed with the Government.

The IRSN presents its activities in an annual report which is distributed to its supervisory ministers, to the HCTISN, the French High Public Health Council (HCSP) and the Working Conditions Guidance Council (COCT).

The TECV Act obliges IRSN to publish the opinions it gives to the authorities who referred matters to it. Thus since March 2016, IRSN publishes twice 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.

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 (non-informed). 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 (CLI/CLIS)

The general mission of the Local Information Committees (CLIs) is usually to monitor, inform and be consulted with regard to nuclear safety and radiation protection. They analyse the impacts on persons and the environment of the nuclear activities of the installations of the nuclear sites around which they have been set up[11].

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 has thus published the first issue of the *Les cahiers de l'ASN* booklets for the CLIs: "Nuclear power plants beyond 40 years: the stakes of the 4th periodic safety review of the 900 MWe nuclear reactors", very widely distributed prior to the public consultation meetings on the 4th safety review. 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[12]. They encourage BNI licensees to facilitate CLIs access to the files concerning procedures in which the CLI's opinion will be required.

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 pages on the website of the local authority that supports them; about twenty of them publish a newsletter (sometimes as a box in a local authority bulletin).

In 2018, the CLI conference – the annual meeting of Local Information Committees organised by ASN in partnership with Anccli – reported on the CLIs' initiatives and questionings. The key theme of this issue, relating to the regulatory news, is the scaling up of the monitoring and informing duties that come with the extension of the perimeters of the Off-site Emergency Plan. The importance and the integration of organisational and human factors in the safety systems were also reiterated through a workshop entitled "Licensee, subcontractor, citizen: all actors of nuclear safety".

11. The operating framework of the CLIs is defined by Articles L. 125-17 to L. 125-33 of the Environment Code and by Decree 2008-251 of 12 March 2008 relative to the CLIs for the BNIs. A decree currently under preparation relating to the Basic Nuclear Installations (BNI) and transparency in the nuclear activities is to detail the new provisions relative to the composition of CLIs (Book I, Title II, Chapter V, Section 12: "Local information committees for basic nuclear installations"), in order to include members from foreign States if the site is located in a département *bordering another country; and to add a provision relative to the organising by the CLI of a public meeting open to everyone at least once a year.*
12. 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.

First-hand news of the CLIs

ASN invited representatives from the three CLIs of South-West France (Blayais, Civaux, Golfech) to tightened "Environment" inspections of the NPPs. A representative of the Belleville-sur-Loire CLI also accompanied ASN during a worksite inspection. The observers were then able to give their testimonial before the CLI members at public meetings devoted to the conclusions of these inspections.

CLI meetings held prior to the emergency exercises organised in the NPPs (such as Nogent-sur-Seine, Chooz, Saint-Laurent-des-Eaux, etc.), informed the public about the preparation of these exercises (implications, scenarios, etc.).

The extension of the radius of the off-site emergency plan zones from 10 to 20 km – one of the major topics in 2018 - was the subject of many public meetings involving the mayors of the municipalities concerned (e.g.: Belleville-sur-Loire, Blayais, Paluel, Penly, etc.). The subjects on the table: the local safeguard plans (PCS) and the municipality information documents on major risks ("Dicrim") for these municipalities. At Nogent-sur-Seine and Chooz, the CLIs particularly monitored the updating of the Off-site Emergency Plans (PPI) by the Prefect's offices concerned: the CLIs were, for example, invited to the consultation meetings with the local elected officials.

At the end of the year, the CLIs of Dampierre-en-Burly, Saint-Laurent-des-Eaux, Cruas-Meysse, Tricastin and Bugey organised public meetings devoted to the national consultation on the 4th periodic safety review of the 900 MWe reactors.

Projects for "Inter-CLI" meetings were revived in 2018; they will be held in early June 2019 for the Sud-Est (South-East) and in early July 2019 for the Val de Loire.

- The Somanu CLI held its last meeting in Maubeuge. Given that the site – whose flagship activity is the maintenance of NPP reactor coolant pump sets – no longer has basic nuclear installation status, it will henceforth be monitored by a Site Monitoring Commission (CSS).
- The Gravelines CLI organised a public meeting on the theme "Living near a nuclear power plant: risk and emergency management" which was attended by about 150 people.
- At a public meeting organised in Soulaines-Dhuys (Aube waste repository), *Santé Publique France* presented a study on the monitoring of cancers in the vicinity of the site.
- In Bure, the public meetings organised by the CLIS (Local Information and Monitoring Committee) focused on the regulations and organisation of the transport of radioactive substances as part of the projected railway connection for the *Cigéo* project.
- At Brennilis and Golfech, the public meeting was devoted to the question of radioactive waste management.
- At Chinon, the CLI public meeting addressed the post-Fukushima measures.
- At Blayais, the public meeting served to assess the situation of nuclear safety, radiation protection and environmental protection at the NPP.
- At Civaux, a general meeting open to the press focused on the anomalies in the steel of the steam generators and on the fuel removals.

The functional framework of the Local Information Committees and the Site Monitoring Committees

The CLIs, whose creation is incumbent upon the President of the General Council of the *département*, comprise various categories of members: representatives of *département* General Councils, of the municipal councils or 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. The 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 BNI sites have a CLI, except for the Ionisos facility in Dagneux in the Ain *département*. This means that there are 35 CLIs governed by the Environment Code.

The CLIs are financed by the regional authorities and by ASN. ASN devotes about one million euros per year to the financial support of the CLIs and their 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 regularly takes part in the meetings and public information or consultation initiatives of the monitoring commissions of former mining sites or of sites contaminated by radioactive substances. This is the case more specifically for the monitoring commissions of the former mining sites of Écarpière (Loire Atlantique *département*), Chardon (Loire Atlantique *département*), Lignol (Morbihan *département*), Malièvre (Vendée *département*), Saint-Priest-la-Prugne (Loire *département*), Gueugnon (Saône-et-Loire *département*), or the Curie Institute (Val-de-Marne *département*) and Fort de Vaujours (Seine-et-Marne *département*) sites. The issues at stake include the tightening of the environmental monitoring requirements and the monitoring of post-operational clean-out worksites.

For the nuclear sites concerning Defence, which are under the oversight of the delegate for nuclear safety and radiation protection for activities and facilities concerning Defence, Articles R. 1333-38 and R. 1333-39 of the Defence Code provide for the setting up of information committees similar to the CLIs but whose members are appointed by the State and not by the President of the departmental council. There are about fifteen such committees. For the Valduc site, in addition to the information committee, an associative consultation structure – the Structure for exchange of information on Valduc (Seiva) – was created in 1996.

(*) Issued in application of Article L. 125-2-1 of the Environment Code.

2.4.4 _ National association of local information committees and commissions (Anccli)

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 groups the 35 CLIs that exist in France. 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.

In 2018, ASN and Anccli worked on the drafting of the agreement that will bind them for the 2019-2022 period and will thus ensure the funding of the Anccli action plan for 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

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International relations

Through a range of bilateral, European and multilateral cooperation frameworks which it develops or in which it participates, ASN aims to promote the definition of ambitious international references, in order to make known French positions and doctrines which could contribute to this promotion and to draw on the best practices from around the world to advance nuclear safety and radiation protection. International actions should enable its approach to nuclear safety and radiation protection issues and the European approach to be consolidated.

This process of sharing, harmonisation and improvement of knowledge and practices also includes cooperation on any significant nuclear events and accidents (Chernobyl and Fukushima Daiichi) in which France has played a key post-accident management role since 2011.

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, harmonising and improving knowledge and practices requires that ASN work in 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 a European level, the regulatory context has changed since 2009, with the adoption, updating and implementation of three European Directives on nuclear safety (Council Directive 2009/71/Euratom of 25 June 2009 creating a community framework for the nuclear safety of nuclear facilities/revised 2014), waste legislation (Council Directive 2011/70/Euratom of 19 July 2011 creating a community framework for the responsible and safe management of spent fuel and radioactive waste) and radiation protection (Council Directive 2013/59/Euratom of 5 December 2013 setting basic standards for health protection against the dangers arising from exposure to ionising radiation and repealing Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom and 2003/122/Euratom).

In the construction of this legal framework for nuclear safety, the European Commission is supported by ENSREG (European Nuclear Safety Regulators Group) which brings together experts from the European Commission and member countries of the European Union[1].

The safety regulators also set up voluntary associations, such as the European Nuclear Regulators Association (WENRA), the Heads of the European Radiological protection Competent Authorities (HERCA) and the European Association of Competent Authorities (EACA) for the transport of radioactive materials, which, jointly with the Technical Support Organisations (TSO), provide the regulators and the Commission with technical support.

At a multilateral level, cooperation takes place within the framework of the International Atomic Energy Agency (IAEA), a UN agency founded in 1957, and the OECD's Nuclear Energy Agency (NEA), created in 1958. These two agencies are the most important inter-governmental organisations in the field of nuclear safety and radiation protection.

1.1 — Giving priority to Europe

Europe is one of the priority areas for ASN's international actions. The aim is to contribute to sharing, harmonisation and improving knowledge and practices in the fields of nuclear safety, the safety of waste and spent fuel management and radiation protection.

With regard to nuclear safety and the safe management of waste and spent fuel, ASN takes part in two informal organisations working more specifically in favour of European harmonisation: ENSREG and WENRA.

ENSREG was created in 2008 and led to a political consensus on European Directives concerning nuclear safety in June 2009, followed by spent fuel management and waste in July 2011. This institution also took part in a process to revise the Nuclear Safety Directive proposed by the European Commission in 2013, following on from the review further to the Fukushima Daiichi accident. Each safety regulator then provided technical advice to its government responsible for the negotiations in Brussels, until its revision on 8 July 2014.

1. *The national delegations are made up half by heads of safety Regulators and half by representatives from Ministries for the Environment or Energy.*

WENRA was created in 1999 and is an association of the heads of nuclear regulatory authorities in European countries with power reactors, with the other countries being observers. This association is based on experience-sharing by safety regulators with a view to harmonising safety rules for reactors and waste management facilities.

In the field of radiation protection, HERCA, which was founded in 2007, aims to create an informal forum for heads of radiation protection authorities, along the lines of WENRA. Its aim is to reinforce European cooperation in radiation protection and the harmonisation of national practices.

1.2 — Cooperation in the fields of nuclear safety and radiation protection outside Europe

ASN multiplies its initiatives to share nuclear safety and radiation protection best practices and regulations outside Europe.

Within the framework of the 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 are also the documentary reference standards for the international audits overseen by the Agency. These notably include the safety regulator audit missions (IRRS, Integrated Regulatory Review Service – ARTEMIS, Integrated Review Service for Radioactive Waste and Spent Fuel Management, Decommissioning and Remediation), as well as the audit missions on NPPs in operation (OSART, Operational Safety Review Team).

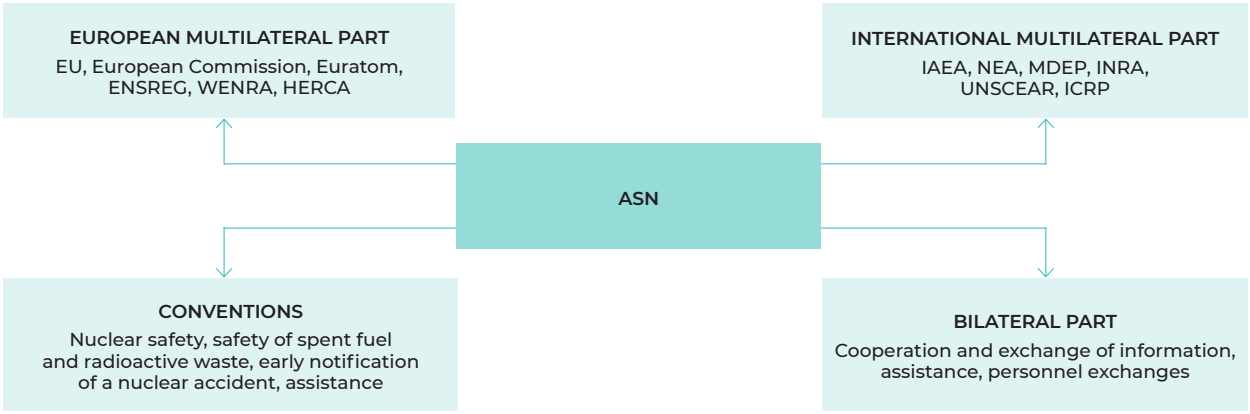
ASN also contributes actively to the MDEP (Multinational Design Evaluation Programme) the aim of which is to discuss and compare the experiences of safety regulators with regard to the evaluation of new reactors, including the EPR. This programme, started in 2006 by ASN and the American Nuclear Regulatory Commission (NRC), currently brings together 16 safety Authorities and aims to develop innovative approaches for sharing the resources and knowledge of the safety regulators in charge of regulatory evaluation of new reactors, in order to contribute to the harmonisation of safety standards and their implementation.

Extensive sharing of operating experience feedback: ASN-driven adoption of a WENRA recommendation on the manufacturing anomalies affecting nuclear reactor components

In the light of the anomalies observed on the French NPP fleet, ASN suggested to the WENRA members that a recommendation be prepared: the working group headed by ASN reached a consensus on a text adopted at the plenary meeting of 24-26 April 2018. The recommendation adopted stipulates that the WENRA members must undertake to have the licensees carry out carbon concentration measurements on the large-sized forged components and analyse the results. It is also recalled that the licensees are responsible for conserving manufacturing records. For new constructions, manufacturing parameters important for safety must also be identified and checked in order to guarantee the quality of the component (zones with a heterogeneity risk, heat treatments, locations of test coupons). Generally speaking, the interaction between the licensee, the designer and the manufacturer must be reinforced. Finally, WENRA will support the work initiated within the framework of the NEA on changes to manufacturing codes and standards, in order to take account of the heterogeneity risks.

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. They issue recommendations helping to improve the protection of exposed persons, whether patients in the medical sector or specific categories of workers.

ASN action on the international stage



2 — Relations within Europe

European harmonisation of nuclear safety and radiation protection principles and standards has always been a priority for ASN. In this context, ASN participates actively in exchanges between the national nuclear safety and radiation protection authorities of the Member States.

2.1 — The EURATOM Treaty

The Treaty creating the European Atomic Energy Community (EURATOM) was signed on 25 March 1957 and constitutes the primary law in the field. It has allowed the harmonised development of a strict oversight system for nuclear safety and security and radiation protection. In an Order of 10 December 2002 (Case C-29/99 Commission of European Communities versus EU Council), the EU Court of Justice, ruling that no artificial boundary could be created between radiation protection and nuclear safety, recognised the principle of the existence of Community competence in the field of safety, as in the field of management of radioactive waste and spent fuel.

Independently of bilateral agreements on information exchanges in the case of an incident or accident with potential radiological consequences, France is committed to applying the Euratom Council Decision of 14 December 1987 on community arrangements for the early exchange of information in the event of a radiological emergency. 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.

ASN chaired the ENSREG from November 2015 to October 2018

While it was Chair, ASN oversaw the work to implement measures resulting notably from the Safety Directive revised in 2014, by allowing correct monitoring of the action plans by the Member States, following the post-Fukushima stress tests, by launching and successfully completing the first peer review on ageing control of power and research (≥ 1 MWth) reactors, with the help of WENRA, by organising stress tests outside the EU, notably in Armenia and Belarus, or by ensuring that the Member States schedule ARTEMIS waste management reviews.

2.2 — European Nuclear Safety Regulators Group (ENSREG)

It supports the European Commission's European legislation initiatives. ENSREG is supported by three working groups, devoted to installations safety (WG1), the safe management of radioactive wastes and spent fuels (WG2) and transparency in the nuclear field (WG3) respectively. A fourth group (WG4) dealing with international cooperation was embedded in the mandate of WG1 and more specifically focuses on the European Commission's Instruments for Nuclear Safety Cooperation (INSC – evaluation and programming).

ENSREG and the European Commission created the stress tests initiative for the European NPPs, organised in 2012 in the wake of the Fukushima Daiichi accident.

New arrangements for following up the recommendations of the stress tests were proposed in 2017 and presented to the ENSREG meeting of WG1.

ENSREG is also organising the first peer review of ageing management for power reactors and research reactors with a power of 1 MWth or more. In this context, each of the 19 countries taking part in this review drafted a national report devoted to an assessment of ageing control for the reactors concerned, which was placed on-line on the ENSREG website. After a cross-examination of these reports by experts appointed by the Member States and a Q&A session, the thematic peer review was held from 14 to 18 May 2018 in Luxembourg: the purpose of this review, which comprised 140 participants, was to establish a picture of the current situation and recommend measures with respect to ageing control. The reports presenting the results of this review, a report on the generic results of this review and a report on the specific results per country, were adopted in the ENSREG plenary session of 4 October last, and were then presented at a public event on 22 November in Brussels. On this basis, each participant shall produce a national action plan to be submitted in September 2019 and which will be monitored by ENSREG.

2.3 — The European Directive on the Safety of nuclear installations

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" section on *asn.fr*).

The Ostrovets NPP in Belarus undergoes European stress tests

At the request of Belarus, the Ostrovets NPP, a third-generation installation under construction, underwent European stress tests in 2017. The review team consisted of 17 European experts (including one representative from ASN) headed by Mark Foy, Chief Inspector of the ONR (Office for Nuclear Regulation): it examined the robustness of the facility to extreme events and its ability to manage a severe accident, in the light of the most recent safety standards. Apart from the design of the installation which has passive systems, the best practices observed include the existence of a full-scale simulator for staff training and the continuous presence on the site of a brigade more than 100 strong.

The recommendations state that additional studies are needed to verify the installation's seismic margins.

The Board, chaired by Marta Ziakova (Slovak safety regulator) assisted by Vice-President Sylvie Cadet-Mercier, ASN Commissioner, presented the review team's report to the Belarus safety regulator in June 2018. This report was then approved by ENSREG on 2 July 2018, presented to the public the following day and posted on-line on the *ensreg.eu* website.

Its recommendations will give rise to a national action plan, the implementation of which will be the subject of a follow-up mission in 2020.

It makes provision for increased powers and independence of the national safety regulators, sets an ambitious safety objective for the entire Union (based on the baseline safety requirements used by WENRA) and establishes a European system of peer reviews on safety topics. 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. Consistently with this transposition, ASN supports actions aiming to define the technical safety objectives being sought.

2.4 _ The European Directive on the Management of spent fuel and radioactive waste

On 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 helps strengthen nuclear safety within the European Union, by making the Member States more accountable for the management of their spent fuel and radioactive wastes.

This Directive is legally binding and covers all aspects of the management of spent fuel and radioactive waste, from production up to long-term disposal. It recalls the prime responsibility of the producers and the ultimate responsibility of each Member State for ensuring the management of the waste produced on its territory, ensuring that the necessary steps are taken to guarantee a high level of safety and to protect the workers and the public from the dangers of ionising radiation.

It clearly defines obligations concerning the safe management of spent fuel and radioactive waste and requires that each Member State adopt a legal framework covering safety issues, stipulating:

- the creation of a competent regulatory authority with a status such as to guarantee its independence from the producers of waste;
- the definition of authorisation procedures involving authorisation requests examined on the basis of the safety cases from the licensees.

The Directive regulates the drafting of the national spent fuel and radioactive waste management policies to be implemented by each Member State. It in particular specifies that each Member State has to adopt a legislative and regulatory framework designed to implement national radioactive waste and spent fuel management programmes.

The Directive also contains provisions concerning transparency and participation of the public, the financial resources for management of spent fuel and radioactive waste, training, as well as self-assessment obligations and regular peer reviews. These aspects constitute significant progress in reinforcing the safety and accountability of spent fuel and radioactive waste management in the European Union. The TECV Act and the Ordinance of 10 February 2016 enabled the provisions of the Directive to be transposed.

European work on the transposition and implementation of the radiation protection basic safety standards (BSS) Directive

The scope of the BSS Directive BSS is a broad one: 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 or "common understandings" on these requirements (can be consulted on *herca.org*) to help the Member States with the transposition of this Directive. Despite the common base that this Directive represents and the clear coordination efforts made upstream, the transposition work 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. The Member States will thus be able to share their experience and facilitate the compatibility of the national approaches adopted.

2.5 _ The Euratom European Directive on Radiation Protection "Basic Standards"

Directive 2013/59/Euratom of 5 December 2013 updates the Basic Standards for health protection against the hazards arising from the exposure of individuals to ionising radiation (BSS Directive, see box page 187). The Member States were required to transpose the provisions of this Directive before 6 February 2018 (see "Regulation" section on *asn.fr*).

2.6 _ The EURATOM Treaty European working groups

ASN also participates in the work of the EURATOM Treaty committees and working groups:

- Article 31 experts group (Basic Radiation Protection Standards);
- Article 35 experts group (checking and monitoring radioactivity in the environment);
- Article 36 experts group (information concerning regulation of radioactivity in the environment);
- Article 37 experts group (notifications concerning radioactive effluent discharges).

2.7 — 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 European Union 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 European Union 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 European Nuclear Regulators Association (WENRA)

WENRA continues to develop a joint approach to nuclear safety and its regulation, more notably within the European Union. WENRA created two working groups with the role of harmonising safety approaches in the fields of:

- nuclear power reactors (Reactor Harmonisation Working Group – RHWG);
- radioactive waste, spent fuel disposal and decommissioning (Working Group Radioactive Waste and Decommissioning – WGWD).

In each of these fields, the groups defined the reference levels for each technical topic, based on the IAEA's most recent standards and on the most stringent approaches adopted within the European Union.

In 2018, two plenary sessions of WENRA were held, in April in Ghent and in November in Schaffhouse (Switzerland). These meetings produced the following major contributions:

- the adoption of a recommendation on carbon segregation for large equipment items;
- continuation of safety improvement work;
- the adoption of a report on the security-safety interfaces, the conclusions of which should be integrated into the reference levels;
- the development of reference levels for research reactors;
- the initiation of work on WENRA strategy for the coming years, taking account of projections regarding the world's civil nuclear landscape.

2.9 — The Western Association of the Heads of the European Radiological Protection Competent Authorities (HERCA)

The Association of the Heads of the European Radiological Protection Competent Authorities (HERCA) was created in 2007 at the initiative of ASN in order to organise close consultation between the heads of the European Authorities with competence for radiation protection. In now comprises 56 Authorities, 32 of which come from European countries.

WENRA meeting – 25-26 April 2018 – Ghent (Belgium)

Six expert groups are currently working on the following topics:

- practices and sources in the industrial and research fields;
- medical applications of ionising radiation;
- preparation and management of emergency situations;
- veterinary applications;
- sources of naturally occurring radiation;
- education and training.

ASN has been the technical secretary for this association since it was created and takes part in all the working groups. Moreover, ASN has chaired the working group on medical applications since 2018.

In 2017, HERCA finalised its action plan which included the publication of several positions concerning the transposition and implementation of the requirements of the BSS Directive. These positions were published on the HERCA website *(herca.org)*.

In the field of preparedness for and response to emergency situations, HERCA monitors the implementation of the HERCA-WENRA approach by the member countries. It should be recalled that this approach, approved in 2014, aims to coordinate population protection measures with those measures decided on by the country in which the accident occurred, in order to create a coherent response in the countries affected by the accident. HERCA is continuing its work to facilitate the effective implementation of this approach.

The 22nd meeting of the HERCA Board in Paris

On 30 and 31 October 2018, the HERCA Board met in the ASN premises in Montrouge. This meeting brought together 45 people from 25 European countries, along with the European Commission in the capacity of observer. Based on more than ten years of activity, HERCA decided to work on the benefits gained by its member countries and on new activities and working methods, the first results of which were presented in Montrouge. This exercise was also an opportunity to identify the challenges faced by HERCA, such as the long-term commitment of the leaders and experts of the member authorities and the definition of ambitious programmes of work involving all of its members.

21st HERCA meeting – 17-18 May 2018 – Prague (Czech Republic)

ASN wins a call for bids from the European Commission

In a consortium with IRSN and GRS, its main partners, ASN won a call for bids in 2018 for the Instrument for Nuclear Safety Cooperation (INSC), headed by the European Commission and providing assistance to the Turkish regulator. This three-year programme comprises four tasks, concerning management of the project (leader ASN), specific technical tasks to reinforce the capabilities of the Turkish regulator (NDK) with regard to safety assessments, manufacturing and construction inspection capability (leader ASN) and improvements to the regulator's management systems.

The Board of HERCA met twice in 2018. These two meetings reviewed ongoing and future activities by the Working Groups and approved the publication of documents, such as the information sheet for the protection of workers during outdoor imaging procedures in the veterinary field, or the country sheets detailing the national structures implemented in response to an emergency situation. The HERCA Board also adopted a position in the light of a ruthenium release incident in the autumn of 2017 and asked that, when abnormal releases are detected, the HERCA members rapidly share the results of measurements taken on their territory by means of the USIE (see point 4.3) or ECURIE tools.

2.10 _ Assistance programmes under the Instrument for Nuclear Safety Cooperation (INSC)

In 1991, the European Commission launched the "nuclear safety" part of the TACIS[2] programme to address the concerns raised by the Chernobyl accident. From 1991 to 2006, more than €1.3 billion were committed to nuclear safety projects. Since 2007, the actions of the European Union with regard to assistance and cooperation in the field of nuclear safety have continued under the Instrument for Nuclear Safety Cooperation (INSC).

Three priority areas for assistance to the countries of Eastern Europe had been defined under these programmes, in the field of nuclear safety:
- contribution to improving the operating safety of existing reactors;
- provision of funding for short-term improvements to the least safe reactors;
- improvement in the organisation of safety regulation, making a clear distinction between the responsibilities of the different entities concerned and reinforcing the role and competence of national nuclear regulatory bodies.

Regulation 237/2014/Euratom of the European Parliament and the Council, dated 13 December 2013, revised the Instrument for Nuclear Safety Cooperation for the period from 1 January 2014 to 31 December 2020 with a budget envelope of €225.3 million, owing to European budget restrictions.

Moreover, regulation 236/2014/EU of the European Parliament and of the Council, dated 11 March 2014, laid out common rules and procedures for the implementation of the Union's instruments for financing external actions. The objectives of the new instrument include the goals of:
- supporting the promotion and implementation of stricter nuclear safety and radiation protection standards in nuclear facilities and of radiological practices in third-party countries;
- supporting the drafting and implementation of responsible strategies for ultimate disposal of spent fuel, for waste management, for decommissioning of facilities and for cleanout of former nuclear sites.

These instruments are supplemented by other international technical assistance programmes, in accordance with resolutions adopted by the G8, or by the IAEA, to improve nuclear safety in third party countries, and which are funded by contributions from donor States and the European Union.

The tangible assistance actually provided by ASN *via* the INSC mainly took the form of aid for the nuclear safety Authorities. Thus, in 2018, ASN took part in regulatory assistance projects on behalf of the safety regulators of China (second phase), Vietnam and Turkey.

2. TACIS: Technical Assistance to the Commonwealth of Independent States (European Union programme to provide aid to the countries of the former USSR).

3 Multilateral International Relations

3.1 The International Atomic Energy Agency (IAEA)

The IAEA is a United Nations 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 Daiichi accident, the IAEA is focusing its work on the following fields:

- **Revision and consolidation of the Safety Standards**, describing the safety principles and practices that the vast majority of Member States use as the basis for their national regulations.
  This activity is supervised by the IAEA's Commission on Safety Standards (CSS), set up in 1996. The CSS consists of 24 representatives from the highest levels of safety regulator organisations, appointed for four years and has been chaired since early 2012 by the Director General of the Czech regulatory body, Dana Drabova. The French representative participating in this Commission is the deputy Director General of ASN. The CSS coordinates the work of five committees tasked with drawing up documents in their respective fields: NUSSC (Nuclear Safety Standards Committee) for installations safety, RASSC (Radiation Safety Standards Committee) for radiation protection, TRANSSC (Transport Safety Standards Committee) for the safe transport of radioactive materials, WASSC (Waste Safety Standards Committee) for safe radioactive waste management and EPReSC (Emergency Preparedness and Response Safety Standards Committee) for preparation and coordination in the event of a radiological emergency. France, represented by ASN, takes part in each one of these committees, which meet twice a year. Representatives of the relevant French organisations also participate in the work of the technical groups drafting the documents. The mandates of the national representatives on these various committees were renewed in 2018 for a period of three years. In 2018, the CSS held its 43rd and 44th meetings.
  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 rise in the number of peer review missions** requested from the IAEA by the Member States and their increased effectiveness.

IAEA's ARTEMIS mission

From 15 to 24 January 2018, a delegation of 10 international experts working under the auspices of the IAEA examined the organisation of radioactive waste management in France. The experts met teams from the General Directorate for Energy and Climate (DGEC), ASN, the Directorate General for the Prevention of Risks (DGPR), IRSN, Andra, and the radioactive waste producers.

This international peer review was carried out within the framework of an ARTEMIS (Integrated Review Service for Radioactive Waste and Spent Fuel Management, Decommissioning and Remediation) mission organised by the IAEA department responsible for the themes of radioactive waste and spent fuel management, decommissioning and post-operational clean-out, thereby enabling foreign experts to examine the French system in the light of best practices.

This review focused on the following subjects:

- the legislative, regulatory and organisational framework for the management of radioactive waste;
- the French National Radioactive Material and Waste Management Plan (PNGMDR), which aims to implement radioactive waste management policy and develop it within a pluralistic working group comprising, more specifically, environmental protection associations, representatives of elected officials and assessment and oversight authorities, alongside the waste producers and Andra;
- the national inventory of radioactive waste and the estimated future quantities of this waste;
- the safety requirements for the facilities intended for the management of radioactive waste, and the provisions regarding the information of and participation by the public prior to their licensing, particularly for the *Cigéo* deep geological disposal project;
- the mechanisms for financing the management of spent fuel and radioactive waste;
- the measures taken to ensure and maintain a high level of competence and expertise within the various organisations involved in radioactive waste management.

The conclusions of the team of auditors, headed by Peter De Preter (Belgium), emphasised that France has established a framework for managing radioactive waste that covers all the issues and displays many strong points, particularly in terms of skills and its commitment to continuous progress. The improvements suggested by the auditors will be taken into account in the preparation of the next National Radioactive Material and Waste Management Plan. This plan will be subject to in-depth consultation with the stakeholders and the public.

These peer reviews enable the French radioactive waste management system to be enhanced thanks to the sharing of experience. They also foster the establishment of ambitious internationally-recognised common rules for radioactive waste management and the protection of persons and the environment.

Along the same lines, the IRRS (Integrated Regulatory Review Service) and OSART (Operational Safety Review team) missions are carried out using the IAEA safety standards as their point of reference.

• The IRRS missions

The IRRS missions are devoted to analysing all aspects of the framework governing nuclear safety and the corresponding activities of a regulatory Authority. ASN is in favour of holding these peer reviews on a regular basis, with widespread dissemination of their results. It is worth noting that through the provisions of the Directive 2009/71/Euratom on the safety of nuclear facilities, revised in 2014, the Member States of the European Union are already subject to periodic and mandatory peer reviews of their general nuclear safety and radiation protection oversight arrangements.

In 2018, ASN took part in several IRRS missions, in Luxembourg, Spain, Belgium and Australia respectively.

• The OSART missions

The OSART missions are carried out by a team of experts from third party country licensees who, for two to three weeks, examine the safety organisation of the nuclear power plants in operation. The actual implementation of the recommendations and suggestions put forward by the team of experts is verified during a follow-up mission, 18 months after the visit by the experts.

Owing to the postponement in the start-up of the Flamanville EPR reactor, the OSART mission which was to take place in 2018 before commissioning of the reactor, was pushed back to 2019.

• 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 2018, ASN representatives therefore went to Burkina Faso, Morocco and Haiti.

In addition and still under the supervision of IAEA, ASN also participated in the RCF (Regulatory Cooperation Forum). This forum, created in 2010, aims to bring those safety regulators in countries adopting nuclear energy for the first time into contact with the safety regulators of the major nuclear countries, so that their needs can be identified and the required support can be coordinated, while ensuring that the fundamental nuclear safety objectives can be met (independence of the regulator, appropriate legal and regulatory framework, etc.). In 2018, in addition to a close examination of the situation of the regulatory authorities in Belarus, Jordan, Poland and Vietnam, the RCF reinforced its cooperation with the European Union (INSC) and with "regional" forums such as ANNuR (Arab Network of Nuclear Regulators), FNRBA (Forum of Nuclear Regulatory Bodies in Africa) and ANSN (Asian Nuclear Safety Network). Finally, the RCF examined the request from Bangladesh for active assistance.

• Harmonisation of communication tools

ASN is heavily involved in the ongoing work to revise the manual for INES (the International Nuclear and Radiological Event Scale), which was updated for the last time about ten years ago. The IAEA aims to publish this revision in 2019.

ASN also 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 INES scale and its updates.

With regard to the rating of radiation protection events involving patients, which will not be included in the revision of the manual, ASN decided to apply the methodology developed at the IAEA. This is currently being assessed, together with the health professionals, in order to ensure that it is fully applicable.

Generally speaking, ASN is closely involved in the various actions carried out by the IAEA, providing significant support for certain initiatives, notably those which were developed following the Fukushima Daiichi accident.

• 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 the 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 exercises" or "ConvEx exercises". These exercises, which are more specifically designed to enable all the participants – both Member States and the 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 2018, ASN took part in one ConvEx-2 type exercise.

ASN is also helping to define international assistance strategy, requirements and resources and to develop the Response and Assistance Network (RANET).

In addition to the four traditional committees which draft its safety standards, IAEA created a committee in 2015 called EPReSC (Emergency Preparedness and Response Standards Committee), to deal with emergency situations. The standards in this field had up to now been monitored by the other existing committees. The document at the top of the standards hierarchy in this field is General Safety Requirement (GSR) Part 7, published in November 2015. ASN represented France at the two meetings of this committee held in 2018. In 2018, ASN also organised a meeting with all the national emergency management stakeholders in France, to present the concept of the emergency situation protection strategy developed by IAEA.

3.2 — The OECD's Nuclear Energy Agency (NEA)

The NEA, created in 1958, now comprises 33 members from Europe, North America and the Asia-Pacific region, with the inclusion of Argentina and Romania in 2017. Its main role is to assist the member countries in maintaining and developing the scientific, technological and legal bases essential for safe, environmentally-friendly and economic utilisation 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 new 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 oversee working groups of experts. Within the CNRA, ASN contributes to the working groups on inspection practices, acquired operating experience, the regulation of new reactors and public communication by safety regulators.

More information about NEA/CNRA activities can be found on the *oecd-nra.org* website.

3.3 — The Multinational Reactor Design Evaluation Program (MDEP)

The MDEP was created in 2006 and is an international cooperation initiative aimed at drawing up common approaches in order to take advantage of the resources and knowledge of national safety regulators in charge of regulatory assessment of new reactor designs. The key goal of this programme is to contribute to the harmonisation and implementation of safety standards.

At the request of the regulatory bodies which are members of the MDEP, the NEA is responsible for the technical secretariat of this programme. An ASN staff member is seconded to NEA to help with this task.

• Members of the programme

With the inclusion of Argentina in 2017, the MDEP now comprises 16 national safety regulators: AERB (India), ARN (Argentina), ASN (France), CCSN (Canada), FANR (United Arab Emirates), HAEA (Hungary), NNR (South Africa), NNSA (China), NRA (Japan), NRC (United States), NSSC (South Korea), ONR (United Kingdom), RTN (Russian Federation), SSM (Sweden), STÜK (Finland), NDK (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 June 2015. 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 group concerning advanced boiling water reactors was set up in 2018, after the dissolution of the ABW Working Group in the NEA Committee on Nuclear Regulatory Activities (CNRA). Initially, several MDEP Working Groups also dealt with cross cutting issues among the various designs. Most of these groups have in recent years been transferred to the CNRA. The last transfer of this type concerned the Working Group on mechanical codes and standards. At present, the only transverse MDEP Working Group concerns the inspection of nuclear component suppliers, or the Vendor Inspection Cooperation Working Group (VICWG).

Each of the groups dedicated to a particular 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 also includes authorities from the United Kingdom, Finland, China, India and Sweden.

• Activities in 2018

Within the EPR group, technical exchanges concerned the deviations found on the welds of the main secondary systems of the Flamanville 3 reactor currently under construction. In addition, work continued on the pooling of tests performed prior to start-up of the Taishan 1 reactor.

A workshop on the management of the supply chain in the nuclear field was organised jointly with the NEA in November 2018. The event attracted about a hundred participants, half of whom came from the nuclear industry (licensees, suppliers) and half from the safety regulatory and certification and inspection organisations.

3.4 — The International Nuclear Regulators' Association (INRA)

The International Nuclear Regulators' Association (INRA) comprises the regulatory bodies from Germany, Canada, South Korea, Spain, the United States, France, Japan, the United Kingdom and Sweden. This association is a forum for regular and informal discussions concerning topical matters in these various countries and the positions adopted on 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, Spain in 2016, United States in 2017 and South Korea in 2018). In 2018, in addition to discussions on the state of nuclear safety, the work of this association more particularly monitored the revision of the INES scale manual, together with the services of the IAEA.

3.5 — The United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR)

The United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) was created in 1955. It compiles all scientific data on radiation sources and the risks this radiation represents for the environment and for health. This activity is supervised by the annual meeting of the national representations of the Member States, comprising international experts.

3.6 — The International Commission on Radiological Protection (ICRP)

The ICRP, a non-governmental organisation, was created in 1928 with the aim of assessing the state of knowledge about the effects of radiation, in order to ensure that it does not call current protection rules into question. The ICRP bases its findings on the results of the research work carried out around the world and examines the work of other international organisations, notably that of UNSCEAR. It issues general recommendations on the protection rules to be adopted and on the exposure levels to be complied with.

4 International agreements

ASN acts as the national point of contact for the two Conventions dealing, on the one hand, with nuclear safety (the Convention on Nuclear Safety) and, on the other, with spent fuel and wastes (Joint Convention on the Safety of Spent fuel Management and on the Safety of Radioactive Waste Management). ASN is also the Competent Authority for the two Conventions dedicated to the operational management of the possible consequences of accidents (the Convention on the Early Notification of a Nuclear Accident and the Convention on Assistance in the case of a Nuclear Accident or Radiological Emergency).

4.1 The Convention on Nuclear Safety

The Convention on Nuclear Safety (CNS) is one of the results of international discussions initiated in 1992 in order to contribute to maintaining a high level of nuclear safety worldwide[3].

The objectives of the Convention on Nuclear Safety are to reach and maintain a high level of nuclear safety worldwide; to establish and maintain effective defences in nuclear facilities against potential radiological risks and to prevent accidents which could have radiological consequences and mitigate their consequences should they occur. The areas covered by the Convention have long been part of the French approach to nuclear safety.

The Convention makes provision for review meetings by the contracting parties every three years, to develop cooperation and the exchange of experience.

In France, ASN acts as the Competent Authority for the Convention on Nuclear Safety. It coordinates all the preparatory phases prior to the review meetings, in close collaboration with the entities concerned. ASN also devotes considerable resources so that it can participate in the review meetings and be present at the various presentations and discussions.

The Vienna Declaration on Nuclear Safety was adopted on 9 February 2015 by the contracting parties to the Convention on Nuclear Safety, who met on the occasion of the diplomatic conference tasked with reviewing a proposal to amend the Convention on Nuclear Safety.

The 8th review meeting of the contracting parties to the CSN will be held from 23 March to 3 April 2020 at the IAEA headquarters in Vienna. It will be chaired by the Director General of the nuclear safety regulator of the Czech Republic, Ms Dana Drabova. The two Vice-Presidents are Mr Carl-Magnus Larsson of the Australian regulator and Mr Manwoong Kim of the South-Korean regulator, respectively.

Several months before the review meeting is held, each contracting party submits a national report describing how it meets the obligations of the Convention. Drafting of the French national report for the 8th review meeting was started in November 2018. The French report will be made public no later than 15 August 2019, in both French and English versions, on the IAEA and ASN websites respectively.

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 equivalent of the Convention on Nuclear Safety for management of the spent fuel and radioactive waste produced by civil nuclear activities. France signed it on 29 September 1997 and it entered into force on 18 June 2001. As at 31 December 2018, there were 80 contracting parties to this convention.

For the 6th review meeting of the Joint Convention, the French national report, the drafting of which had been coordinated by ASN, was submitted to the IAEA at the end of 2017. In accordance with the peer review process stipulated in the Convention, 140 questions and comments were sent to France concerning its 6th national report. Drafting of the answers to these questions was coordinated by ASN, as was the drafting of questions and comments sent by France to the other countries. A total of 238 questions and comments was sent by France to 51 countries. The 6th review meeting of the contracting parties to the Joint Convention was held at the IAEA headquarters in Vienna, from 21 May to 1 June 2018. Like the previous exercises and with the support of the ASN departments and divisions, plus the IRSN, France was able to attend all the national presentations and much was learned from them. The French presentation aroused keen interest and helped gain international recognition for the French radioactive waste and spent fuel management and nuclear facilities decommissioning programme.

4.3 The Convention on Early Notification of a Nuclear Accident

The Convention on Early Notification of a Nuclear Accident came into force on 27 October 1986, six months after the Chernobyl accident and as at 31 December 2018, it has 122 contracting parties.

The contracting parties agree to inform the international community as rapidly as possible of any accident leading to uncontrolled release into the environment of radioactive material likely to affect a neighbouring State. For this purpose, the 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, called USIE (Unified System for Information Exchange in Incidents and Emergencies), in use in ASN's Emergency Centre and 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 to the international institutions without delay, to rapidly provide the pertinent information about the situation, in particular to border countries, to enable them to take the necessary population protection measures and, finally, to provide the ministers concerned with a copy of the notifications and the information transmitted or received.

3. This Convention sets a certain number of nuclear safety objectives and defines measures for achieving 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, as at 15 December 2018, there were 85 contracting parties.

4.4 — The Convention on Assistance in the Case of a Nuclear Accident or Radiological Emergency

The Convention on Assistance in the Case of a Nuclear Accident or Radiological Emergency came into force on 26 February 1987 and as at 31 December 2018, there are 117 contracting parties.

Its purpose is to facilitate cooperation between countries if one of them were to be affected by an accident with radiological consequences. This Convention has already been used on several occasions for irradiation accidents due to abandoned radioactive sources. France's specialised services have notably already taken charge of treating victims of such accidents.

4.5 — Other conventions linked to nuclear safety and radiation protection

Other international conventions, the scope of which does not fall within the remit of ASN, may be linked to nuclear safety.

Of particular relevance is the Convention on the Physical Protection of Nuclear Material, the purpose of which is to reinforce protection against malicious acts and against misappropriation of nuclear materials. The Convention came into force on 8 February 1987. It had 155 contracting parties in 2017. An amendment to this convention, which entered into force in 2016, was ratified by 115 of them.

5 — Bilateral relations

ASN collaborates with numerous countries through bilateral agreements, which can take the form of governmental agreements (such as with Germany, Belgium, Luxembourg and Switzerland) or administrative arrangements between ASN and its counterparts (about twenty). ASN and its counterparts hold discussions on subjects which frequently concern topical national safety and radiation protection matters (legislation, safety topics, incidents, inspection approach, etc.).

Maintaining and strengthening bilateral relations with neighbouring and the other European countries is also one of ASN's priorities.

Many topics were the subject of ASN bilateral relations in 2018 and they can be placed in three main categories:

- new constructions with regard to start-up tests and manufacturing inspections;
- peer inspections of installations concerning a broad diversity of topics: decommissioning, radiation protection, unit outages, post-operational clean-out inspection, fuel cycle and new medical technologies;
- emergency management, more specifically coordination between border countries in the event of an accident in a facility.

5.1 — Bilateral cooperation between ASN and its foreign counterparts

Bilateral relations between ASN and its foreign counterparts are built around an approach incorporating nuclear safety and radiation protection, including preparedness for managing and responding to emergency situations, for each of the countries with which ASN maintains such relations.

ASN's bilateral relations with its partners were primarily marked by the events listed below:

South Africa

In 2018, under the Convention on Assistance in the case of a Nuclear Accident or Radiological Emergency, ASN was contacted for an assistance request concerning a person subjected to accidental over-exposure during medical treatment.

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.

From 18 to 19 June 2018, a plenary meeting of the Franco-German commission was held in Ludwigsburg (Germany). This meeting covered the latest changes to the national regulatory frameworks and the work of the commission's Working Groups (WG). It also confirmed the need for work on the "waste" and "decommissioning" topics.

Working Group No.1, dedicated to the safety of NPPs in a border area, met on 18 September in Givet (Ardennes *département*). The discussions focused on site assessments, the significant events situation and technical subjects of mutual interest (lifting the suspension of the test certificate for the Fessenheim steam generator, thermal sleeves on the 1,300 MWe

Emergency exercise at Fessenheim on 12 June 2018 – Germany & Switzerland

On 12 June 2018, a nuclear emergency exercise was held in the Fessenheim NPP. It was more particularly aimed at testing the alert and information chain for the services, municipalities and border countries (Germany and Switzerland), activation of the emergency centres and the decision-making process.

International coordination at the local and national level took place in good conditions and was considered to be satisfactory. However, it required significant resources, in particular at the local level, which may not necessarily always be available in the event of a real emergency.

In addition to the notifications sent to the international bodies, ASN also invited two foreign counterparts to its emergency centre. In the capacity of observers, they were able to gain a more detailed and more rapid understanding of the emergency situation than the contacts at the local level, thus confirming the benefit of having foreign liaison staff present in the country where the accident occurred.

reactors, etc.). A visit was organised to Chooz A – being decommissioned – and reactors 1 and 2 of Chooz B, which is in operation.

Working Group No. 2, dedicated to emergency situations, met in Paris on 3 May. The meeting brought together the national and local stakeholders in preparedness for emergency situations and emergency management. The two parties more particularly discussed their participation in the Cattenom exercise (17 October 2017) and preparations for that in Fessenheim (12 June 2018).

Two joint inspections were organised, one in Germany, on the Mülheim-Kärlich decommissioning site to look at the subjects of waste release and monitoring the calibration of the corresponding measuring instruments, and the other at Fessenheim in France, on the subjects of pressure equipment and the Recognised Inspection Service (SIR).

Belgium

ASN cooperates on all subjects in its field of competence with its counterpart, the Belgian AFCN. This leads to cooperation both nationally and locally, involving the Châlons-en-Champagne and Lille regional divisions.

From 14 to 18 May 2018, AFCN and its technical support organisation, BELV, took part in the in-depth inspection of the Gravelines NPP.

Numerous cross-inspections were also organised with the Châlons-en-Champagne, Lille and Marseille regional divisions:
- the Marseille division invited the AFCN to two inspections of the Gammaster irradiator, concerning general topics and the periodic safety review;
- the AFCN and the Lille division took part in inspections, concerning industrial sources of radiation and the commissioning of radiotherapy and nuclear medicine facilities in Belgium and concerning the commissioning of nuclear medical facilities in France;
- the Châlons-en-Champagne division took part in a visit to the Chooz NPP, with the Municipal Council of Beauraing (Belgium), a border municipality.

On 9 November 2018, a meeting and a visit to the Framatome FBFC site in Dessel were organised, on the topic of waste management and decommissioning work in progress.

Canada

On 9 and 10 July 2018, discussions took place with the Canadian Nuclear Safety Commission (CNSC) in its premises in Ottawa, on topical matters concerning nuclear safety and radiation protection, decommissioning and waste management practices and regulations, the problem of extending NPP lifetimes, plus the risk of fraud. In addition, on 11 July, the CNSC organised a technical inspection of facilities being decommissioned and waste storage facilities on the Chalk River Laboratories (CRL) site operated by the Canadian Nuclear Laboratories (CNL) company. Decommissioning of facilities is a major concern for Canada and, during the meeting, the CNSC showed itself to be particularly attentive to ASN's arguments concerning the need for immediate dismantling, regardless of the type of facility, on the one hand, and the need to create waste routes comprising processing and packaging facilities and appropriate storage and disposal facilities for these wastes, on the other. CNSC-ASN discussions on this topic are to be continued and expanded.

Exchanges on proton therapy

Faced with the development of projects to set up proton therapy facilities in Spain and Belgium, ASN, the CSN and FANC met on 12 and 13 December 2018 for discussions on feedback from the licensing of three proton therapy facilities in operation in France: the Curie Institute in Orsay, the Antoine Lacassagne centre in Nice and the Archade centre in Caen. The discussions also concerned the rules for the design of these facilities, along with the operating and maintenance procedures adopted. The technical discussions will continue in 2019. In the light of the safety issues inherent in these large facilities and their simultaneous deployment in several European countries, the HERCA association also adopted ASN's proposal to take advantage of these bilateral actions and share them at European level as of 2019.

China

In 2018, exchanges with the Chinese safety regulator, the NNSA (National Nuclear Safety Administration) took place mainly within the framework of multilateral projects and meetings. They concerned the start-up tests on the EPR built in Taishan and on oversight of equipment manufacturing.

A high-level bilateral meeting is scheduled for 2019 in China.

ASN is also overseeing a three-year European assistance project, which began in February 2017, aimed at reinforcing the development of the Chinese safety regulator and its technical support organisation, the NSC (Nuclear Safety Center) on the following topics: management of radioactive waste, decommissioning, preparedness for emergency situations, radioactive material transports, fuel reprocessing, seismic evaluation and development of nuclear safety R&D skills.

In addition, **from 21 to 23 August 2018**, the Lyon division welcomed a delegation of three inspectors from NNSA for discussions on the steps taken in the wake of the Fukushima Daiichi nuclear accident. They more specifically visited the Ultimate Back-up Diesel generating sets (DUS) installation work being done on the Bugey site.

Spain

On 28 September 2018, discussions with the *Consejo de Securidad Nuclear* (CSN) concerned topical nuclear safety and radiation protection subjects in the two countries, progress on previously defined cooperation measures and updating of the roadmap for this cooperation between the two authorities for the next two years. This future cooperation will more particularly cover:
- licensing of proton therapy centres and the corresponding regulatory oversight;
- the holding of cross-inspections to compare and discuss nuclear waste transport rules;
- continued discussions on intermediate level, long-lived waste management issues.

In addition, **in 2018**, ASN took part in the exercise concerning a transport accident in a tunnel between France and Spain, organised by the offices of the Prefect of the Pyrénées-Atlantiques *département*.

United States

On 23 and 25 January 2018, the NRC took part in a technical seminar on decommissioning held in Lyon. Following this event, visits to the Bugey A, Iceda and Orano Tricastin sites were organised.

On 6 June 2018, discussions with the NRC in the ASN premises in Montrouge covered the latest regulatory changes in the fields of nuclear safety and radiation protection, information of and participation by the public, the reasons that led ASN to ask for the temporary shutdown of the Tricastin NPP in autumn 2017, as well as the respective approaches deployed in the area of nuclear safety (which for ASN is limited to the security of radioactive sources, while for the NRC it extends to the protection of nuclear installations against malicious acts). The discussions confirmed the benefits of sharing experience and best practices on many technical subjects: inspection practices, emergency situations management, nuclear safety, ageing and resistance of materials and equipment over time and so on. An action plan for 2018-2019, drawn up jointly by the two safety regulators, will ensure monitoring of the performance of cooperative work regarding these subjects (notably through joint inspections and visits to fuel cycle facilities in France and the United States and on the topic of the environment). The situation of personnel secondments between the two Authorities was also reviewed.

At the 62nd IAEA General Conference, in **September 2018**, the NRC and ASN also signed and thereby ratified the renewal of the bilateral cooperation agreement between the two Authorities.

Finally, **in 2018**, an American delegation came to ASN for discussions on emergency situations and took the opportunity to visit the ASN Emergency Centre.

Finland

From 17 to 19 September 2018, a technical meeting was held in Helsinki between ASN and STÜK, followed by a visit to the EPR construction site of Olkiluoto. This annual meeting was a chance to discuss the progress of the EPR projects in the two countries. The discussions mainly concerned feedback from the start-up tests and other topical technical subjects on the construction sites.

Visit to the Fukushima NPP. Bilateral ASN-NRA meeting of 3 to 5 September 2018 – Fukushima (Japan)

Japan

From 26 February to 2 March 2018, inspectors from the Lyon regional division went to Japan as part of a programme of exchanges with the NRA on changes to the oversight of nuclear safety in France and Japan. The inspectors were able to visit the Tokaimura site as well as the Fukushima Daiichi site, to observe how the NRA is overseeing the remediation work.

On 3 and 4 September 2018, a bilateral meeting in Tokyo enabled the Chairmen and technical experts from the two authorities to discuss topical regulatory subjects in both countries and control of the ageing of facilities in the fast neutron reactors and gas-cooled reactors. A visit to the damaged Fukushima Daiichi NPP took place the next day.

ASN also received a large number of Japanese delegations in Paris and in the regions, under technical or university exchanges.

Luxembourg

The Franco-Luxembourg joint commission on nuclear safety held its sixteenth meeting on **1 February 2018** in Paris. 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 subject of nuclear safety and radiation protection, including the 2018 results from the Cattenom NPP, experience feedback from

ASN participation in emergency exercises in Japan and Taiwan

In 2018, at the invitation of its counterparts, ASN took part in two national emergency exercises as an observer:

- in Japan, in August, concerning the Ohi and Takahama NPPs (north-west of Kyoto);
- in Taiwan, in September, concerning the Chin Shan NPP.

The two exercises mobilised considerable human and technical resources in the field. The population also played an active role and participated in the evacuation exercises (public spaces, beach, heli-hoisting, etc.) and in the decontamination workshops.

Even though, in both cases, the exercise appeared to be more a demonstration of complete management of an accident than an assessment of the ability to actually respond to a nuclear emergency, certain aspects of interest to the French emergency management stakeholders were identified. For example:

- in Japan, the visit to a retirement home showed that it was equipped with filtration and tightness systems which meant that the residents who could not be evacuated could take shelter in the premises in the event of an accident with radioactive releases;
- in Taiwan, each person inside the zone concerned by the accident is alerted by a message sent to their smartphone. Furthermore, in the event of evacuation of a school, the procedure makes allowance for parents to be able collect their children.

Bilateral meeting and signing of an ASN-ONR cooperation agreement, 29 June 2018 – ASN Montrouge

the Cattenom emergency exercise held in October 2017, and monitoring of the private radiotherapy centre in Metz.

Malta

On 28 and 29 May 2018, the Paris division carried out a mission to Malta in order to understand the workings and problems of an administration in charge of radiation protection oversight in a small country. The division learned lessons that could be transposed to French Polynesia and New Caledonia, which are two territories that the division assists in implementing an appropriate regulatory framework and deploying a locally trained team.

Norway

On 16 May 2018, discussions with the NRPA (Norwegian Radiation Protection Authority), in its Oslo premises, concerned decommissioning and waste management (issue of shutdown of the IFE Halden research reactor), the implementation of the EU's BSS Directive, management of the radon risk, and emergency situations (rapid alert protocol, iodine distribution strategy and so on). During this meeting, the document renewing the protocol between NRPA and ASN concerning early notification and the exchange of information in the case of a nuclear disaster or radiological accident or incident was signed.

Poland

The Franco-Polish steering committee met **on 11 April 2018**. In addition to topical subjects in the two countries, the questions of radioactive waste management, measures to reinforce nuclear safety in French nuclear facilities in the wake of the Fukushima-Daiichi accident, ageing control and the possible secondment to ASN of a trainee from the Polish safety regulator (PAA) were also covered.

United Kingdom

On 29 June 2018, a bilateral meeting was held in Montrouge between ASN and the British Office for Nuclear Regulation (ONR). The subjects covered include discussions on the EPR projects in France and the United Kingdom. The meeting ended with the signing of a renewed cooperation agreement, comprising actions to be taken over the coming two years.

The Caen regional division and the Waste, Research Facilities and Fuel Cycle Facilities Department (DRC), in addition to the ASND, invited the ONR and the UK Environment Agency to a workshop on case studies. A visit to the La Hague site was also organised.

The Nantes division for its part continued its collaboration with Public Health England (PHE), the British authority with competence for the protection of patients, with the participation in joint inspections on the topic of radiotherapy.

Russia

On 17 July 2018, a workshop/seminar on the safety of fuel cycle facilities was held for three days in Lyon and on the Tricastin and Romans-sur-Isère sites. The discussions concerned the regulatory baseline requirements and inspection practices by the safety regulator.

On 6 December 2018, a meeting of the ASN-*Rostechnadzor* steering committee was held in Montrouge. The subjects tackled covered control of the ageing of facilities, the safety of the ITER facility under construction and the decommissioning of graphite reactors.

Sweden

On 8 and 9 February 2018, a bilateral meeting was held with the Swedish safety regulator, the SSM, in Stockholm. The two parties signed an administrative arrangement structuring the existing exchanges between ASN and the SSM. This meeting addressed more precise technical subjects such as carbon segregation, the continued operation of reactors beyond 40 years, the "hardened safety core" approach adopted following the Fukushima Daiichi accident, radioactive waste management and decommissioning.

On 11 and 12 October 2018, the Orleans division received two SSM inspectors under a programme of exchanges on decommissioning and reactors in service. As part of this programme, a visit was organised to the Saint-Laurent-des-Eaux site.

Switzerland

The Franco-Swiss commission 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 Lyon and Strasbourg regional divisions.

The annual Franco-Swiss meeting of the Nuclear Emergency Experts Group (GECN) was held **on 26 and 27 March 2018** to look at the problems of preparedness for and responses to emergency situations arising from facilities located close to the Franco-Swiss border.

From 1 to 5 October 2018, the Lyon division received an inspector from the Swiss Federal Nuclear Safety Inspectorate (IFSN) to take part in a campaign of tightened inspections on the topic of radiation protection in the Bugey and Saint-Alban NPPs.

In 2018, under its cooperation agreement with the Swiss Federal Office for Public Health (OFSP), the Lyon division also carried out three joint inspections with the OFSP on the CERN, which is situated in both France and Switzerland.

Competencies of the main civil nuclear activity regulatory Authorities*

COUNTRY/ REGULATORY AUTHORITY	STATUS			ACTIVITIES						
	ADMINIS-TRATION	GOVERNMENT AGENCY	INDEPENDENT AGENCY	SAFETY OF CIVIL INSTALLATIONS	RADIATION PROTECTION			SECURITY (PROTECTION AGAINST MALICIOUS ACTS)		SAFETY OF TRANSPORT
					LARGE NUCLEAR FACILITIES	OUTSIDE BNIS	PATIENTS	SOURCES	NUCLEAR MATERIALS	
Europe										
Germany/ BMUB + *Länder*	■			■	■	■	■	■	■	■
Belgium/AFCN		■		■	■	■	■	■	■	■
Spain/CSN			■	■	■	■	■	■	■	■
Finland/ STÜK		■		■	■	■	■	■	■	■
France/ASN			■	■	■	■	■	■***		■
United Kingdom/ONR		■		■	■			■	■	■
Sweden/SSM		■		■	■	■	■	■	■	■
Switzerland/ ENSIi			■	■	■				■	■
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.
** National transports only.
*** Responsibility for source security was given to ASN by the Ordinance of 10 February 2016. This provision came into force on 1 July 2017.

5.2 _ ASN bilateral assistance

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 (Instrument for Nuclear Safety Cooperation (INSC) and international (IAEA's Regulatory Cooperation Forum – RCF). The purpose of this cooperation is to enable the beneficiary countries to acquire the safety and transparency culture that is essential for a national system of nuclear safety and radiation protection oversight. Nuclear safety oversight must be based on national competence and ASN consequently only provides support for the establishment of an adequate national framework and advises the national safety regulator, which must retain full responsibility for its oversight of the nuclear facilities. It pays particular attention to countries acquiring technologies of which it has experience in France.

ASN considers that developing an appropriate safety infrastructure takes at least fifteen years before operation of a nuclear power reactor can begin in good conditions.

For these countries, the goal is to set up a legislative framework and an independent and competent safety regulator with the financial and human resources it needs to perform its duties and to develop competence in terms of safety, safety and regulatory culture and management of radiological emergency situations.

China

In 2018, ASN continued with its coordination of a three-year European assistance project aiming to reinforce the development of the Chinese regulator, the NNSA (National Nuclear Safety Administration) and its technical support organisation, the NSC (Nuclear Safety Center) on the following topics: management of radioactive waste, decommissioning, preparedness for emergency situations, radioactive material transports, fuel reprocessing, seismic evaluation and development of nuclear safety R&D skills.

This is the second INSC cooperation programme with China, which started in February 2017 for a period of three years.

Vietnam

In 2018, ASN continued to manage the second assistance programme for Vietnam under the INSC, in order to develop the safety, safety culture and regulatory capabilities of the Vietnam Agency for Radiation and Nuclear Safety (VARANS).

This assistance project, which started in May 2016, is scheduled to last for three years.

ASN is also involved in assistance to Vietnam *via* the RCF, the forum for exchanges between safety regulators, created under the aegis of the IAEA. In this context, a meeting was held on **27 and 28 June 2018** in Brussels, with a view to facilitating the sharing of experience between regulators and rationalising the assistance given to those countries looking to develop nuclear energy.

Turkey

In 2018, 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, the 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.

It is important to note that a new Act was passed by Turkey on **9 July 2018** creating the new safety regulator, the NDK. The impact of these changes will be taken into account in the implementation of this project.

5.3 Staff exchanges between ASN and its foreign counterparts

Better understanding how foreign nuclear safety and radiation protection regulators actually function is a way to learn pertinent lessons for the working of ASN itself and to enhance staff training. One of the means used to achieve this is to develop personnel exchanges, such as those carried out with the ONR (Office for Nuclear Regulation) and the NRC.

Provision is made for several types of exchange:

- very short term actions (a few days) are a means of offering ASN's counterparts a chance to take part in peer-observation of inspections and nuclear and radiological emergency exercises. For example, in 2018, about 20 peer-observations of inspections on the field of nuclear safety and radiation protection were organised with Germany, Belgium, including the in-depth inspection of the Gravelines NPP, the United Kingdom, Switzerland and Turkey under the ongoing INSC European training project;
- short-term assignments (2 weeks to 6 months) aimed at studying a specific technical topic;
- long-duration exchanges (one to three years) for immersion in the activities and workings of the nuclear safety regulator receiving the seconded staff member. Whenever possible, this type of exchange should 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; the first year of the secondment took place at the Office of New Reactors (NRO). One of the main goals of this secondment is to promote exchanges between the NRC and ASN on subjects of common interest. Thus, in order to comply with the requests from certain departments at ASN, the ASN staff member seconded to the NRC drafted a memo on the subject of nuclear safety and another on the facilities for dry storage of spent nuclear fuel in the United States. Exchanges between ASN and the US NRC continued in 2018 on these subjects. More particularly, when the ASN senior inspector visited the United States for the NRC annual Regulatory Information Conference (RIC), from 13 to 15 March 2018, particular points of interest were identified with regard to American inspection and safety practices. In 2018, the process for secondment of an NRC staff member to ASN was also initiated. Moreover, in 2018, the exchange of personnel between ASN and the British safety regulator took the form of a mutual secondment of two inspectors.

6 Outlook

ASN will devote efforts to creating an ambitious international framework in the field of doctrine and regulations, drawing on best practices. ASN will encourage and contribute to international reflection on major technical issues.

Particular attention will be given to WENRA and its development, in order to reinforce actions with countries looking to implement new reactor designs. ASN will also take part in ensuring improved coordination between the European Commission, ENSREG, WENRA and the TSOs with regard to safety improvements under way as a result of the 2014 Directive. It will thus share the safety targets and modifications implemented for the continued operation of the reactors, more particularly VD4-900.

At a time when certain countries are opting for safe containment of their shut down facilities, primarily for financial reasons, ASN will in its bilateral relations and in the international and European working groups, continue to promote the French approach, which is consistent with IAEA's position and which involves complete dismantling as rapidly as possible.

ASN will state how it intends to reinforce transparency, more particularly with regard to the public consultation processes, for the VD4, the PNGMDR or the *Cigéo* project.

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07

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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.

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 above all the risks of external exposure generated by the medical devices (devices containing radioactive sources, X-ray generators or particle accelerators) or by sealed and unsealed sources (particularly after administering radiopharmaceuticals). When using unsealed sources, the risk of internal contamination must also be taken into consideration in the risk assessment (in nuclear medicine and in the biology laboratory).

According to the data collected in 2017 by IRSN, 208,921 persons working in the areas of medical and veterinary activities were subject to dosimetric monitoring of their exposure. Radiology activities (radiodiagnosis and interventional radiology) account for the largest proportion of exposed medical personnel (36%).

Nearly 99% of the health professionals monitored in 2017 received an annual effective dose below 1 millisievert (mSv). One exceedance of the annual effective dose limit of 20 mSv was observed in a hospital porter who worked in several departments (total annual effective dose of 43.7 mSv). Four cases in which the annual equivalent dose at the extremities (500 mSv) was exceeded were registered in 2017, all in the radiology sector. The average annual individual dose for people having received a dose exceeding the registration threshold is 0.29 mSv/year, slightly down on the value for 2016.

In 2017, the very large majority of routine internal exposure monitoring was carried out by radiotoxicological analyses of urine and whole-body radiation measurement examinations (less than 5% of exposed medical professionals); 1,392 people underwent routine monitoring by radiotoxicological analyses of urine. The majority of these analyses concern workers in the nuclear medicine sector. Only one worker underwent a committed effective dose calculation in 2017, and the dose was below 0.1 mSv.

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 along with a second plan in 2018 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 healthcare 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).

1.2.4 _ 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.

Furthermore, no trace of these radionuclides has ever 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 notified to ASN since 2007. These notifications provide professionals with increasingly valuable experience feedback, helping to improve radiation protection in the medical field. In 2018, ASN published a *Bulletin on the safety of radiotherapy patients* (No.12) concerning the risks of misidentification of the vertebral landmarks on a repositioning image, and an experience feedback sheet concerning an error in mounting an accessory on a CyberKnife® system. Following the occurrence of an exposure incident during a computed tomography examination (see section 6), a technical sheet was drawn up and widely disseminated in France and Europe. Furthermore, the incident notices are published on *asn.fr*.

Since July 2015, radiotherapy departments can report ESRs 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.

Since 2012, the number of ESR notifications stands at about 500 per year. In 2018, a total of 592 ESRs (Graph 1) in the medical domain were reported to ASN (+33 with respect to 2017, +95 with respect to 2016). This increase is primarily due to a larger number of ESRs reported in both nuclear medicine and radiology (conventional and computed tomography). The number of ESRs reported in radiotherapy, however, has dropped since 2015.

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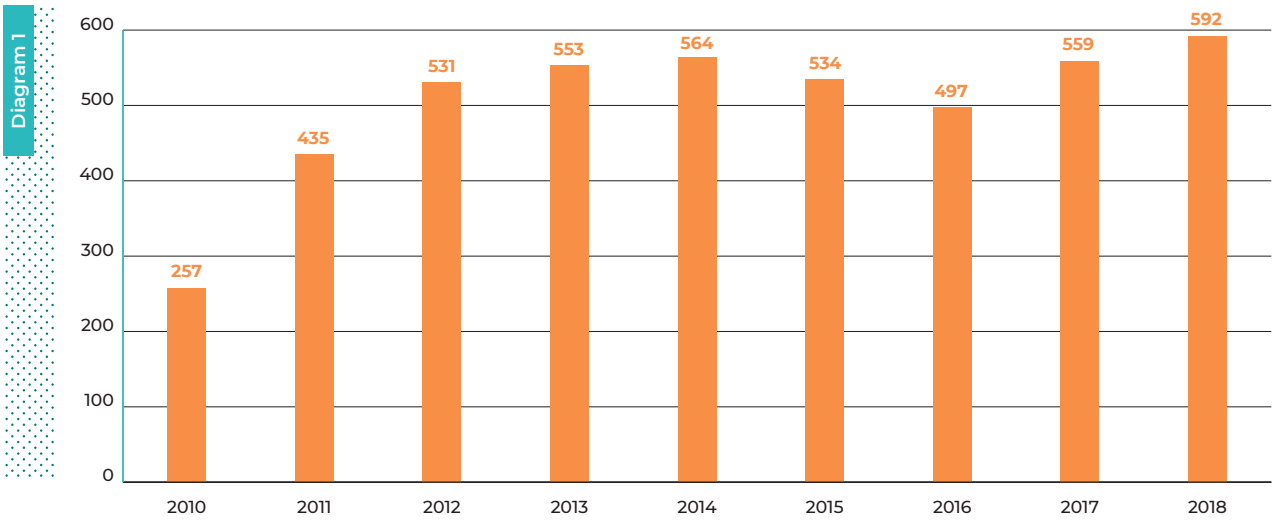
Graphs 2, 3 and 4 below illustrate the distribution of the number of ESRs in 2018 by activity category, how they have evolved since 2010, and the distribution of events by area of exposure (impact on the environment, exposure of the public, exposure of patients, exposure of medical workers), and the activity category concerned.

About 80% of the notified events originate from either computed tomography (29%), radiotherapy (22%) or nuclear medicine (29%) departments. For the first time since the ESR notification system was put in place in 2007, computed tomography and nuclear medicine are the activity sectors in which the number of ESRs reported per year is the highest.

The events reported in the medical sector chiefly concern the exposure of patients (56%) and foetuses in pregnant women unaware of their pregnancy (30%), the latter showing a distinct rise.

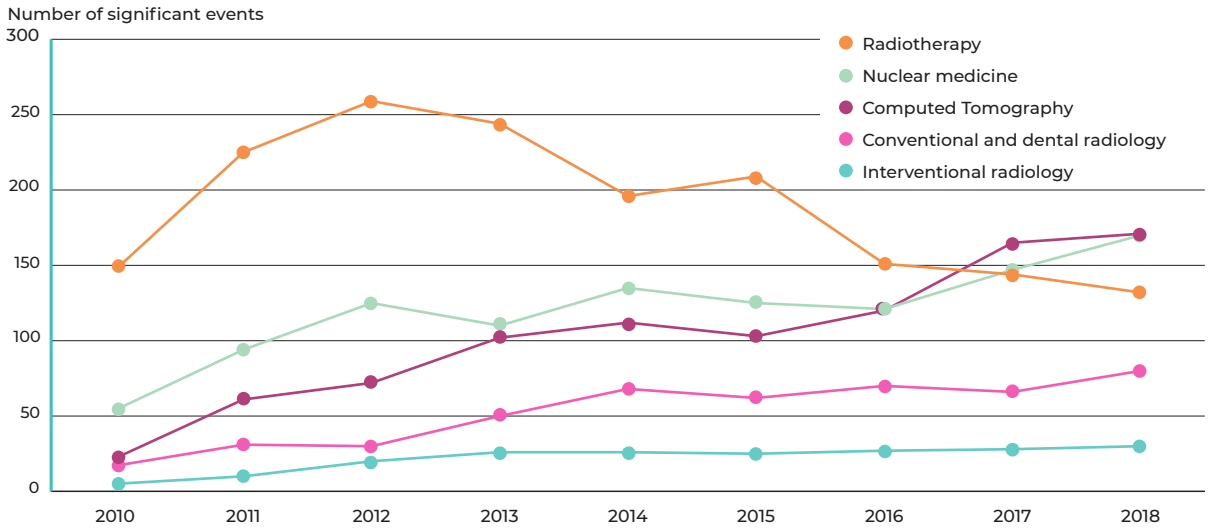
Trends in the number of annual ESR notifications from 2010 to 2018

Diagram 1



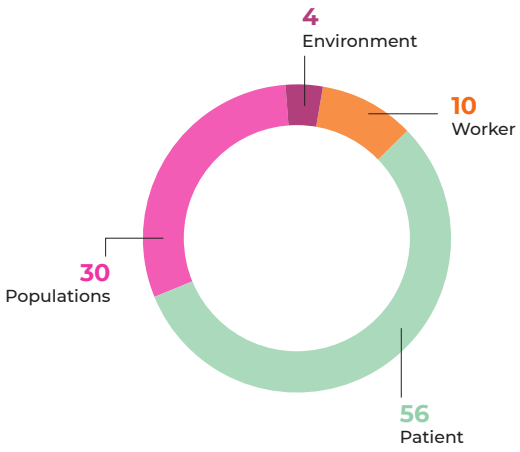
Number of ESRs per activity category during the period 2010-2018

Diagram 2



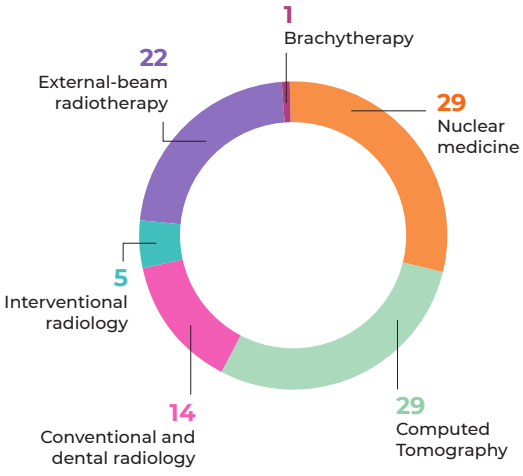
Breakdown of ERSs per area of exposure in 2018 (%)

Diagram 3



Breakdown of ESRs per activity category concerned in 2018 (%)

Diagram 4



In the light of the events reported to ASN in 2018, the most significant consequences from the radiation protection aspect concern:

- for medical workers: fluoroscopy-guided interventional practices (external exposure of operators, and their hands in particular) with cases where dose limits are exceeded, and nuclear medicine (contamination of workers, external exposure);
- for the patients: interventional practices with deterministic effects observed in some patients having undergone long and complex procedures, radiotherapy with overdoses linked more particularly to overlapping[1] procedures and prescription errors and, lastly, nuclear medicine, with radiopharmaceutical administration errors;
- for the public and the environment: nuclear medicine, with losses of sources, leaks from radioactive effluent pipes and containment structures.

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.

1. *Treatment overlap: irradiation during a second treatment of an anatomical region which has already been irradiated; the area concerned by an overlap receives summed doses resulting from several separate irradiations.*

Nuclear-based medical activities: the main risks

Table 1

ACTIVITIES	PATIENTS	MEDICAL PROFESSIONNELS	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

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.

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.

In view of the experimental nature of this new inspection strategy, the radiation protection situation in the medical environment has been assessed essentially on the basis of the indicators associated with the inspection 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 technical decisions (see points 4, 5 and 6).

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. Additional requirements shall be issued in 2019 by Ministerial Order (currently under preparation).

The radiopharmaceutical drugs (RPD) used in nuclear medicine are covered by a marketing authorisation (MA) delivered by ANSM (French Health Products Safety Agency) or by 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 (Art. R. 1333-45 to R.1333-80). The principles of justification of procedures and optimisation of the doses delivered are the basis of these regulations. However, contrary to the other applications of ionising radiation, the principle of dose limitation does not apply to patients due to the need to adapt the dose delivered to each individual patient according to the therapeutic objective or to obtain an image of adequate quality to make the diagnosis.

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.

Regulatory work in progress in the area of patient radiation protection

Table 2

	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 approved in February 2019
Diagnostic reference level	Order of 24 October 2011	Draft resolution presented for public consultation in November 2018
Continuous training of health professionals in the protection of persons exposed for medical purposes	Resolution 2017-DC-0585 of 14 March 2017	Draft amending resolution presented for public consultation in July 2018
Qualifications of physicians involved in the exercise of nuclear-based medical activities	Resolution 2011-DC-0238 of 23 August 2011	Updating planned in 2019

1.3.4 _ The 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[2]; conventional radiology and dental radiology continue to be covered by the notification system.
- The new registration system expected in 2019 should be applied to computed tomography and the use of radionuclides in medical biology laboratories (see point 4.1.2.), currently subject to licensing, and to fluoroscopy-guided interventional practices which involve radiation protection risks (in the meantime, the latter are still simply subject to notification).
- The licensing system shall be maintained for external-beam radiotherapy, brachytherapy and diagnostic and therapeutic nuclear medicine.

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[3] are treated each year, representing nearly four 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, 2017), the radiotherapy facilities comprise 505 particle accelerators in 173 radiotherapy centres subject to an ASN license. ASN issued 114 licenses in 2018. The majority of these cases concerned the updating of an existing license.

Graph 5 shows the distribution of the pool of facilities under ASN oversight and the licenses issued, updated or renewed in 2018.

Eight hundred and ninety-five radiation oncologists were listed in SFRO (French Society for Radiation Oncology) directory in 2017.

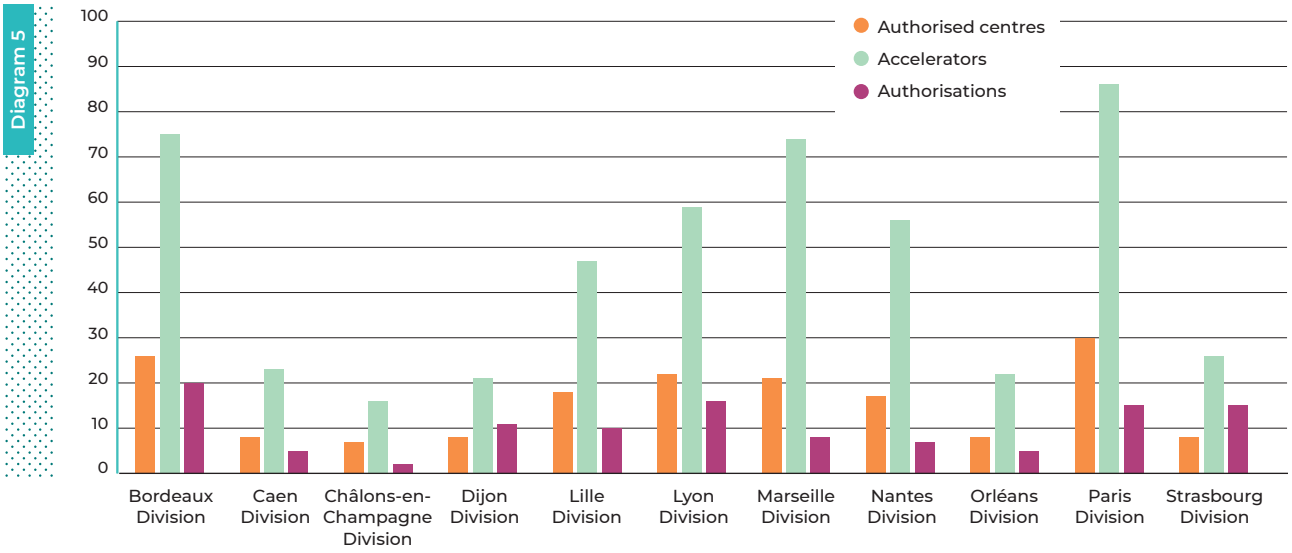
The irradiation sessions are always preceded by preparation of a treatment plan which precisely defines the dose to be delivered, the target volume(s) to be treated, the volumes at risk to be protected, the irradiation beam setting and the estimated dose distribution (dosimetry) for each patient. Preparation of this plan, which aims to set conditions for achieving a high dose in the target volume while preserving surrounding healthy tissues, requires close cooperation between the radiation oncologist, the medical physicist and, when applicable, the dosimetrists.

In the vast majority of treatments, irradiation is ensured using linear particle accelerators with an isocentric arm emitting beams of photons produced at a voltage varying from 4 to 25 megavolts (MV) or electrons with an energy level of between 4 and 25 megaelectronvolts (MeV) and delivering dose-rates that can vary from 2 to 6 grays per minute (Gy)/min. 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. *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.*
3. *213,204 cancer patients were treated by radiotherapy in 2016: 117,196 in the public sector and 96,008 in the private sector.*

Breakdown of the number of external-beam radiotherapy facilities inspected by ASN in 2018

Diagram 5



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 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®, RapidArc®) depending on the manufacturer, is achieved using isocentric linear accelerators equipped with this technological option.

• Helical radiotherapy

Helical radiotherapy, marketed under the name TomoTherapy®, or RadixactTM for the subsequent generation, enables radiation treatment to be delivered by combining the continuous rotation of an accelerator with the longitudinal movement of the patient during the treatment. The technique employed is similar to the principle of helical image acquisitions obtained with computed tomography. A photon beam, emitted at a voltage of 6 MV and a dose-rate of 8 Gy/min, shaped by a multileaf collimator enabling the intensity of the radiation to be modulated, allows the irradiation of large volumes of complex shape as well as extremely localised lesions, which may be in anatomically independent regions. The system requires the acquisition of images under the treatment conditions of each session for comparison with reference computed tomography images in order to reposition the patient.

Thirty-two systems of this type were inventoried in France in 2017 (Radiotherapy Observatory, INCa 2017).

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 sources of cobalt-60 whose emission is directed towards a single focal point (5 units in service);

Stereotactic radiotherapy with robotic arm

This technique consists in using a small particle accelerator producing 6 MV photons, placed on the arm of an industrial robot with six degrees of freedom, marketed under the name CyberKnife®. Furthermore, the treatment table is also positioned on a robot of the same type. By combining the movement possibilities of the two robots, it is possible to use multiple, non-coplanar beams to irradiate small tumours that are difficult to access using surgery and conventional radiotherapy. This technique enables irradiation to be carried out under stereotactic conditions, and with respiratory tracking.

Given the movement capabilities of the robot and its arm, the usual standards do not apply to the radiation protection of the treatment room and a specific study is therefore required.

- robotic stereotactic radiotherapy (see box); CyberKnife® is a miniaturised linear accelerator mounted on a robotic arm (17 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.

2.1.5 _ Contact radiotherapy

Contact therapy or contact radiotherapy is an external-beam radiotherapy technique. The treatments involve an X-ray generator delivering low-energy beams varying from 50 to 200 kV. These low-energy beams are suitable for the treatment of skin cancers because the dose they deliver decreases rapidly with depth.

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. One of the objectives of this call for proposals was to carry out a medico-economic assessment of radiotherapy treatments involving a small number of sessions compared with standard breast cancer treatments. Seven projects deploying an INTRABEAM® accelerator producing X-rays with a voltage of 50 kV were selected and launched between 2011 and 2012.

The French National Authority for Health (HAS) published the results of its assessment in April 2016. According to the HAS, current knowledge is insufficient to demonstrate the benefits of intraoperative radiotherapy in the adjuvant treatment of breast cancer compared with standard external-beam radiotherapy. The HAS concludes that at present, the elements necessary to propose that it be covered by the health insurance scheme are not yet established and considers that the clinical and medico-economic studies must be continued in order to acquire clinical data over the longer term. At the end of this assessment, the HAS does however recommend continuing the assessment of intraoperative radiotherapy for clinical research purposes.

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 (Bragg's peak). 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

NORMANDIE Proton therapy accelerator of the Archade Centre in Caen

In 2018, the Caen division of ASN authorised the François-Baclesse Centre to carry out the acceptance of the proton therapy accelerator of the Archade Centre in Caen and then to treat the first patients by proton therapy. The third French proton therapy centre thus started treating its first patient at the end of July 2018. ASN carried out three on-site inspections during the year, one of them in September after the first treatments. These inspections revealed that the project had been conducted in a highly satisfactory manner, taking account of the recommendations of the GPMED (Advisory Committee for Radiation Protection in Medical and Forensic Applications of Ionising Radiation) concerning innovative techniques in external-beam radiotherapy. The work carried out in the very early stages enabled them to use the prospective risk analysis as a true risk management tool.

A second accelerator should be deployed in the years to come; it will be able to be used for hadron therapy treatments and research into beams.

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 Archade Centre in Caen, François-Baclesse Centre (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 per 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 m to 2.5 m of ordinary concrete). A radiotherapy installation comprises a treatment room including a technical area containing the treatment device, a control station outside the room and, for some accelerators, auxiliary technical premises.

The protection of the premises, in particular the treatment room, must be determined in order to respect the annual exposure limits for the workers and/or the public around the premises. A specific study must be carried out for each installation by the machine supplier, together with the medical physicist and the Radiation Protection Expert-Officer (RPE-O).

This study defines the thicknesses and nature of the various protections required, which are determined according to the conditions of use of the device, the characteristics of the radiation beam and the use of the adjacent rooms, including those vertically above and below the treatment room. This study should be included in the file presented to support the application for a license to use a radiotherapy installation, examined by ASN.

In addition, a set of safety systems informs the operator of the machine operating status (exposure in progress or not) and switches off the beam in an emergency or if the door to the irradiation room is opened.

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 showing weaknesses or risks, implemented in 2018 in particular in some centres having necessitated tightened inspections assisted by experts (Bourgogne Cancerology Institute in Dijon, Lucien-Neuwirth Cancerology Institute in Saint-Priest-en-Jarez) and placing under tightened surveillance (case of the Private Radiotherapy Centre in Metz).

ASN inspected 95 centres in 2017, representing 55% 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.

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 2018 reveal no major problems in this sector:
- The effective designation of Radiation Protection Expert-Officers (RPE-O) was confirmed in the majority of the centres inspected.
- The radiation protection technical controls were carried out in slightly more than 80% of the centres inspected.

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.

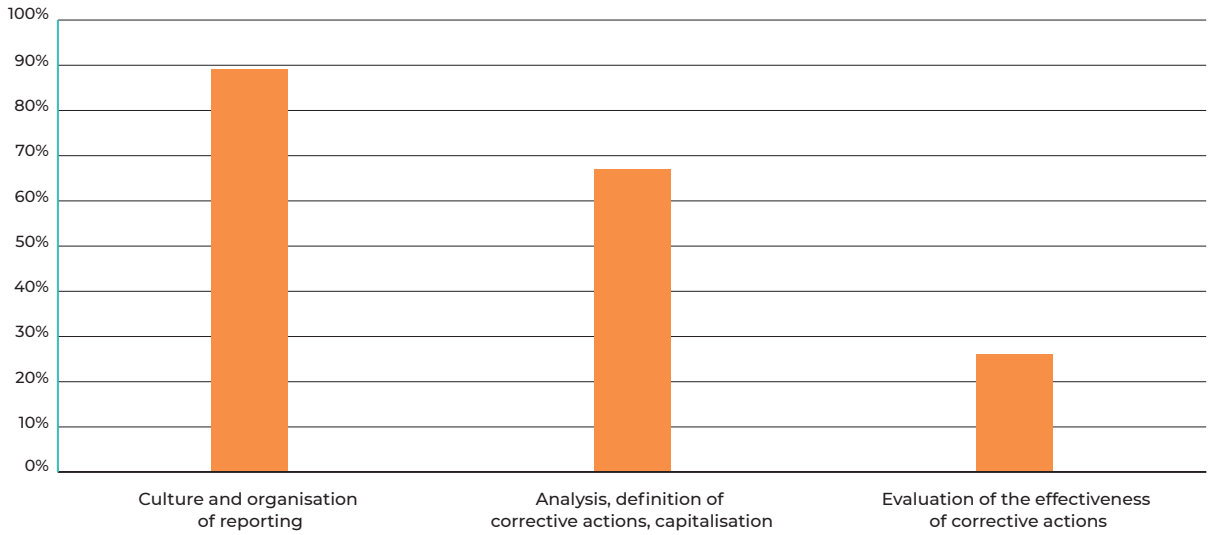
The assessment shows that the detection of adverse events, their reporting (internally or to ASN) and their recording are deemed satisfactory on the whole. In contrast, the analysis of these adverse events is only satisfactory on the whole in 64% of the inspected centres:
- The analysis of the causes 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, a decrease of 10% compared 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 do not involve themselves, especially the physicians, 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 the experience feedback to assess and enrich the prospective risk analysis, required by the abovementioned ASN resolution 2008-DC-0103 of 1 July 2008.

Percentage of conformity of the facilities concerning the management of events giving rise to corrective actions in 2018

Diagram 6



In addition to the verifications performed, the ability of the centre to deploy a risk management procedure was again investigated, with the following findings:

- 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. Thus, the prospective risk analysis - which is mandatory - is only available 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 2018 that the technical, organisational or human changes are not sufficiently anticipated. The impact a change can have on the operators' activity is not analysed, despite the fact that these changes can weaken the existing lines of defence.

GRAND EST REGION Placing the Private Radiotherapy Centre of Metz (CPRM) under tightened surveillance

The inspections conducted by ASN in 2016 and 2017, accompanied by IRSN representatives, in the CPRM and in the radiotherapy centres of the U2R group which is affiliated to it, revealed persistent deviations in the management of the quality assurance system and in the risk analysis approach, and questions concerning the utilisation of an internally developed software used as a single support for the administration of the entire patient care pathway.

An expert assessment and inspection mission was carried out on 23 and 24 April 2018, coordinated by the Grand Est Regional Health Agency (ARS) and ASN, in collaboration with the ANSM, in order to assess the medical practices of the centre and the control of risks for the patients, in the presence of two experts.

Concluding that there was no immediate risk for the treatment of patients, but confirming an extremely conflictual relational situation that was starting to have a significant impact on the functioning of the centre and ultimately representing a risk for treatment safety, ASN decided to place the CPRM under tightened surveillance. This tightened surveillance may be relaxed once the following points can be confirmed:

- a quality management system has been reinstated;
- an appropriate and consistent risks analysis has been carried out and presented;
- observable collegiality has been restored in the analysis and decision-making authorities addressing the issues relating to radiation protection and patient safety;
- a continuity plan has been put in place for the subcontracted functions, capable of guaranteeing the sustainability, robustness and conformity of functioning of the corresponding activities.

AUVERGNE-RHÔNE-ALPES REGION Tightened surveillance of the Lucien-Neuwirth Cancerology Institute (ICLN) in Saint-Priest-en-Jarez (Loire *département*)

In 2018, ASN continued the tightened surveillance of the ICLN radiotherapy department, which began in 2017.

A first inspection carried out by ASN on 14 and 15 September 2017 had revealed conflictual relations within the radiotherapy department, resulting in insufficient communication between professionals and deadlock situations, particularly regarding the medical physics organisation and management of quality and safety. These findings led ASN to subject this department to tightened monitoring in 2018 through two inspections.

A second inspection on 25 and 26 January 2018 aimed at assessing the conditions of performance and safety of the stereotactic radiotherapy activity. This inspection was carried out jointly with the Auvergne-Rhône-Alpes ARS in the presence of experts: it led the inspectors to conclude that the quality and risk management was insufficient and that the centre's ability to conduct a stereotactic radiotherapy activity was not demonstrated. Given this situation, the Auvergne-Rhône-Alpes ARS decided to suspend the stereotactic radiotherapy activity at the ICLN for six months.

On 11 July 2018, a further inspection conducted by a joint team of ARS and ASN inspectors was organised to check the effective undertaking of risk management actions. The inspection team observed in particular the development of a positive momentum in the radiotherapy department.

ASN will continue to monitor this centre in 2019, by verifying in particular the results of the work to harmonise and formalise the practices and to formalise the prospective risk analysis.

BOURGOGNE-FRANCHE-COMTÉ REGION Inspection of the Bourgogne Cancerology Institute (ICB) on its Chalon-sur-Saône site

On 20 and 21 June 2018, ASN conducted an inspection of the Bourgogne Cancerology Institute (ICB) on its Chalon-sur-Saône site, assisted by two experts. This inspection confirmed the strong points of this radiotherapy centre, and in particular the competence and the professional conscience of the healthcare personnel involved in the safety of the treatments delivered to the patients. It did however also reveal malfunctions and deviations which call for organisational and functional changes. More specifically, the human resources of the centre are currently below European standards for the number of patients treated, which necessitates sound management of skills and jobs pending the commissioning of a new accelerator. The age of one of the machines and the potential for failures, the prospect of the forthcoming retirement of a number of physicians and the coexistence of heterogeneous medical practices are also risk factors to be taken into account.

Given this situation, ASN asked the activity supervisors to establish an action plan, which they presented to the ASN Dijon division and the ARS on 11 October 2018.

During this meeting, the ARS and ASN underlined the quality of the action plan which had been drawn up collegially by the medical corps and the staff of the ICB. In 2019, in collaboration with the ARS, ASN will regularly monitor the progress of the plan through follow-up meetings or inspections.

2.3.3 _ Significant events in external-beam radiotherapy

In 2018, 132 significant events concerning radiotherapy were reported. In the last few years, ASN has noted a significant reduction in the ESRs reported by radiotherapy departments. Indeed, as from 2008, some 240 ESRs were notified each year. This phenomenon must be analysed with the assistance of the radiotherapy professionals to find out the reasons for this drop in numbers.

Most of the events reported in 2018 concern patient radiation protection, and the majority of them are not expected to have any clinical consequences.

Fifty-three percent of the events in 2018 were rated level 1 on the ASN-SFRO. Five events in 2018 were rated level 2 on the ASN-SFRO. These five events concern one volume error during palliative treatment of cervical metastases, three laterality errors in patients treated for breast cancer, lung cancer and sinus cancer respectively, and one error in the dose delivered to a patient.

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, among other things, an impact on treatment ranges or the deployment of a new technique or practice, constitute situations which can foster errors. ESRs rated level 2 on the ASN-SFRO are always subject to immediate inspection by the ASN division concerned.

Medical prescription errors in radiotherapy

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 26 events rated level 2 and two events rated level 2+ over the 2014-2018 period, 7 «wrong side» errors have been reported, 3 of them in 2018. Further work on this subject will be conducted with the SFRO and the SFPM (French Society of Medical Physics) in 2019.

Example of an event concerning a laterality error in a breast cancer treatment (left breast):

The consultation report first indicates the left breast, then ends by mentioning the right breast.
The prescription document was then drawn up with a laterality reversal: «right breast» indicated instead of «left breast»: the conventional treatment process was carried out, ordered on an incorrect prescription.
Factors contributing to this event:

- *the absence of surgical clips (*);*
- *the poorly visible scar on the left-hand side;*
- *the lack of an injection of patent blue dye (**) to look for sentinel ganglions which would have alerted the radiographers.*

Observed clinical consequences:

- *overall treatment (surgery, chemotherapy, radiotherapy, hormone therapy) sub-optimal for the left breast;*
- *irradiation of healthy tissue of the right breast.*

It should be noted that the entire treatment was delivered to the patient without checking the prescription against the other mandatory medical file documents (operative report, pathological anatomy report and minutes of the multidisciplinary consultation meeting).

** Surgical clips are metal clips that make it easy to relocate the areas to be treated by radiotherapy after conservative surgery (case of breast cancer).*
*** Patent blue dye is a diagnostic medication used to identify sentinel ganglions prior to a biopsy (breast cancer).*

SUMMARY

In external-beam radiotherapy, the improvement in treatment safety, which has been seen for several years now, is continuing. It is nevertheless still confronted with major technological changes, bringing potential risks if the organisational and human factors are not correctly controlled. These technological changes necessitate prospective risks studies, but the methodology is not yet fully mastered by the professionals. ASN moreover observes that, after a significant increase in ESR notifications in this area of activity, the number has been falling steadily over the last three years. The causes of this reduction must be identified.

3 Brachytherapy

Brachytherapy allows specific or complementary treatment of cancerous tumours, particularly in the head and neck, the skin, the breast, the genitals and the bronchial tubes.

This technique consists in implanting radionuclides, exclusively in the form of sealed sources, either in contact with or inside the solid tumours to be treated.

The main radionuclides used in brachytherapy are iridium-192 and iodine-125.

Brachytherapy techniques involve three types of applications.

Sixty-two brachytherapy centres are licensed by ASN, and 47 of them use the High Dose-Rate (HDR) technique (see point 3.3.1.). ASN issued 26 licenses in 2018. 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 grays/hour (Gy/h);
- by means of iodine-125 sources in the form of permanently implanted seeds.

These iodine-125 sources (seeds) are used to treat prostate cancers. The seeds - which are implanted permanently in the patient's prostate gland - have unit activity levels of between 10 and 30 megabecquerels (MBq), and as a treatment requires about one hundred seeds, this gives a total activity of 1 to 2 gigabecquerels (GBq).

3.1.2 Pulsed Dose-Rate (PDR) brachytherapy

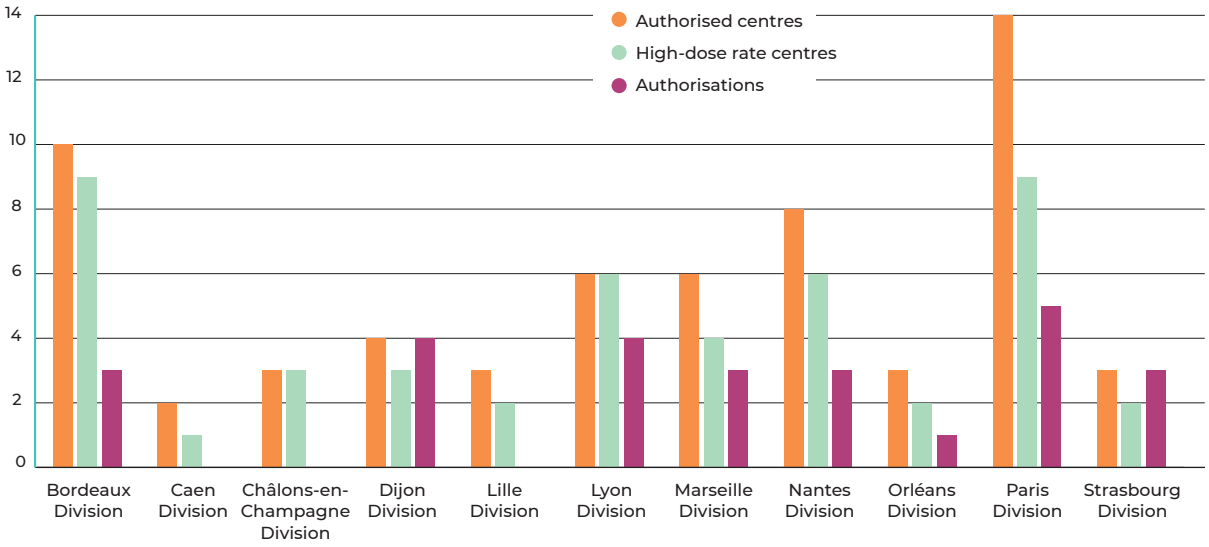
- delivers dose rates of between 2 and 12 Gy/h;
- using sources of iridium-192 displaying a maximum activity of 18.5 GBq and applied using a specific afterloader.

This technique requires patient hospitalisation for several days in a room with radiological protection appropriate for the maximum activity of the radioactive source used. It is based on the use of a single radioactive source which moves in steps, and stops in predetermined positions for predetermined times.

The doses are delivered in sequences of 5 to 20 minutes, sometimes even 50 minutes, every hour for the duration of the planned treatment, hence the name pulsed dose-rate brachytherapy.

Distribution of brachytherapy centres and high-dose rate brachytherapy centres inspected by ASN in 2018

Diagram 7



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 provisions for accident situations related to the operation of the source afterloader and to the high dose-rate delivered by the sources used.

3.1.3 _ High Dose-Rate (HDR) brachytherapy

- delivering dose-rates in excess of 12 Gy/h;
- using sources of iridium-192 displaying a maximum activity of 370 GBq and implemented with a specific afterloader (some afterloaders use a high-activity cobalt-60 source {91 GBq}).

This technique does not require the patient to be hospitalised in a room with radiological protection; it is performed on an out-patient basis in a room with a configuration comparable to that of an external-beam radiotherapy room. The treatment is performed with an afterloader containing the source and involves one or more sessions lasting a few minutes, spread over several days.

High dose-rate brachytherapy is used mainly for gynaecological cancers. This technique can also be used to treat prostate cancers, and can be combined with an external beam radiotherapy treatment.

3.2 _ 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.

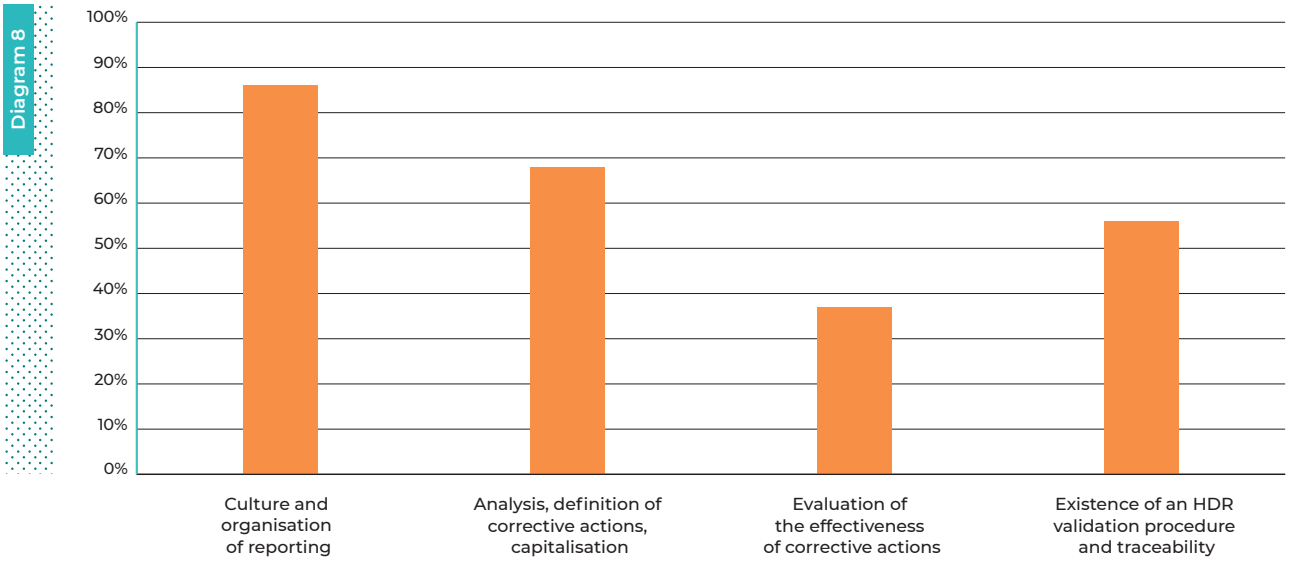
En 2017, 23 centres practising brachytherapy were inspected (representing 36% of the centres). 21 centres were inspected in 2018, meaning that about two-thirds of the brachytherapy departments have been inspected in two years.

3.3.1 _ Radiation protection of workers

The occupational radiation protection measures deployed in 2018 by the brachytherapy departments were considered satisfactory on the whole:
- All the inspected centres have designated a Radiation Protection Expert-Officer (RPE-O) dedicated to this activity with defined duties.
- The majority of the centres inspected have drawn up the technical programme of internal and external radiation protection controls. Progress with respect to 2017 has been observed insofar as these controls have been carried out at the required frequency;

Percentage of conformity of the facilities concerning the management of events giving rise to corrective actions in 2018

Diagram 8



- Improvements must be made however in the reinforced training for emergency situations. In about a third 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 workers if a high activity source is possessed.

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 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 treatment quality and safety management system

The qualitative result of the inspections carried out in 2018 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 2017.

The effectiveness of corrective actions put in place following adverse events is found to be insufficient in about 57% of the centres inspected in 2018, which leaves a large margin for improvement.

The prior validation of HDR brachytherapy treatments is formalised in just 54% of the cases, which is still insufficient given the risks associated with the use of high-activity sources.

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 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 replacing the sources. 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.

Events rated level 2 on the ASN-SFRO scale

One event was rated level 2 on the ASN-SFRO scale in 2018. It involved an excessive dose during a treatment of keloid scars by HDR brachytherapy. The patient displayed necrosis and bleeding of the treated area and healing difficulties that were discovered late.

This adverse effect was caused by a calculation error in the dosimetry step, which resulted in the treated area receiving twice the planned dose. Several factors were found to have caused this event, notably poor ergonomics of the treatment programming software and the fact that the medical staff were frequently interrupted when carrying out the tasks necessary for the preparation of this treatment.

Further to an inspection, the centre was also asked to better formalise the requirements and responsibilities associated with the brachytherapy verifications and validations, to organise audits to test the robustness of the human verifications and to adapt the staff workloads in order to foster continuity and serenity in the performance of tasks associated with treatment safety.

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.

Areas for improvement have nevertheless been identified regarding the safeguarding of access to the high activity sources, given that only 54% of the centres inspected in 2018 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 2019 for the centres holding high- activity sealed sources.

3.3.4 _ Emergency situations and management of malfunctions

An event involving the jamming of a source in a PDR afterloader was reported in 2018. There was no risk of overexposure for either the personnel or the patient given that the emergency procedure planned for by the centre was duly applied.

This event, like those reported in the preceding years, underlines the importance of training personnel in emergency measures. This training must focus in particular on the emergency measures to implement in the event of loss of control of a high-activity source (jamming of the source, for example). Nevertheless, the exercises intended to prepare for and assess the intervention procedures are still insufficiently deployed by the centres (only 67% of the inspected centres have put such exercises in place).

3.3.5 _ Significant events in brachytherapy

Seven ESRs concerning brachytherapy were reported in 2016.

Furthermore, the jamming of an iridium-192 source in a PDR afterloader without any radiation protection consequences for the staff or patients workers was reported, as was the interruption of an HDR brachytherapy treatment because the patient removed the treatment material. It was decided to stop the treatment.

Lastly an error occurred in the dosimetric planning of an HDR brachytherapy treatment resulting in an incorrect treatment time during one session (treatment time underestimated) and underdosing of the area to treat.

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 sources and emergency situations.

SUMMARY

With regard to treatment safety, the situation in brachytherapy is comparable with 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.

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 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) (see point 4.1.1).

• The nuclear medicine units

At the end of 2017, this sector comprised 236 nuclear medicine units licensed by ASN. 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.

The distribution of the nuclear medicine units under the oversight of the ASN regional divisions, of the number of cameras installed (SPECT and PET) and of the number of hospital rooms dedicated to internal targeted radiotherapy (ITR) is shown in Graph 9.

Some fifty *in vitro* diagnostic laboratories were inventoried in 2017, but this number is tending to drop due to the gradual phasing out of this activity in favour of analysis methods that do not use radionuclides.

The nuclear medicine facilities are located in public healthcare institutions (40%), in private companies (40%) and in Non-profit Private Healthcare Institutions (ESPIC) (10%), the remaining 10% being managed by Economic Interest Groupings (GIE), Sanitary Cooperation Groupings (GCS) or others.

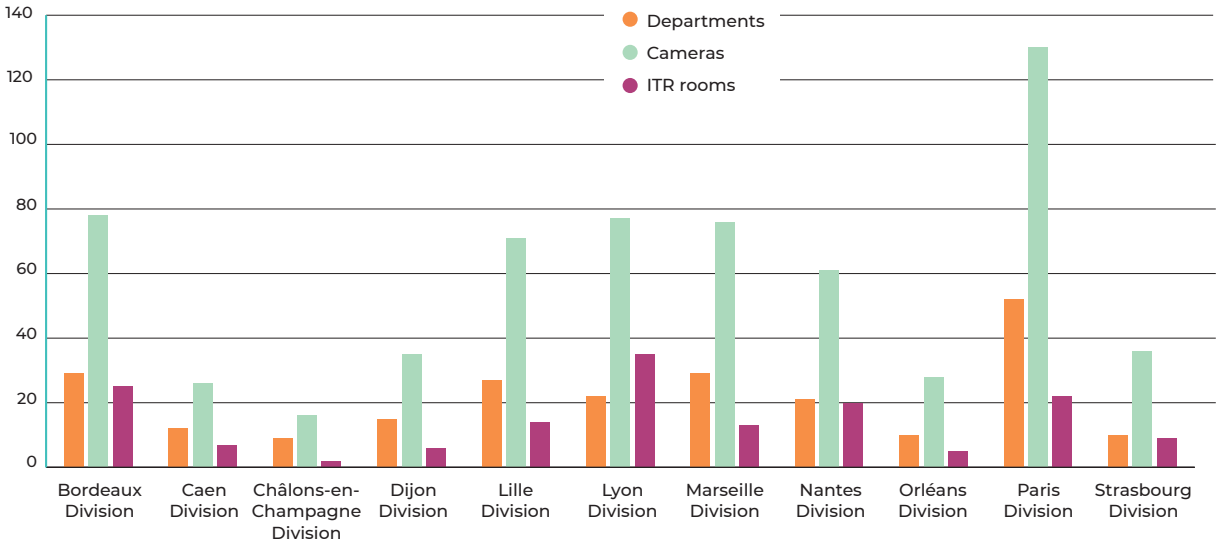
Some 160 licenses were issued by the ASN divisions in 2018. They concerned more particularly changes of cameras or license extensions to allow the use of new radionuclides.

• Medical dispensaries

When a medical dispensary is authorised in a healthcare centre, the room in the nuclear medicine department in which the radiopharmaceutical drugs are prepared, called the «nuclear pharmacy» or «radiopharmacy», are part of the medical dispensary. There are 128 nuclear pharmacies among the 236 nuclear medicine units in public healthcare institutions and non-profit private healthcare institutions, such as the cancer centres. The radiopharmacist is primarily responsible for managing the radiopharmaceutical drug circuit (procurement, possession, preparation, control, dispensing and traceability)

Distribution of the number of nuclear medicine departments, the number of cameras installed and the number of radiation-protected rooms inspected by ASN in 2018

Diagram 9



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 (Graph 9), 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.

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 – 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, fluorodeoxyglucose (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 radiopharmaceuticals marked with other positron emitters, notably gallium-68, are starting to be used. PET cameras equipped with the TOF (Time of Flight) system allow a lower activity radiopharmaceutical 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 are equipped with a CT scanner (SPECT-CT).

Main radionuclides used in diverse *in vivo* nuclear medicine explorations

Table 3

TYPE OF EXAMINATION	RADIONUCLIDES USED
Thyroid metabolism	Iodine-123, Technetium-99m
Myocardial perfusion	Thallium-201, Technetium-99m, Rubidium-82
Lung perfusion	Technetium-99m
Lung ventilation	Technetium-99m, Krypton-81m
Osteo-articular process	Technetium-99m, Fluorine-18
Renal exploration	Technetium-99m
Oncology - search for metastasis	Technetium-99m, Fluorine-18, Gallium-68
Neurology	Technetium-99m, Fluorine-18

The installation of semi-conductor cameras (CZT -Cadmium Zinc Telluride), which have very high detection sensitivity, is continuing to develop, particularly in healthcare 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 kBq.

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, etc.);
- treatments administered by selective systemic route (treatment of liver cancers by administration of microspheres marked with yttrium-90 *via* a catheter placed in a hepatic artery, treatment of neuroendocrine or prostate cancers by molecules marked with lutetium-177 (lutetium therapy).

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 158 Internal Targeted Radiotherapy (ITR) 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 iododine-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 lung 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 radiopharmaceuticals means that the radiation protection requirements associated with their use must be integrated as early as possible in the process. Indeed, given the activity levels involved, the characteristics of certain radionuclides and the preparations to produce, appropriate measures must be implemented with regard to operator exposure and environmental impact.

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 instance). Provision is also made for the collection, storage and disposal of radioactive wastes and effluents produced in the facility, particularly the radionuclides contained in patients' urine.

• 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. ASN published its Guide No. 32 clarifying certain aspects of this resolution in May 2017.

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 division 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 the 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).

The verifications shall be continued in 2019.

• 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[4].

• 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[5] 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.).

ASN inspection in the Morvan Hospital in Brest – September 2018

4.3 _ Radiation protection situation in nuclear medicine

Sixty-nine nuclear medicine departments, i.e. 30% of the facilities, were inspected in 2018.

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 radiopharmaceuticals, and a risk of internal exposure through accidental intake of radioactive substances.

The results for radiation protection of the medical professionals (Graph 10) show that the radiation protection measures deployed by the nuclear medicine departments are on the whole satisfactory. It is noted, for example, that all the inspected departments have appointed an RPE-O dedicated to this activity, with a valid certificate delivered by the employer.

Two areas for improvement have nevertheless been brought to light, namely the refreshing of personnel training and, above all, the coordination with outside companies (only 30% of departments have established coordination measures with all these companies).

4.3.2 _ Radiation protection of nuclear medicine patients

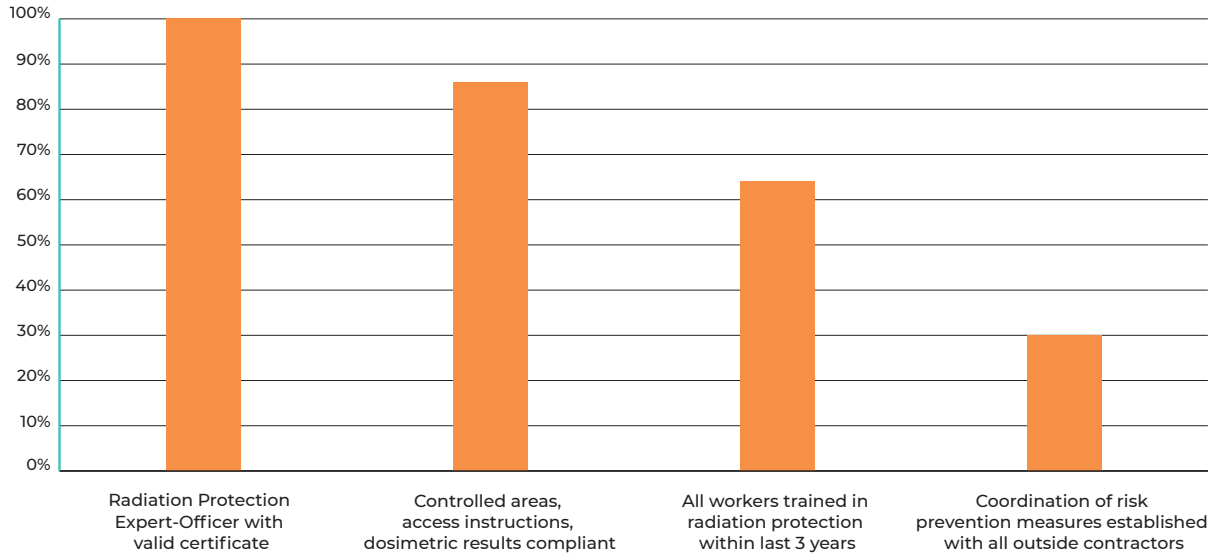
The radiation protection of nuclear medicine patients can also be considered satisfactory in the departments inspected in 2018. Thus, in more than 90% of the departments that perform therapy or diagnostic procedures using iodine-131 (43 of the 69 departments inspected), a printed information leaflet is given to the patient in accordance with the order of 21 January 2004 and the recommendations of the SFMN (French Society of Nuclear Medicine).

The external quality controls of the last two years have been carried out on all the medical devices at the correct frequency and any nonconformities discovered have been remedied in nearly 90% 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.

4. 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.
5. 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.

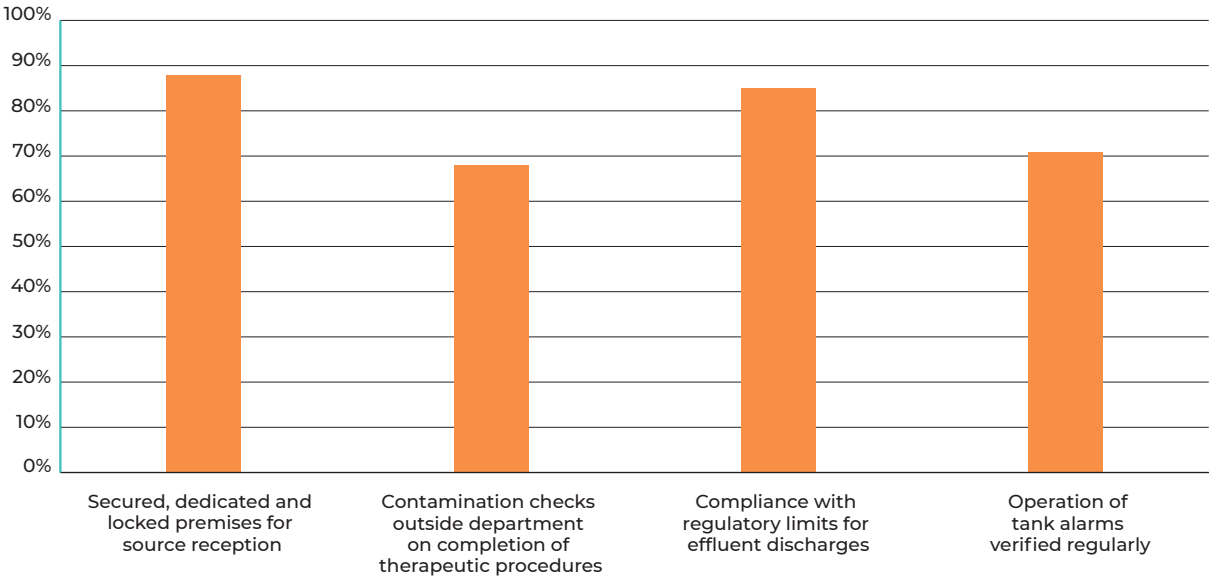
Percentage of conformity of the facilities inspected with regard to radiation protection of medical professionals in 2018

Diagram 10



Percentage of conformity of the facilities with regard to protection of the public and the environment in 2018

Diagram 11



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 a third of the cases, the POPM (Medical Physics Organisation Plan) does not cover all the requirements of ASN Guide No. 20, or the medical physics organisation described in the POPM is insufficient with regard to the risks linked 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 85% 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 comply with the regulatory limits (10 Bq/L 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 70% of them have carried out non-contamination verifications at the end of therapeutic procedures in accordance with the planned protocol;
- in nearly 20% of the inspected units the traceability of alarm device inspections was incomplete or the systems were not operational.

Implementation of the recommendations of ASN circular letter of 17 April 2012 concerning feedback on leaks in pipes carrying contaminated liquid effluents in nuclear medicine units is not totally effective: the pipe networks of the departments, and of the ITR rooms where applicable, are mapped in 60% of the facilities, the condition of the pipes and tanks is monitored in

half the facilities, and an intervention protocol and reflex action sheet for work in the event of a leak in a tank are available in about one third of the facilities. Nonetheless, more than 40% of the departments have no such documents available.

4.3.4 _ Significant events in nuclear medicine

Seventy-two percent of the inspected departments have a system for recording adverse events which have been analysed and reported to ASN.

One hundred and seventy-one ESRs were reported in 2018, representing an increase of 15% with respect to 2017. It is probable that the opening of the ASN on-line notification portal in 2017 and the efforts of the SFMN to encourage the reporting of events contributed to this increase.

As in the preceding years, most of the notified events (66%) concerned patients, of which 65% had undergone a procedure for diagnostic purposes. The majority of the reported events have no expected clinical consequences.

• Significant events concerning patients (113 ESRs, or 66% 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).

Twenty-nine extravasations[6] were reported, with no expected clinical consequences.

One reported event was linked to the administration of microspheres of yttrium-90 in part of a healthy organ (kidney) after movement of the microcatheter for an interventional CT procedure. Due to the possible consequences, the patient will be subject to medical monitoring.

• Significant events concerning workers (13 ESRs, i.e. 8% of the notified ESRs)
Thirteen events concerning workers were reported in 2018, three of which concerned projections of radiopharmaceuticals or effluents, two result from needle injuries when removing needles from syringes, and two concerned internal contaminations.

None of the doses received by these workers exceeded the regulatory exposure limits.

• Significant events concerning the public (19 ESRs, i.e. 11% of the notified ESRs)
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).

• Significant radiation protection events concerning radioactive sources, waste and effluents (19 ESRs, i.e. 11% of the notified ESRs)
Most of these ESR were associated with the loss of radioactive sources (old sources or cobalt rod), the dispersion of radionuclides (leaks of radioactive effluents from pipes or tanks or discharge of effluents before radioactive decay) or the transfer of waste to an inappropriate disposal route.

• Other events (7 ESRs, i.e. 4% of the notified ESRs)
The other events concerned, for example, forgetting to close a door after a radiopharmaceutical drug delivery, contamination of an enclosure interior due to the explosion of a medication bottle during preparation by heating, or forgetting to retrieve a radiopharmaceutical drug syringe in a syringe shield after cancelling an examination (in the electroencephalogram video-surveillance room during an epileptic fit).

SUMMARY

The radiation protection of patients and workers in nuclear medicine is duly taken into account. 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.

6. The extravasation of a radiopharmaceutical, administered by a peripheral intravenous device, is an abnormal passage of the substance outside the catheterised vessel (passage through tissue). Its consequences in terms of lesions caused on neighbouring tissues depend primarily on the volume and the energy level of the extravasated radiopharmaceutical (diagnostic or therapeutic procedure).

5 — Interventional practices using ionising radiation

5.1 — Overview of the techniques and the equipment

Interventional practices using ionising radiation (fluoroscopy-guided interventional practices) group «*all the techniques using ionising radiation to perform invasive medical or surgical procedures for diagnostic, preventive and/or therapeutic purposes, and surgical and medical procedures using ionising radiation for the purpose of guidance or verification*».

• The 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 healthcare centres

On the basis of the codes of the common classification of medical procedures and the activity data reported by the healthcare centres to the Agency for Information on Hospital Care (AIHC), 901 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.

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 the new ASN technical resolution 2017-DC-0591 of 13 June 2017 mentioned in point 4.2.

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 notified 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).

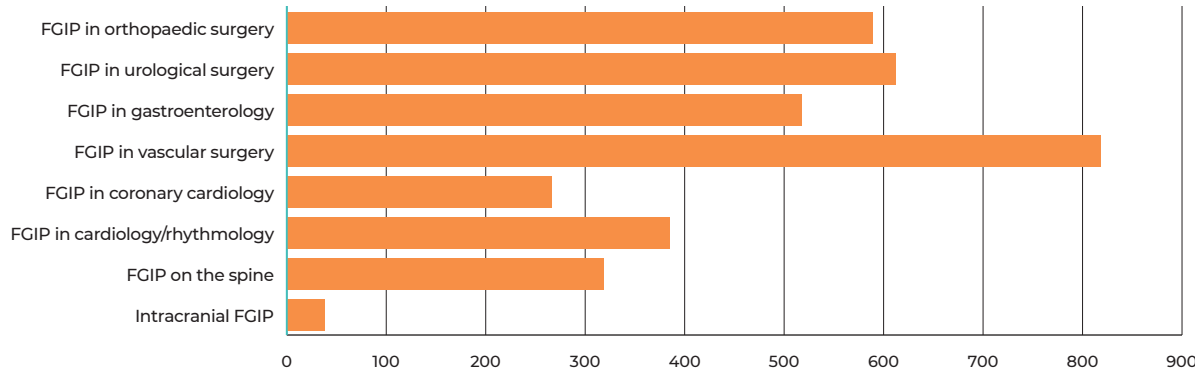
On account of the radiation exposure risks, ASN has increased the number of inspections it carries out in this sector in the last few years. In 2018, 243 inspections were carried out in interventional imaging departments (rooms dedicated to interventional vascular and osteoarticular radiology, to neuroradiology and to cardiology) surgical departments (operating theatre) performing fluoroscopy-guided interventional procedures.

• Characteristics of the inspected centres and departments

Within these 243 inspected centres, 342 departments were visited (202 operating theatre departments, 46 cardiology - coronary angiography departments, 50 cardiology - rhythmology

Breakdown of the number of centres by category of fluoroscopy-guided interventional practices

Diagram 12



FGIP: fluoroscopy-guided interventional practices.

departments, 32 vascular and osetoarticular interventional radiology departments and 12 neuroradiology departments):

- of the 202 operating theatre departments, 187 had at least one mobile C-arm, 12 had fixed C-arms and 4 had mobile CT scanners;
- of the 140 interventional imaging departments, 110 had at least on fixed C-arm, 28 had mobile C-arms and 10 had fixed CT scanners.

To summarise, in more than 90% 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 (90%) to guide their surgical procedures. It is also observed that ever-more 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.

Graph 13 shows the distribution of the medical devices according to the interventional procedures performed.

5.3.1 _ Radiation protection of medical professionals

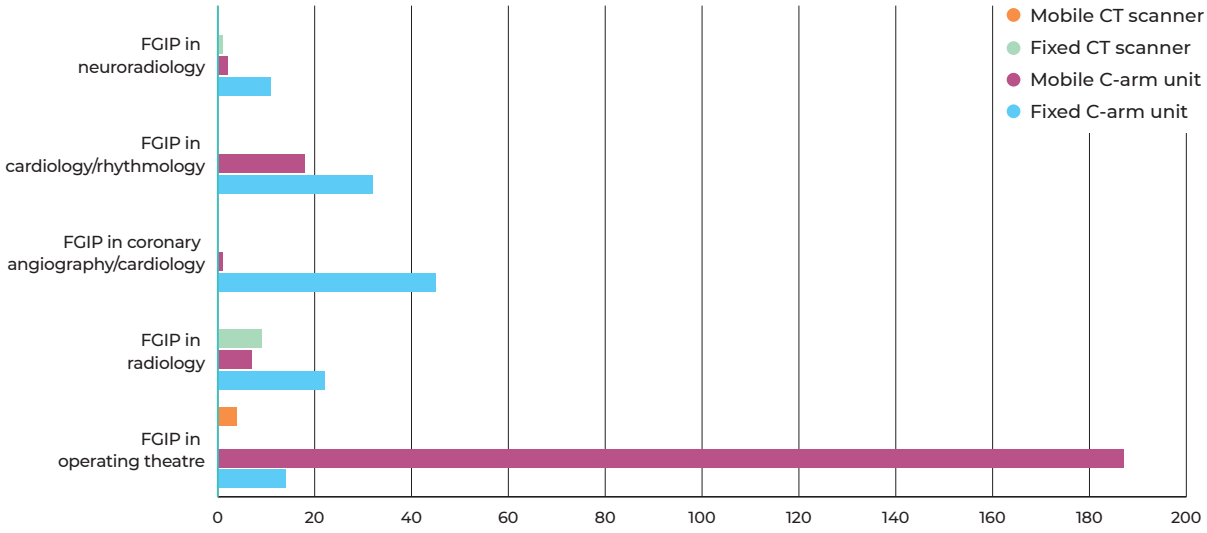
• In interventional imaging departments and in operating theatres...

Occupational radiation protection seems to be taken into account effectively, with the appointment of an RPE-O (in about 90% of the departments inspected), display of access instructions in controlled areas (about 70% of the departments inspected) and radiological zoning of the facilities (more than 80% 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 training of medical and paramedical professionals who use machines with

Number of medical devices according to the nature of the fluoroscopy-guided interventional practices

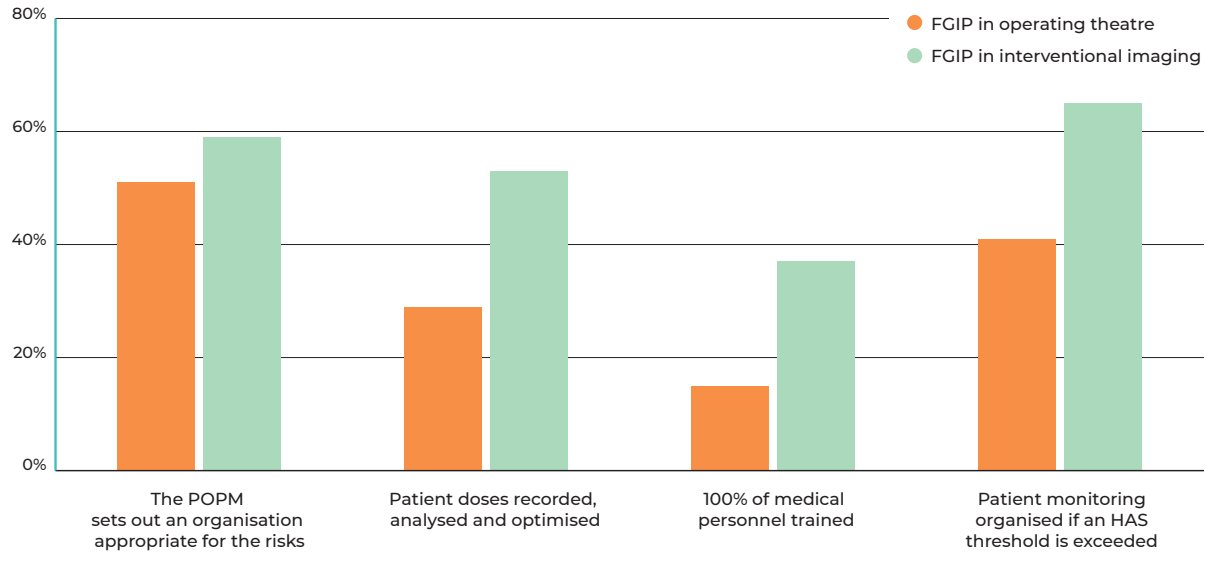
Diagram 13



FGIP: fluoroscopy-guided interventional practices.

Percentage of conformity of the facilities inspected with regard to radiation protection of patients

Diagram 14



FGIP: fluoroscopy-guided interventional practices.
POPM: Medical Physics Organisation Plan.
HAS: French National Authority for Health.

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 (17% 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 only 60% of the inspected sites do the operating theatre professionals have at their disposal dosimetric monitoring devices that are appropriate for the worker exposure and in sufficient quantity.

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 status of worker radiation protection in the operating theatres. ASN nevertheless observes improvements in the departments having been inspected previously.

There were still organisational difficulties for the RPE-Os who did not always have the means or the necessary authority to perform their duties in full. 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 the private sector, in the operating theatres, the dosimetric monitoring, the medical monitoring and, where applicable, that of the employees, represent a recurrent difficulty.

• Radiation protection technical controls...

Radiation protection external technical controls were carried out in more than 70% of the interventional imaging departments and about 55% of the operating theatres. In both cases, the nonconformities observed previously had either been or were being corrected in slightly more than 70% of the inspected facilities when the inspection took place.

5.3.2 _ Radiation protection of patients

The findings established on completion of the inspections in 2018 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 fluoroscopy-guided interventional 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 constitutes a hindrance to application of the principle of optimisation; greater involvement of the medical physicist would, in particular, permit more effective utilisation of the equipment, with the implementation of protocols adapted to the procedures performed, recording of doses delivered and the evaluation with regard to the 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, the protocols used and the practices.

ASN observes that although doses are recorded, they are rarely analysed (29% for operating theatres, 53% for imaging departments). Patient monitoring if the exposure threshold is exceeded (skin exposure threshold) defined by the HAS[7] is not very satisfactory, particularly in the operating theatres.

Reference levels for the most common examinations were being developed locally more and more often. This approach also enables, among other things, alert levels to be set to trigger appropriate medical monitoring of the patient according to the dose levels received. The 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 quality controls of the medical devices are generally carried out at the right frequency and on the day of 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 had insufficient knowledge of the reference dose levels for the type 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 _ Reported events relating to fluoroscopy-guided interventional practices

The putting in place of a system for recording adverse events in operating theatres and interventional imaging departments is moving forward (80% of the departments inspected in 2018 have put this system in place).

29 significant events were reported in this area in 2018. Among these events:

- fifteen concerned overexposure of patients, some of which led to deterministic effects such as transient hair loss (alopecia) (4 cases) or slight erythema (1 case) .
- thirteen concerned exposure of workers;
- two concerned pregnant women exposed during a fluoroscopy-guided interventional 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, complex and repetitive procedures.

One case of patient overexposure was reported for an interventional procedure carried out on a CT scanner described below (reported as a CT scanner ESR notifications).

The reported ESRs concerning worker overexposure were due to accidental exposure: in one case during the cleaning of operating theatre rooms (device powered on), in the other case during a surgical procedure (personnel not protected).

Three workers received a high level of exposure to the hands during fluoroscopy-guided interventional practices. The

7. *Improving patient monitoring in interventional radiology and fluoroscopy-guided procedures – reducing the risk of deterministic effects.*

regulatory limit was exceeded in just one of these cases, and this ESR was rated level 1 on the INES scale. The centre concerned was inspected in early 2019.

The other cases concern exposures of dosimeters lost by the personnel, one case concerns intentional exposure of a dosimeter to test the operation of a mobile C-arm, while others concern active dosimetry malfunctions.

Overexposure of a female patient when performing a biopsy with CT guidance

The patient was exposed to a high dose of ionising radiation that could have subsequent consequences on her health, according to the expert assessment requested of IRSN.

The inspection showed that the complexity of the procedure necessitates a particular image reconstruction technique and that the CT scanner used did not integrate the latest developments for optimising the doses delivered to patients. Furthermore, a number of organisational malfunctions led to the failure to prevent the occurrence of this event (lack of knowledge and training of the personnel, poor communication within the teams, constraints linked to the work environment).

ASN subsequently limited the license of this hospital's CT scanner to diagnostic procedures.

SUMMARY

In the areas of fluoroscopy-guided interventional practices, ASN considers that the urgent measures it has been recommending for several years to improve the radiation protection of patients and professionals in the exercise of interventional practices have still not been sufficiently implemented, particularly for surgical procedures performed in operating theatres. The inspections frequently reveal deviations from the regulations, concerning the radiation protection of patients as much as 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 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 (see box on next page).

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.

Medical imaging: several imaging techniques can be used for a given organ

The physician's diagnostic approach based on the history of the illness and the clinical examination of the patient can be supplemented by specific examinations (medical imaging, biological analyses, etc.).

Four broad medical imaging techniques are available today. They use X-rays (radiology), gamma rays (nuclear medicine), ultrasounds (ultrasonography) and magnetic fields (MRI - Magnetic Resonance Imaging). These techniques enable the morphology of an organ to be analysed or its function to be studied; the intrinsic qualities and the medical interpretation of the resulting images are fundamentally dependent on the physical principle used:

- Radiology reveals differences in density in a tissue (due to the presence of a tumour, for example) or between different organs. Radiology, mammography and X-ray computed tomography are radiological examinations. The scanner enables an organ to be reconstructed in 3D and slices of an organ to be created (slice imaging or tomography).
- Nuclear medicine analyses the distribution of a radiopharmaceutical (a drug consisting of a vector marked by a radioactive isotope or an isolated radionuclide) administered to a patient. This is functional imaging which enables the physiopathological processes to be studied and provides important information on the normal or pathological functioning of a tissue or organ. The radiopharmaceutical is chosen according to the target and the studied organ.
- Ultrasonography uses the properties of ultrasounds to echo (reflect) off interfaces, whether these interfaces are the anatomical boundaries of organs or heterogeneous areas within an organ or tissue. The recorded echoes allow the reconstruction of an image of the explored area. By combining this with the Doppler effect it is also possible to measure the rate of blood flow in the vessels.
- MRI uses the magnetic properties of hydrogen nuclei placed in a strong and stable magnetic field. The proton (H^+) is the main constituent of the molecule of water, an element that is present to a greater or lesser extent in all the tissues of the human body. After "excitation" by radiofrequency waves, the signals from the protons in the water of the human body are picked up by dedicated antennas and analysed by computer in order to produce a slice image.

The use of a new technique for three-dimensional imaging of the breast called "tomosynthesis", which reconstructs the breast from a series of slice images, is developing in Europe. The evaluation of this technique, currently in progress in several European countries, should enable its advantages compared with the traditional planar technique to be determined. At present, this technique is not recognised for use in organised breast cancer screening.

Radiology and nuclear medicine that use ionising radiation are regulated by ASN. Ultrasonography and MRI do not use ionising radiation.

• Computed Tomography

Computed Tomography (CT) scanners use a beam of X-rays emitted by a tube which moves in a spiral around the body of the patient (spiral or helical CT scanner). Based on a computerised image acquisition and processing system, these scanners produce a three-dimensional reconstruction of the organs with very much better image quality than that of conventional radiology devices. The number of rows of detectors (multi-detector-row CT scanner, also known as a multi-slice or volumetric CT scanner) has been increased in recent machines, enabling thinner slices to be produced. An examination can comprise several helical image acquisitions of a specific anatomical region (with or without injection of a contrasting agent) or of different anatomical regions.

This technique can, like Magnetic Resonance Imaging (MRI), be associated with functional imaging provided by nuclear medicine in order to obtain fusion images combining functional information with structural information.

The technologies developed over the last few years have made examinations easier and faster to perform, and led to an increase in exploration possibilities (example of dynamic volume acquisitions) and in the indications[8]. The placing of mobile computed tomography systems on the market for intraoperative use is to be underlined, as is the increase in fluoroscopy-guided interventional CT procedures.

On the other hand, these technological developments have led to an increase in the number of examinations, resulting in an increase in the doses delivered to patients and thus reinforcing the need for strict application of the principles of justification and optimisation (see chapter 1). Technical progress has nevertheless brought a new mode of image reconstruction in the form of iterative reconstruction. Computed tomography can thus provide consistent image quality at reduced doses. 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 (ex: an emergency doctor), who is not a radiologist, to perform the radiological examination and then send the images to a radiologist in order to obtain an interpretation. If necessary the radiologist can guide the radiological operator during the examination and imaging process. In this case, the doctor on the scene is considered to be the doctor performing the procedure and assumes responsibility for it.
- Tele-expertise, which is an exchange of opinions between two radiologists, where one asks the other – the "expert radiologist" (teleradiologist) – for a remote confirmation

8. 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.

or contradiction of a diagnosis, to determine a therapeutic orientation or to guide a remote examination. The data transmissions are protected and preserve medical secrecy and image quality.

Teleradiology involves many responsibilities which must be specified in the agreement binding the practitioner performing the procedure to the teleradiologist. The teleradiology procedure is a medical procedure in its own right, like all other imaging procedures, and cannot be reduced to a simple interpretation of images. Teleradiology therefore fits into the general healthcare organisation governed by the Public Health Code and obeys the rules of professional ethics in effect (Teleradiology Charter).

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 HERCA (Heads of the European Radiological protection Competent Authorities), 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 rules for fitting out radiology and tomography installations

• Radiology installations

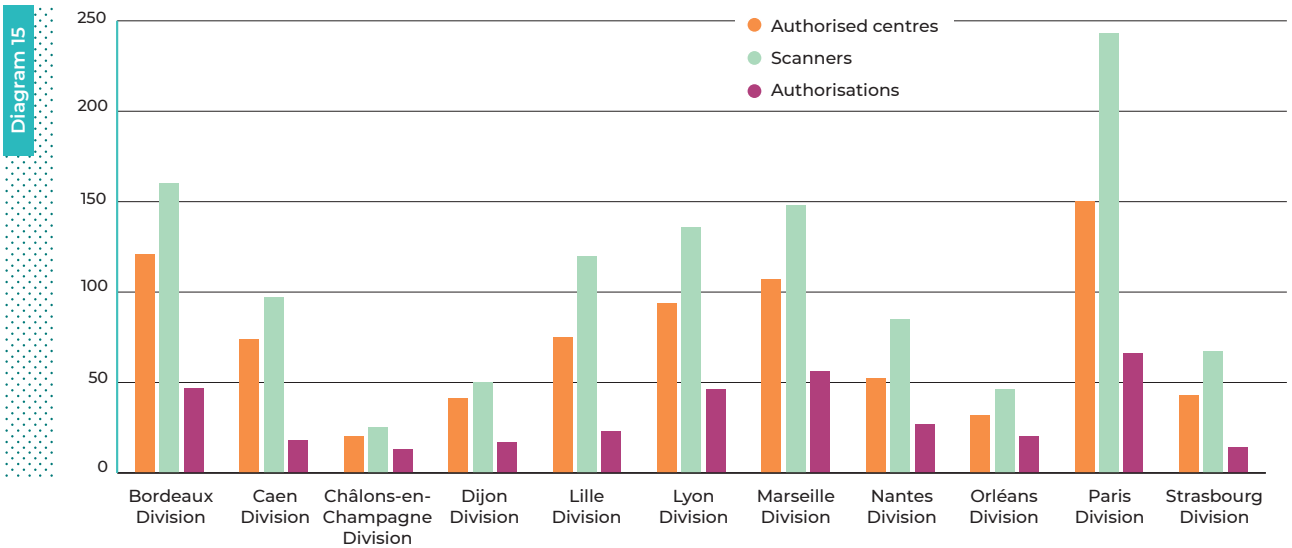
A conventional radiological facility usually comprises a generator (high-voltage unit, X-ray tube), associated with a support (the stand) for moving the tube, a control unit and an examination table or chair.

Mobile facilities, but which are often 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.

Distribution of the number of scanners by geographical area covered by ASN and the number of licences examined in 2018

Diagram 15



An ESR of an unusual nature in computed tomography

This ESR concerns a pregnant woman who required a computed tomography examination in an emergency situation. Due to the inappropriate utilisation of one of the CT scanner control buttons, the woman and her foetus were accidentally exposed to a radiation dose very much higher than that usually delivered in this type of examination. The utilisation of this control button did not trigger any alert signal and the radiographer did not have immediate access to the information relative to the total dose delivered.

Further to this ESR, which also led to a medical devices vigilance notification to the ANSM, ASN decided to set up a national experience feedback group for medical imaging ESRs, comprising experts from the learned societies and representatives of the institutions. In this context, an operational technical sheet on the utilisation of the CT scanner control button was sent to the centres equipped with this model of scanner. Given the large number of CT scanners of this type installed in France and abroad, ASN has published and translated into English its technical recommendations and has widely distributed them, particularly through a HERCA meeting last September, where this procedure for experience feedback to the European authorities was very favourably received.

6.3 — The computed tomography scanner pool

1,177 CT scanners are held in some 800 centres and covered by ASN licenses. Graph 15 opposite shows the distribution of CT scanners by geographical area covered by the ASN regional divisions and the number of license or license update applications examined in 2018 (for a total of 347).

In a report published in September 2018, IRSN notes that:
- the average age of the CT scanner pool is 3.6 years, higher in the public sector;
- the average age of the CT scanners at the time of renewal is 6.1 years, higher in the public sector;
- 83% of the 41 CT scanners aged over 10 years are located in public sector centres.

6.4 — The radiation protection situation in computed tomography

The ASN regional divisions carried out 26 inspections in 2018. The conclusions of these inspections are in line with the findings of the previous years.

6.5 — Events reported in conventional radiology

82 significant Radiation protection Events (ESR) in conventional radiology were reported to ASN in 2018. The majority of them concern pregnant women who were unaware of their pregnancy (59 cases, i.e. 72% of the ESRs).

171 ESRs in computed tomography were reported to ASN in 2018. They chiefly concern women unaware of their pregnancy (105 case), deficiencies in practices, such as patient identity error, wrong protocol, etc. (52 cases) and situations of worker exposure (11 cases).

SUMMARY

The growing number of diagnostic examinations performed using CT scanners contributes to high collective doses, as medical imaging is the leading source of artificial exposure of the public to ionising radiation. The medical justification for these procedures is still insufficiently well-founded due to the highly insufficient training of the referring doctors, and sometimes the unavailability of alternative diagnostic methods (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 at reinforcing the application of justification of the procedures and optimisation of the ionising radiation doses delivered to the patients.

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 an average dose of about 20 to 25 grays.

Since 2009, source irradiators have been gradually replaced by X-ray generators, for which notification to ASN has been required since 2015. In 2018, 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 (fire, flooding, break-in, etc.). Access to the device, which must have a lockable control console, must be limited to authorised persons only.

Irradiators equipped with X-ray generators must be installed in rooms that comply with the provisions of ASN's new technical resolution 2017-DC-0591 of 13 June 2017 mentioned in section 4.2.

8 Synthesis and prospects

ASN considers that the radiation protection situation in the medical sector remained stable in 2018; no particular deficiency was detected in the areas of radiation protection of workers, 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 should be 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 qualification of physicians using ionising radiation and the updating of diagnostic reference levels.

ASN is going to continue developing its inspection programme, giving priority to radiotherapy, nuclear medicine and fluoroscopy-guided interventional practices. The preparation in 2019 of the new registration system applicable to fluoroscopy-guided interventional practices involving risks, which is to replace the existing notification system, is part of the drive to tighten oversight in this sector.

ASN also plans to start the updating of the doctrine concerning the discharging of artificial radionuclides into the public sewage networks, and then to examine the changes in the management of contaminated effluents necessary to accompany the announced development of cancer treatments based on the administration of new radiopharmaceutical drugs.

With regard to imaging, the development of a communication scale applicable to significant radiation protection events, like the one that has existed for radiotherapy since 2008 (the ASN-SFRO scale), and the setting up of a national experience feedback committee to study these events, are also scheduled for 2019.

In radiotherapy, ASN will be 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 will be continued in 2019, with volunteer radiotherapy centres and the assistance of the professionals, hospital federations and healthcare institutions.

Lastly, the new committee for analysing new practices or techniques using ionising radiation will be set up in 2019. It will comprise members from learned societies and professional associations involved in radiotherapy and medical imaging.

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08

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CHAPTER 08

Sources of ionising radiation and their industrial, veterinary and research applications

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 ensure that the safety of workers, the public and the environment is achieved. This protection involves more specifically ensuring proper management of the sources, which are often portable and used on worksites, and monitoring the conditions of their possession, use and disposal, from fabrication through to end-of-life. It also involves monitoring the main stakeholders, that is to say the source manufacturers and suppliers, and enhancing their accountability.

The ongoing updating of the regulatory framework for nuclear activities established by the Public Health Code and the Labour Code 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 developments will start to bring substantial changes in the oversight of industrial, research and veterinary activities as of January 2019, which will continue over the years to come.

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 (BNI) 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, prometheum-147 and americium-241. The source activity ranges from a few kilobecquerels (kBq) to a few gigabecquerels (GBq).

These sources are used for the following purposes:

- Atmospheric dust measurement: the air is permanently filtered through a tape placed between the source and detector, running at a controlled speed. The intensity of radiation received by the detector depends on the amount of dust on the filter, which enables this amount to be determined. The most frequently used sources are carbon-14 (with an activity of 3.5 megabecquerels - MBq) or prometheum-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 prometheum-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 – baryum-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 – baryum-137m (with an activity of 100 MBq) or cobalt-60 (with an activity 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 characterize ancient objects, in geochemistry for mining prospecting and in industry (study of the composition of semiconductors, analysis of raw mixes in cement works).

Given the activation of the material analysed, this requires particular vigilance with regard to the nature of the objects analysed. Article R. 1333-2 of the Public Health Code prohibits the use of materials and waste originating from a nuclear activity for the manufacture of consumer goods and construction products if they are, or could be, contaminated by radionuclides, including by activation (see point 2.2.1).

1.1.3 _ Other common applications

Sealed radioactive sources can also be used for:
- industrial irradiation, used for sterilization in particular (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.

Graph 1 specifies the number of facilities authorized to use sealed radioactive sources for the applications identified. It illustrates the diversity of these applications and their development over the last five years.

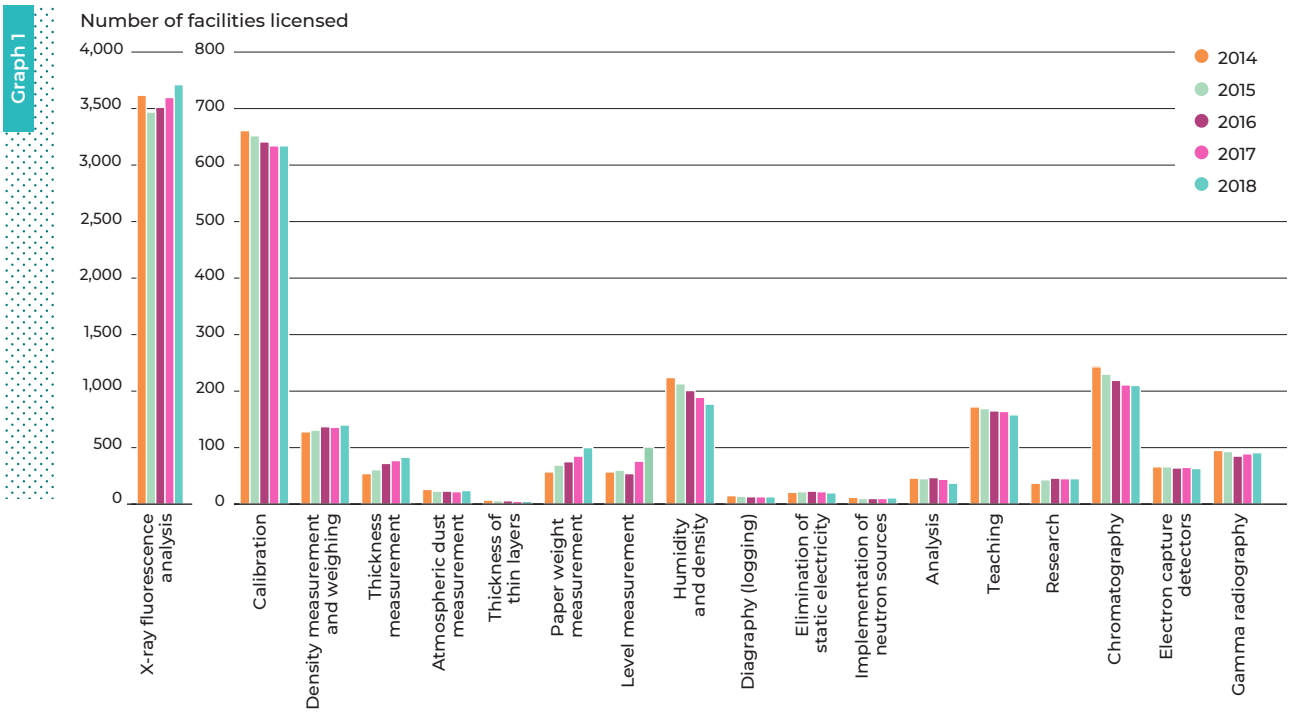
It should be noted that a given facility may carry out several of these activities, and if it does, it appears in Graph 1 and the following diagrams for each activity.

1.2 _ 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 are a powerful investigative tool in cellular and molecular biology. Using radioactive tracers incorporated into molecules is common practice in biological research. There are also several industrial uses, for example as tracers or for calibration or teaching purposes. Unsealed sources are used as tracers for

Used of sealed radioactive sources

Graph 1



measuring wear, looking for leaks or friction spots, building hydrodynamic models and in hydrology.

As at 31 December 2018, the number of facilities authorised to use unsealed sources stood at 724.

Graph 2 specifies the number of facilities authorised to use unsealed radioactive sources in the applications inventoried in the last five years.

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.

Graph 3 specifies the number of facilities authorised to use electrical devices generating ionising radiation in the listed applications. It illustrates the diversity of these applications which have evolved over the last five years. This evolution is closely related to the regulatory changes which have gradually created a new licensing or notification system concerning the use of these devices. At present, the situation of the professionals concerned is being brought into compliance in many activity sectors.

The electrical devices emitting ionising radiation are chiefly X-ray generators. They are used in industry for non-destructive structural analyses (analysis techniques such as tomography, diffractometry, also called X-ray crystallography, etc.), for checking the quality of weld beads or inspecting materials for fatigue (in aeronautics in particular).

These devices, which function using the principle of X-ray attenuation, are used as industrial gauges (measurement of drum filling, thickness measurement, etc.), inspection of goods containers or luggage and also the detection of foreign bodies in foodstuffs.

The number of types of device available on the market can be explained more particularly by the fact that when possible, they replace devices containing radioactive sources. The advantages of this technology with regard to radiation protection are linked in particular to the total absence of ionising radiation when the equipment is not in use. Their utilisation does however lead to worker exposure levels that are comparable to those resulting from the use of devices containing radioactive sources.

• Baggage inspection
Ionising radiation is used constantly in security screening checks, whether for the systematic verification of baggage or to determine the content of suspect packages. The smallest and most widely used devices are installed at the inspection and screening checkpoints in airports, in museums, at the entrance to certain buildings, etc.

The devices with the largest inspection tunnel cross-section are used in airports for screening air freight, large baggage items and hold baggage in airports. These devices are supplemented by tomographs, which give a series of cross-sectional images of the object being examined.

The irradiation zone inside these appliances is sometime delimited by doors, but most often simply by one or more lead curtains.

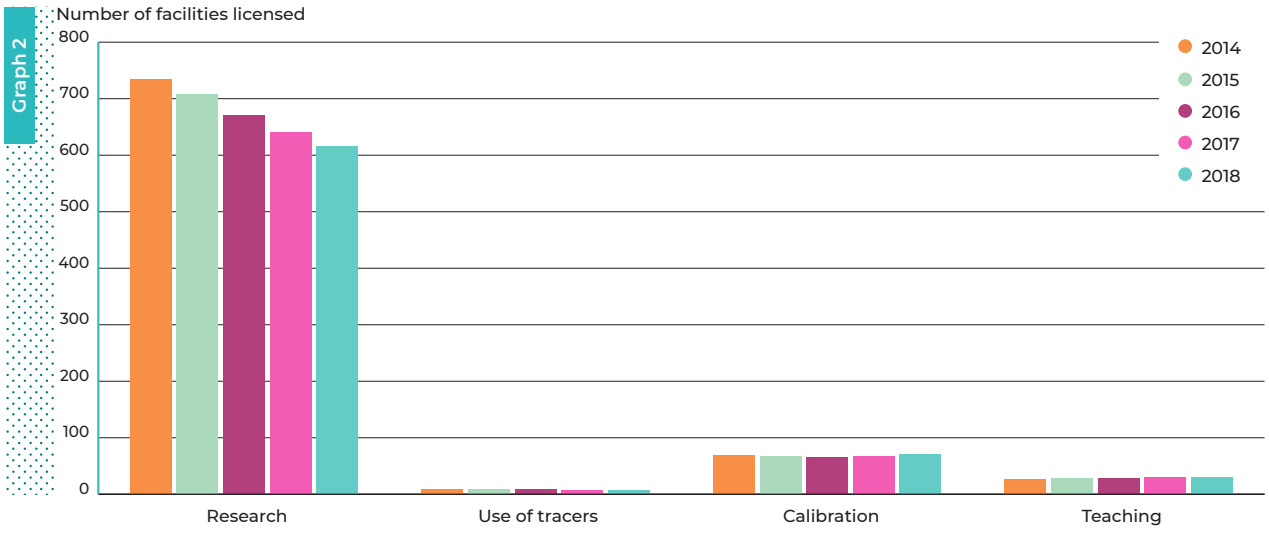
• X-ray body scanners
This application is mentioned for information only, since the use of X-ray scanners on people during security checks is prohibited in France (in application of Article L. 1333-18 of the Public Health Code). Some experiments have been carried out in France using non-ionising imaging 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.).

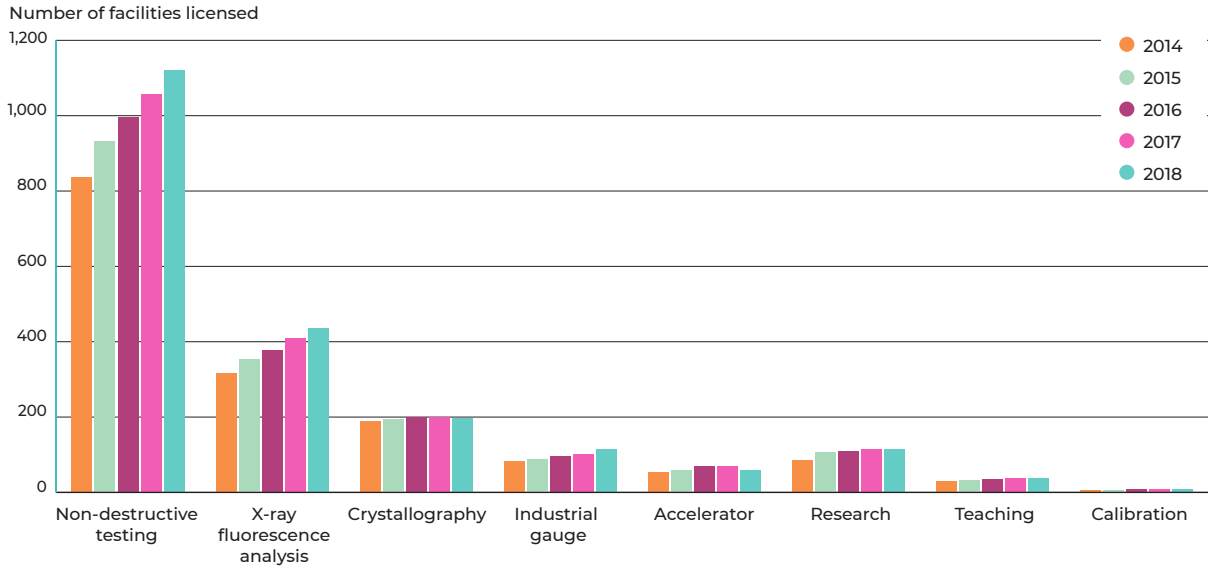
• X-ray fluorescence analysis
Portable X-ray fluorescence devices are used for the analysis of metals and alloys.

Use of unsealed radioactive sources



Use of electrical devices generating ionising radiation (veterinary sector excluded)

Graph 3



• 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.

Radiography for checking the quality of weld beads or for the fatigue inspection of materials is detailed in point 3.1.1.

1.3.2 _ Veterinary diagnostic radiology

The profession counts approximately 16,000 veterinary surgeons and 14,000 non-veterinarian employees. Veterinary surgeons use diagnostic radiology devices in a context similar to that of the devices used in human medicine. Veterinary diagnostic radiology activities essentially concern pets:

- 90% of the 5,793 veterinary structures in France have at least one diagnostic radiology device;
- about 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 and external-beam radiotherapy.

The treatment of large animals (mainly horses) requires the use of more powerful devices installed in specially equipped premises (radiography of the pelvis, for example) and of portable X-ray generators, used indoors - whether in dedicated premises or not - or outside in the open air. This activity has significant radiation protection implications for veterinary surgeons and grooms.

In order to better ensure compliance with regulatory requirements, ASN introduced a notification system in 2009 for what were 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 structures (see Graph 4) with more than 90% of the structures 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.

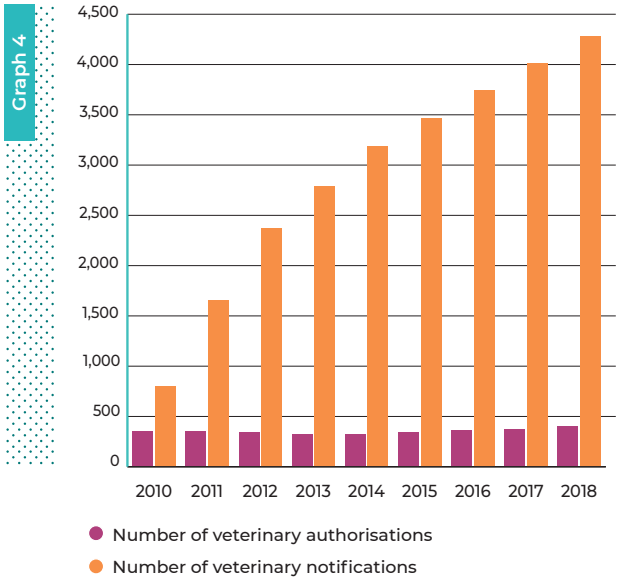
With regard to veterinary facilities, the administrative situation has been continuously improving for a number of years now. At the end of 2018, ASN counted 4,681 notified or licensed facilities out of approximately 5,000 veterinary structures using ionising radiation in France.

Among the veterinary activities, those performed on large animals (primarily horses) and outside specialised veterinary facilities (in so-called "worksite" conditions), are considered to be those with the most significant radiation risks, more specifically for persons external to the veterinary practice taking part in these procedures. The inspections carried out by ASN on these veterinary clinics have revealed areas for improvement regarding which ASN remains vigilant when reviewing licensing applications and performing inspections:

- worker monitoring by active dosimetry and in-house radiation protection checks;
- setting up supervised or controlled areas;
- the necessity to reinforce the radiation protection of persons external to the veterinary practice who participate in the diagnostic procedures.

The conventional radiology activities performed on pets (called "canine activities" in France) are carried out in a very large number of veterinary clinics but involve lower radiation risks. 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 adressed 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.

Use of electrical devices generating ionising radiation for veterinary activities



During this campaign, ASN detected no major shortcomings, save exception, and considers that the organisation of radiation protection in conventional veterinary clinics is satisfactory on the whole. The radiation protection organisation should nevertheless be stepped up on the following points:

- 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 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.

The extensive nationwide commitment of this profession to harmonising practices, raising awareness, training student veterinary surgeons and drafting framework documents and guides is viewed as 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.

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 and certain electrical devices such as high-voltage fuse tests.

Lastly, some applications use particle accelerators (see point 3.3.1).

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, that will issue the registration decisions and receives the notifications, 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. These concern 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 it delivers, radiation protection requirements for the nuclear activities carried out on the site.
- The installations and activities relating to national defence for which ASND (Defence Nuclear Safety Authority) is responsible for regulating the radiation protection aspects.
- The installations authorised under the BNI System. ASN regulates the radioactive sources and electrical devices emitting ionising radiation necessary for the operation of these installations under this system. Holding and using other sources within the bounds of the BNI remain subject to licensing pursuant to Article R. 1333-118 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 Prefectural Order under the Environment Code for the possession and use of radioactive substances are now regulated by ASN under the Public Health Code. The requirements applicable to these installations are therefore now those of the Public Health Code. However, Article 4 of the abovementioned Decree provides that the license or notification issued under section 1715 of the nomenclature shall continue to be valid and deemed a license or notification under the Public Health Code until a new authorisation is obtained under the

Public Health Code or, failing this, for a maximum period of five years, that is to say until 4 September 2019 at the latest. Before any change relating to the license is made, it shall either be notified to ASN or form the subject of a new license application, depending on the case.

Only establishments holding unsealed radioactive substances or managing radioactive waste in quantities exceeding 10 m^3 for either of these activities are subject to the ICPE System (excluding the medical sector and particle accelerators). Any sealed radioactive sources also possessed or used by these establishments are regulated by ASN under the Public Health Code.

Nuclear materials are subject to specific regulations provided for in Article L. 1333-1 and following 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 states that waivers to these prohibitions can, if justified by the advantages they bring, be granted by order of the Minister responsible for Health and, depending on the case, by the Minister responsible for Consumption or the Minister responsible for Construction, after consulting ASN and HCSP (French High Public Health Council).

ASN considers that this mechanism of granting waivers to the regulations must remain the exception. It was implemented for the first time in 2011 for a waiver request concerning the use of a neutron analysis device in several cement works (Order of 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, thorium-232 or tritium), 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 certain 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 2018, two new waiver applications (from a cement works and the company building the Lyon-Turin tunnel) were submitted to the Ministry responsible for the Environment, which then asked ASN for is opinion (examination in progress).

2.2.2 _ Application of the justification principle for existing activities

The justification of existing activities must be re-assessed periodically in the light of current knowledge and technological changes in accordance with the principle described in point 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 transitional period for definitive withdrawal from the market may be necessary, depending on the technical and economic context, particularly when a technological substitution is necessary.

• Smoke detectors containing radioactive sources

Devices containing radioactive sources have been used for several decades to detect smoke in buildings, as part of firefighting policy. Several types of radionuclides have been used (americium-241, plutonium-238, radium-226). The activity of the most recent sources used does not exceed 37 kBq, and the structure of the detector, in normal use, prevents any release of radioactive substances into the environment.

New non-ionising technologies have gradually developed for smoke detection. Optical devices now provide comparable detection quality, and can therefore satisfy the regulatory and industrial standard fire detection requirements. ASN therefore considers that smoke detection devices using radioactive sources are no longer justified and that the seven million Ionisation Chamber Smoke Detectors (ICSDs) installed on 300,000 sites must be progressively replaced.

The regulatory framework governing their withdrawal was put in place by the Order of 18 November 2011 and the 2 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.

Seven years after the implementation of the new regulatory system for ICSD removal and maintenance activities, as at 31 December 2018 ASN had delivered 350 notification acknowledgements and 7 national licenses (delivered to industrial groups with a total of 107 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 tracking of the pool of ICSDs, in 2015, in collaboration with ASN, 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 certifies the companies that comply with the regulations relative to radiation protection and fire safety. The list of QUALDION-certified companies is available on the association's website page. ASN participates with the association in communication campaigns targeting the holders of ICSDs and professionals (Expoprotection trade fair, Mayor's trade fair, etc.).

• Surge suppressors

Surge suppressors (sometimes called lightning arresters), not to be confused with lightning conductors, are small objects with a very low level of radioactivity used to protect telephone lines against voltage surges in the event of lightning strike. These are sealed devices, often made of glass or ceramic, enclosing a small volume of air containing radionuclides to pre-ionise the air and facilitate 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. There can be a very low risk of exposure and/or contamination if these objects are handled without the necessary precautions or if they are damaged. ASN issued a reminder of this to the company *Orange* (formerly *France Télécom*), which has begun an experimental process of inventorying, removing, sorting, storing and disposing of surge suppressors in the Auvergne region and has proposed a national removal and disposal plan. This plan was presented to ASN and led in September 2015 to the granting of a license governing the removal of all surge suppressors containing radionuclides present on the *Orange* network in France and their storage on designated sites. The search for a disposal route is in progress in collaboration with Andra, the French national agency for radioactive waste management. This removal plan is being implemented progressively over an eight-year time frame.

• Lightning conductors

Radioactive lightning conductors were manufactured and installed in France between 1932 and 1986. The ban on the sale of radioactive lightning conductors was declared in 1987. This Order did not make the removal of installed radioactive lightning conductors compulsory. Consequently, there is no obligation at present to remove the radioactive lightning conductors installed in France, except in certain ICPEs (Order of 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 placed in the care of 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 L. 1333-2, 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 450 per year.

Additional information on radioactive lightning conductors is available from *andra.fr* and the INAPARAD association's website.

2.3 _ The regulatory changes

2.3.1 _ Reinforcement of the regulation of electrical devices generating ionising radiation

ASN considers that the regulatory oversight of suppliers of ionising radiation generators is still insufficient, when the marketing of such devices contributes significantly to optimising the future radiation exposure of the 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. This resolution 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 exclusively directed at the utilisation 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 covering various fields, including radiation protection. Furthermore, experience feedback shows that a large number of devices do not have a certificate of conformity to the industrial standards applicable in France. These standards have been mandatory for many years now, but some of their requirements have become partly obsolete or inapplicable due to the lack of recent revisions.

On the basis of the work done by the LCIE (Electrical Certification and Testing Entity for *Bureau Véritas*), CEA and IRSN, draft texts have been produced by ASN with the aim of defining minimum radiation protection requirements for the design of X-ray generators, and an informal technical consultation of the stakeholders (suppliers, French and foreign manufacturers and the principal users) was conducted in 2015. The various contributions are currently being analysed with the assistance of IRSN and the reference players (CEA and LCIE). The conclusions of this work will be taken into account to adapt the regulatory framework and subject the distribution of devices generating ionising radiation to licensing, in the same way as for radioactive sources.

2.3.2 _ Implementation of oversight of the protection of ionising radiation sources against malicious acts

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 Agency (IAEA), which published a Code of conduct on the safety and security of radioactive sources, approved in 2003. As of the following year, France confirmed to the IAEA that it was working with a view to applying the guidelines set out in this code.

• The organisation adopted for the oversight of protection against malicious acts

The oversight of sources for radiation protection and safety purposes and oversight to combat malicious acts have many aspects in common. Generally speaking, ASN's counterparts in other countries are responsible for oversight in these two 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 HFDS (Defence and Security High Official) of the Ministry responsible for Energy (Ministry of Ecological and Solidarity-based Transition).

The recent changes in regulations 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 oversight;
- 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 divide up the oversight competences in the various installations, 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 (combating malicious acts) concern all sources of ionising radiation. Additional regulatory requirements will nevertheless be issued to increase the security of the sources presenting the greatest security risks: this concerns sealed 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 / batches of sources in category A than in category C. Sources that are not in category A, B or C are classified in category D.

In the civil sector, there are about 4,918 sources presenting such risks held in some 250 installations in France. These sources are held essentially for the purpose of industrial irradiation, telegammatherapy, brachytherapy and industrial radiography. Due to their frequent use on worksites, industrial radiography sources present particular security risks during transport.

As was said earlier, oversight of the security of these sources is ensured essentially by ASN.

Because they are grouped together when in storage, sources of one category can find themselves alongside sources in a higher category and therefore be subject to stricter security measures.

• Initial assessment regarding the security of high-activity sealed sources

For five years, ASN has worked to gather baseline data on actual provisions implemented to ensure the security of high-activity sealed sources or presenting equivalent security risks. This work led to ASN making some 350 visits. Virtually all the licensees holding sealed sources in categories A, B and C, who are now under ASN oversight on account of the protection of sources against malicious acts, have therefore received such a visit.

A synthesis of the information gathered during these visits was one of the inputs for the development of the future legally-binding requirements, coordinated by the HFDS of the Ministry responsible for Energy, and enabled the impact of these requirements to be assessed (see next paragraph).

• 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 aggregation (batching) of radioactive sources into category A, B, C or D (R. 1333-14);
- the prompt notification to various administrative authorities, and the regionally competent 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).

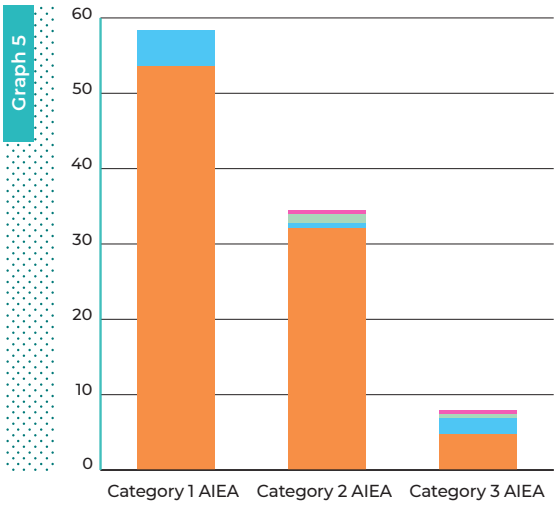
Categorisation of radioactive sources

Since 2011, the IAEA has classified radioactive sources into five categories, from 1 to 5, on the basis of predetermined exposure scenarios, 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 therefore must not under any circumstance 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.

Breakdown of the regulatory oversight of protection of sources against malicious acts

Graph 5



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.

In 2018, the working group coordinated by the HFDS of the Ministry responsible for the Environment and in which ASN participates, continued its work to prepare a Ministerial Order setting technical and organisational requirements to be implemented by those responsible for nuclear activities to protect their sources against malicious acts. This order, whose publication is planned for 2019, will enter into effect progressively. The requirements aim in particular, applying a graded approach based on categories A, B, C and D, to put in place an internal organisation with regard to security, to limit source access to duly authorised persons, to place one or more physical protective barriers between the sources and persons not authorised access to them, and to make intrusion detection devices mandatory or to ensure the tracking of these sources. It will cover the installations and transport. Operators and stakeholders have been invited to take part in some of this work in order to give their opinions and comments on the proposed principles. They will be consulted on the draft Ministerial Order.

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

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 a 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 on the part of the professionals. ASN considers in particular that the suppliers of devices are at the core of the optimisation approach (see point 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 any 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 licensing system

Small-scale nuclear activities stand out through their extreme heterogeneity and the very large number of licensees concerned. The licensing system is designed to regulate the nuclear activities involving the greatest radiation protection implications, for which ASN checks, when examining the application file, that the applicant has identified the risks and that the barriers intended to limit their effects have been studied and planned for. As part of this licensing simplification process, ASN has produced licensing application forms adapted to each activity which are available on *asn.fr*.

These documents 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. The 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, more proportionate to the risks.

Its initial work focused on the notification system. Notification is a simple procedure which does not require the transmission 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 on p. 22), ASN has extended the list of activities subject to notification. The notification system extension should concern about 6,000 files which were previously subject to the licensing system.

International think tank on alternative technologies

Radioactive sources present safety and security risks for their users, the general public and the environment, which must be taken into consideration when considering the inititiation of a nuclear activity. Consequently, in France, when technologies presenting lower risks than a nuclear activity are available under technically and economically acceptable conditions, they must be implemented instead of the nuclear activity initially envisaged: this is the principle of justification.

On this basis, as of 2014 and subsequently at the Washington Summit on nuclear security in April 2016, France was the initiator of an international initiative now supported by 31 States and by Interpol. The aim is to support research into and the development of technologies that do not use high-activity sealed radioactive sources and to promote their use.

In this context, since April 2015 ASN has, along with the National Nuclear Security Administration (United States), initiated an informal think tank involving several States 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.

The think tank continued its meetings in 2018. Other foreign licensees shared their experience, particularly in the use of electrical irradiators emitting X-rays for research activities. These 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.

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.

2.4.3 _ Statistics for 2018

• 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 2018, 81 radioactive source distribution license applications or license renewal applications were examined by ASN, and 43 inspections were carried out (all ionising radiation sources combined).

• Users

Case of radioactive sources

In 2018, ASN examined then issued 256 new licenses, 907 license renewals or updates and 176 license cancellations. Graph 6 presents the licenses issued or cancelled in 2018 and trends in this area for the last five years.

Once the license is obtained, the licensee can procure radioactive sources. To do this, it collects supply request forms from IRSN, enabling the institute to verify – as part of its duty to keep the inventory of ionising radiation sources up to date – that the orders are in conformity with the licenses of both the user and the supplier. If the order is correct, the transfer is then recorded by IRSN, which notifies the interested parties that delivery can take place. If there is any difficulty, the transfer is not validated and IRSN refers the case to ASN (see box).

Case of ionising radiation generators

ASN has been responsible for the oversight of these devices since 2002, devices for which numerous administrative compliance actions are required. In 2018, it granted 150 licenses and 289 license renewals for the use of X-ray generators. ASN also issued 435 notification acknowledgements for devices emitting ionising radiation in 2018.

A total of 2,333 licenses and 5,005 notification acknowledgements have been delivered for devices emitting ionising radiation since 2002. Graph 7 illustrates this trend over the past five years.

Administrative tracking of radioactive sources

Articles R. 1333-154, 156 and 157 of the Public Health Code provide for prior registration by IRSN of transfers of radioactive sources and Article R. 1333-158 for administrative tracking of these sources.

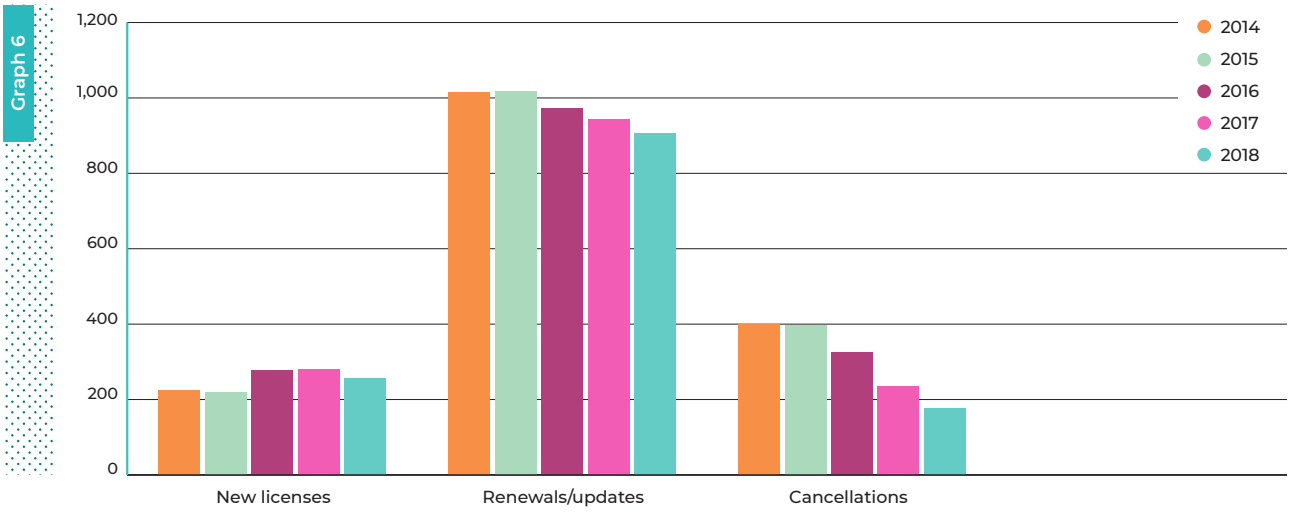
ASN resolution 2015-DC-0521 of 8 September 2015 relative to the tracking and methods of registering radionuclides in the form of radioactive sources and products or devices containing them details the methods of registering transfers and the rules for tracking radionuclides in the form of radioactive sources.

This resolution, applicable as of 1 January 2016, takes into account the existing practice 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.

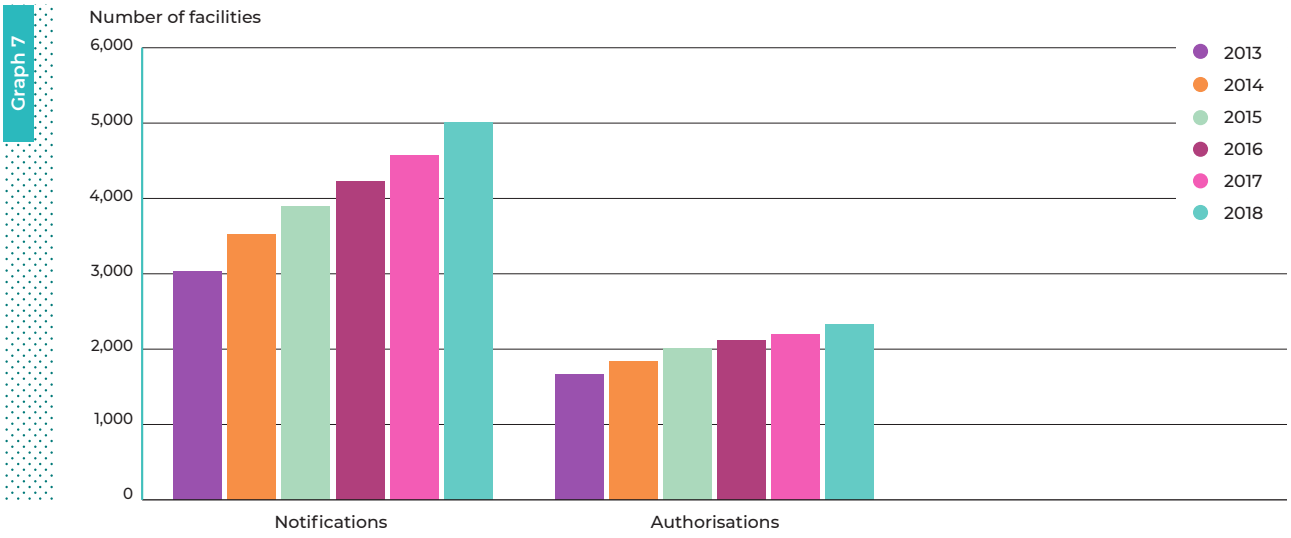
Radioactive source "user" licenses issued each year

Graph 6



"User" licenses and notifications acknowledgement issued for electrical devices generating radiation

Graph 7



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 with 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 source, 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, 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 adiography 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 replace gamma radiography devices if the utilisation conditions 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, with 100 inspections per year in this area on average (excluding inspections in BNIs).

The ASN inspectors perform their inspections by observing the practices in the field; half the inspections in this area are unannounced inspections on worksites which generally take place at night (in 2018, 54 inspections took place in agencies and 52 on worksites).

The system of on-line notification of worksite schedules for industrial radiography contractors put in place by ASN in 2014 facilitates the organisation of these inspections. ASN notes that virtually all the licensees concerned generally use this system for the worksite notifications. This being said, the reliability of the transmitted information is still variable. The points to improve concern in particular:

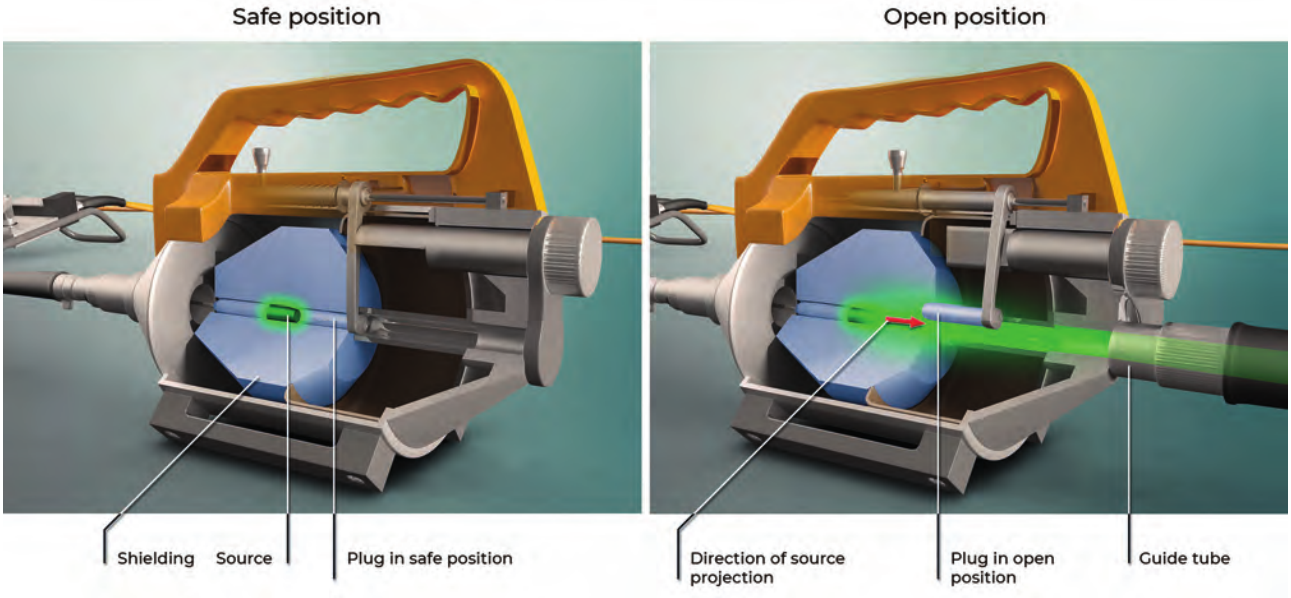
- the updating of schedules when changes are made;
- the accuracy of the worksite location information (not to be confused with the address of the ordering company);
- the completeness of the worksite notification.

From its inspection findings, ASN considers that the way risks are taken into account varies between companies. The risks of incidents and the doses received by the workers are generally well controlled by the licensees when this activity is conducted in a bunker in conformity with the applicable regulations.

Selenium-75 gamma radiography

The use of selenium-75 in gamma radiography has been authorised in France since 2006. Implemented in the same devices as those functioning with iridium-192, selenium-75 offers significant radiation protection advantages in gamma radiography. The reason for this is that equivalent dose rates are about 55 millisieverts (mSv) per hour and per TBq one metre from the source, as opposed to 130 mSv/h/TBq for iridium-192. In France, about 19% of portable devices are equipped with selenium-75 sources. Although the use of selenium has been increasing constantly since 2014, ASN considers that it is still insufficiently used by the industry professionals. Yet it can be used in place of iridium-192 in numerous industrial fields, especially the petrochemical or boilermaking industry, and it enables the safety cordoned-off area to be significantly reduced and facilitates intervention in the event of an incident.

Operating schematic of a gamma ray projector



ASN notes that the companies comply with the regulatory obligations with respect to the radiation protection advisor (only 6% of the licensees did not have one during the inspections performed in 2018) and the frequency of the verifications by a radiation protection organisation or IRSN (less than 10% of deviations noted). The inspectors also noted that worker dosimetric monitoring was satisfactory.

Conversely, ASN still considers the deficiencies in cordoning off the work zones on worksites to be cause for concern. Cordoning off was noncompliant in more than one inspection in four carried out under worksite conditions in 2018.

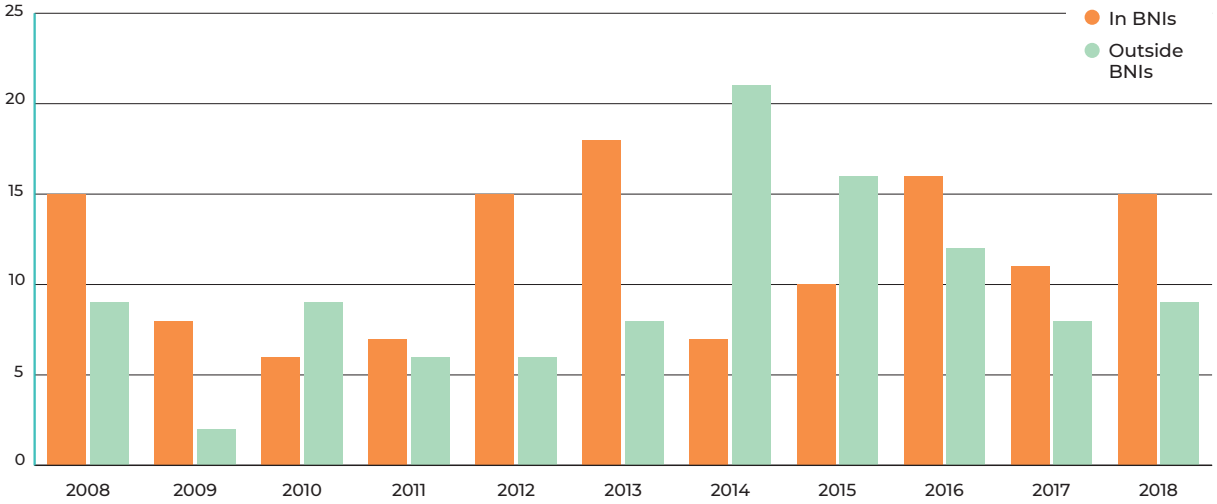
ASN points out that the work area must be cordoned off before the work begins and, in all events, before the radiography equipment is installed. To ascertain that cordoning off ensures compliance with the regulatory dose rate values, it is vital to take at least one measurement and to record the result. Cordoning off must be continuous and signal lights must be provided in sufficient quantity. Zoning is effectively the main safety barrier in worksite configurations, particularly to prevent incidental exposures.

ASN has also noted that the shortcomings observed in occupational radiation protection training might be one of the probable causes of the observed deviations. The radiation protection training must be provided before the workers are likely to be exposed, and must be refreshed regularly (and at least every three years) taking into account all the particularities of the company (radiation protection organisation, protection against malicious acts, safety procedures and instructions, collective and personal protective equipment, etc.). One inspection out of three in 2018 found deficiencies in the organisation of training for new employees.

With regard to application of the principles of justification and optimisation, the long-term reflections undertaken by the non-destructive inspection professionals have resulted in guidelines which aim to promote the use of alternative methods to industrial radiography. The work is continuing within the professional bodies, in particular with the updating of the construction and

Trend in the number of industrial radiography events reported to ASN

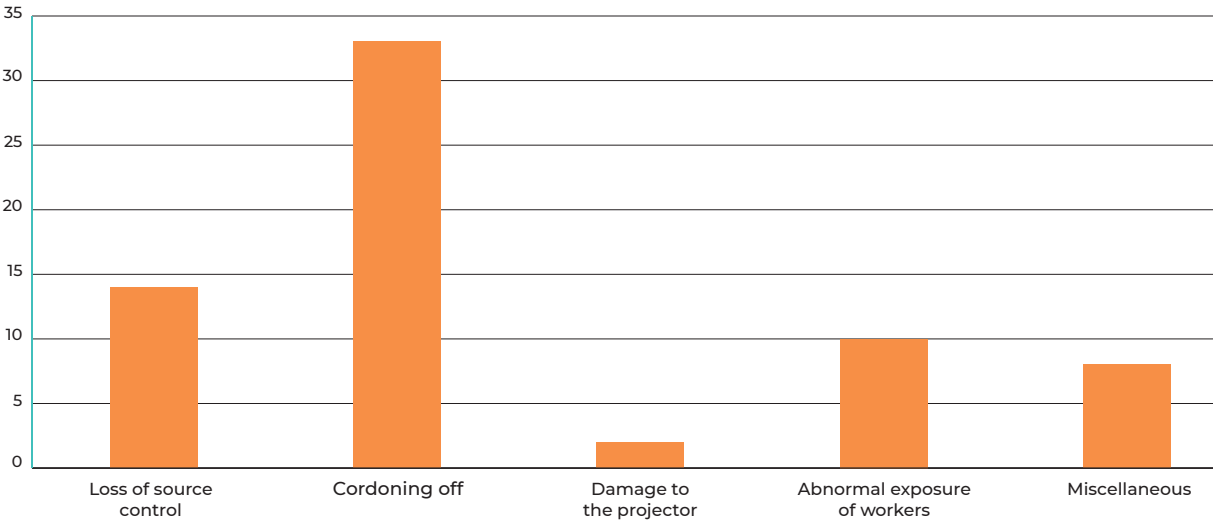
Graph 8



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.

Main causes of industrial radiography events reported to ASN over the 2016-2018 period

Graph 9



Gamma radiography: serious accidents abroad

The number and consequences of gamma radiography accidents in France have remained limited since March 1979, when a worker had to have a leg amputated after having picked up a 518 GBq source of iridium-192 and put it in his pocket. This incident had led to a tightening of the regulations in effect at the time. ASN keeps a watchful eye for accidents occurring abroad which have had major deterministic effects. Recent examples brought to ASN's attention include:

- In 2016, in Turkey, the operators had apparently not verified that the source had returned to the safe position after using a gamma ray projector. A 16-year old adolescent found the source the day after the inspection and took it home where several persons said they handled it. 20 people in all were reportedly exposed, with most severely exposed person reportedly receiving a dose of 1 gray (Gy). This event was rated level 2 on the INES scale.
- In 2015, in Iran, two operators were exposed to effective doses of 1.6 and 3.4 gray (Gy) respectively. The gamma ray projector source (iridium-192 of 1.3 TBq) became disconnected and remained blocked in the guide tube without the operators realising it. The operators then spent the night in their vehicle near the guide tube and the source.
- In 2014, in Peru, an employee was exposed to 500 mSv whole body and 25 Gy on the left hip when he moved a guide tube and a collimator without realising that the source was disconnected from the remote control cable and had remained in the collimator (iridium-192, 1.2 TBq, 30 minutes of exposure).
- In 2013, in Germany, an employee of a non-destructive testing company was exposed to more than 75 mSv whole body and 10 to 30 Gy at the extremities (hands) while attempting to release a source from a guide tube.
- In 2012, a Peruvian employee was admitted to Percy hospital in Clamart following exposure of 1 to 2 Gy (whole body) and of 35 Gy to the hand (70 Gy at the fingertips) after handling a guide tube with his bare hands, without first checking the position of the source.
- In 2011, 5 Bulgarian workers were admitted to Percy hospital in Clamart for major treatment following irradiation of 2 to 3 Gy owing to an error in the handling of a gamma ray projector, from which they believed the source had been removed.
- In 2011, in the United States, an apprentice radiographer disconnected the guide tube, noticed that the source was protruding from the source applicator and tried to push the source into the device with his finger. The estimated dose received at the extremities is 38 Gy.

maintenance codes for industrial equipment, in order to promote the use of non-ionising inspection methods.

ASN considers that the ordering customers have a key role to play in ensuring progress in radiation protection in industrial radiography. Through its 2018 inspections, ASN has noted that the drafting of occupational risk prevention plans with the user companies needs to be improved. This shortcoming shows that worksite preparation is not always commensurate with the risks of the 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 events which are attracting growing interest from the actors of this professional branch.

According to the survey carried out by ASN in the sector, 70% of the industrial radiography agencies have a specialised fixed facility (bunker) and 70% of the agencies also operate in "worksite" configuration. 50% of the industrial radiography tests performed are in worksite configuration. In this configuration, devices with iridium-192 sources are the most commonly used, representing two-thirds of the worksites. X-ray generators are mainly used on the other worksites. Very few non-destructive tests are conducted outside bunkers using particle accelerators or gamma ray projectors with cobalt-60 or selenium-75. The worksites are primarily located in industrial units and processes and in BNIs.

The large proportion of radiography work carried out in worksite configuration in industrial workshops suggests that the principle of justification is not sufficiently applied because, in many cases, the parts could very probably have been transferred to a protected bunker for inspection.

Since the noteworthy incidents that occurred in the early 2010's concerning blocked industrial gamma radiography sources, the stakeholders and IRSN have looked into defining, on the basis of experience feedback, typical loss of source control scenarios, developing the technical retrieval solutions and defining good practices in the event of a loss of control incident. Generic technical solutions to facilitate the retrieval of gamma radiography sources following loss of control (see box p. 247) have been identified. Several specific tools have been designed and implemented by the supplier for this purpose.

It should be noted that in 2018, for the first time, no incident was rated level 1 or above on the INES scale. A relatively large number of significant events are still linked to loss of control of the source when using a gamma ray projector. Nevertheless, 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 have not yet all been identified. Nevertheless, the worksite work conditions (difficult access, work at height, night work, etc.) and the maintenance of the equipment (spotlights and accessories) were contributory factors in at least two source jamming events that occurred in 2018.

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.

Actual example of loss of control of a source during gamma radiography work at the SOBEGI chemical plant in Lacq (Pyrénées-Atlantique *département*)

Early on the night of 26 July 2018, a gamma radiography source jamming incident occurred at the SOBEGI chemical plant in Lacq, in the Pyrénées-Atlantique *département*. The radiography work was carried out by the company TENEO, using a GAM80 gamma ray projector loaded with a selenium-75 source of 2.247 TBq. The selenium source remained jammed a few centimetres from the projector, at a height of 4 metres on outdoor scaffolding. The jamming was correctly identified by the operator. The operators of the device immediately put new cordoning off means in place and alerted the site safety officers. The ASN on-call team was contacted during the night of 26 to 27 July *via* the toll-free emergency number provided for that purpose.

The configuration of the gamma ray projector, situated at height and outdoors on a narrow platform, made the safeguarding operations difficult. Two intervention protocols were thus necessary and developed successively by ACTEMIUM (the device manufacturer) in collaboration with TENEO (the user company), then authorised by ASN.

A safety perimeter was set up and placed under surveillance and permanently guarded throughout the duration of the event, that is to say for 17 days. The surface occupied by this perimeter hindered other work scheduled by the plant operator. An organisation dedicated to this event was therefore put in place and the ASN Bordeaux division organised regular conference calls with all the companies involved. ASN inspectors also performed an unannounced inspection on the site to check the adequacy and the surveillance of the cordoned-off area.

The doses received by all the workers concerned by this event were satisfactorily controlled, with the collective dose remaining below 500 man-µSv.

The *in situ* examination of the equipment showed that jamming was caused by the presence of a stone in the remote control guide tube, at the connection between the source holder and the remote control cable.

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 can also be used to modify the properties of materials, such as for the hardening of polymers.

These consumer product irradiation techniques can be authorised because, after being treated, the products display no residual artificial radioactivity (the products are sterilised by passing through radiation without themselves being "activated" by the treatment).

Industrial irradiators often use cobalt-60 sources, whose activity can be very high and exceeds 250,000 terabecquerels (TBq). Some of these installations are classified as BNIs (see chapter 12). In many sectors, X-ray generators are gradually replacing high-activity sealed sources for the irradiation of products (see point 1.3.1).

3.2.2 _ The radiation protection situation

BNIs excluded, ASN carried out five inspections in this area in 2018 at 16 licensed installations. These inspections show that the radiation protection organisation (in particular the appointing of a radiation protection advisor) and the 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 of the files submitted with the licensing applications. In addition to this, no significant radiation protection events were reported in 2018.

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 megaelectronvolt (MeV).

When they meet the characteristics specified in Article 3 of Decree 2007-830 of 11 May 2007 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 pool of particle accelerators, whether linear (linacs) or circular (synchrotrons), comprises about 60 listed installations (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 conditions in order to comply with the radiation protection rules applicable to workers and the public, in particular:

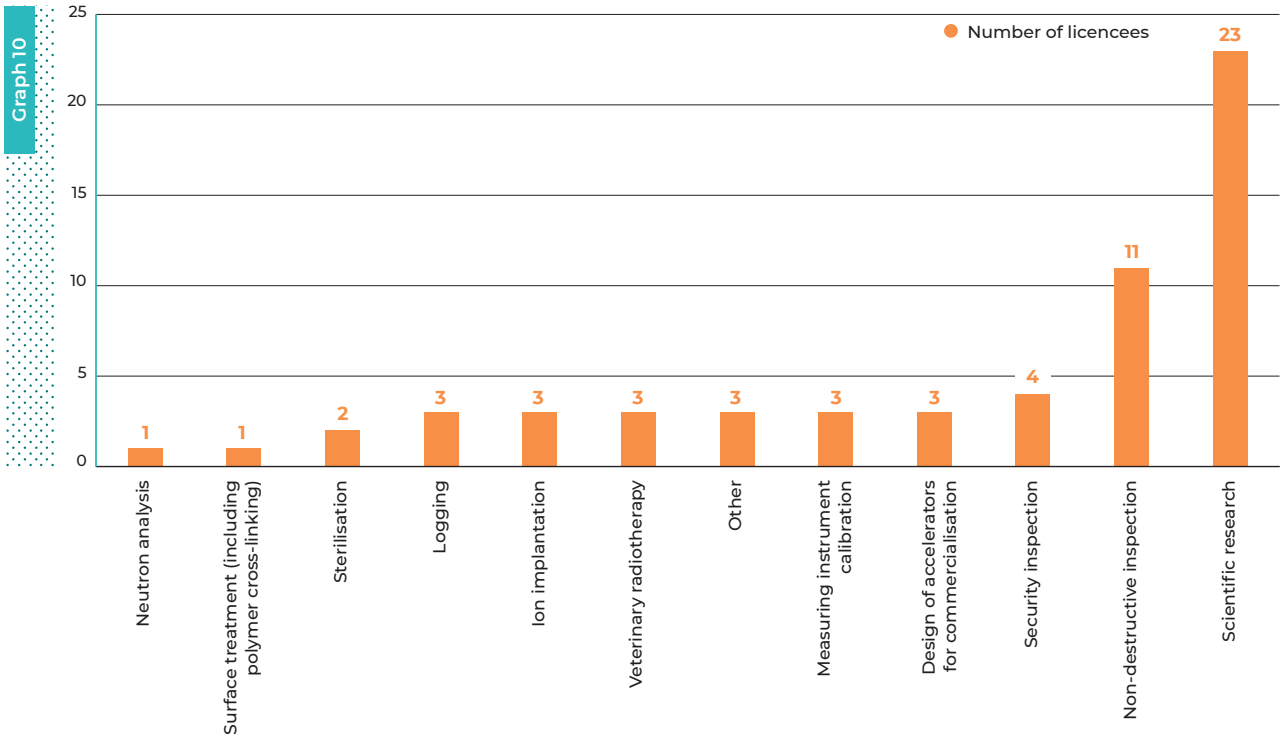
- A ban on activation of construction products, consumer goods and foodstuffs as specified by Article R. 1333-2 of the Public Health Code, by ensuring that the maximum energy of the particles emitted by the accelerators used excludes any risk of activation of the materials being verified.
- A ban on the use of ionising radiation on the human body for purposes other than medical.

Synchrotrons

The synchrotron is a member of the same family of circular particle accelerators 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.

- 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 thus prohibited in France. During customs inspections of trucks using scanner technologies, 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.

Distribution of particle accelerators by end-use



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.

12 centres equipped with these devices were inspected by ASN in 2018 (i.e. 20% of the national pool).

ASN considers the radiation protection situation in the centres using these devices to be satisfactory on the whole. In effect, the main 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 concerned.

Nevertheless, the inspections carried out in 2018 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 nonconformities detected during these checks;
- the presence of an unlocking device which can be actuated from inside the rooms in which particle accelerators are used.

Lastly, with regard to experience feedback, no significant radiation protection event was reported to ASN in 2018, 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 committed doses of just a few µSv.

3.4 _ Research activities involving unsealed radioactive sources

3.4.1 _ The devices used

In the research sector, as at 31 December 2018, ASN counts more than 700 licenses delivered under the Public Health Code, of which 90% are delivered to public or mixed (public/private) structures. The majority of these institutions and laboratories use unsealed sources for medical and biomedical research, molecular biology, the agri-food industry and the sciences of matter and materials, etc. The can also be suppliers of unsealed sources. They also use sealed sources for performing gas-phase chromatography, liquid scintillation counting or in irradiators. X-ray generators are also used for X-ray fluorescence and X-ray diffraction spectroscopy. Particle accelerators are used in research into matter or for the manufacture of radionuclides.

3.4.2 _ The radiation protection situation

In 2018, ASN carried out 53 inspections in this sector (46 inspections per year on average over the 2016-2018 period). Generally speaking, the steps taken in the last few years have brought improvements in the implementation of radiation protection in research laboratories thanks to enhanced overall awareness of radiation protection issues.

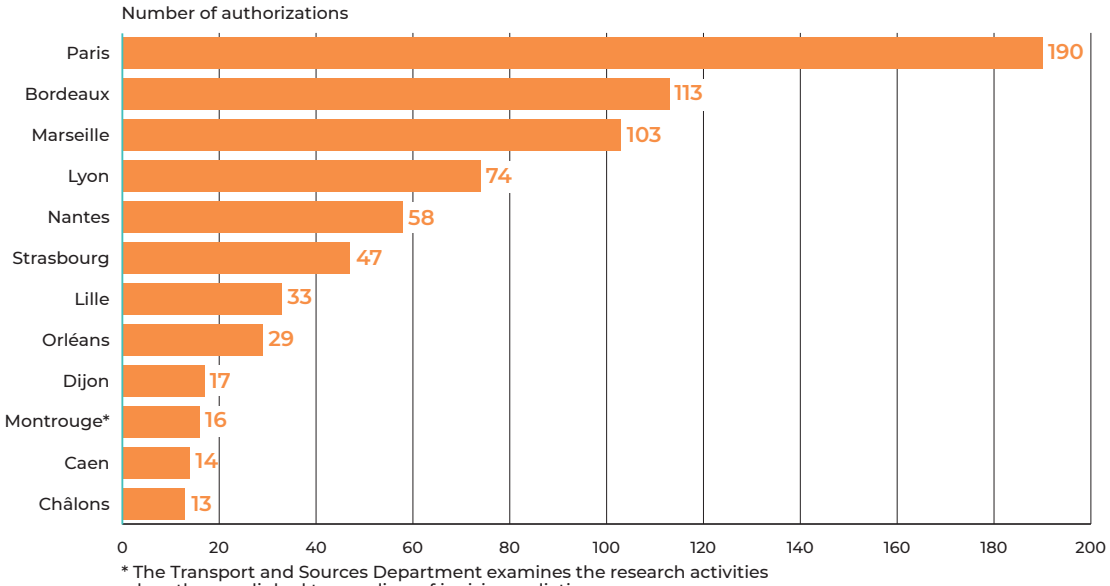
The most notable improvements concern the conditions of waste and effluent storage, particularly the setting up of pre-disposal checking procedures. ASN nevertheless remains particularly attentive in this respect, especially given the reporting of several Significant Radiation protection Events (ESR) in 2018 (see Graph 12).

ASN has also observed strong involvement of the Radiation Protection Advisors (RPA) with the research teams, resulting in radiation protection being better taken into account in operations involving ionising radiation sources.

ASN has identified areas for improvement, particularly regarding the classification of people working with ionising radiation, which is usually overestimated by the employers, and the non-systematic implementation of systems for recording ESRs.

Distribution over the French territory, according to the ASN entity responsible for licensing, of institutions authorised to used unsealed radioactive sources in the research sector

Graph 11



* The Transport and Sources Department examines the research activities when they are linked to suppliers of ionising radiation sources.

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 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 medical schools should also be noted. Particle accelerators are used in research into matter or for the manufacture of radionuclides.

ASN will be particularly attentive to this latter point in the future inspections of research centres.

The technical, economic and regulatory difficulties concerning the disposal of old sealed sources are still brought up by the licensees 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 the original supplier.

ASN is continuing its collaboration with the IGAENR (General Inspectorate of the National Education and Research Administration), which has competence for labour inspection in the public research sector. An agreement signed in 2014 provides for mutual information sharing to improve the effectiveness and complementarity of the inspections. An annual meeting is held to assess the functioning of this collaboration. In 2018, the first inspection conducted jointly with the IGAENR inspectors provided the opportunity to compare inspection practices.

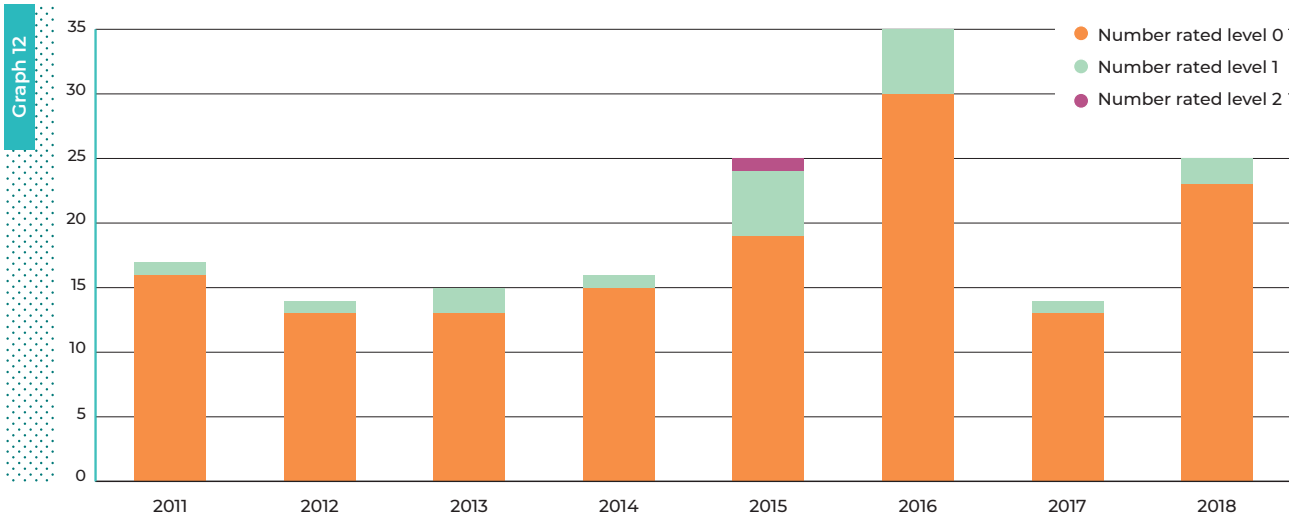
ASN notes a lack of systematic recording and analysis of events that could lead to accidental or unintentional exposure of people to ionising radiation. 35% of the inspected structures do not have a system for recording and analysing these events. In 2018, ASN recorded 25 ESRs concerning research activities, which is 10 more than in 2017.

The reported significant events are of three main types:
- theft or loss of radioactive sources (21%);
- discovery of sources (25%);
- the unauthorised discharging of radionuclides into the environment or waste disposal *via* the wrong route (17%).

The predominance of the first two causes of ESRs tallies with findings made for the 2014-2016 period. The losses and discoveries of sources can be explained in particular by poor overall traceability: 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 the wrong 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.

Trends in the number of events reported to ASN in the research sector



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 of sources with significant business, and among them, 33 low and medium-energy cyclotrons that are currently licensed under the Public Health Code in France.

4.2 – Cyclotrons

• Functioning

As at 31 December 2018, 30 cyclotrons were in operation. Among these, 17 are used exclusively for the daily production of radiopharmaceuticals, 6 are used for research purposes and 7 are used 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 is the subject of a complete examination by ASN. The main radiation protection issues on these facilities must be considered as of the design stage. Application of 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.

The 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.

As a result of the activity discharged and the short half-life of the radionuclides discharged in gaseous effluents,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 work which involved both IRSN and the licensees, served to establish general principles on gaseous effluent discharges in 2018, the salient points of which will be taken up in a draft regulatory text (see below). This work will continue in 2019 with updated assessments of the impact of discharges from facilities situated near residential areas.

Cyclotrons

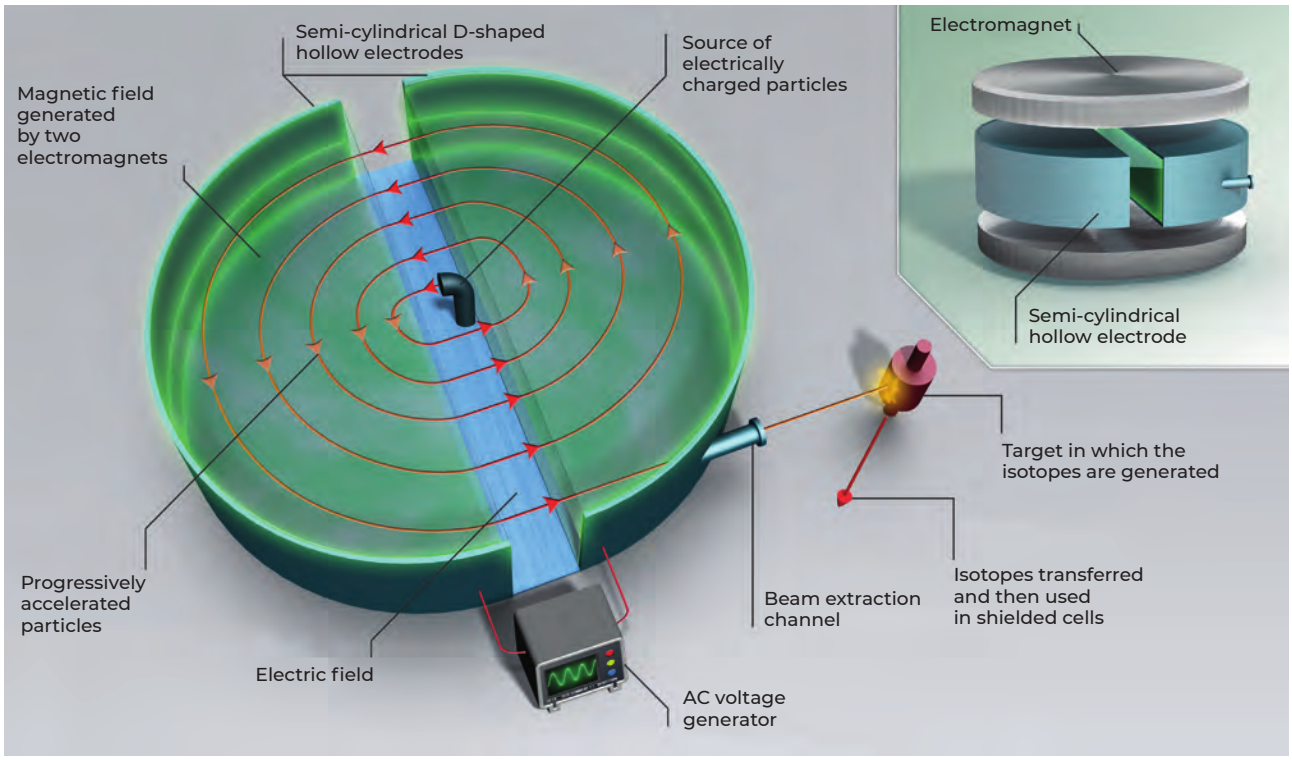
A cyclotron is a device 1.5 to 4 metres in diameter, belonging to the circular particle accelerator family. The accelerated particles are mainly protons, with energy levels of up to 70 MeV. A cyclotron consists of two circular electromagnets producing a magnetic field and between which there is an electric field, allowing the rotation of the particles and their acceleration at each revolution. The accelerated particles strike a target which is activated and produces radionuclides.

Low and medium energy cyclotrons are primarily used in research and in the pharmaceutical industry to produce positron emitting isotopes, such as fluorine-18 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. Their utilisation is however still limited due to their very short half-life.

The approximate levels of activities involved for the fluorine-18 usually found in pharmaceutical facilities vary from 30 to 500 GBq 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



ASN performs about ten inspections at facilities of this type each year. Matters relating to radiation protection and safe and correct operation of cyclotrons and production platforms receive particular attention during the inspections. The scope of the inspections performed includes – apart from the aspects relating to radiation protection – management of internal events, monitoring and maintenance of the production equipment, inspection of the surveillance and control systems and the gaseous discharge results. The radiation protection organisation of these facilities is satisfactory and staff are familiar with the regulations. National action plans have been put in place by the licensees and are monitored by ASN in order to ensure continuous improvement of radiation protection and safety in these facilities.

No significant radiation protection events were reported to ASN in 2018.

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.

A cyclotron in Guadeloupe

This is the first cyclotron equipped with a Positron Emission Tomography (PET) scanner in the Caribbean.

On 30 August 2017, after 11 months of examinations, ASN issued the Molecular Imaging Centre of the Guadeloupe (CIMGUA) a license to possess and use a cyclotron of 12 MeV (final energy of the accelerated particles). A PET scan camera also installed in the CIMGUA allows optimised performance of medical examinations, as the radiopharmaceuticals are produced and available on site (*in situ* technology).

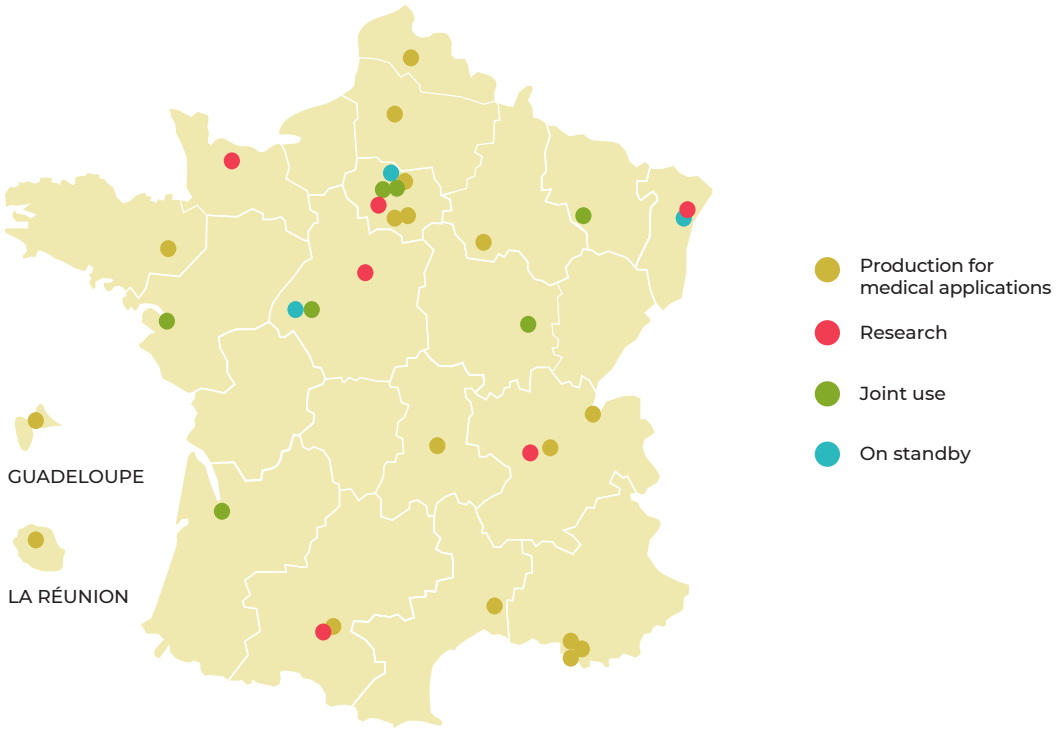
ASN has provided regulatory advice to the CIMGUA during the licensing procedures and has followed project progress from the file examination phase through to finalisation of construction of the facility. Regular situation reviews were held between ASN, IRSN and the CIMGUA, particularly to validate the technical solutions proposed by the licensee.

This is effectively the first time a cyclotron of this type, whose key characteristic is its compactness, is used on French territory.

The CIMGUA started to use the cyclotron on the first patients in 19 June 2018, after an on-site inspection by ASN.

The ISOTRACE cyclotron in its bunker

Location of cyclotrons in France



This second version of this draft will likewise be subject to consultation by the stakeholders in 2019. The conclusions of these initial works are nevertheless already used in the ASN examination of the license application and to set license conditions.

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 wish to distribute in France.

In 2018, 29 inspections of suppliers of sources other than cyclotrons were conducted at manufacturers/distributors of sealed and unsealed sources, companies involved in the removal of ICSDs, companies recovering lightning conductors and companies maintaining X-ray generators (although they do not yet have a distribution license, the utilisation of these devices is regulated, including the maintenance operations carried out by the companies that sell them).

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 example the 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 in these companies to be satisfactory on the whole. The large majority of the licensees concerned meet the main requirements and assume their responsibilities (verifications prior to supply, technical verifications of the supplied sources, setting up the source recovery streams, transmission of information to IRSN) adequately.

Nevertheless, the inspections carried out in 2018 also revealed points requiring particular attention, including in particular:

- the ability of the suppliers to fully and exhaustively 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 years administrative limit counting from the date of the 1st registration figuring on the IRSN supply form) are not identified sufficiently far in advance, which slows down the recovery procedure;
- the ability of the suppliers to ascertain beforehand, and particularly for unsealed sources, that the delivery of a source will not lead to the customer's license limits being exceeded. This has led to the reporting of some significant radiation protection events.

It should be noted that the national indicators deployed in 2018 will have been applied to nearly all the suppliers with safety-significant business (excluding cyclotrons) at the end of 2020, thereby enabling this assessment to be supplemented.

5 Conclusion and outlook

• Implementation of new administrative systems governing nuclear activities

In 2018, with the aim of stepping up its graded approach to oversight, ASN updated the resolution setting the list of nuclear activities subject to notification by extending this system to the use of certain sealed radioactive sources, such as those used for the detection of lead in paint. In line with this objective, ASN in 2019 will prepare the draft resolution relative to the registration system newly established for nuclear activities by Decree 2018-434 of 4 June 2018 laying down various provisions concerning the nuclear field. It will be based on its previously established classification nomenclature for the various categories of nuclear activities using ionising radiation sources. This resolution will define more specifically the content of the simplified license application and the general conditions licensees must comply with in the exercise of the nuclear activity.

• Overseeing the protection of radioactive sources against malicious acts

Since 2017, ASN has been the designated authority 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, for their transfer, and for access to sensitive information. These provisions shall be subject to verifications during the inspections in 2019 and must henceforth be documented in the license application. Security requirements shall be gradually detailed and be implemented according to upcoming regulations. To this end, ASN and its institutional partners will in 2019 continue preparation of the Ministerial Order necessary for operational implementation of the general requirements to protect radioactive sources against malicious acts and preparation to ensure their oversight.

ASN has moreover continued the actions it has undertaken to keep ahead with its staff training and the development of appropriate tools to efficiently embrace this new mission. Several training sessions have already been organised in 2017 and 2018. The training work will continue in 2019. Furthermore, ASN will adapt the tools it uses for the oversight of radiation protection (content of license applications, associated forms, publication of guides for the professionals and inspectors, provisions relative to the inspections and the reporting of malicious acts, etc.) as and when the requirements of the upcoming Ministerial Order enter into effect. It will also ensure that targeted and regular communication actions are directed towards those in charge of the activities concerned.

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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. It is based on stringent international regulations.

1 Radioactive substances traffic

The regulations divide the dangerous goods liable to be transported into nine "classes" according to the nature of the corresponding risk (for example: explosive, toxic, flammable). Class 7 covers radioactive substances.

The transport of radioactive substances stands out through its considerable diversity. Packages of radioactive substances can weigh from a few hundred grams up to about a hundred tons and the radiological activity of their content can range from a few thousand becquerels to billions of billions of becquerels for the packages of spent nuclear fuel. The safety 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.

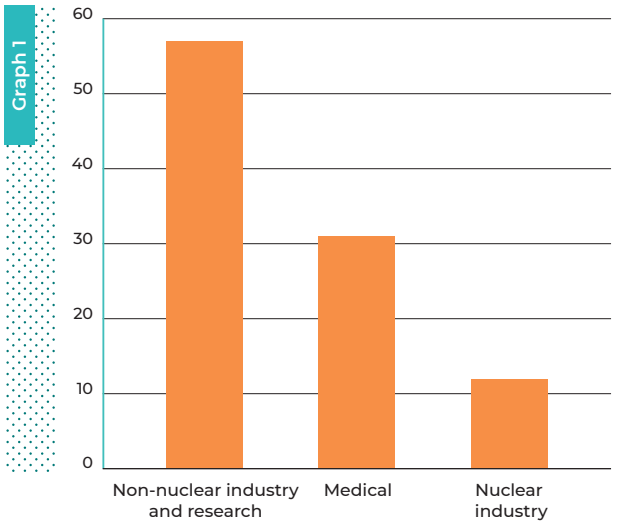
About one third of the packages transported are used in the medical sector: this involves providing health care centres with radioactive sources, for example sealed sources used in radiotherapy, or radiopharmaceutical products, and removing the corresponding radioactive waste. The activity of radiopharmaceutical 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 NPPs around the country (see map below). Depending on the step in the cycle, the physicochemical form and radiological activity of the substances varies widely. The transport operations with very high safety implications are shipments of uranium hexafluoride (UF_6) whether or not enriched (dangerous more specifically owing to the toxic and corrosive properties of the hydrogen fluoride formed by UF_6 in contact with water), the spent fuel shipments to the La Hague reprocessing plant and the transport of certain nuclear wastes. The annual transports linked to the nuclear industry can be broken down approximately as follows:

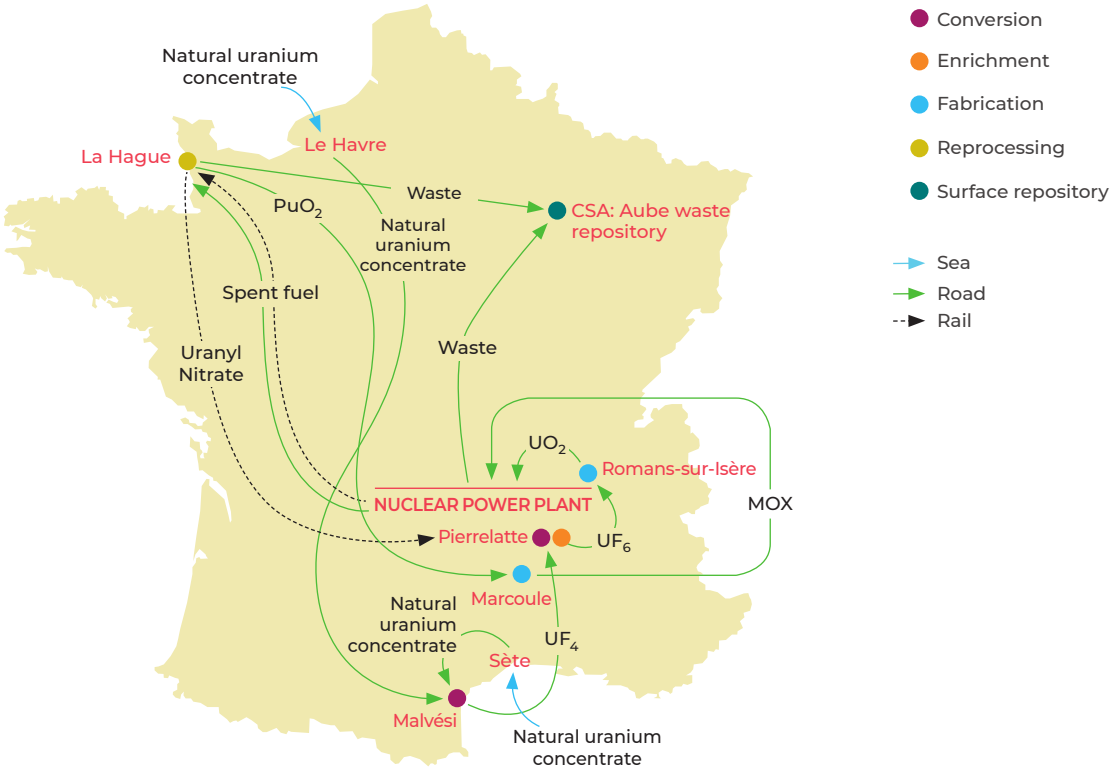
- 200 shipments transporting spent fuel from the nuclear power plants operated by EDF to the Orano reprocessing plant at La Hague;
- about 100 shipments of plutonium in oxide form between the La Hague reprocessing plant and the MELOX fuel production plant in the Gard *département*;
- 250 shipments of uranium hexafluoride (UF_6) used for fuel fabrication;

Proportion of packages transported per field of activity in %

Graph 1



Transport operations relating to the fuel cycle in France



Breakdown per mode of transport (rounded figures)

Table 1

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

- 400 shipments of fresh uranium-based fuel and some 50 shipments of fresh uranium and plutonium-based "MOX" fuel;
- 2,000 shipments from or to foreign countries or transiting *via* France, representing about 58,000 packages shipped (industrial, 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 (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*[1].

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);

1. *www.asn.fr/Informer/Actualites/Enquete-de-l-ASN-sur-les-flux-de-transport-de-substances-radioactives (ASN survey on radioactive substances traffic)*

- the risk of inhalation or ingestion of radioactive particles in the event of release of radioactive substances out of the packaging;
- contamination of the environment in the event of a release of radioactive substances;
- the onset of an uncontrolled nuclear chain reaction (criticality risk) that can cause serious irradiation of persons. This risk only concerns fissile substances.

Radioactive substances can also present a chemical risk. This, for example, is the case with shipments of natural uranium with low radioactivity, for which the major risk for humans is related to the chemical nature of the compound, more particularly if it is ingested. Similarly, uranium hexafluoride, used in the manufacture of fuels for nuclear power plants can, in the case of release and contact with water, form hydrofluoric acid, a powerful corrosive and toxic agent.

By their very nature, transport operations take place across the entire country and are subject to numerous contingencies that are hard to control or anticipate, such as the behaviour of other vehicles using the same routes. A transport accident at a given point in the country cannot therefore be ruled out, possibly in the immediate vicinity of the population. Unlike events occurring within Basic Nuclear Installations (BNI), the personnel of the companies concerned are generally unable to intervene immediately, or even 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 implementation 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 severe 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 qualification tests. They must nevertheless comply with some general specifications, notably with regard to radiation protection, to guarantee ensure that the radiation around the excepted packages remains very low.

2.3.2 _ Type A packages and industrial packages containing non-fissile substances

Type A packages can, for example, be used to transport 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 1m.

Additional tests are required if the content of the package is in liquid or gaseous form.

Industrial packages allow the transportation of material with a low specific activity, or objects with limited surface contamination. Uranium-bearing materials extracted from foreign uranium mines are, for example, carried in France in industrial drums with a capacity of 200 litres loaded into industrial packages. Three sub-categories of industrial packages exist according to the risk presented by the content. Depending on their sub-category, the industrial packages are subjected to the same tests as type A packages, some of the tests or only the general provisions applicable to excepted packages.

As a result of the restrictions on the authorised contents, the consequences of 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 issues, type A and industrial packages are not subject to ASN approval: the design of the packages and the performance of the tests are the responsibility of the manufacturer. These packages and their safety 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 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 9m drop test onto an unyielding target. The fact that the target is unyielding means that all the energy from the fall is absorbed by the package, which is highly penalising. If a heavy package actually falls onto real ground, the ground will deform and thus absorb a part of the energy. A 9m drop onto an unyielding target can thus correspond to a fall from a far greater height onto real ground. This test can also be used to simulate the case of the vehicle 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 file. This demonstration is usually provided by means of tests on a reduced-scale mock-up representing the package and by numerical calculations (to simulate the mechanical and thermal behaviour, or to evaluate the criticality risk).

Breakdown of transported packages by type

Table 2

TYPE OF PACKAGE		APPROXIMATE SHARE OF PACKAGES TRANSPORTED ANNUALLY
Packages approved by ASN	Type B packages, packages containing fissile materials and packages containing UF_6	2%
Packages not requiring approval by ASN	Type A packages not containing fissile radioactive substances	32%
	Industrial packages not containing fissile radioactive substances	8%
	Excepted packages	58%

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 30B 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 millisievert (mSv) per year. However, this limit is not intended to be an authorisation to expose the public to up to 1mSv. Moreover, the justification and optimisation principles applicable to all nuclear activities also apply to the transport of radioactive substances (see chapter 2).

Radiation protection is the subject of specific requirements in the regulations applicable to the transport of radioactive substances. Thus, for transport by road, the regulations stipulate that the radiation at the surface of the package must not exceed 2 mSv/h. This limit may be raised to 10 mSv/h in "exclusive use" conditions[2], because the consignor or consignee can then issue instructions to restrict activities in the vicinity of the package. In any case, the radiation should not exceed 2 mSv/h in contact with the vehicle and should be less than 0.1 mSv/h at a distance of 2 metres from the vehicle. Assuming that radiation at the surface of a transport vehicle reaches the limit of 0.1 mSv/h at 2 metres, a person would have to spend 10 consecutive hours at a distance of 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): 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.

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 2019, to take account of the new 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 2019, it will continue with measures to educate professionals, dealing more specifically with changes to the regulations.

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 "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.

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.

2. 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.

2.4.3 _ 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 prescriptions concerning them have been satisfied. It must more specifically take dose rate measurements on the package after receipt in order to detect any problems that may have occurred during shipment.
- The package owner must set up a maintenance system in conformity with that described in the safety 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 assurance 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 assurance system is a key element in ensuring the reliability of transport operations.

The regulations also require that all operators involved in transport receive training appropriate to their functions and responsibilities. This training must in particular cover the steps to be taken in the event of an accident.

Contractors who carry, load, unload or handle (after loading and before unloading) packages of radioactive substances on French soil shall declare themselves to ASN.

The transport of certain radioactive substances (notably fissile substances) must first by 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 2018, 1,388 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.

In this respect, the regulations set obligations on the various stakeholders in the field of transport. All those involved must therefore immediately alert the emergency services in the event of an accident. This is more particularly true for the carrier, who would in principle be the first party to be informed. It must also transmit the alert to the consignor. Furthermore, the vehicle crew must have written instructions available in the cab, stipulating the first steps to be taken in the event of an accident (for example, trip the circuit-breaker, if the vehicle is so equipped, to prevent any outbreak of fire). Once the alert has been given, the parties involved must place themselves at the disposal of the public authorities to assist with the response operations, more specifically by providing all pertinent information in their possession. This in particular concerns the carrier and the consignor who have information about the package and its contents that is of great value for determining the appropriate measures to be taken. To meet these regulatory obligations, ASN recommends that the parties

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 orange-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.

involved implement 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 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, 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, or the mobile units of certain nuclear licensees (such as CEA or EDF), which could be requisitioned by the Prefect if necessary, even if the shipment in question does not concern these licensees.

As with other types of emergency, communication is an important factor in the event of a transport accident so that the population can be informed of the situation and given instructions on what to do.

In order to prepare the public authorities for the eventuality of an accident involving a shipment of radioactive substances, exercises are held to test the entire response organisation that would be put into place. ASN will continue in 2019 to work towards achieving a satisfactory level of preparedness by the public authorities for emergency situations involving a transport operation, in particular by promoting the performance of local emergency exercises and issuing recommendations on the steps to be taken in the event of an accident.

Finally, ASN intends in 2019 to update the guide on the performance of risk assessments required for transport installations able to accommodate dangerous goods. The purpose of this guide is to ensure that the risks linked to radioactive substances are correctly assessed, to enable the licensees to define any pertinent measures needed to reduce them, under the supervision of the Prefect. It will also tie in with the assessments of the consequences of an external hazard on a high-risk package, carried out as part of the stress tests performed in the wake of the accident at the Fukushima Daiichi NPP (Japan) 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 regulation package design criteria cannot be ruled out. For packages carrying the most dangerous contents, the consequences for the above-mentioned interests could be significant.

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 ofthe transport personnel and exercises or simulations.

• 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 drafted a document to help direct the actions of the emergency services. It contains general information about radioactivity, general recommendations for the emergency services so that their response can take account of the specific nature of radioactive substance transports, plus sheets organised per type of substance, providing more detailed information and advice for the emergency response coordinator during phase 2.

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 highways.

Since 1 July 2013, these transport operations have 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 on-site transport of dangerous goods presents the same risks and inconveniences as the transport of dangerous goods on the public highway. Their safety must be overseen with the same rigour as for any other risk or inconvenience present within the perimeter of the BNI.

In 2017, ASN published Guide No. 34 providing the licensees with recommendations for implementing the regulatory requirements concerning on-site transport operations. In 2018, ASN also authorised the new general rules for the on-site transport of dangerous goods within the installations of the French Alternative Energies and Atomic Energy Commission (CEA).

Given that certain BNI licensees have not yet incorporated on-site transport operations into their general operating rules, ASN will continue its actions with regard to these licensees in 2019.

3 — Roles and responsibilities in regulating the transport of radioactive substances

3.1 — Regulation of nuclear safety and radiation protection

In France, ASN has been responsible for regulating the safety and the radiation protection of transports of radioactive substance for civil uses since 1997, while ASND (the Defence Nuclear Safety Authority) fulfils this role for transports relating to national defence. Within its field of competence, ASN is responsible, in terms of safety and radiation protection, for the regulation and oversight of all steps in the life of a package: design, manufacture, maintenance, shipment, actual carriage, receipt 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.

In 2019, ASN intends to update its resolution 2015-DC-0503 of 12 March 2015 relative to the notification system for companies transporting radioactive substances on French territory. This update aims to introduce an authorisation system for the transport of the highest activity sealed sources, in the light of their safety and security implications. ASN will ensure satisfactory interfacing with the provisions established in the future regulations on the protection of ionising radiation sources and batches of category A, B, C and D radioactive sources against malicious acts 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 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 (CITMD – Interministerial Hazardous Materials Transport Committee) that is consulted for its opinion on any draft regulations relative to the transport of dangerous goods by rail, road or inland waterway. Inspections in the field are carried out by land transport inspectors attached to the Dreals (Regional Directorates for the Environment, Planning and housing).

For the regulation of dangerous goods to be as consistent as possible overall, ASN collaborates regularly with the authorities concerned. In 2019, ASN will take part in the training of DGAC (General Directorate for Civil Aviation) staff responsible for inspecting the 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 kg of UF_6 must be covered by an ASN transport approval. The designers of the package models who request approval from ASN must support their application with a safety case demonstrating the compliance of their package with all the regulatory requirements. Before deciding whether or not to issue approval, 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 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 GPT met on 8 November 2018 to examine the safety of the new DN 30 package model developed by the DAHER NUCLEAR TECHNOLOGIES GmbH company for the transport of uranium hexafluoride (UF_6), enriched to 5% with ^{235}U, obtained from natural uranium or reprocessed uranium, between the uranium enrichment plants and the nuclear fuel fabrication plants. The DN 30 is a new overpack containing a 30B cylinder filled with enriched UF_6, providing mechanical and thermal protection during the regulation tests. The design of the DN 30 significantly improves safety with respect to existing 30B cylinder overpacks which have been on the market for decades.

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).

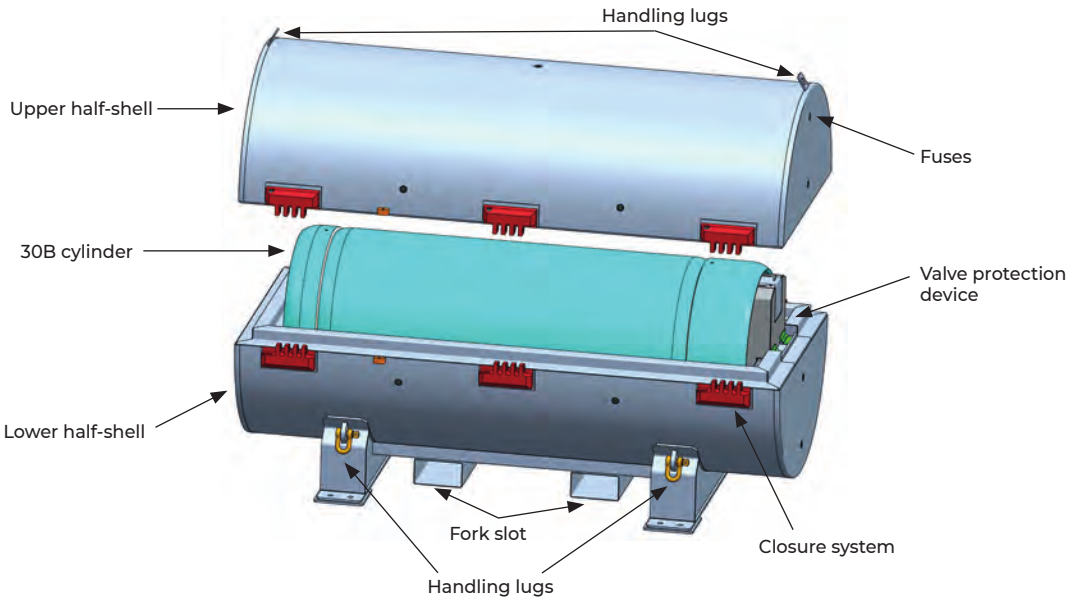
These approval certificates are usually issued for a period of five years.

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 9-metre drop, a compensatory measure may be to reduce the speed of the vehicle and have it escorted. The probability of a serious accident (and thus of a violent shock on the package) is thus considerably reduced. A shipment under special arrangement is only possible with the approval of the competent authority, which then issues approval for shipment under special arrangement, stipulating the compensatory measures to be applied.

In the case of certificates issued abroad, the international regulations provide for their recognition by ASN. In certain cases, this recognition is automatic and the foreign certificate is directly valid in France. In other cases, the foreign certificate is only valid if validated by ASN, which then issues a new certificate. In 2018, 50 approval applications were submitted to ASN by the manufacturers.

ASN delivered 37 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 certificates is shown in Graph 3.

In 2018, TN International began development work on a new packaging designed for exclusive land and sea transport of spent fuel assemblies, as well as for their interim storage. In 2019, ASN will give conclude its review of 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.



New DN 30 packaging

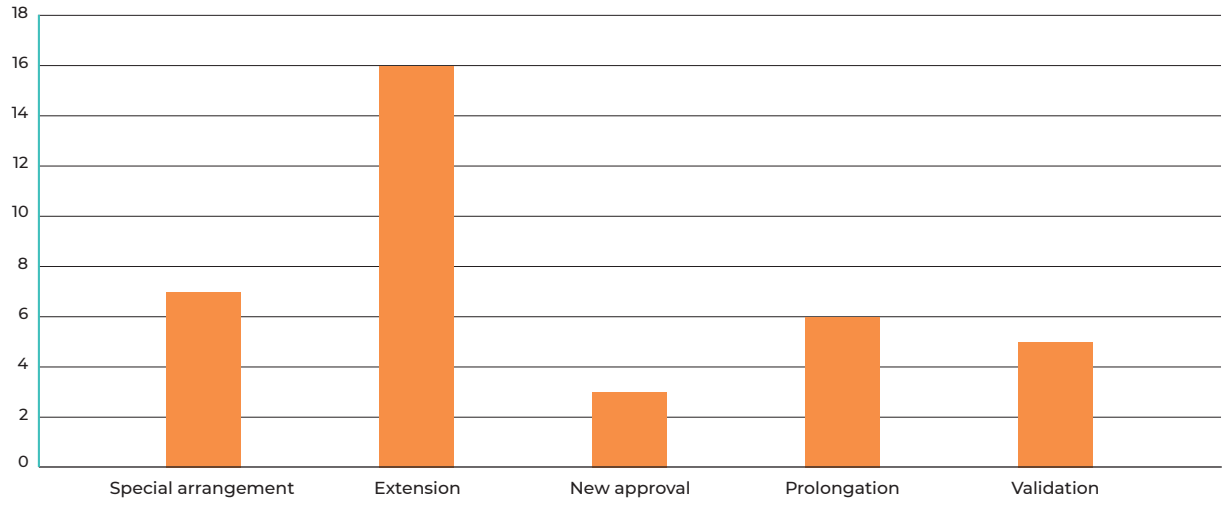
Administrations responsible for regulating the mode of transport and the package

Table 3

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.

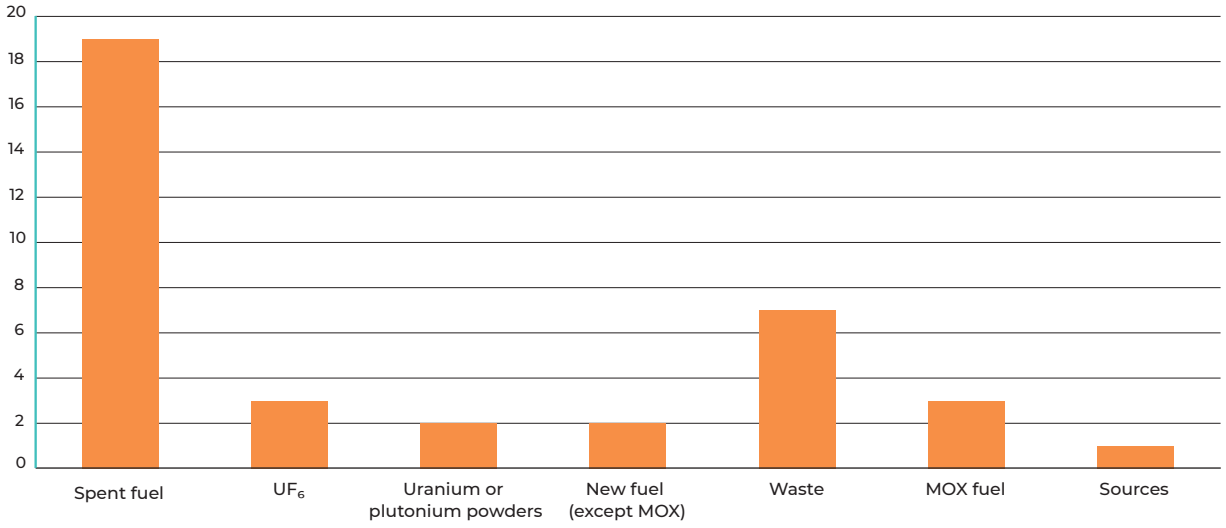
Breakdown of number of approvals according to type, in 2018

Graph 2



Breakdown of number of approvals according to content transported, in 2018

Graph 3



Certificate of approval for the TN G3 package

In 2018, ASN issued an approval certificate for the new TN G3 package model developed by TN International (subsidiary of Orano). This new model will, by 2025, be replacing the TN 12/2 and TN 13/2 packagings currently authorised for the transport of spent fuels from EDF's NPPs to the Orano reprocessing plant at La Hague. Because they do not have a double tightness barrier, these packagings do not actually meet all the requirements applicable since the 2012 edition of the IAEA regulations (SSR-6).

New TN G3 packaging

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 2018, ASN carried out 109 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 assurance system covering all the operations from procurement of parts and materials up to final inspections. Furthermore, the manufacturer must be able to prove to ASN that it complies with the regulatory provisions and, in particular, that the packagings manufactured are compliant with the specifications of the safety case.

The inspections carried out by ASN in this field aim to ensure that the manufacturer satisfactorily fulfils its responsibilities.

In 2018, ASN carried out five 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. For example, on 25 September 2018, ASN inspected the manufacture in China of twenty-five 30B cylinders used to transport UF_6. The inspectors examined how Orano Cycle, the ordering customer, monitored its subcontractors.

ASN inspection on the Orano Cycle site at Tricastin, concerning the maintenance of packagings loaded with UF_6 – September 2018

During these inspections, ASN checks the quality assurance procedures implemented for the manufacturing of a package 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 traceable. It also visits the manufacturing shops to check the package components storage conditions, the calibration of the inspection instruments and compliance with the technical procedures at the various manufacturing steps (welding, assembly, etc.).

ASN checks the monitoring of package manufacturing by the lead contractor and may intervene directly on the sites of any subcontractors, who may sometimes be located abroad.

ASN may also inspect the manufacture of the specimens used for the regulation drop tests and fire tests. The objectives are the same as for the series production model because the specimens must be representative and comply with the maximum requirements indicated in the mock-up manufacturing file, which will determine the minimum characteristics of the actual packaging to be manufactured.

In 2019, ASN intends to continue spot-check inspections of transport packaging manufacturing. This is because the irregularities detected at the Creusot Forge plant, which more particularly affected a few transport packagings, highlighted the importance of checking 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 of 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 2018, ASN carried out three inspections on the conformity of maintenance operations. For example, on 6 June 2018, ASN examined the maintenance carried out on the R73 packagings intended for the transport of contaminated and activated waste. The ASN inspectors more particularly examined the organisation put into place by Robatel Industries 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 certificate delivered by the manufacturer attesting full compliance with the model specifications, must be held at the disposal of ASN.

The various inspections carried out in recent years confirm the progress made concerning the documents presented to ASN and the implementation of the ASN recommendations detailed in its guide concerning packages which are not subject to approval (Guide No.7, volume 3).

In 2016, ASN published the updated version of this guide. The guide proposes a structure and a minimum content for the safety 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 certificate 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 that some of the players (designers, manufacturers, distributors, owners, consignors, companies performing the regulatory drop tests, package maintenance, etc.) display shortcomings in the demonstration of package conformity with the regulations. The areas for improvement focus in particular on the following:

- the description of the authorised contents per type of package;
- the demonstration that there has been no loss or dispersion of the radioactive content under normal 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 limits with the maximum authorised content.

In 2018, 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 marketed under the name of the ARPACK company with the regulations for the transport of radioactive substances. These packages are of the industrial type (IP) or type A, as defined by the regulations. They are used to transport, among others, contaminated items. During the inspection, the company marketing these packages was unable to present the safety cases corresponding to the package models currently used and was unable to justify that the safety case for the new ARPACK package model was able to fully demonstrate its safety. If the consignor is unable to prove the compliance of the packages used with the regulations, they are not authorised to transport radioactive substances. ASN therefore asked the company which leases and supplies packages of the ARPACK range to identify all the package models currently used and not covered by a conformity certificate or safety case compliant with ASN requirements and to implement an action plan, duly detailed and substantiated in the light of the corresponding safety issues, to remedy this situation. ASN also asked for details on the steps taken to inform the owners and users of the packages lacking a safety case demonstrating full compliance with the regulatory requirements.

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 2019, ASN will therefore continue its efforts regarding the monitoring of package models not requiring approval.

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 small-scale nuclear activities, the ASN inspections confirm significant disparities from one transport operator to another. Among the observations or inspection findings, the most frequent discrepancies concern quality assurance, actual implementation of established procedures and worker radiation protection.

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, nor have the responsibilities of each member of staff involved in receiving and dispatching packages. Moreover, 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.

Finally, chocking and stowing defects are still found during gamma ray projector transport inspections.

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. This demonstration is sometimes carried out by a third-party company. The consignor's responsibilities require that, at the least, it verify that this demonstration exists and is sufficient, and that it monitor the third-party company in accordance with the usual methods of a quality assurance system.

ASN has moreover observed that an increasing number of BNI licensees are using contractors to prepare and ship packages of radioactive substances. ASN is particularly attentive to

Inspection of shipment of spent fuels from a research reactor in Australia to the Orano site at La Hague

In September 2018, the ASN inspectors went to the port of Cherbourg to inspect an arriving ship carrying four containers, each holding a TN MTR package of spent fuel, as well as a container of contaminated tools. They inspected the hold of the ship before the containers were offloaded. They more particularly checked the good condition and stowage of the packages, as well as the required distances between them. They questioned the captain of the vessel and examined the loading plan, the ship's radiological protection plan, the applicable emergency measures and the crew training and awareness-raising sessions carried out. The inspectors then attended the offloading of the packages from the vessel and their loading onto trailers for transport by road. They examined the handling means used and checked the compliance of the vehicles, the signage and the labelling, as well as the qualification of the drivers.

They also checked the measurement means and the qualifications of the operators in charge of radiological measurements on behalf of the consignor. Before the vehicles left, the inspectors examined the transport documents to verify the traceability of package conformity since their departure.

The inspectors also had IRSN personnel carry out dose equivalent rate and contamination measurements on a package, on the containers and on a trailer. The results obtained confirmed compliance with the applicable regulatory limits.

In the light of this examination, the inspectors considered that the safety of the transport operations and its organisation were satisfactory.

the licensee's organisation set up for the monitoring of these contractors.

Finally, ASN considers that the NPPs must maintain their level of vigilance to ensure compliance with package stowage rules for on-site transport operations.

4.2.5 _ Oversight of preparedness for emergency management

In order to reinforce the preparedness of the transport operators (mainly consignors and carriers) for emergency management, ASN published Guide No. 17 in December 2014 on the content of accident and incident management plans concerning the transport of radioactive substances. This guide recommends the drafting of plans to prepare for emergency management and stipulates their minimum contents.

In order to check correct application of this guide, ASN carried out an inspection in 2018 at Actemium – a supplier of gamma ray projectors –on the topic of preparedness for emergency situations. The inspectors in particular examined the organisation in place, the material and human resources available, personnel training and the emergency exercises held.

4.2.6 _ Analysis of transport events

The safety of the transport of radioactive substances 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 require that ASN must be notified of the most important events so that it 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. The ASN guide was entirely revised in 2017 and is available for consultation on *asn.fr*. After notification, a detailed event report must be sent to ASN within two months.

• Events notified in 2018

In 2018, with regard to the transport of radioactive substances, ASN was notified of 88 INES level 0 events and 3 INES level 1 events. Graph 4 shows the trend in the number of significant events notified since 2001.

In addition, ASN was notified of 30 events of lesser importance (Events of Interest for the safety of Transport – EIT). Given that they have no actual or potential consequences, these events are not rated on the INES scale (International Nuclear and Radiological Event Scale). There is thus no obligation to notify ASN of them, although ASN nonetheless wishes to be kept periodically informed in order to have an overview of the various events of lesser importance and detect any accumulation or any trends which could be indicative of a problem.

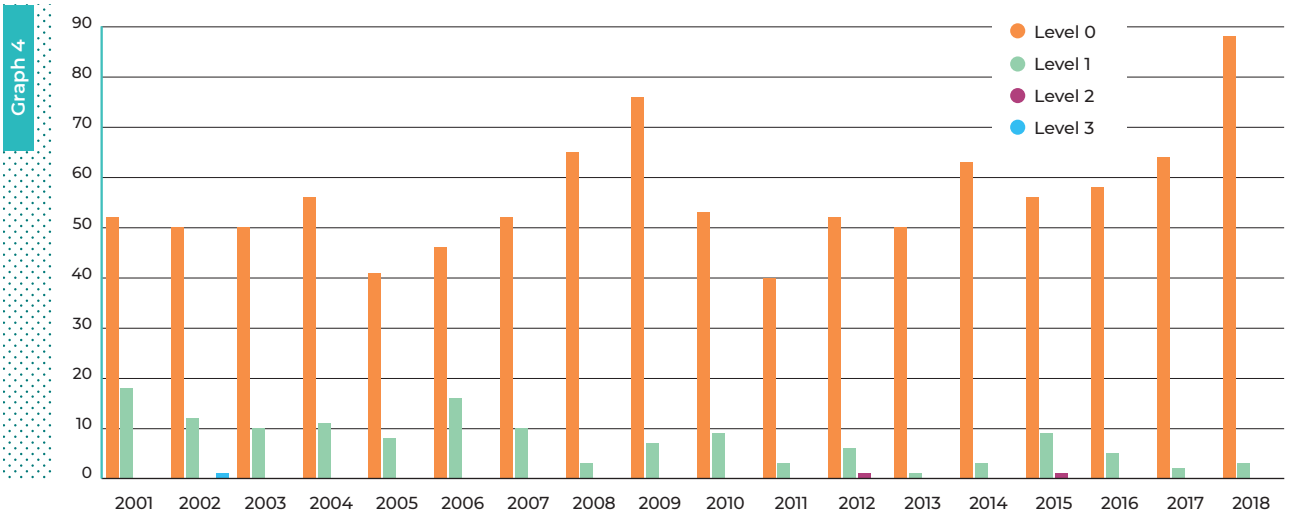
• Sectors concerned by these events

More than half of the significant events notified concern the nuclear industry. More than one quarter concerns radioactive pharmaceutical products. The other events concern transport related to non-nuclear industrial activities (gamma radiography for example).

When compared with the transport traffic concerned, the non-nuclear industry and medical sectors still report few transport-related events. This low ratio can be explained by a lack of understanding of the process and of the purpose of event notification. However, ASN observes a significant rise in the number of events notified in 2018 by comparison with previous years, as a result of ASN's communication efforts with the 2017 publication of its Guide No. 31. With the deployment of its on-line services portal, ASN is also expecting to see a further improvement in the notification ratio in these sectors by comparison with previous years.

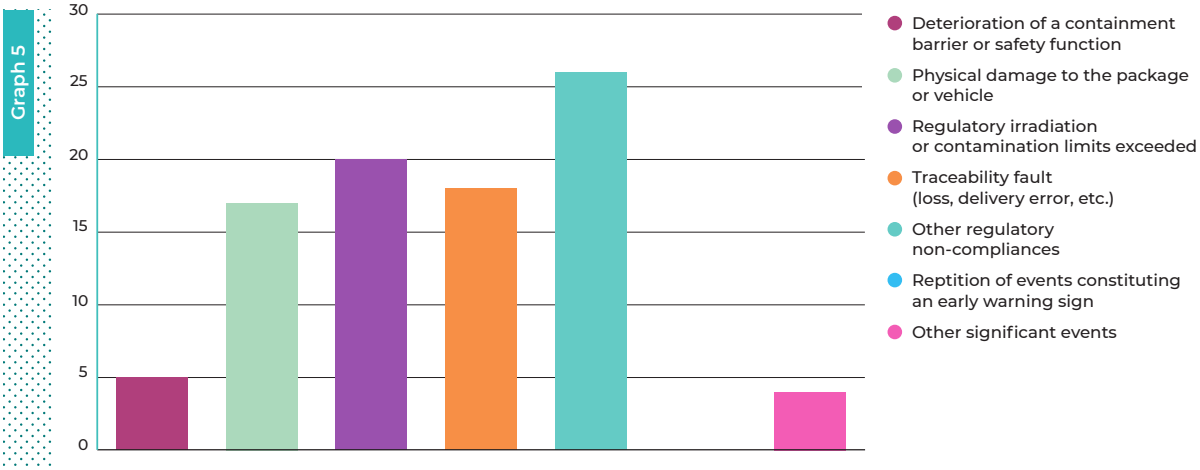
Trend in the number of significant events affecting the transport of radioactive substances notified between 2001 and 2018

Graph 4



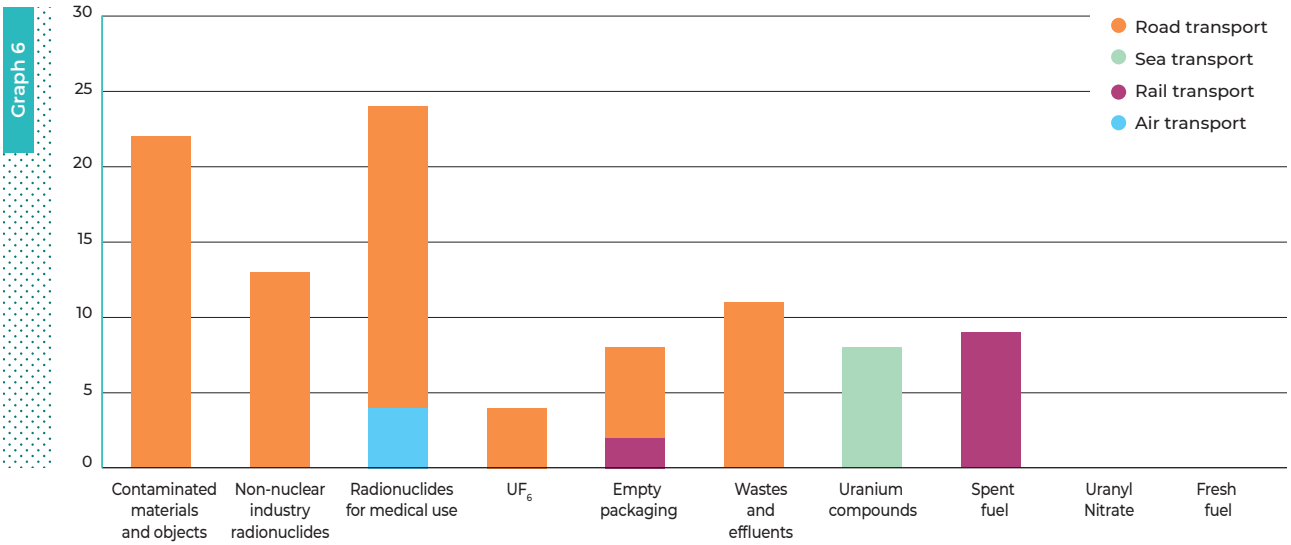
Breakdown of significant events notified in 2018 by notification criterion

Graph 5



Breakdown of notified transport events by content and mode of transport in 2018

Graph 6



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Modification of the TMD Order: remote-notification of 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 on-line services portal will also be extended during the course of 2019 to the notification of on-site transport events of dangerous goods within Basic Nuclear Installations (BNI).

Notification of an event as stipulated in the guide does not take the place of the obligation of immediately alerting ASN to any emergency situation.

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.

ASN observes that about 80% of EIT are reported by nuclear industry players, with few reports from players in the medical and non-nuclear industry sectors by comparison with the transport traffic concerned. ASN does however point out that notification of EITs is not a regulatory obligation.

• Causes of events

The causes of the significant events notified and requiring particular vigilance on the part of ASN include the following:

- material non-conformities affecting a package: use of inappropriate containment seals, loosening of screws during transport, periodic maintenance date exceeded, non-performance of a pre-departure tightness test, etc. These events had no actual consequences for safety or radiation protection. However, in the event of an accident, a non-conformity can impair the robustness of the package;
- the shipment of packages containing radioactive substances, without notification, as well as delivery errors or packages being temporarily mislaid;
- the packaging of radiopharmaceutical products and medical sources in inappropriate packagings;
- non-compliance with internal procedures, leading to the shipment of non-conforming packages (for example, container door not properly locked) or with inappropriate labelling;
- the presence of contamination spots exceeding the regulation limits. The impact of these events on radiation protection is low, because the contamination spots were present on the drums containing the ore, which are themselves carried inside closed metal containers. By comparison with 2017, the situation improved for packages of uranium ore from the mines, as the shipment procedures had themselves been improved.

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 the presence of foreign bodies that are larger or of a different nature could lead to radiolysis or criticality phenomena in certain conditions. ASN therefore requested that the licensees exercise particular vigilance regarding the procedures for loading of 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 Transport Safety Standards Committee (TRANSSC) which, under the auspices of the International Atomic Energy Agency (IAEA), brings together experts from all the countries in order to draw up the founding document for regulations concerning the transport of radioactive substances. With the aim of ensuring continuous improvement in the level of safety, ASN more particularly played an active part in drafting the new 2018 edition of this document, entitled "*Specific Safety Requirements – 6*" (SSR-6).

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 (Interministerial Hazardous Materials Transport Committee) that is consulted for its opinion on any draft regulations concerning the transport of dangerous goods by rail, road or inland waterway. ASN is also consulted by the Ministry responsible for Transport when a modification of the three Orders mentioned above can have an impact on the transport of radioactive substances. In 2018, ASN thus issued two opinions on draft orders modifying the Orders of 23 November 1987 and 29 May 2009.

The regulatory framework for the protection of radioactive substances against malicious acts, excluding nuclear materials which are dealt with separately, will be developed in 2019. ASN will ensure that appropriate attention is given to their transport, during which the substances are particularly vulnerable.

4.4 _ Contributing to public information

Ordinance 2012-6 of 5 January 2012, modifying Books I and V of the Environment Code, extends the public information obligations to the persons responsible for nuclear activities. It is Article L. 125-10 of the Environment Code that sets the threshold beyond which the person responsible for transport must communicate the information requested by a citizen. The thresholds are defined as being those "*above which, in application of the international conventions and regulations governing the transport of dangerous goods, of the Code of Transport and of 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 progress in the level of safety of radioactive substance transports, and encourages exchanges with its counterparts in other States.

4.5.1 _ Work of the European Association of Competent Authorities on transport

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.

ASN hosted the 14th EACA meeting on 23 and 24 May 2018, in Montrouge. Fifteen countries were represented. The agenda included the procedures for transposing Directive Euratom 2013/59 laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation, the content of package approval requests and approval certificates, the regulatory framework for cylinders transporting UF_6 and changes to the regulations internationally.

4.5.2 _ Bilateral relations with ASN's foreign counterparts

ASN devotes considerable efforts to maintaining close ties with the competent authorities of the countries concerned by the numerous shipments to and from France. Prominent among these are Germany, Belgium, the United Kingdom and Switzerland.

• Germany

In 2016, the French and German Authorities decided to meet regularly to discuss a range of technical subjects. ASN also participates in two Franco-German technical committees concerning the programme for returning German spent nuclear fuel reprocessing waste. A new package is currently being designed in Germany for the transport of compacted waste. The German safety regulator thus informs ASN of the progress being made in the technical review of the approval application. Once issued, the approval certificate will have to be validated by ASN so that the package model can be used in France.

• Belgium

For its production of electricity from nuclear power, Belgium more particularly uses French-designed packagings 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 examination of safety cases for French package models for which approval is validated in Belgium and inspection practices in each country. In 2018, the Belgian and French authorities carried out a joint inspection of a carrier.

• 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 a good level of communication between the two Authorities.

• Switzerland

ASN began bilateral exchanges on transports with the Swiss Federal Nuclear Safety Inspectorate (IFSN) in 2012. ASN and IFSN have decided to meet annually in order to discuss the packaging model safety cases and the checks on the requirements associated with the correct utilization of these transport packages.

The 14th EACA meeting being held at ASN head offices

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EDF Nuclear Power Plants

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CHAPTER 10

EDF Nuclear Power Plants

Nuclear power reactors are at the heart of the nuclear industry in France. Many other installations described in the other chapters of this report produce the fuel intended for NPPs or reprocess it, are used for disposal of the waste produced by NPPs, or are used to study the physical phenomena related to the operation and safety of these reactors.

The French reactors are technologically similar to each other and form a standardised fleet operated by *Électricité de France* (EDF). Although this standardisation enables the licensee and ASN to acquire extensive experience of their operation, it does entail an increased risk in the event of a generic design, manufacturing, or maintenance fault being detected on one of these facilities, which could affect all the reactors. ASN thus requires a high degree of responsiveness on the part of EDF and considerable rigorousness when analysing the generic nature of these faults and their consequences for the protection of people and the environment, as well as when processing them.

ASN exercises particularly strict oversight of nuclear safety, environmental protection measures and radiation protection in the NPPs and adapts it continuously, more particularly on the basis of operating experience feedback relating to the design, manufacture, operation and maintenance of the nuclear power reactor components. Monitoring the safety of the reactors in service, under construction and planned for the future, is the daily task of around 200 members of ASN staff working in the Nuclear Power Plant Department (DCN), the Nuclear Pressure Equipment Department (DEP) and the regional divisions. It also calls on the services of some 200 experts from the Institute for Radiation Protection and Nuclear Safety (IRSN).

ASN is developing an integrated approach to facilities monitoring. It intervenes at all stages in the life of the nuclear power reactors, from design up to decommissioning and delicensing. Through its expanded scope of intervention it examines the fields of nuclear safety, organisational and human factors, environmental protection, radiation protection, occupational safety and the application of labour laws, at all stages in the life of the NPP reactors. For each of these fields, it monitors all aspects, whether technical, organisational, or human. This approach requires that it take account of the interactions between these fields and that it define its regulation and oversight actions accordingly. The resulting integrated view allows ASN to develop a finer appreciation of the state of nuclear safety, radiation protection, environmental protection and the protection of NPP workers.

1 — Overview of nuclear power plants

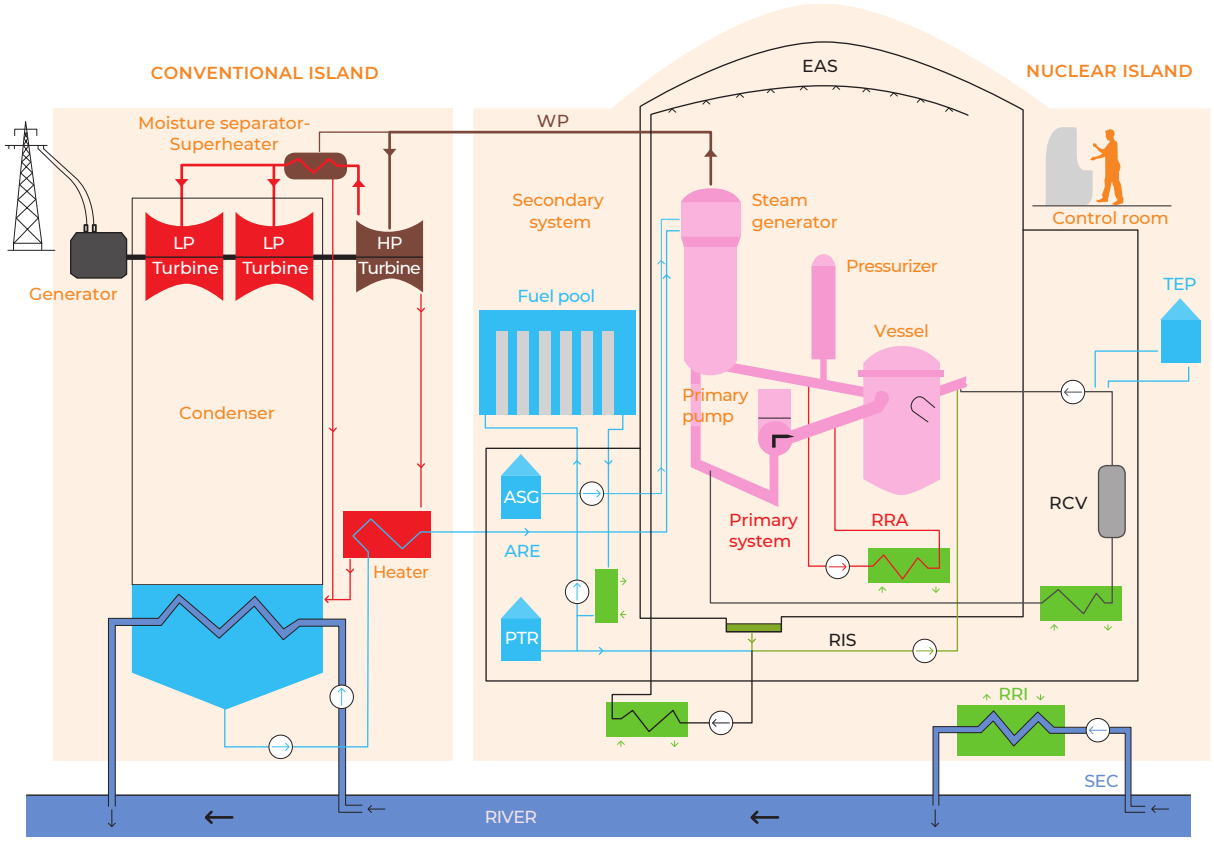
1.1 — General presentation of a pressurised water reactor

In routing heat from a heat source to a heat sink, all thermal electric power plants produce mechanical energy, which they then transform into electricity. Conventional thermal power plants use the heat given off by the combustion of fossil fuels (fuel oil, coal, gas). Nuclear plants use the heat resulting from the fission of uranium or plutonium atoms. The heat produced in a pressurised water reactor 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 river or an atmospheric cooling circuit. The condensed water is reused in the steam production cycle.

Each reactor comprises a nuclear island, a conventional island, water intake and discharge infrastructures and possibly a cooling tower.

The nuclear island mainly consists of the reactor vessel, the reactor coolant system, the steam generators and the circuits and systems ensuring reactor operation and safety: the chemical and volume control, residual heat removal, safety injection, containment spray, steam generator feedwater, electrical, I&C and reactor protection systems. Various support function circuits and systems are also associated with these elements: primary effluent treatment, feedwater, ventilation and air-conditioning, and backup electrical power (diesel generating sets).

The principle of pressurised water reactor operation



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

The nuclear island also comprises the systems removing steam to the conventional island as well as the building housing the new 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 equipment includes the turbine, the AC generator and the condenser. Some components of this equipment contribute to reactor safety. The secondary systems belong partly to the nuclear island and partly to the conventional island.

1.2 — Core, fuel and fuel management

The reactor's core consists of fuel assemblies in the form of "rods" comprising "pellets" of uranium oxide or oxides of depleted uranium and plutonium (known as MOX fuel) contained in closed metal tubes, referred to as the "cladding". As a result of fission, the uranium or plutonium nuclei, referred to as "fissile", emit neutrons which, in turn, produce further fissions: this is known as the chain reaction. These nuclear fissions release a large amount of energy in the form of heat. The primary system water enters the core from below at a temperature of about 285°C, heats up as it flows up along the fuel rods and exits through the top at a temperature close to 320°C.

At the beginning of the operating cycle, the core has a considerable energy reserve. This gradually falls during the cycle, as the fissile nuclei are consumed. The chain reaction, and hence reactor power, is controlled by:

- inserting control rod cluster assemblies, which contain elements that absorb neutrons, to varying depths in the core. This enables the reactor's reactivity to be controlled and its power adjusted to the required production of electricity. Dropping the control rod assemblies under the effects of gravity enables the reactor to be shut down in an emergency;
- adjusting the boron concentration (which absorbs neutrons) in the primary system water during the cycle as the fissile material in the fuel gradually becomes depleted;
- the presence of neutron-absorbing elements in the fuel rods which, at the beginning of the cycle, compensate the excess core reactivity after partial renewal of the fuel.

At the end of the cycle, the reactor core is unloaded for renewal of part of the fuel.

EDF uses two types of fuels in its Pressurised Water Reactors (PWR):

- uranium oxide based fuels (UO_2) with uranium-235 enrichment to a maximum of 4.5% by mass. These fuels are fabricated in several French and foreign plants, by Framatome and Westinghouse;
- fuels consisting of a Mixture of depleted uranium oxides and plutonium (MOX). The MOX fuel is produced by the Orano Melox plant. The maximum authorised plutonium content is currently limited to 9.08% (average per fuel assembly) and provides an energy performance equivalent to UO_2 fuel enriched to 3.7% with uranium-235. This fuel can be used in the twenty-eight 900 MWe reactors for which the Creation Authorisation Decrees (DAC) provide for the use of 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 used and its initial fissile content;
- the maximum degree of fuel depletion at removal from the reactor, characterising the quantity of energy extracted per tonne of material (expressed in gigawatt days per tonne – GWd/t);
- the duration of a reactor operating cycle;
- the number of new fuel assemblies loaded at each reactor refuelling outage (generally 1/3 or 1/4 of the total number of assemblies);
- the reactor operating mode (at constant power or by varying the power to match demand), which determines the loads to which the fuel is subjected.

1.3 — Primary system and secondary systems

The primary system and the secondary systems transport the energy given off by the core in the form of heat to a turbo-generator set which produces electricity.

The primary system consists of cooling loops, of which there are three for a 900 megawatt (MWe) reactor and four for the 1,300 MWe, 1,450 MWe or 1,650 MWe EPR type reactors. The role of the primary system is to extract the heat given off in the core by circulating pressurised water, referred to as the primary coolant or reactor coolant. Each loop, connected to the reactor vessel containing the core, comprises a circulating pump (known as the primary or reactor coolant pump) and a Steam Generator (SG). The primary water, heated to more than 300°C, is kept at a pressure of 155 bar by the pressuriser, to prevent it from boiling. The entire primary system is located inside the containment.

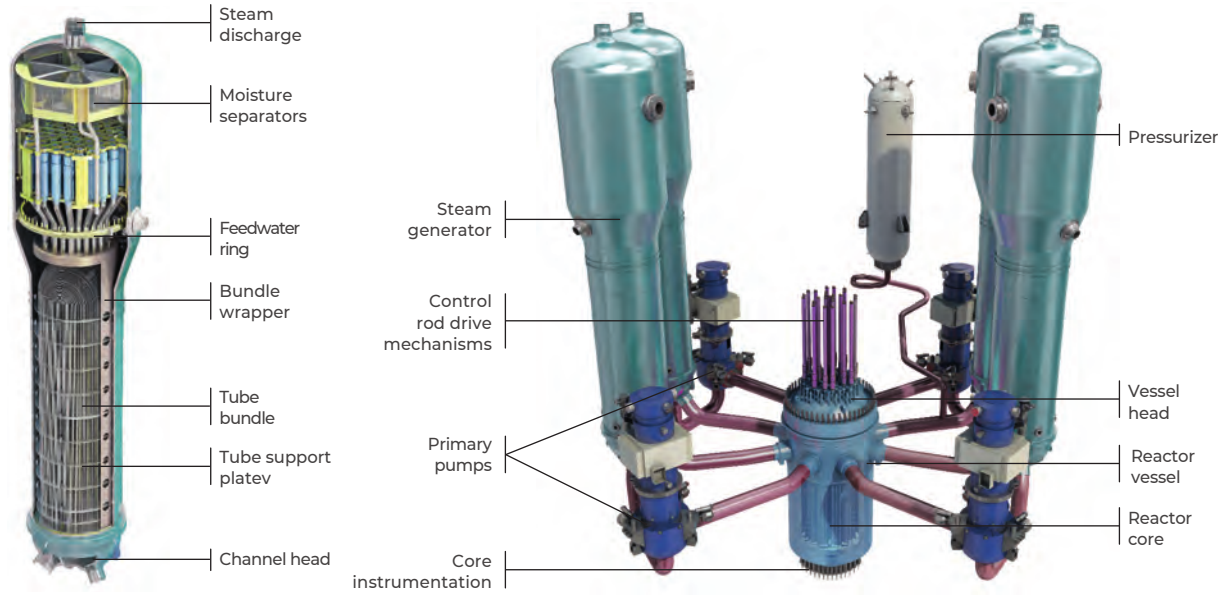
The water in the primary system transfers its heat to the water in the secondary systems in the steam generators. The steam generators are heat exchangers that contain 3,500 to 5,600 tubes, depending on the model, through which the reactor coolant circulates. These tubes are immersed in the water of the secondary system and boil it, without ever coming into contact with the primary water.

Each secondary system principally consists of a closed loop through which water runs in liquid form in one part and as steam in the other part. The steam produced in the steam generators is partly expanded in a high-pressure turbine and then passes through moisture separators before final expansion in the low-pressure turbines, from which it is then routed to the condenser. The condensed water is then sent back to the steam generators by the condensate extraction pumps and the feedwater pumps, after passing through the reheaters.

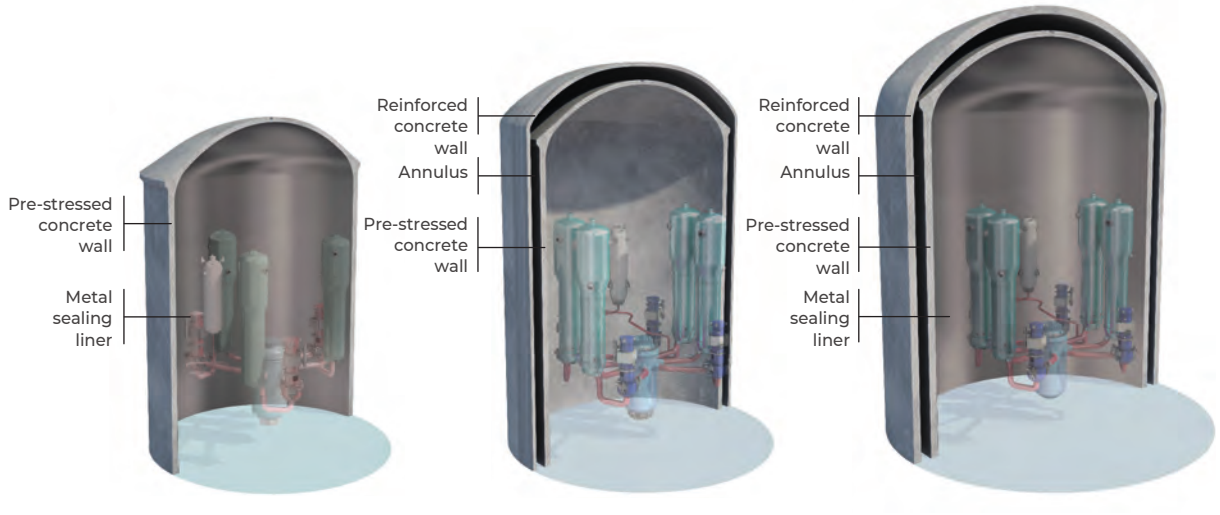
1.4 — The secondary system cooling system

The function of the secondary system cooling system is to condense the steam exiting the turbine. This is achieved by a condenser comprising a heat exchanger containing thousands of tubes through which cold water from outside (sea or river) circulates. When the steam comes into contact with the tubes it condenses and can be returned in liquid form to the steam

A steam generator and a main primary system of a 1,300 MWe reactor



Reactor containments



900 MWe reactor containments | 1,300 MWe/ 1,450 MWe reactor containments | 1,650 MWe reactor containments

generators (see point 1.3). The cooling system water that is heated in the condenser is then discharged to the natural environment (open circuit) or, when the river flow is too low or heating is too great in relation to the sensitivity of the environment, it is cooled in a Cooling Tower (TAR) (closed or semi-closed circuit).

The cooling systems are environments favourable to the development of pathogenic micro-organisms. Replacing brass by titanium or stainless steel in the construction of riverside reactor condensers, in order to reduce metal discharges into the natural environment, requires the use of disinfectants, mainly by means of biocidal treatment. The copper contained in brass has bactericidal properties that titanium and stainless steels do not. Cooling towers can contribute to the atmospheric dispersal of legionella bacteria, whose proliferation can be prevented by reinforced treatment of the structures (descaling, implementation of biocidal treatment, etc.) and monitoring.

1.5 – Reactor containment building

The PWR containment building has two functions:
- confine radioactive products liable to be dispersed in the event of an accident. The containments are therefore designed to withstand the pressures and temperatures that could result from the most severe reactor loss of coolant accident (double-ended circumferential rupture of a pipe in the primary system) and offer sufficient leaktightness in such conditions;
- protect the reactor against external hazards.

There are three containment model designs:
- Those of the 900 MWe reactors comprise a single pre-stressed concrete wall (concrete comprising tensioned steel tendons to compress the structure in order to increase its tensile strength). This wall provides mechanical pressure resistance and ensures the integrity of the structure in the event of an external hazard. Tightness is provided by a metal liner covering the entire internal face of the concrete wall.
- The 1,300 MWe and 1,450 MWe reactor containments consist of two walls: an inner wall made of pre-stressed concrete and an outer wall made of reinforced concrete. Leaktightness is provided by the inner wall and the ventilation system (EDE) which, in the annulus between the two walls, collects and filters residual leaks from the inner wall before they can be released. Resistance to external hazards is primarily provided by the outer wall.
- The Flamanville EPR reactor containment consists of two concrete walls and a metal liner covering the entire internal face of the inner wall.

1.6 – The main auxiliary and safeguard systems

In normal operating conditions, at power, or in reactor outage states, the auxiliary systems control nuclear reactions, remove heat from the primary system and residual heat from the fuel in outage states, as well as providing containment of radioactive substances. This chiefly involves the Chemical and Volume Control System (RCV) and the Residual Heat Removal System (RRA).

The purpose of the safeguard systems is to control incidents and accidents and mitigate their consequences. This chiefly concerns the following systems:
- the Safety Injection System (RIS), the role of which is to inject water into the primary system in the event of its leaking;
- the reactor building Containment Spray System (EAS), the role of which is to reduce the temperature and thus the pressure in the containment in the event of a major leak from the primary system;
- the Steam Generators Auxiliary feedwater System (ASG), which supplies water to the SGs if the normal feedwater system is lost, thus enabling heat to be removed from the primary system. This system is also used in normal operation during reactor outage or restart phases.

1.7 _ Other systems important for safety

The other main systems or circuits important for safety and required for reactor operation are:

- the Component Cooling System (RRI) which cools a certain number of nuclear equipment items. This system functions in a closed loop between the auxiliary and safeguard systems on the one hand and the systems carrying water from the river or sea (heatsink) on the other;
- the Essential Service Water System (SEC) which cools the RRI system with water from the river or sea (heatsink). This is a backup system comprising two redundant lines. In certain situations, each of its lines is capable of removing heat from the reactor to the heatsink;
- the Reactor Cavity and Spent Fuel Pool Cooling and Treatment System (PTR), used notably to remove residual heat from fuel elements stored in the fuel building pool;
- the ventilation systems, which confine radioactive materials by depressurising the premises and filtering all discharges;
- the fire protection water systems;
- the instrumentation and control system, which processes the information received from all the sensors in the NPP. It uses transmission networks and sends orders to the actuators from the control room, through the programmable logic controllers or operator actions. Its main role with regard to reactor safety is to monitor reactivity, control the removal of residual heat to the heatsink and take part in the containment of radioactive substances;
- the electrical systems, which comprise sources and electricity distribution. The French nuclear power reactors have two external electrical sources: the step-down transformer and the auxiliary transformer. These two external sources are supplemented by two internal electrical sources: the backup diesel generators. Finally, in the event of total loss of these external and internal sources, each reactor has another electricity generating set comprising a turbine generator and each NPP has an ultimate backup source, the nature of which varies according to the plant in question. Over the next few years, these latter resources will be supplemented by an "ultimate back-up" diesel generator set for each reactor.

2 ___ Monitoring of nuclear safety

2.1 _ Fuel

2.1.1 _ Changes to fuel and fuel management in the reactor

In order to enhance the availability and performance of the reactors in operation, EDF, together with the nuclear fuel manufacturers, is developing improvements to fuels and their use in the reactor.

EDF has standardised its fuel management methods. ASN ensures that each change in fuel management is the subject of a specific safety case for 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. When these changes are significant, their implementation requires an ASN resolution.

Fuel behaviour is an essential element in core safety in normal operation or accident conditions, and its reliability is therefore of prime importance. The leaktightness of the fuel rods, of which there are several tens of thousands in each core and which constitute the first containment barrier, are therefore the subject of particular attention. In normal operation, leaktightness is monitored by EDF through permanent measurement of the activity of the radionuclides contained in the primary system. Any increase in this activity beyond predetermined thresholds indicates a loss of leaktightness in the fuel assemblies. During each shutdown, EDF must look for and identify the assemblies containing leaking rods, which may not then be reloaded. If this activity in the primary system becomes too high, the General Operating Rules require reactor shutdown before the end of its normal cycle.

ASN ensures that EDF looks for and analyses the causes of the observed leaktightness losses, in particular by examining the leaking rods in order to determine the origin of the failures and prevent them from reoccurring. Preventive and remedial actions may therefore affect the design of rods or assemblies, their manufacture, or the reactor operating conditions. Furthermore, the conditions of assembly handling, of core loading and unloading, and the measures taken to exclude foreign material from the systems and pools are also the subject of operating requirements, some of which contribute to the safety case and for which EDF's compliance is verified by ASN spot-checks 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 _ Evaluation of the condition of the fuel and its management in the reactor

In 2018, the state of the first containment barrier was on the whole satisfactory in all the NPPs, with the exception of Nogent-sur-Seine. On this site, ASN found recurring shortcomings in compliance with the provisions designed to prevent the entry of foreign material into the reactor coolant system and the reloading of a leaking fuel assembly.

ASN notes that the progress observed in 2017 continued in 2018 with regard to the risk of entry of foreign material into the reactor coolant system. For example, several sites set up training programmes for outside contractor personnel, without which they are not authorised to work. However, despite this progress, ASN once again repeatedly found the presence of foreign material in the reactor coolant systems and will thus maintain close attention on this subject in 2019.

In 2018, the number of significant events linked to fuel handling remained low, as was the case in 2017.

The recurring blockages encountered during control rod operation or dropping in 2017 and 2018 on certain 1,300 MWe reactors, owing to wear of the reactor vessel closure head thermal sleeves, led EDF to initiate an inspection programme on all the reactors and replace the most heavily worn thermal sleeves (see box). Until such time as these inspections are carried out during the reactor outages, operating restrictions are in place at the request of ASN.

Inspection of main primary system welds – Flamanville EPR

Finally, with regard to fabrication of the fuel assemblies, ASN is continuing its inspections, notably as a result of the anomalies encountered in 2017 on MOX (presence of large sized plutonium-enriched islands) and the fuel cladding (cladding compliance inspection anomalies). EDF's notification of a significant nuclear safety event concerning the phenomenon of rising neutron flux at the bottom of the fissile column of MOX fuel assemblies, led ASN in 2018 to ask EDF to characterise the loss of the first barrier integrity margin and take compensatory measures pending the deployment of a change to the design of these assemblies. ASN will remain attentive to the deployment and effectiveness of these measures.

2.2 _ Nuclear pressure equipment

2.2.1 _ Monitoring of the design and manufacturing conformity of Nuclear Pressure Equipment

ASN assesses the compliance with regulatory requirements by the Nuclear Pressure Equipment (NPE) that is most important in terms of safety, said to be "level N1", which are the reactor pressure vessel, the steam generators, the pressuriser, the reactor coolant pumps, the piping and the control valves and relief valves.

These regulatory requirements are a guarantee of their safety. They are defined by a European Directive on Pressure Equipment and supplemented by requirements specific to NPE.

This conformity assessment concerns the equipment intended for the new nuclear facilities (more than 200 items are concerned on the Flamanville EPR) and the equipment spares intended for nuclear facilities already in operation (replacement steam generators in particular). For the performance of these duties, ASN can rely on the organisations that it approves, which it can task with performing some of the inspections on the level N1 equipment. They are also responsible for assessing conformity with the regulatory requirements applicable to NPE that is less important for safety, referred to as "level N2 or N3". Oversight by ASN and its approved organisations comes into play at different stages of design and manufacture of nuclear pressure equipment. It takes the form of examination of the technical documentation for each item of equipment and of inspections in the manufacturers' facilities as well as in those of their suppliers and subcontractors. Five inspection organisations or bodies are currently approved by ASN to assess ESPN conformity: Apave SA, Asap, *Bureau Veritas Exploitation*, Vinçotte International and the EDF users inspection entity.

Analysis of the irregularities detected in the manufacturing files at the Creusot Forge plant for components installed in reactors in service

Following the detection of irregularities in certain manufacturing files at the Areva NP Creusot Forge plant in 2016, ASN resolution 2017-DC-0604 of 15 September 2017 ordered EDF to send ASN the review report of the manufacturing files for the components forged by the Creusot Forge plant for each reactor in operation and no later than two months prior to restart following its next refuelling outage.

EDF submitted the review report as required by the resolution of 15 September 2017. Certain additional clarifications will be sent to ASN during the course of 2019.

The ASN examination of the deviations brought to light by this review, which began in 2017 and continued in 2018, gave rise to additional justification requests but did not reveal any deviation requiring the repair or immediate replacement of an equipment item. Requests were made for subsequent on-site inspections and representative tests to confirm the justifications provided by EDF and the corresponding elements will be examined in 2019.

Furthermore, data concerning the castings produced by the foundry on the Le Creusot industrial site, which were requested from EDF by the above-mentioned resolution, will be analysed in 2019.

In 2018, ASN finalised the examination of the file concerning the irregularity detected on the lower shell of a steam generator on Fessenheim NPP reactor 2. Following the discovery of this anomaly, ASN suspended the steam generator test certificate on 18 July 2016, the effect of which was to keep this reactor shut down. In July 2017, Areva NP transmitted a file demonstrating the mechanical strength of the component concerned.

With the support of IRSN, ASN examined this information which was presented on 27 February 2018 to the Advisory Committee for Nuclear Pressure Equipment (GPESPN). On the basis of the conclusions of the examination, ASN considered that the irregularity affecting the steam generator did not compromise its serviceability and therefore lifted the suspension of the steam generator test certificate on 12 March 2018.

In 2018, the approved organisations carried out 7,704 inspections on NPE design and manufacture for the NPE intended for the Flamanville EPR and 3,196 inspections for the replacement NPE intended for the NPP reactors in operation. These inspections are performed under ASN supervision.

2.2.2 _ Evaluation of the design and manufacture of NPE

• Irregularities in the manufacturing plants

2017 and 2018 were marked by analysis of the consequences of the detection of irregularities in 2016, of varying scope and severity, in several NPE manufacturing plants. This was in particular the case in the Framatome Creusot Forge plant, where these practices had continued for several decades.

Considering that these irregularities reveal unacceptable practices and that the industry needs to take fundamental measures to restore a high level of quality in the supply chain, ASN asked Framatome to conduct a review of the files of the components manufactured by Creusot Forge, to analyse the reasons the irregularities were not detected and to develop a quality and safety culture to guarantee the required irreproachable level of quality. At the same time, ASN asked EDF to analyse the causes of the breakdown in Framatome monitoring and to assess the steps taken by Framatome.

These requests were extended to all the Areva NP plants. The fact that these requests were addressed and additional measures implemented satisfactorily by the Creusot Forge plant meant that at the end of January 2018, ASN considered that the resumption of manufacturing of components intended for French nuclear facilities could be envisaged in this plant under certain conditions, more particularly monitoring of the activities performed.

In conjunction with this step and together with the organisations it approves, ASN is examining the handling of the deviations detected during the files review when evaluating the conformity of new equipment. Similar action is also carried out for the components integrated into equipment in service on the basis of analyses carried out by Framatome and EDF (see the box concerning the Creusot Forge plant).

At the same time, EDF has begun work to adapt its inspection practices in order to counter the risk of fraud, more particularly by carrying out unannounced or cross-inspections.

• Reinforcing justification of the design of NPE

ASN has regularly observed that the justifications and demonstrations provided by the manufacturers with regard to NPE regulations, more particularly concerning the correct design of this equipment, are 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 measures, most of which were carried out within the framework of the French Association for NSSS design, construction and monitoring rules (AFCEN) and involved the majority of the profession. ASN considers that this approach is a positive one and, for most of the problems identified in 2015, considers that the AFCEN guidelines 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 guidelines 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 the operation of the Main Primary and the Main Secondary Systems of nuclear pressurised water reactors. These systems are thus monitored and periodically maintained by EDF. This monitoring is itself checked by ASN.

These systems are subject to periodic re-qualification every ten years, comprising a complete inspection of the systems involving non-destructive examinations, pressurised hydrotesting and verification of the good condition and proper operation of the over-pressure protection accessories.

• Nickel-based alloy areas

Several parts of pressurised water reactors are made with nickel-based alloy. The use of this type of alloy is justified by its resistance to generalised or pitting corrosion. However, in reactor operating conditions, one of the alloys adopted, Inconel 600, proved to be susceptible to stress corrosion. This particular phenomenon occurs when there are high levels of mechanical stress. It can lead to the appearance of cracks, as observed on certain SG tubes in the early 1980s or, more recently in 2011, on a vessel bottom head penetration in Gravelines reactor 1 and in 2016 on a vessel bottom head penetration in Cattenom reactor 3.

These cracks require that the licensee repair the zones concerned or isolate the part of the system concerned.

At the request of ASN, EDF adopted an overall monitoring and maintenance approach for the areas concerned. Several parts of the main primary system made of Inconel 600 alloy are thus subject to special monitoring. For each of them, the in-service monitoring programme, defined and updated annually by the licensee, is submitted to ASN, which ensures that the performance and frequency of the checks carried out by EDF are satisfactory and able to detect the deteriorations in question.

• The strength of reactor pressure vessels

The reactor pressure vessel is an essential component of a pressurised water reactor and contains the reactor core and its instrumentation. For the 900 MWe reactors, the vessel is 14 m high, 4 m in diameter, 20 cm thick and weighs 330 tonnes. For the EPR, currently under construction 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 monitoring of the state of the reactor pressure vessel is essential for two reasons:

- The vessel is a component for which replacement is not envisaged, owing to both technical feasibility and cost.
- Monitoring contributes to the break preclusion approach adopted for this equipment. This approach is based on particularly stringent design, manufacturing and in-service inspection provisions in order to guarantee its strength throughout the life of the reactor, including in the event of an accident.

In operation, the vessel's metal gradually becomes brittle under the effect of the neutrons from the fission reaction in the core. This embrittlement makes the vessel particularly sensitive to pressurised thermal shocks or to sudden pressure surges when cold. This susceptibility is also aggravated when technological defects are present, which is the case for some of the reactor vessels that have manufacturing defects under their stainless steel liner.

ASN regularly examines the evidence to substantiate the in-service resistance of the vessels transmitted by EDF, to ensure that it is sufficiently conservative.

In mid-2016, EDF more specifically sent ASN a file substantiating the in-service resistance of the 900 MWe reactor vessels after 40 years of operation and this is currently being reviewed by ASN. A first part of this file was submitted to the GPESPN for its opinion on 20 November 2018 and the second part should also be submitted during the course of 2019.

• Maintenance and replacement of steam generators

The SGs comprise two parts, one of which is a part of the primary system and the other a part of the secondary system. The integrity of the main steam generator components, more specifically the tubes making up the tube bundle, is monitored. This is because any damage to the tube bundle (corrosion, wear, cracking, etc.) can lead to a leak from the primary system to the secondary system. A steam generator tube rupture would lead to bypassing of the reactor containment, which is the third containment barrier. Steam generators are therefore the subject of a special in-service monitoring programme, established by EDF, reviewed periodically and examined by ASN. After inspection, tubes that are too badly damaged are plugged to remove them from service.

• Clogging of the tubes and internals of the secondary part of the steam generators

Over time, the SGs tend to become clogged with corrosion products from the secondary system exchangers. This leads to a build-up of soft or hard sludge at the bottom of the SGs, fouling of the tube walls and clogging of the tube bundle tube support plates. The corrosion products form a layer of magnetite on the surface of the internals. On the tubes, the layer of deposits (fouling) reduces the heat exchange capacity. In the tube support plates, the deposits prevent the free circulation of the water-steam mixture (clogging), which creates a risk of damage to the tubes and the internal structures and which can degrade the overall operation of the steam generator.

To prevent or mitigate the fouling effects described above, various solutions can be used to minimise metal deposits: preventive chemical cleaning or remedial mechanical cleaning (using hydraulic jets), material replacement (brass by stainless steel or titanium alloy, which are more corrosion-resistant) in certain secondary system exchanger tube bundles, modification of the chemical products used for conditioning of the systems and an increase in the pH of the secondary system. Some of these operations require licensing for the discharge of 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 particularly non-destructive examinations of the zones potentially exposed to this risk.

The principles of demonstrating the resistance of reactor vessels

The regulations in force require in particular that the licensee:

- identify the operating situations with an impact on the equipment;
- take measures to understand the effect of ageing on the properties of the materials;
- take steps enabling it to ensure sufficiently early detection of defects prejudicial to the integrity of the structure;
- eliminate all cracks detected or, if this is impossible, provide appropriate specific justification for retaining such a type of defect as-is.

• Replacement of steam generators

Since the 1990s, EDF has been running a programme to replace the steam generators with the most heavily degraded tube bundles, with priority being given to those made from Inconel 600 without heat treatment (600 MA) and then those made from Inconel 600 with heat treatment (600 TT).

The replacement campaign for SGs with a tube bundle made of 600 MA (26 reactors) was completed in 2015 on reactor 3 at the Le Blayais NPP. It is being continued with the replacement of SGs with 600 TT tube bundles (26 reactors). In 2018, replacement of the SGs of the Paluel NPP reactor 2 was completed.

• Monitoring methods applied to main primary and secondary system pressure equipment

The Order of 10 November 1999 specifies that the non-destructive testing processes used for in-service monitoring of the pressure equipment of the main primary and secondary systems of nuclear power reactors must be qualified before they are used for the first time. This qualification is granted by a body comprising experts from both inside and outside EDF whose expertise and independence are verified by the French accreditation committee.

Qualification is a means of guaranteeing that the non-destructive testing process actually achieves the anticipated level of performance as described in specifications drawn up beforehand.

Owing to the radiological risks associated with radiographic inspection, ultrasound inspections are preferred, provided that they offer equivalent inspection performance.

To date, more than 90 non-destructive test processes have been qualified for the in-service inspection programmes. New development and qualification processes to meet new needs are currently being drawn up.

With regard to the Flamanville EPR, virtually all of the test processes for in-service monitoring of the pressure equipment of the main primary and secondary systems were qualified ahead of the Pre-Service Inspection (VCI) of the main primary system and the main secondary systems, corresponding to more than 30 qualified processes specific to the EPR.

2.2.4 _ Assessment of pressure equipment in operation

Owing to the difficulties encountered in controlling fouling or in the replacement of some steam generators, the situation of the second containment barrier, that is the reactor coolant system, was given particular attention by ASN in 2018.

On the one hand, very high levels of fouling were found in certain steam generators in several reactors, which could be liable to impair their operating safety. These fouling levels are the result of insufficient maintenance to ensure satisfactory cleanness and they highlight the need, for some types of steam generators, to continue to improve the strategy for monitoring and preventing this phenomenon. This situation meant that in 2018, ASN asked for advance chemical cleaning prior to restart on the steam generators of the Dampierre-en-Burly NPP reactor 4.

On the other, ASN observes that the last SG replacement operations for the 900 MWe reactors were postponed, notably owing to the numerous deviations in the manufacture of this equipment. These postponements led to operations to make cracked tubes on certain steam generators safe, by plugging or sleeving, until such time as they are replaced. With regard to the 1,300 MWe reactors, the first steam generator replacement was completed in 2018 on the Paluel NPP reactor 2.

Finally, with regard to the other equipment on the main primary system, ASN considers that their in-service monitoring, pursuant to the provisions of the Order of 10 November 1999, is carried out appropriately. In 2017, the detection of a new crack on a vessel bottom head penetration in Cattenom NPP reactor 3, for which no change was detected in 2018, nonetheless illustrates the risk of further deterioration associated with the ageing of the facilities and confirms the need to adapt the level of in-service monitoring accordingly and to bring forward the development of repair processes.

2.3 _ The containments

2.3.1 _ Monitoring the containments

The containments undergo inspections and tests to check their compliance with the safety requirements. Their mechanical performance in particular must guarantee a good degree of reactor building tightness in the event of its internal pressure exceeding atmospheric pressure, which can happen in certain types of accidents. This is why, at the end of construction and then during the ten-yearly inspections, these tests include an inner containment pressure build-up with leak rate measurement. These tests are required by the Order of 7 February 2012 setting the general rules relative to 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 remains on the whole satisfactory, even if a complete formal definition is sometimes not yet available. Even if EDF has taken steps to maintain dedicated systems in good condition, improvements are still needed regarding the containment condition of the third barrier and its components, in particular maintenance of the floor drains and the components of the doors contributing to static containment.

• Single wall containments with an internal metal liner

The ten-yearly tests performed on the 900 MWe reactor containments since 2009 have brought to light no particular problems liable to compromise their operation for a further ten years, with the exception of Bugey NPP reactor 5. This latter is now regularly monitored since an unfavourable change in the leaktightness of its containment was revealed in 2011. This containment was repaired in 2017.

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 guarantee that there was no stagnant water, debris, moss and other vegetation.

• Double-wall containments

The test results for the double-wall containments performed during the first ten-yearly outages of the 1,300 MWe reactors detected a rise in the leak rate from the inner wall of some of them, under the combined effect of concrete deformation and loss of pre-stressing of certain tendons that was higher than anticipated in the design.

EDF then initiated significant work consisting in using a resin sealant locally to cover the interior surface of the inner wall of the most severely affected 1,300 MWe reactors, but also 1,450 MWe reactors.

The tests performed since this work, during the second and the third ten-yearly outages of the 1,300 MWe reactors and the first ten-yearly outages of the 1,450 MWe reactors all complied with the regulation leak rate criteria. In order to ensure that these criteria will continue to be met for the long-term, EDF decided to improve the leaktightness of the inner wall of these reactor buildings by applying the sealant to their outer surface.

ASN remains vigilant with regard to changes in the leaktightness of these containments and to maintaining the long-term effectiveness of the coatings. The effectiveness of the containment function of the double-wall system was examined in 2013. ASN concluded that:

- In addition to EDF's satisfactory monitoring of the condition of the concrete, additional measures to prevent or mitigate the ingress of water from outside must also be envisaged because, given the current state of knowledge, this is the primary means of protecting containments from concrete swelling pathologies.
- EDF must reinforce in-service monitoring and visual inspection of certain containment singularities (sleeves, equipment hatch).
- EDF must give a safety classification to the instrumentation system providing continuous monitoring of the containment leak rate (Sexten) along with in-service monitoring of its correct operation.

EDF has begun steps in response to these conclusions. ASN checks that they are correctly implemented, notably by means of inspections.

2.4 — Risk prevention and control

2.4.1 — Monitoring the drafting and application of the general operating rules

The General Operating Rules (RGE) cover the operation of nuclear power reactors. These are drafted by the licensee and are the operational implementation of the hypotheses and conclusions of the safety assessments constituting the nuclear safety case. They set the limits and conditions for operation of the installation.

• Normal and degraded operations

Operating Technical Specifications

The Operating Technical Specifications (STE), which constitute Chapter III of the General Operating Rules, define the normal operating conditions based on the design and sizing hypotheses of the facility and require the systems necessary for maintaining the safety functions, in particular the integrity of the radioactive substances containment barriers and the monitoring of these functions in the event of an incident or accident. They also stipulate what is to be done if a required system momentarily fails or if a limit is exceeded, situations which constitute "degraded operation".

The STE evolve to take account of the lessons learned from their application and the modifications made to the reactors. On an occasional basis, the licensee can also modify them temporarily, for example to carry out an intervention in conditions that are different from those initially considered in the nuclear safety case. It must then demonstrate the pertinence of this temporary modification and define adequate compensatory measures in order to control the corresponding risks.

Depending on their importance, STE modifications likely to affect protected interests require either an authorisation application sent to ASN, or notification to ASN before they are implemented.

During inspections in NPPs, ASN verifies that the licensee complies with the STE and, as necessary, checks the compensatory measures associated with any temporary modifications. It also checks the consistency between the modifications made to the facilities and the normal operating documents, such as instructions, alarm sheets, the STE and the training of the persons responsible for implementing them.

Periodic tests

Elements Important for the Protection (EIP) of persons and the environment are equipment items identified by the licensee. They undergo qualification to guarantee their ability to perform their assigned functions in the situations in which they are needed. The periodic tests of this equipment help verify that this qualification is maintained and regularly ensure that these elements are available when required. The corresponding rules, incorporated into the reactor general operating rules, set the nature of the technical checks to be performed, their frequency and the criteria for determining the satisfactory nature of these checks, in other words the compliance of the equipment concerned with the qualification requirements.

ASN ensures that the periodic tests on the EIP are relevant and are continuously improved. It carries out this verification when examining the application for authorisation to start-up the reactor and then the applications for authorisation to modify the RGE. In addition, during inspections, it verifies that these periodic 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 chapter concerning EDF reactor core physics tests, are performed periodically.

The physics tests at restart are comparable to requalification tests following reloading of the core. The physics tests 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

Incident or accident operations

The strategies and reactor operating rules for an incident or accident situation are defined in the RGE. These evolve more particularly to take account of experience feedback from incidents and accidents, to correct the anomalies detected during their application or to take account of modifications made to the facilities, in particular those resulting from the periodic safety reviews. 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 at least one exercise per 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 as much as possible (see chapter 4, point 1.3.1). The implementation of these strategies requires the participation of the local and national emergency teams. These teams use the On-site Emergency Plan (PUI) plus the severe accident operation guide and the emergency team action guides in particular.

ASN periodically examines the strategies presented by EDF in these documents, in particular for the reactor periodic safety reviews.

2.4.2 _ Assessment of reactor operations

• Normal and degraded operation

In 2018, EDF encountered difficulties in controlling its operating and maintenance activities, notably in the restarts following reactor outages. ASN has not observed any significant improvement in the quality of NPP operations by comparison with 2017, in that the underlying causes of the faults appear to be structural and the effects of the steps taken by EDF are not yet measurable.

The control of certain sensitive activities, such as temporary system configuration changes in order to carry out periodic tests on certain equipment, which is the origin of operating non-quality, would appear to be progressing on certain sites. This progress, which must be placed in the context of the action plans being run by EDF for several years now, still remains to be consolidated.

However, alarms processing in the control room - from their acknowledgement by the operating team to the performance of the control actions required by the alarm sheets – is less satisfactory. ASN more particularly notes that the personnel become accustomed to recurring alarms, which is particularly prejudicial when a given alarm can indicate different failures.

Maintenance quality defects are regularly the cause of an increase in the length of the restart phases following reactor refuelling outages. Recurring activities, such as periodic tests, were also the cause of deviations in the preparation and performance phases. The stakeholders concerned have insufficiently assimilated error-reduction practices for these interventions.

As a result of this situation, ASN continued with the adapted oversight arrangements implemented in 2018. This more particularly leads to tightened inspections on the most under-performing sites.

ASN also observes that the processes EDF implemented for the design of technical operating specifications and periodic test rules requiring its authorisation, were deficient on several occasions. More specifically, EDF was required to revise the general operating rules for the 1,300 MWe reactors applied following their third ten-yearly outage inspection to ensure that the actual state of the facilities was consistent with the operating documents. The tightened inspections performed by ASN in 2018, led EDF to initiate a profound overhaul of its design processes for the documentation used to ensure the maintained operation of the reactors within the scope covered by their nuclear safety case.

The scheduling, performance and analysis of the results of periodic tests are areas in which virtually all the sites need to improve. This observation has been made repeatedly for numerous sites. The filled-out periodic test procedures are documents that are regularly inspected by the ASN inspectors. ASN observes that the lack of preparation for the periodic tests sometimes leads to the performance frequencies being exceeded and to inadequate conditions for performance of the tests. The other reason for the delays in performance of tests is the implementation of the new IT system in the NPPs, in which certain periodic tests were sometimes incorrectly transposed. Furthermore, ASN's inspectors on several occasions found incorrect conclusions regarding equipment availability following periodic testing. ASN also observes that the sites experience difficulties in translating the requirements of the periodic test rules into actual test procedures. All of these situations have led to numerous significant safety events.

A significant safety event concerning the lack of metrological monitoring of the sensors used to validate safety criteria during periodic tests notably attracted ASN's attention and it ensured that the sites update the metrological monitoring of the sensors and are also able to demonstrate the availability of any equipment which was tested with sensors that were not monitored.

ASN also found recurring monitoring faults during the core physics tests performed at reactor restart and during operation. These anomalies more particularly concern the rod control cluster drop time measurements and compromise the detection of possible deviations regarding reactivity control. Moreover, ASN considers that the analysis of early warning signs regarding the unavailability of equipment that would be needed during primary coolant dilution accidents needs to be reinforced.

As in 2017, ASN in 2018 observes that the follow-up of the opinions expressed by the Independent Safety Organisation (FIS) in place within each EDF entity, varies significantly from one NPP to another. ASN more particularly found that the EDF decision-making process, which notably includes the FIS, does not always ensure that priority is given to the protection of interests.

• Operation in an incident, accident, or severe accident situation

In the same way as every year, ASN carried out several inspections in 2018 on the organisational and technical arrangements made by EDF to deal with an incident and accident situation. One of them was a reactive inspection following a severe pressure control malfunction on the reactor coolant system of Bugey NPP reactor 5.

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 functional capabilities of certain necessary equipment. These inspections almost always include a simulation involving the EDF teams. In 2018, they revealed that the field operators need to be more familiar with the instructions regarding the actions they are required to carry out. ASN also found that these instructions sometimes contain errors, ambiguities, or even instructions that are impossible to carry out, which had not been identified during EDF's internal inspections.

So that EDF can reinforce its ability to control accident situations requiring application of these instructions, ASN more particularly asked EDF to reinforce its technical inspections during the phase validating the documents placed at the disposal of the operators, to ensure the *in situ* applicability of these documents before they are applied, to improve the clarity and usability of the documents covering the use of mobile equipment in a degraded or emergency situation and to carry out exercises with the use of local instructions.

The inspections on the organisation and emergency resources confirmed that the organisation, preparedness and management principles for emergency situations covered by a PUI have been correctly assimilated.

Although operating experience feedback from exercises and actual situations is correctly identified by EDF, it does not fully assimilate it, given that certain points requiring improvement are identified time and time again. However, this operating experience feedback shows that the relations between each NPP and the third-parties involved in the management of an emergency situation (hospitals, emergency services) are satisfactory and enhance the interest of such exercises.

The Independent Safety Organisation (FIS)

EDF's in-house Independent Safety Organisation (FIS) verifies the actions and decisions taken by the departments in charge of operating the installations, from the viewpoint of safety. On each NPP, the FIS comprises safety engineers and auditors, who conduct a daily check on the safety of the reactors. The working of each FIS is checked and evaluated at a national level by the FIS at EDF's Nuclear Production Division. Finally, the EDF internal inspection services, 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.

None of EDF's NPPs activated its PUI in 2018.

In 2019, ASN will continue to check the application of the provisions of its resolution 2017-DC-0592 of 13 June 2017 concerning the obligations incumbent upon BNI licensees in terms of preparedness for and management of emergency situations and the content of the on-site emergency plan. Work to ensure compliance with the provisions of the resolution is continuing.

2.4.3 _ Monitoring maintenance of the facilities

Preventive maintenance is an essential line of defence in maintaining the conformity of a facility with its baseline safety requirements. This is an important topic, checked by ASN during its inspections in the NPPs.

In order to improve the reliability of the equipment contributing to safety but also to industrial performance, EDF is optimising its maintenance activities, drawing on other practices in use in conventional industry and by the licensees of NPPs in other countries.

Since 2010, EDF has been deploying 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 mid-2016, EDF aimed to develop 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 _ Evaluation of maintenance

ASN observes that EDF has implemented action plans to reduce the occurrence of maintenance quality defects, but it also observes that too many of these still persist. Some of them could have been avoided by taking greater account of operating experience feedback from other reactors, including on the same site. An insufficiently questioning and proactive attitude in the implementation of appropriate corrective actions is all too often observed in identifying and processing maintenance-related deviations.

ASN still observes activity management problems owing to difficulty with the procurement of spares, in particular because spares are unavailable or non-conforming, but the slight improvement trend observed in 2017 was confirmed in 2018.

ASN also regularly observes a lack of rigour in technical oversight of interventions and in monitoring of contractors, along with deficiencies in the traceability of and error-reduction in the interventions. The workers still have to deal with constraints linked to work organisation, such as insufficient preparation for certain activities, unplanned scheduling changes and problems with worksite coordination, leading to activity delays or postponements. These difficulties are more particularly encountered with regard to unscheduled activities such as dealing with unexpected events.

Management of maintained qualification of equipment for accident conditions should be improved, notably owing to the sites' incorrect integration of the binding documents into their operational documents, or to their incorrect application. Post-maintenance requalification of equipment is not always able to detect any work that has been incorrectly performed. Consequently, the reactor restart phases are all too often the time when maintenance quality faults are detected, which can lead to a significant extension of these phases.

The AP-913 maintenance method (see point 2.4.3) gives the licensee a clearer picture of the condition of its facilities and enables it to ensure more regular maintenance. However, ASN considers that proactive measures must be taken by EDF to reinforce its maintenance processes. EDF must in particular more strictly manage their implementation and allocate the necessary resources. EDF must also ensure that all participants follow the recommended methods for filling out the equipment monitoring indicators, for the preparation, performance and write-up of field inspections and for the traceability of maintenance decisions.

Despite this, ASN considers that most sites have successfully been able to organise themselves to carry out large-scale maintenance operations, such as the preparation for and performance of the ten-yearly outage inspections, which constitute a considerable drain on their human resources, notably those with the most experience, owing to the particularly intense maintenance phases.

With a view to extending the service life of the reactors, and in the light of the "major overhaul" programme and the lessons learned from the Fukushima Daiichi accident, ASN considers that it is important for EDF to continue the efforts started to resolve the difficulties encountered and improve the effectiveness of its maintenance work.

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 on rules applicable to BNIs for the control of fire risks.

Controlling the fire risk in nuclear power plants is built around the principle of defence in depth, based on three levels: facility design, prevention and fire-fighting.

Design rules must prevent a fire from spreading and mitigate its consequences; they are based primarily on "fire zoning". This involves dividing the facility into sectors and containment areas designed to keep the fire within a given perimeter bounded by items (doors, walls and fire dampers) offering a specific fire resistance duration. The main purpose is to prevent a fire from spreading to two redundant equipment items performing a fundamental safety function.

Prevention primarily consists of the following:
- ensuring that the nature and quantity of combustible material present in the premises remain below that of the scenarios used for zoning;
- identifying and analysing the fire risks in order to take steps to avoid them. In particular, a "fire permit" must be issued and protective measures must be taken for all work liable to cause a fire.

Finally, fire detection and fire-fighting procedures should enable a fire to be tackled, brought under control, and extinguished within a time compatible with the fire resistance duration of the zoning elements.

ASN checks that the fire risk is taken into account in the NPPs, notably through an analysis of the licensee's baseline safety requirements, monitoring of significant events notified by the licensee and inspections performed on the sites.

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 will be submitted to the GPR for its opinion in 2019.

• Explosion risks

An explosion can damage elements that are essential for maintaining safety or may lead to failure of the containment with the release of radioactive materials into the facility, or even into the environment. Steps must therefore be taken by the licensee to protect the sensitive parts of the facility against explosions.

ASN checks these prevention and monitoring measures, paying particular attention to ensuring that the explosion risk is included in EDF's baseline safety requirements and organisation. ASN also ensures compliance with the "Explosive Atmospheres" (ATEX) regulations with respect to worker protection.

• Internal flooding risks

An internal flood, in other words which comes from within the facility, may lead to failure of equipment necessary for reactor shutdown, fuel cooling and containment of radioactive products. Steps are therefore taken to prevent internal flooding (maintenance of piping carrying water, etc.), or mitigate its consequences (presence of floor drains and water extraction pumps, installation of sills or leaktight doors to prevent the flood from spreading, etc.). These measures are regularly inspected by ASN.

ASN remains vigilant with regard to the risks of internal flooding as a result of an earthquake, as well as with regard to the integration of operating experience feedback, in particular the processing of deviations affecting certain internal flooding protection measures.

• External flooding risks

The partial flooding of the Le Blayais NPP in December 1999 led the licensees, under the supervision of ASN, to reassess the safety of their facilities with respect to this risk in more severe conditions than previously and to make a number of safety improvements, with a schedule proportionate to the potential consequences. In accordance with the ASN requirements, EDF completed the required work on all its nuclear power reactors in 2014.

At the same time, to ensure more exhaustive and more robust integration of the flooding risk, as of the facilities design stage, ASN published Guide No. 13 in 2013 concerning BNI protection against external flooding. For the existing facilities, ASN asked EDF in 2014 to take account of the recommendations of the Guide on all its reactors.
- for the 1,300 MWe reactors, ASN asked EDF to do this as a priority during the third periodic safety review;
- for the other reactors in service, EDF will do this as a priority during the next periodic safety reviews (fourth reviews for the 900 MWe reactors and second reviews for the 1,450 MWe reactors).

Following the stress tests performed in the wake of the Fukushima Daiichi accident, ASN considered that, with regard to protection against flooding, the requirements arising from the complete reassessment performed after the flooding of the Le Blayais NPP in 1999 provided the nuclear power plants with a high level of protection against the risk of external flooding. However, in June 2012, ASN issued several resolutions to ask the licensees:
- to reinforce NPP protection against certain hazards, such as intense rainfall and earthquake-induced flooding;
- to define and implement a "hardened safety core" of material and organisational measures to control the fundamental safety functions in extreme situations and in particular in the case of flooding beyond the design-basis safety requirements (see point 2.9).

• Seismic risks

Although seismic activity in France is moderate or slight, EDF's inclusion of this risk in the safety case for its nuclear power reactors is the subject of constant attention on the part of ASN, given the potential consequences for the safety of the facilities. Seismic protection measures are taken into account in the design of the facilities. They are periodically reviewed in line with changing knowledge and changes to the regulations, on the occasion of the periodic safety reviews.

Basic Safety Rule (RFS) 2001-01 of 31 May 2001 defines the methodology for determining the seismic risk for surface BNIs (except for radioactive waste long-term repositories).

This RFS is supplemented by ASN Guide 2/01 of May 2006, which defines acceptable calculation methods for study of the seismic behaviour of nuclear buildings and particular structures such as embankments, tunnels and underground pipes, supports or tanks.

Buildings and equipment important for the safety of NPPs are designed to withstand earthquakes of an intensity greater than the most severe earthquakes that have ever occurred in the region. EDF's NPPs are thus designed for seismic levels with incorporation of the local geological features specific to each one.

As part of the periodic safety reviews, the seismic reassessment consists in verifying the adequacy of the seismic design of the facility, taking account of advances in knowledge about seismic activity in the region of the site or in the methods for assessing the seismic behaviour of elements of the facility. The lessons learned from international experience feedback are also analysed and integrated into this framework.

Changing knowledge leads EDF to reassess the seismic hazard during the periodic safety reviews, more specifically:
- third periodic safety reviews of the 1,300 MWe reactors;
- fourth periodic safety reviews of the 900 MWe reactors;
- second periodic safety reviews of the 1,450 MWe reactors.

Following the Fukushima Daiichi NPP accident, ASN instructed EDF to define and install a "hardened safety core" of material and organisational measures to control the fundamental safety functions in extreme situations which, in the French context, are comparable to 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 the levels adopted in the design or periodic safety review of the installations.

In order to define this exceptional level earthquake, ASN asked EDF to supplement the deterministic approach to defining the seismic hazard with a probabilistic approach, which would be more closely in line with international best practices.

ASN considers that the assessments of the seismic hazards determined by EDF are acceptable, with the exception of those concerning the NPPs of Saint-Alban/Saint-Maurice, Fessenheim, Chinon and Chooz which are insufficient in the light of current knowledge. ASN therefore asked EDF in 2015 and 2016:
- to reassess the seismic spectra for the SaintAlban/Saint-Maurice, Fessenheim, Chinon and Chooz Nuclear power plants in order to take account of the uncertainties;
- to define a working programme to verify the strength of the equipment and civil engineering structures and make any seismic reinforcements for the periodic safety reviews.

• Heat wave and drought risks

During the heat waves in recent decades, some of the rivers used to cool NPPs experienced a reduction in their flow rate and significant warming. Significant temperature rises were also observed in certain NPP facilities housing heat-sensitive equipment.

EDF took account of this experience feedback and initiated reassessments of the operation of its facilities in air and water temperature conditions more extreme than those initially included in the design. In parallel with development of these "extreme heat" baseline safety requirements, EDF initiated the deployment of priority modifications (such as an increase in the capacity of certain heat exchangers) and adopted operating practices optimising the cooling capacity of the equipment and improving the resistance of equipment susceptible to high temperatures.

For the periodic safety review of the 1,300 MWe reactors, EDF has initiated a modifications programme on its facilities designed to provide protection against the effects of a heat wave situation. The capacity of certain cooling systems for equipment required for the nuclear safety case will in particular be improved.

EDF has also initiated a climatic monitoring programme in order to anticipate climate changes, which could compromise the temperature hypotheses adopted in its baseline safety standards.

With regard to the 900 MWe reactors, ASN gave its consent in 2012 to the implementation of the baseline safety requirements and integration of the resulting modifications. ASN also asked EDF to take account of the comments it made during this examination process with a view to drafting and implementing baseline requirements applicable to other types of reactors.

In 2016, ASN asked EDF to take account of the lessons learned from the heat wave events of 2015 and 2016, along with their effects on the facilities, in the studies planned for the fourth periodic safety reviews of the 900 MWe reactors. The conclusions of these studies could, as applicable, be taken into account in the revision of the studies concerning other types of reactors.

• Lightning risks

The measures taken to address the lightning risk for the NPPs is currently primarily based on the steps specified by the regulations applicable to installations classified for protection of the environment. These regulations require the performance of a lightning risk assessment to identify whether or not it is necessary to protect the various buildings, along with a technical study to determine the nature of the protection systems to be installed (mainly lightning arresters and lightning conductors), where they are installed and how they are checked and maintained.

For the purposes of the fourth periodic safety review of the 900 MWe reactors, ASN informed EDF that the application of this order would not enable a sufficient level of safety to be attained on the NPPs and asked EDF to transmit a new methodology more particularly taking account of plausible combinations with other hazards and the secondary effects of lightning (fires, loss of off-site electrical power supplies). The new methodology proposed by EDF is currently being reviewed by ASN.

• Other hazards

The safety case for the EDF NPPs also takes account of other hazards such as high winds, snow, tornados, cold air temperature, man-made hazards (transport of dangerous goods, industrial facilities, airplane crashes, etc.), and hazards affecting the heatsink.

2.4.6 _ Evaluation of the risk prevention measures relating to hazards

The Fukushima Daiichi accident led EDF to reinforce its organisation for the control of risks relating to 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

On the basis of its inspections, ASN observes that the integration of operating experience feedback regarding the fire risk is on the whole satisfactory and that the refurbishment of the fire detection system is continuing on the nuclear reactors.

The number of outbreaks of fire recorded for 2018 is below that for 2017.

However, the findings made in previous years are still valid with regard to some of the sites inspected:
- management of zoning anomalies in the premises could be improved in order to prevent the spread of fire;
- deviations linked to the management of fire detection inhibitions;
- deviations in the management of stores of equipment representing significant heat potential, in particular during reactor outage phases;
- deviations in the use of fire permits and sometimes incorrect 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 2018, 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 notes the efforts made by certain sites to reduce these deviations through the deployment of tools and action plans, but considers that if they are to be effective, the personnel must receive more comprehensive assistance with their implementation. ASN thus observed that in 2018, EDF had more specifically initiated an action plan aimed at identifying the premises particularly sensitive to the fire risk and, in them, to eliminate errors in the control of the risks entailed by this hazard.

In addition the time taken to remedy certain deviations or to take corrective actions as a result of experience feedback could be reduced.

ASN asked EDF to pay particular attention to the management of combustible materials brought into the reactor building, notably during the reactor outage phases.

• Explosion risks

Despite the steps taken by EDF, control 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 (periodic test procedures and documents concerning protection against explosions), the integration of lessons learned, the handling of certain deviations and the deployment of certain modifications are sometimes postponed, which cannot always be justified with regard to the potential safety consequences.

ASN notes the efforts made by EDF to reduce these deviations through the implementation of reinforced monitoring and deployment of the action plan. However, ASN considers that EDF must continue to pay particular attention to this point and to application of the regulations concerning the explosive atmospheres formation risk (ATEX), and ensure that the explosion risks prevention approach is implemented with all necessary rigour on all the sites.

• Internal flooding risks

The provisions for the prevention and management of the internal flooding risk are also regularly checked by ASN. These inspections show that the steps taken to manage this type of hazard are not up to the level expected for all the sites. ASN more specifically observes that on some sites, the network of coordinators is still being set up and is not fully operational.

EDF has initiated walkdowns to identify the piping which could cause internal flooding in the electrical buildings, which are particularly vulnerable to this risk, in order to assess the need to reinforce their maintenance. In accordance with ASN's requests, EDF will extend these surveys to the other buildings. ASN sees as positive the fact that EDF has initiated the refurbishment of the circuits of certain cooling systems that are particularly susceptible to corrosion.

In 2016 and 2017, EDF sent ASN notification of several significant safety events concerning the flow of water caused by leaks from piping in poor condition or valve lock-out errors during maintenance operations.

Considerable efforts are required on most sites to improve the management of the flooding risk, in particular with respect to:
- maintenance of the necessary equipment (piping, floor drains, etc.);
- risk assessments during maintenance operations and in the event of detection of a malfunction of a necessary equipment item;
- compliance with the action deadlines identified by the annual reviews;
- the training of the coordinators and awareness-raising among the EDF and contractor personnel.

• Seismic risks

The operating and maintenance conditions of the seismic detection equipment are considered to be satisfactory. The annual reviews allow the identification of areas for progress and these are on the whole implemented. EDF is however required to continue with its efforts, notably with regard to the training of staff and awareness-raising among contractors. ASN notes that the operating instructions in the event of an earthquake are not always sufficiently operational and that more regular simulations would improve their applicability.

Significant safety event concerning lack of seismic resistance

In 2018, EDF reported a significant safety event concerning a lack of seismic resistance with regard to metal catwalks in Belleville-sur-Loire NPP reactor 2, Cattenom NPP reactors 2, 3 and 4, Flamanville NPP reactors 1 and 2, Golfech NPP reactor 1, Paluel NPP reactors 1, 2, 3 and 4, Penly NPP reactors 1 and 2 and Saint-Alban/Saint-Maurice NPP reactors 1 and 2.

EDF stated that these catwalks could constitute a hazard to equipment important for the protection of interests located nearby or underneath, in the event of an earthquake. An earthquake could then lead to situations not covered by the nuclear safety case.

EDF has started work to reinforce these catwalks and defined a schedule for all the reactors concerned. ASN considers this to be acceptable in the light of the nuclear safety implications. For the reactors with catwalks still to be reinforced, ASN oversaw performance of this work and stipulated compliance with this schedule.

In the light of its potential consequences for nuclear safety in the event of an earthquake, ASN rated this significant event level 1 on the INES scale for the 15 reactors concerned.

EDF regularly reports 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. EDF must therefore continue with these inspections to ensure the compliance of its facilities with the provisions for dealing with an earthquake. In 2018, EDF more particularly reported a significant safety event concerning a lack of seismic resistance on the part of catwalks (see box).

• Hazards linked to extreme temperatures

The inspections concerning the hazards associated with extreme temperatures show that EDF's organisation needs to be improved on the majority of sites. On several sites, ASN more particularly found a lack of forward planning in preparing the facility for the summer or winter configuration.

During its inspections ASN repeatedly notes that EDF does not systematically initiate the required measures if certain temperature thresholds are exceeded. These findings led ASN to issue requests for corrective action. The risk assessments associated with the deployment of countermeasures should also be improved.

• Lightning risks

The inspections relating to lightning reveal the need on all sites to set up an organisation and reinforced oversight to improve the integration of the regulatory requirements concerning the management of this hazard.

The lightning risk assessments can be based on information which does not actually reflect the real situation on the facilities. ASN also observes a significant delay in the performance of the work identified in the technical studies. The deadlines for performance of the periodic checks on the lightning protection systems by the competent inspection organisations are on the whole not adhered to. These points were the subject of requests for corrective action. EDF has defined a programme of work to improve the situation.

2.4.7 _ Monitoring facilities compliance with the requirements

Maintaining the compliance of the facilities with their design, construction and operating requirements is a major issue insofar as this compliance is essential in demonstrating the protection of interests. The processes employed by the licensee, notably during reactor outages, contribute to maintaining the compliance of the facilities with the requirements resulting from this demonstration.

• Reactor outages

Nuclear power reactors need to be periodically shut down in order to renew the fuel, which gradually becomes depleted during the electricity production cycle. One third or one quarter of the fuel is thus renewed at each outage.

These outages allow temporary access to certain parts of the facility which are not accessible during production, although with specific radiation protection precautions. They are therefore an opportunity to verify the condition of the equipment by running checks and tests and performing maintenance work, as well as to carry out work on the facility.

These refuelling outages can be of several types:

- Refuelling Outage (ASR) and Partial Inspection (VP) outage: these outages last a few weeks and are devoted to renewing part of the fuel and conducting a programme of verification and maintenance that is more extensive during a Partial Inspection (VP) than during a Refuelling Outage (ASR).
- Ten-yearly Outage (VD): this outage entails a wide-ranging verification and maintenance programme. This type of outage, which lasts several months and takes place every 10 years, enables the licensee to carry out major operations such as a complete inspection and hydrotesting on the primary system, a containment test or incorporation of design changes as a result of the periodic safety reviews.

These outages are scheduled and prepared for by the licensee several months in advance. ASN checks the steps taken by the licensee to ensure the safety of the facility, protection of the environment and radiation protection of the workers during the outage, as well as the safety of the reactor for the next production cycle.

The defined requirements

The Order of 7 February 2012 states that a defined requirement is a "*requirement assigned to an Element Important for Protection (EIP) of persons and the environment, so that, with the expected characteristics, it performs the function stipulated in the safety case mentioned in the second paragraph of Article L. 593-7 of the Environment Code, or to an Activity Important for Protection (AIP) of persons and the environment so that it meets its objectives with respect to this safety case*".

For the EIP, these requirements can in particular concern:
- the characteristics of the materials used;
- the manufacturing, assembly, erection and repair processes;
- the physical parameters and criteria characteristic of the performance of the EIP.

For the AIP, these requirements can in particular concern:
- the skills needed to perform the activity;
- any qualifications necessary;
- checks and hold points;
- the equipment and hardware needed to enable the activity to be carried out in accordance with the regulatory or even contractual requirements, such as to guarantee compliance with the safety case.

Deviation handling

A deviation is non-compliance with a defined requirement or a requirement set by the licensee's integrated management system. A deviation may thus affect a structure, a system or a component of the facility. It may also concern compliance with an operating document or the working of an organisation.

The regulations require that the licensee identify all deviations affecting its facilities and handle them. The activities related to the handling of deviations are activities important for the protection of persons and the environment. They are thus subject to oversight and monitoring requirements, the implementation of which is regularly checked by ASN.

The monitoring performed by ASN, in the light of the provisions of its resolution 2014-DC-0444 of 15 July 2014 concerning shutdowns and restarts of pressurised water reactors, primarily concerns:
- during the outage preparation phase, the content of the outage programme drawn up by the licensee. As necessary, ASN may ask for additions to this programme;
- during the outage – through regular briefings and inspections – the implementation of the programme and the handling of any unforeseen circumstances;
- at the end of outage, when the licensee presents its reactor outage report, the condition of the reactor and its readiness for restart. After this inspection, ASN will either approve reactor restart, or not;
- after the reactor restarts, the results of all tests carried out during the outage and during the restart phase.

• The identification and handling of deviations

The checks initiated by EDF for its operating baseline requirements and the additional verifications requested by ASN on the basis more particularly of operating experience feedback, can lead to the detection of deviations from the defined requirements, which must then be processed. These deviations can have a variety of origins: design problems, construction errors, insufficient control of maintenance work, deterioration through ageing, organisational shortcomings, etc.

The measures for detecting and correcting deviations, prescribed by the Order of 7 February 2012, play an essential role in maintaining the level of safety of the facilities.

• "Real time" verification

The performance of periodic tests and preventive maintenance programmes on the equipment and systems helps identify deviations. Routine 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 that cannot be performed when the reactor is in production. These operations are mainly used to remedy anomalies already identified, but also lead to the detection of new ones. Before each reactor restart, ASN asks EDF to identify any anomalies not yet remedied, to take appropriate compensatory measures and to demonstrate the acceptability of these anomalies with respect to the protection of persons and the environment for the coming production cycle.

• 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 designed to check the parts of the facility which are not covered by a preventive maintenance programme.

• The additional verifications in response to ASN requests

In addition to the steps taken by EDF with regard to its operating baseline requirements, additional checks are carried out at the request of ASN, whether with regard to operating experience feedback about events which have occurred on other facilities, after inspections, or after examination of the provisions proposed by the licensee within the context of the periodic safety reviews.

• Informing ASN and the public

When a deviation is detected, and in the same way as any BNI licensee, EDF is required to assess the impacts on nuclear safety, radiation protection and protection of the environment. If necessary, EDF sends ASN a significant event notification. As of level 1 on the INES scale, the public is informed on *asn.fr* of the events thus notified by the licensees.

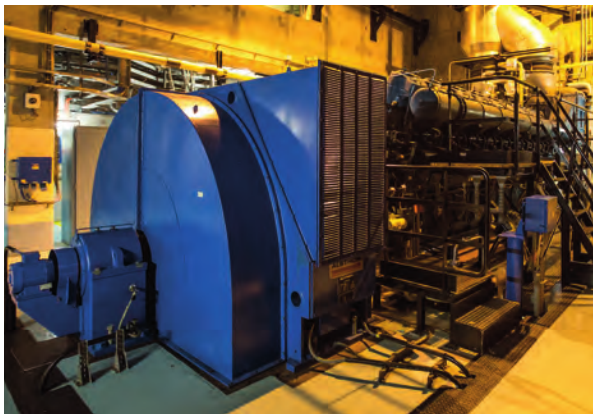
Seismic resistance of the auxiliary systems of the emergency diesel generating sets

In 2017, EDF reported a significant safety event concerning the failure to demonstrate the seismic resistance of the civil engineering anchors of the auxiliary systems of the emergency diesel generating sets for itsnuclear power reactors. ASN rated this event level 2 on the INES scale.

The event covers both design problems which are generic to all the reactors concerned and local problems relating to the poor condition or poor installation of the anchors. This was the subject of ASN information notices on 20 June 2017, 30 October 2017 and 17 January 2018. At that time, it concerned 26 reactors of 900 and 1,300 MWe.

On 3 April 2018 and then on 16 November 2018, following analysis of the results of additional inspections, EDF informed ASN that other 900 MWe reactors were also concerned by this event. ASN thus rated this significant event level 2 on the INES scale for an additional 11 reactors.

Each of the reactors in the French NPPs has two emergency diesel generating sets. This equipment provides a redundant electrical power supply to certain safety systems in the event of the loss of off-site electrical power, more particularly in the wake of an earthquake. The emergency diesel generator sets comprise a generator, a diesel engine and auxiliary systems (cooling, pre-lubrication, etc.). If off-site electrical power is lost as a result of an earthquake, the operation of the emergency diesel generating sets could no longer be guaranteed owing to the failure of their auxiliary systems.



Emergency diesel generator set in the Penly NPP

On all of the reactors concerned by this event, work has been carried out to reinforce the anchors of the emergency diesel generating sets. Certain inspections which can only be performed when the reactor is shut down for refuelling must however still be conducted and assessed.

During the course of its inspections, ASN checks correct performance of the inspections and the reinforcement work on the anchors.

• ASN's remediation requirements

For the more important deviations, ASN published Guide No. 21 on 6 January 2015 covering the processing of compliance 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 time 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 significant events reported (a summary of their analysis for 2018 is given in point 2.4.8) and checks that EDF has dealt with them. The significant events considered to be noteworthy owing to their severity or their recurring or generic nature, are the subject of an in-depth analysis by ASN.

During inspections in the NPPs and the EDF head office departments, ASN checks the licensee's organisation and the steps taken to learn the technical and organisational lessons from operating experience feedback.

2.4.8 _ Evaluation of facilities compliance with their applicable requirements

The periodic testing, equipment maintenance and replacement programmes, the reactor periodic safety review approach and the correction of deviations should enable the licensee to check and ensure the lasting ability of the equipment in an NPP to perform the functions assigned to it for the protection of persons and the environment.

ASN in-depth inspection at the Gravelines NPP – May 2018

The detection, characterisation and handling of deviations are covered by regulatory provisions of the Order of 7 February 2012. These provisions are important because they contribute to controlling the conformity of the facilities with the requirements for protection of the interests stipulated by the law, a pre-condition for their operation. Moreover, control of conformity should enable the improvements that result from the periodic safety reviews to be based on a known and robust actual status of the facilities.

In recent years, ASN identified the management of deviations affecting NPPs as one of its priority inspection topics. The results of these inspections brought to light difficulties encountered by the NPPs in identifying, characterising and processing deviations.

The checks carried out by EDF or requested by ASN in 2018, during reactor scheduled outages and during reactor operating periods, revealed a number of deviations calling into question the ability of certain systems important for safety to perform their functions, such as the electrical systems, control rod assemblies, back-up systems, certain ventilation systems or the heat sink.

Some of the deviations identified are linked to failure modes not considered in the design of the reactors. This is for example the case with the significant safety event concerning the lack of seismic resistance of the catwalks on certain 1,300 MWe reactors and the significant safety event concerning the risk of control rod blockage as a result of significant wear on the thermal sleeves of the reactor pressure vessel closure heads (see relevant boxes).

Other deviations are linked to poor condition or to non-compliance with the equipment drawings. This is for example the case with the inadequate seismic resistance of certain flanges positioned on the discharge from the emergency service water system (heat sink), or the non-compliance of the supports on the auxiliary piping of the medium-pressure safety injection system pumps. Finally, ASN served EDF with formal notice to carry out the work needed to ensure the compliance of 14 pressure equipment items on certain 900 MWe reactors, which were under-sized.

In 2018, ASN carried out a tightened inspection on the topic of identifying and processing deviations in the Cruas-Meysse NPP. In the field, the inspectors more particularly observed several examples of serious deterioration liable to affect the working of various systems (steam generators emergency power supply, emergency generating systems, spent fuel storage pool cooling system).

The deviations identified in 2018 and the findings of the inspections lead to the same conclusion as that presented in the 2017 annual report: the actual conformity of the facilities needs to be appreciably improved.

In 2018, EDF undertook a revision of its internal baseline requirements applicable to its NPPs in order to improve deviations processing and ensure that ASN receives information that is both reactive and proportionate to the safety implications. In 2018, ASN more particularly noted that EDF's rapid rectification of deviations had improved.

ASN will be particularly attentive as to how the situation develops in 2019 and will in this respect continue its inspections of the condition of equipment and systems. Control of the conformity of the facilities in operation will be a major focus for ASN oversight in 2019, notably on the occasion of the fourth ten-yearly outage inspection of the Tricastin NPP reactor 1.

• Analysis of significant events statistics

In accordance with the rules concerning the notification of significant events (see point 3.3 of chapter 3), EDF in 2018 notified ASN of 686 significant safety events, 169 radiation protection events and 75 environmental protection events.

Table 1 shows how the number of significant events notified by EDF and classified on the INES scale has evolved since 2008.

Table 2 shows the trend since 2008 in the number of significant events according to the notification field: Significant Safety Events (ESS), Significant Radiation Protection Events (ESR) and Significant Environmental Events (ESE). Events off the INES scale are also taken into account.

Several events which are similar or the result of common causes affect several NPPs. They are grouped under the term Generic Significant Events (ESG). Twenty-six were notified in 2018, of which twenty-five were in the field of safety and one in the field of radiation protection.

The number of significant events increased by about 1.5% in 2018 by comparison with the previous year.

Risk of blockage of control rods in the 1,300 MWe reactors

On 14 February 2018, EDF notified ASN of a significant safety event involving a risk of blockage of control rod clusters owing to significant wear of the thermal sleeves on the vessel closure heads of Belleville-sur-Loire NPP reactor 2 and Saint-Alban/Saint-Maurice NPP reactor 2. ASN rated this event level 1 on the INES scale.

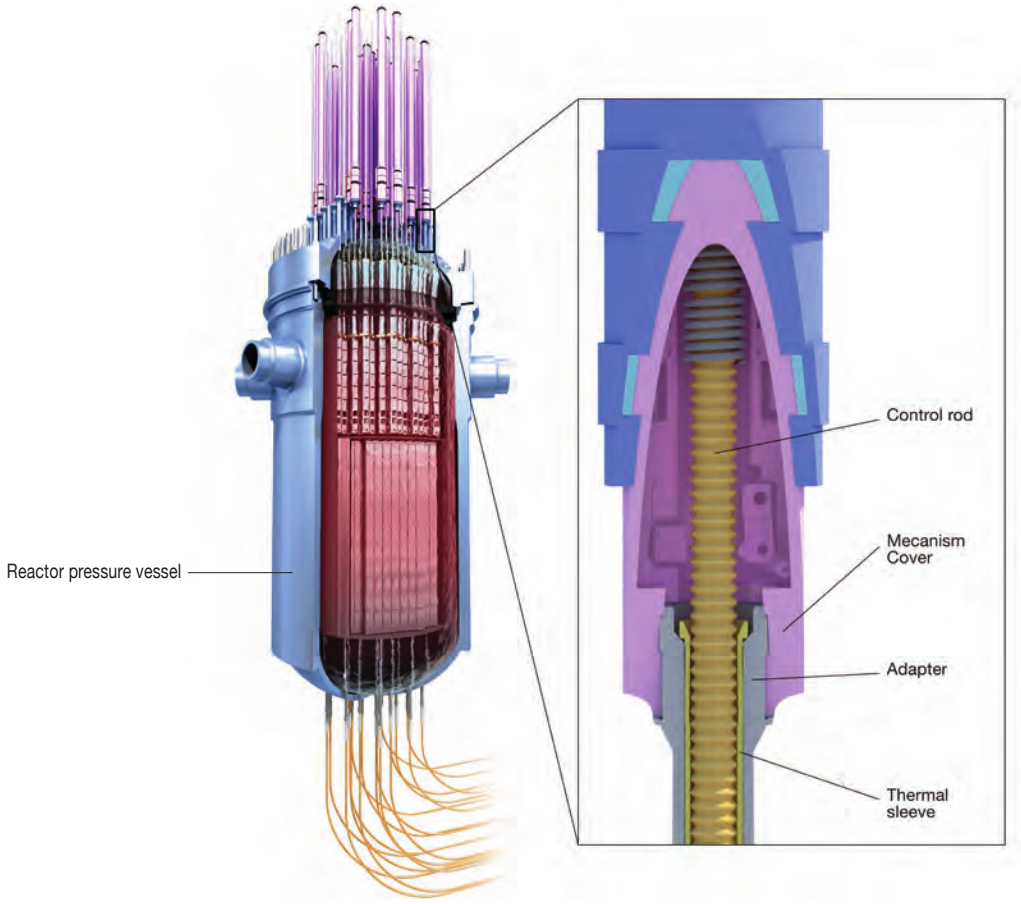
The nuclear power reactor vessel closure heads are fitted with thermal sleeves where they are penetrated by the control rod clusters. The control rod clusters are groups of mobile rods joined together and containing a neutron absorbing material. They are used to control the reactor's power level when inserted into the reactor core and thus stop the nuclear reaction in the event of an incident or accident situation.

The significant wear of several thermal sleeves led to the rupture of their upper part, which then formed a metal ring. This ring then blocked the movement of one of the control rod clusters. A blockage of this type had been observed by EDF on 3 November 2017 on the Saint-Alban NPP reactor 2, on 5 and 13 December 2017 on the Belleville-sur-Loire NPP reactor 2 and on 17 August 2018 on the Nogent-sur-Seine NPP reactor 1.

The checks and any repairs require shutdown of the reactor. Since this wear has been detected, EDF checks the thermal sleeves on all its reactors. The investigations carried out showed that twenty of EDF's 1,300 MWe reactors are particularly susceptible to being affected by this significant wear. They will be inspected no later than during their next refuelling outage, with the last ones being scheduled for the first quarter of 2019.

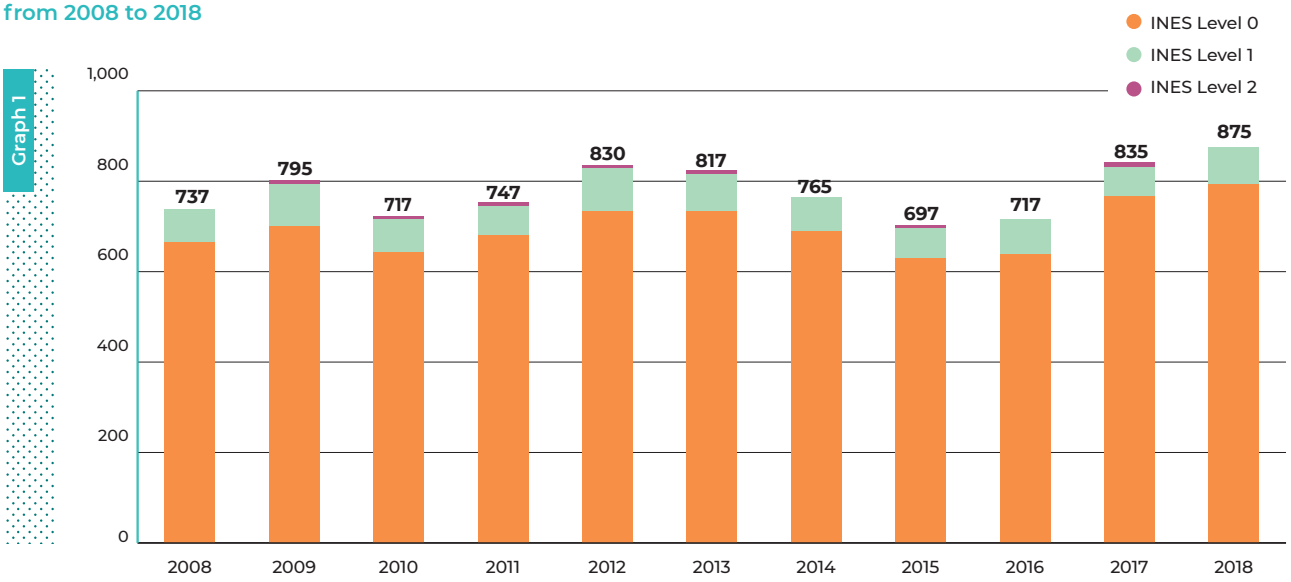
For the 1,300 MWe reactors not yet inspected, ASN asked EDF to carry out monthly control rod drop tests and to take operational measures to ensure reactor scram even if several control rod clusters are blocked.

ASN checked the investigations carried out by EDF and the implementation of the provisions it requested.



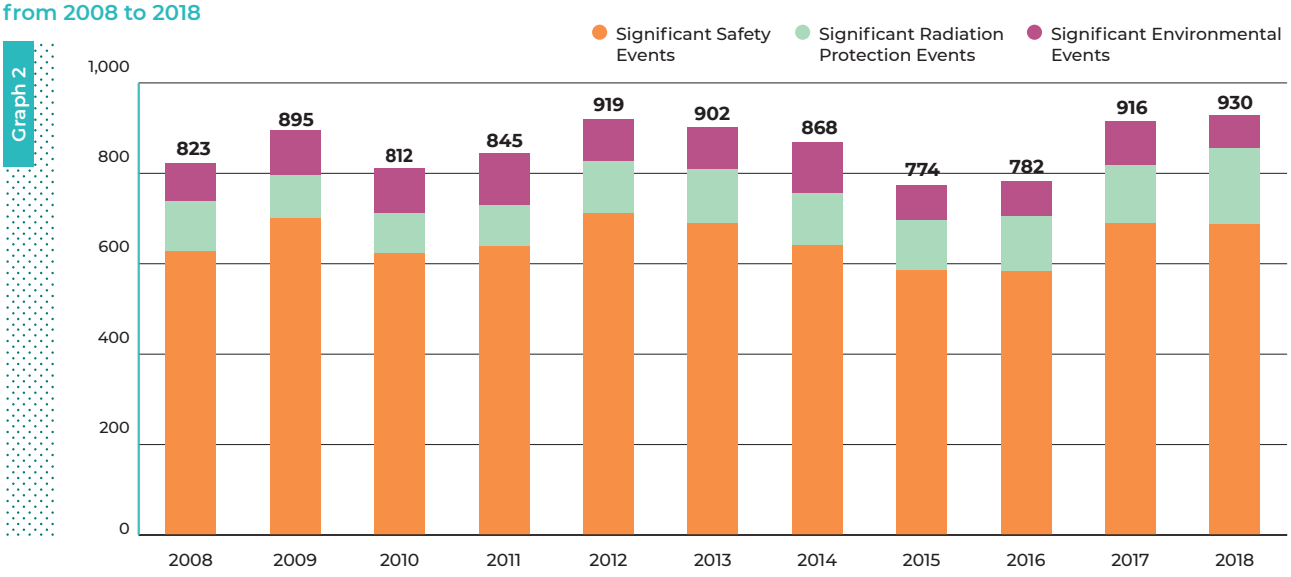
Trend in the number of significant events rated on the INES scale in EDF nuclear power plants from 2008 to 2018

Graph 1



Trend in the number of significant events per domain in EDF nuclear power plants from 2008 to 2018

Graph 2



2.5 _ Prevention and management of environmental and health impacts

2.5.1 _ Monitoring of discharges and waste management

• Monitoring the management of water intake and environmental discharges

The Environment Code empowers ASN to issue binding requirements concerning BNI water intake and effluent discharges (see point 4.1 of chapter 3). The laws and regulations concerning environmental protection which apply to French NPPs comprise regulations, primarily the Environment Code, the Order of 7 February 2012 and ASN resolutions 2013-DC-0360 of 16 July 2013 concerning the management of detrimental effects and the health and environmental impact of BNIs, and 2017-DC-0588 of 6 April 2017 concerning procedures for water intake and consumption, effluents discharge and environmental monitoring for PWRs, as well as regulations specific to each of the NPPs:

- decisions setting the procedures for water intake and consumption and environmental discharges of liquid and gaseous effluents (chemical and radioactive);
- decisions setting the environmental discharge limits for liquid and gaseous effluents (chemical and radioactive). These decisions are approved by the Minister responsible for Nuclear Safety;

Improved confinement of liquid dangerous substances in NPPs

Further to an ASN request in 2013, EDF initiated a review of its ability to ensure reliable and lasting prevention of accidental flows into the environment of dangerous substances and effluents liable to result from fire-fighting. If not collected upstream, these flows are liable to spill into the site's wastewater and rainwater drainage network and into the environment.

This review led to the implementation of a national programme, some parts of which are still being deployed.

A first part consists in developing technical solutions to collect any pollution not retained upstream of the wastewater network. The preferred solution is to build retention tanks to collect the polluted waters and avoid their spilling into the environment. When this solution cannot be envisaged on a site, for example owing to a lack of space, other systems are used. This involves plugs or valves which confine the pollution directly in the wastewater system and prevent it from being drained away.

Work was also carried out on the operation and maintenance of the equipment used in the collection of spills, notably retention areas. After examining operating experience feedback, EDF defines a set of operational management rules for its sites designed to prevent pollution.

Finally, EDF is improving its personnel training to make them aware of the pollution risk and the corresponding prevention measures.

More particularly during the course of inspections, ASN carries out spot-checks on the effective implementation of this national improvement programme and issues requests for the necessary corrective measures as applicable.

- the Orders of the Prefect authorising water intake and discharges of liquid and gaseous effluents: pre-dating November 2006, they contain binding requirements concerning the procedures and discharge limits specific to a nuclear site. In order to apply the new regulatory architecture to all the French NPP reactors, revision of the orders has led to them being repealed, with the adoption of ASN resolutions.

For each site, ASN sets the limit values for emissions, water intake and discharge of effluents on the basis of the best 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 on health and the environment of the pressurised water reactor NPPs. These binding requirements are notably applicable to the management and monitoring of water intake and effluent discharge, to environmental monitoring and to information of the public and the authorities (see point 4.1 of chapter 3).

In order to set these requirements, ASN bases its work on operating experience feedback from all the reactors, while taking account of operational changes (change in conditioning of systems, anti-scaling treatment, biocidal treatment, etc.) and changes to the general regulations.

Finally, every year, the NPP licensees send ASN an annual environmental report which notably contains a summary of the intakes from and discharges into the environment, any impacts they may have, the significant events which have occurred and the future outlook.

• The impact on thermal discharges from the NPPs

NPPs discharge hot effluents into rivers or the sea, either directly, from those NPPs operating with direct or "once-through" cooling, or after cooling of these effluents in cooling towers, enabling some of the heat to be dissipated to the atmosphere. Thermal discharges from NPPs lead to a temperature rise between the points upstream and downstream of the discharge which, depending on the reactors, can range from a few tenths of a degree to several degrees. These thermal discharges are regulated by ASN resolutions.

Since 2006, provisions have been incorporated into these resolutions in order to define in advance the operating modes of NPPs in exceptional climatic conditions that would lead to significant warming of the watercourse. These special provisions are however only applicable if the security of the electricity grid is at stake.

• Oversight 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 French 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 "Regulation" section 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.

ASN's oversight of the management of the waste produced by EDF's NPPs is based on the data taken from the annual reports transmitted by the licensee to ASN, the waste management studies and its findings made during the course of its inspections.

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 that could give rise to pollution.

The licensee must thus for instance precisely identify the location of each dangerous substance on its site, along with the relevant quantities. Drums and tanks must be labelled in compliance with the European CLP (Classification, Labelling, Packaging) regulation and there must be retention areas designed to collect any spills. The NPPs must also adopt an organisation and resources to prevent pollution of the natural environment (groundwater, river, soil).

For several years and at the request of ASN, EDF has been carrying out measures to improve its control of the pollution risk by working to improve the containment of dangerous liquid substances on its sites (see box p. 297).

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

Some cooling systems in NPPs are environments that are favourable to the development of legionella and other amoebas (see point 1.4).

ASN resolution 2016-DC-0578 of 6 December 2016 on the prevention of risks resulting from the dispersal of pathogenic micro-organisms (legionella and amoeba) by PWR secondary system cooling facilities sets requirements concerning:
- the design, upkeep and monitoring of the facility;
- the maximum legionella concentrations in the water in the facility and downstream of it with regard to amoeba;
- the steps to be taken in the event of proliferation of micro-organisms in the systems or identified infection in the vicinity of the facility;
- information of the public and the administrations in the event of proliferation of micro-organisms.

Through its investigations and its field checks, ASN closely monitors the preventive or remedial measures taken by EDF to reduce the risk of the proliferation of these micro-organisms and the results of these actions, including the chemical discharges resulting from biocidal treatment.

As there can be a different number of reactors on each site, the results are given "per pair of reactors", to enable a comparison to be made from one site to another. This for example entails:
- keeping the results as-are for the Golfech site, which has two reactors;
- dividing by two those of Chinon, which has four reactors (Chinon/2);
- dividing by three those of Gravelines, which has six reactors (Gravelines/3).

In addition, the discharge data transmitted by EDF to ASN for each site are not representative of the operating time of the installations or of the activities performed on the sites.

2.5.3 _ Evaluation of control of detrimental effects and impact on the environment

• Evaluation of prevention of detrimental effects, control of environmental discharges and waste management

In 2018, in the same way as every year, 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 Civaux, Golfech and Le Blayais NPPs thus underwent a tightened inspection.

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 these topics.

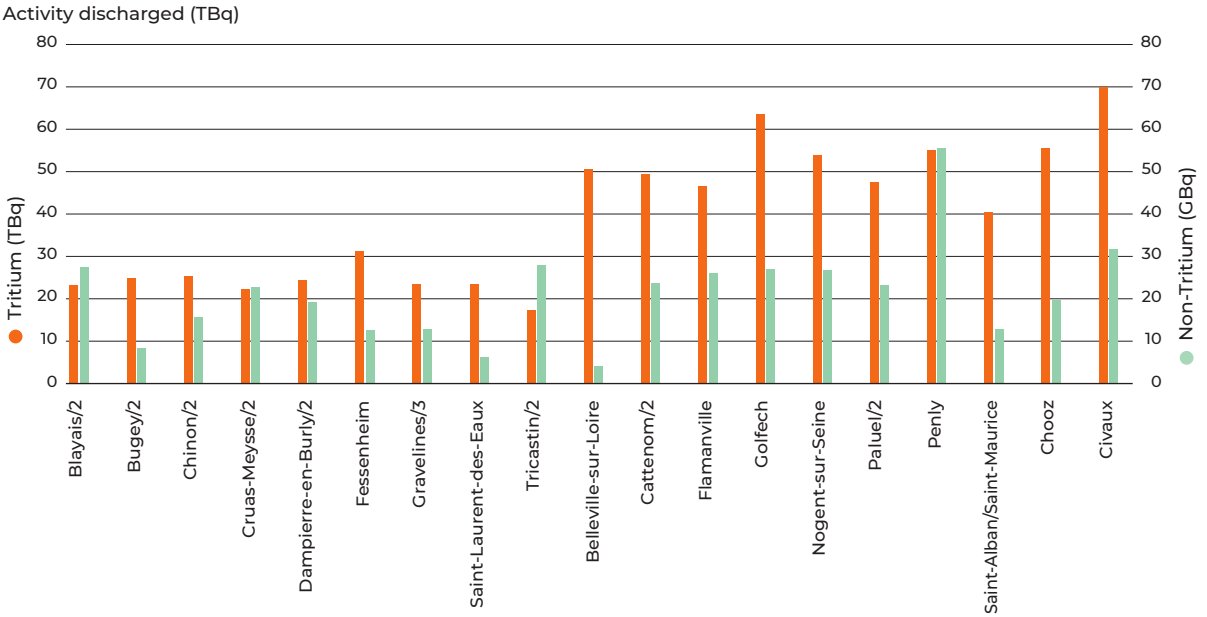
Despite the action plan implemented by EDF to limit the incidents of liquid spillage which could flow into the environment, events leading to such spills were still considered by ASN to be too numerous in 2018. Although these situations had no significant impact on the environment, they highlight the need for the licensee to step up its efforts on this point.

Exercises simulating a spillage, carried out during the tightened inspections, also led ASN to ask the three sites concerned to take steps rapidly to improve pollution prevention. From 23 January to 7 February 2019, ASN notably gave the public

Monitoring the environment of the Golfech NPP

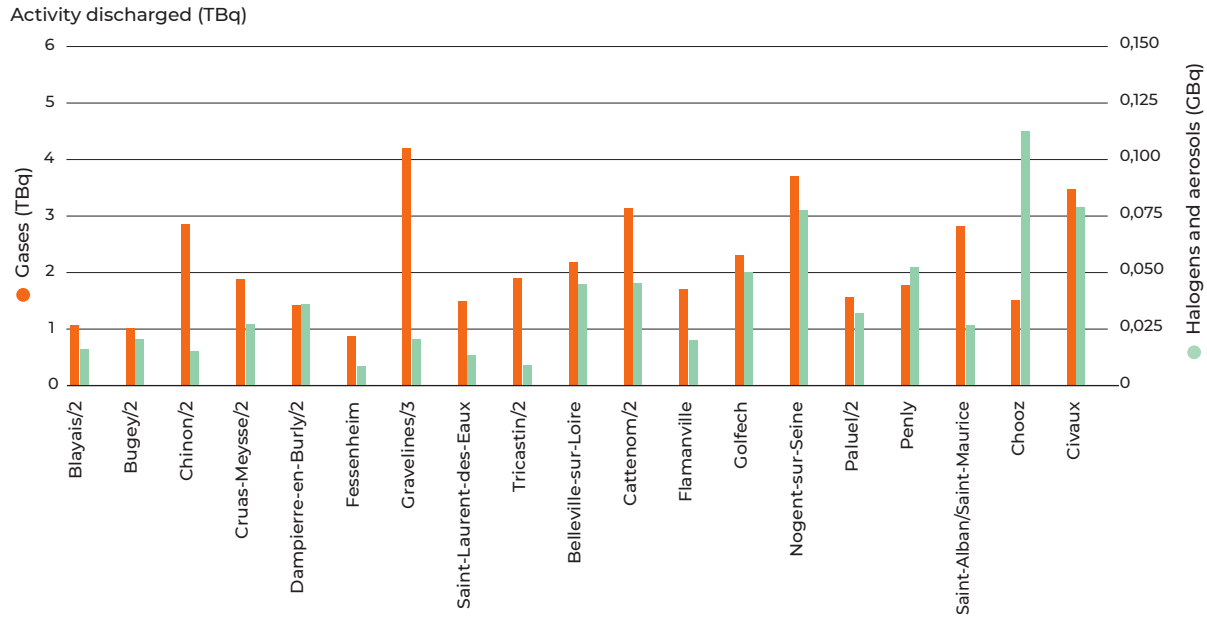
Liquid radioactive discharges for the NPPs in 2018 (per pair of reactors)

Graph 3



Gaseous radioactive discharges for the NPPs in 2018 (per pair of reactors)

Graph 4



As there can be a different number of reactors on each site, the results are given "per pair of reactors", to enable a comparison to be made from one site to another. This for example entails: • keeping the results as-are for the Golfech site, which has two reactors; • dividing by two those of Chinon, which has four reactors (Chinon/2); • dividing by three those of Gravelines, which has six reactors (Gravelines/3). In addition, the discharge data transmitted by EDF to ASN for each site are not representative of the operating time of the installations or of the activities.

access to its draft resolution on the EDF action plan concerning the implementation of new containment works on the Civaux site, where the pollution containment strategy was considered to be ineffective.

The organisation adopted by the sites to prevent risks resulting from the dispersion of pathogenic micro-organisms by the cooling towers needs to be further improved. The time needed to ensure compliance of the methodical risks assessment document led ASN to serve the Chinon site with formal notice on this point on 14 June 2018.

Although ASN has observed progress by some sites that had previously been under-performing on the subject of waste management, it is still waiting for EDF to make significant improvements to the organisation on most sites with regard to this topic.

On the whole, discharges are considered to be well-managed on the sites. However, evaluation errors detected by the licensee in 2018, or monitoring equipment unavailability constitute occasional weak points in the control of discharges which need to be remedied.

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 sites on the Loire Valley, those of the Rhone Valley and the Chooz and Cattenom NPPs, the NPPs of Le Blayais, Golfech and Civaux underwent tightened inspections in March and April 2018.

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 (up to sixteen ASN inspectors and three IRSN experts per site) enabled the control of discharges, waste management and 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.

Although the inspectors found that the EDF teams had taken account of certain points raised by ASN in previous years, these inspections nonetheless showed that a general improvement is needed in the way the environmental protection issue is dealt with. In addition, the ineffectiveness of the pollution confinement strategy on the Civaux NPP, observed during the spillage exercise, led ASN to instruct EDF to reinforce its pollution confinement management resources. After the inspection campaign, the licensee therefore drew up an action plan for which ASN will continue to monitor the implementation.

In 2019, ASN will continue its oversight of the prevention of pollution and detrimental effects, the control of environmental discharges and waste management.

2.6 _ Prevention and control of organisational risks

The contribution of people and organisations to the safety of NPPs is a decisive factor in all steps of the lifecycle of the facilities (design, construction, commissioning, operation, decommissioning). ASN therefore focuses on the conditions which are favourable or prejudicial to a positive contribution to NPP safety by the operators and worker groups. It defines Social, Organisational and Human Factors (SOHF) as being all the aspects of working situations and of the organisation that will have an influence on the work done by the operators.

2.6.1 _ Monitoring how organisations works

• 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. Of these, the processing of significant events requires an in-depth analysis of the organisational and human causes in addition to the technical causes.

Furthermore, the above-mentioned Order requires the licensee to define and implement an Integrated Management System (IMS) to ensure that the requirements concerning the protection of interests are systematically considered in any decision concerning the facility. This IMS must specify the steps taken with regard to organisation and to resources of all types, in particular those adopted to manage the activities important for the protection of persons and the environment.

ASN monitoring of the working of EDF's organisations put into place by EDF focuses on how the IMS is implemented. ASN more particularly ensures that the design or modification approach adopted by the engineering centres when a new facility is designed or an existing facility is modified takes account of the users' needs and does not compromise compliance with the defined requirements.

More broadly, ASN checks the organisation put into place by EDF to manage the resources needed to perform these activities.

• Control of subcontracted activities

Maintenance and modification activities on French reactors are to a large extent subcontracted by EDF to outside contractors. EDF justifies the use of subcontracting by the need to call on specific or rare expertise, the highly seasonal nature of reactor outages and thus the need to absorb workload peaks.

EDF's decision to resort to subcontracting must not compromise the technical skills it needs to retain in-house in order to carry out its licensee's responsibility for the protection of interests and be able to effectively monitor the quality of the work performed by the subcontractors. Poorly managed subcontracting is liable to lead to poor quality of work and have a negative impact on the safety of the facility and the radiation protection of the workers involved.

EDF 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 necessary (tools, documentation, etc.) for the performance of the tasks, in particular when these means are made available by EDF.

2.6.2 _ Evaluation of the working of the organisations and control of activities

In 2018, ASN in certain cases observed inappropriate working environments. In terms of organisation, this sometimes takes the form of a disparity between the workload and the available workforce, excessive time pressure or joint-contractor work in conditions that are not always satisfactory. In ergonomic terms, ASN regularly observes cramped premises, poor ventilation, degraded lighting, non-conforming scaffolding, or barely legible equipment identification. In equipment terms, this means missing or inappropriate operating documents, tools or spare parts. These recurring problems can be partly ascribed to more deep-rooted organisational causes, for example degraded relations between the site and the contractor responsible for logistics, delays in the preparation of the work, difficulties in obtaining working conditions or inefficient coordination between trades.

In 2018, ASN observes that the vast majority of the NPPs are making real efforts to reinforce the application of error-reduction practices by all those involved (pre-job briefing, stop and think phase, self-checks, cross-checks, secure communication, debriefing), but that the results differ considerably from one site to another. The "immediate" debriefing which takes place immediately after the end of the work, remains the weak point on most sites and is prejudicial to the creation of operating experience feedback which could be beneficial for future activities. ASN also considers that in a certain number of significant event reports, the inadequacies observed in the application of these practices are over-estimated by the analysts, which runs the risk of creating a blinkered view of the situation, simply pinpointing the responsibility of the persons involved and hiding the deeper human or organisational causes (time pressure, inappropriate working environment, etc.).

For all the NPPs, EDF must improve its control of the operational documentation. The cause of many significant events reported in 2018 is operational documentation that is hard to use (poor legibility, lack of consistency between the various documents, lack of diagrams or photos, etc.), or inappropriate (incomplete or obsolete documentation, procedures which do not take account of the reactor states, etc.).

In the face of these findings, ASN decided to reinforce its monitoring of EDF's organisations and defined documentation management as one if its inspection priority topics for 2019.

• Skills, training and qualifications management

The organisation in place on the sites for managing skills, qualifications and training remains on the whole satisfactory. On most of the sites, the steps taken to manage skills are satisfactory in that employment and skills are managed with four to five years of visibility and arrivals in and departures from the various departments are planned in advance. Skills are acquired and maintained by means of training (training worksites, training and refresher courses, tutoring and mentoring with simulation work) that is appropriate and well followed.

In 2018, on a few sites, ASN nonetheless observed the difficulties experienced by certain departments with formally identifying rare and sensitive skills and with maintaining adequate means and human resources for the work to be performed over the course of the year. Moreover, the ASN inspectors sometimes found the technical skills of certain staff members to be insufficient (lack of knowledge of equipment leading to equipment unavailability, out of date knowledge of equipment which has been modified, monitoring supervisors with insufficient technical expertise of the subjects being monitored, and so on). ASN finds that the weak points identified on these sites, some of which contributed to significant events, can be explained by sometimes inadequate training or mentoring (notably new hardware and software installed and changes to the regulations) or insufficiently rigorous monitoring of the clearances and qualifications required for the contractors.

• Monitoring of subcontracted activities

In 2018, ASN observes that the monitoring processes for subcontracted activities still indicate difficulties on a certain number of sites. These difficulties are persisting despite a clearly stated commitment on the part of the site managements (awareness-raising, seminars, management presence in the field, deployment of a new tool to facilitate the preparation of monitoring programmes, etc.). The origins of these shortcomings can be ascribed to difficulties in guaranteeing the long-term availability of the resources assigned to contractor monitoring and to monitoring supervisors who do not always have the necessary technical skills for the subject being monitored. ASN is encouraging EDF to continue with its actions to promote the presence of staff in the field and develop their ability to detect anomalies.

ASN nonetheless finds that progress was observed in 2018 in terms of preparation of the monitoring programmes. The monitoring supervisors highlight the contribution of the new tool currently being deployed in all the plants and which enables them to save time and be more efficient.

Tightened radiation protection inspections

Since 2011, ASN has carried out tightened inspections on the subject of protection of workers against ionising radiation. The Bugey, Cruas-Meysse, Saint-Alban/Saint-Maurice and Tricastin NPPs, located in the Rhone Valley, were the subject of a tightened inspection campaign in September and October 2018.

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 the teams on the sites had taken account of certain points raised by ASN in previous years and that good practices were implemented. However, they did note that in certain NPPs, the synergy between the department in charge of the prevention of radiological risks and the operational departments needs to be strengthened so that the radiation protection advisor can carry out the tasks entrusted to them by the Labour Code. This point will be given particular attention by ASN during the forthcoming examination of the applications for approval of the radiation protection centres of expertise required by Article R. 4451-125 of the Labour Code.

• 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. Despite this, ASN found shortcomings in 2018 with regard to the detection and characterisation of the difficulties and deviations reported in the field. The encouragement given to the contractors to transmit positive or negative findings *via* the dedicated database is only bearing fruit on a minority of sites. The contractor assessments are also proving to be sometimes incomplete, more specifically given the safety implications. Weaknesses have also been identified in the processing of operating experience feedback and the sharing of experience with the outside contractors. In addition, the assessments conducted by the sites following significant events are pertinent, but the analysis of the root causes often leads to corrective measures that are too basic and frequently nothing more than awareness-raising sessions for the staff, departments or companies identified as being responsible for the deviation. The analysis of the root causes should on the contrary be able to identify organisational shortcomings. Finally, too many sites are still particularly limited when it comes to assessing the effectiveness of the corrective measures.

2.7 _ Personnel radiation protection

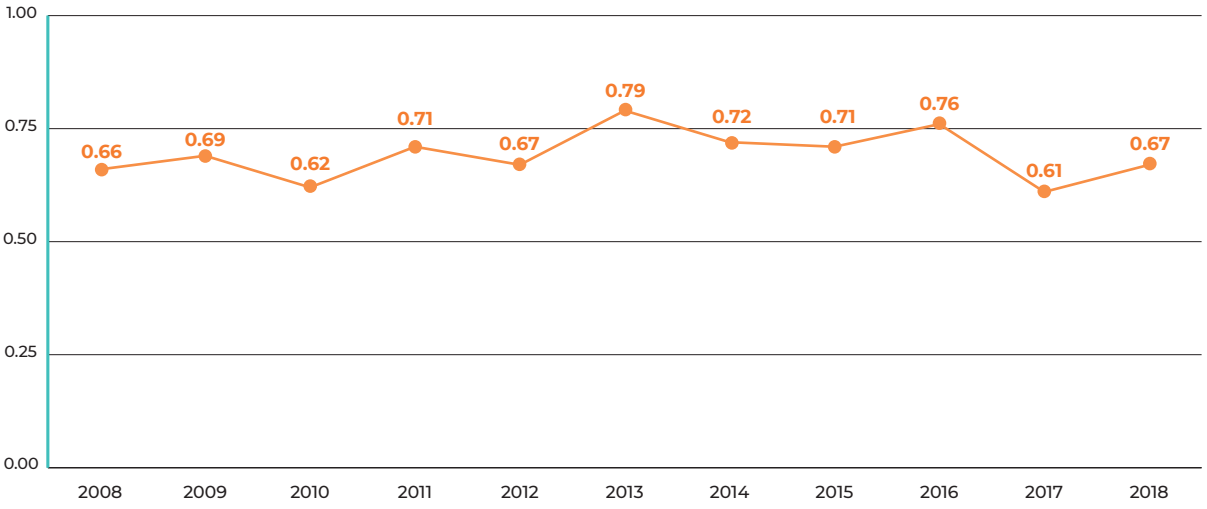
2.7.1 _ Monitoring of personnel radiation protection

Exposure to ionising radiation in a nuclear power reactor comes from activation of primary system corrosion products (mainly) and from fuel fission products. All types of radiation are present (neutrons, α, β and γ) and the risk of exposure is both external and internal. In practice, more than 90% of the doses received come from external exposure to β and γ radiation. Exposure is primarily linked to maintenance operations during reactor outages.

ASN checks compliance with the regulations relative to the protection of workers liable to be exposed to ionising radiation in NPPs. In this respect, ASN concerns itself with all workers active on the sites, whether EDF or contractor personnel.

Mean collective dose per reactor (Man.Sv/reactor)

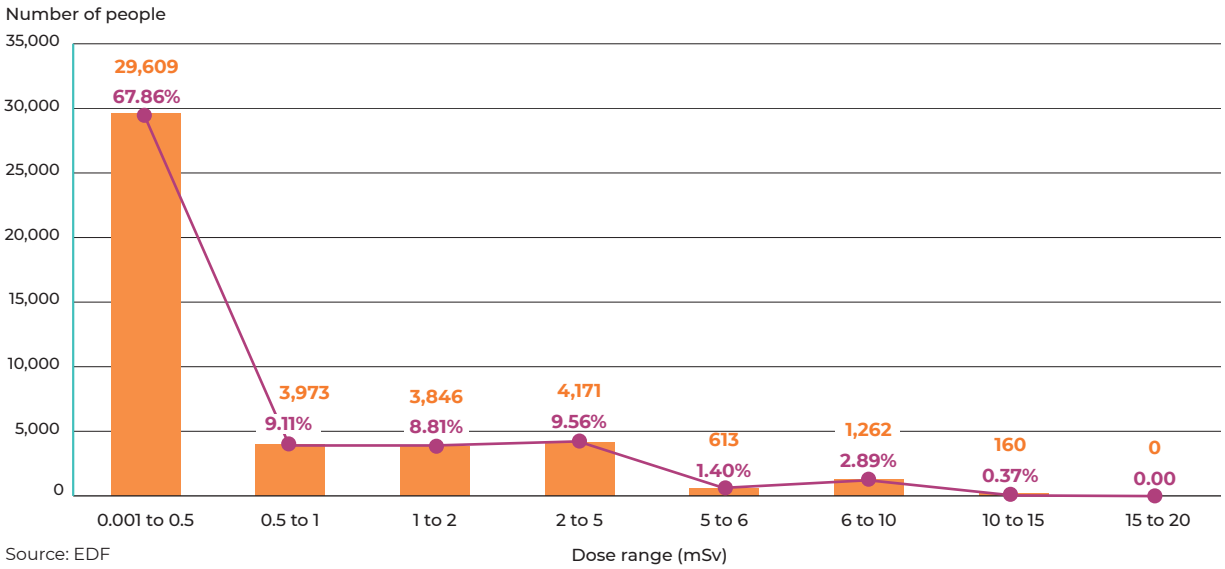
Graph 5



Source: EDF

Number and percentage of workers per dose range (in mSv) for 2018

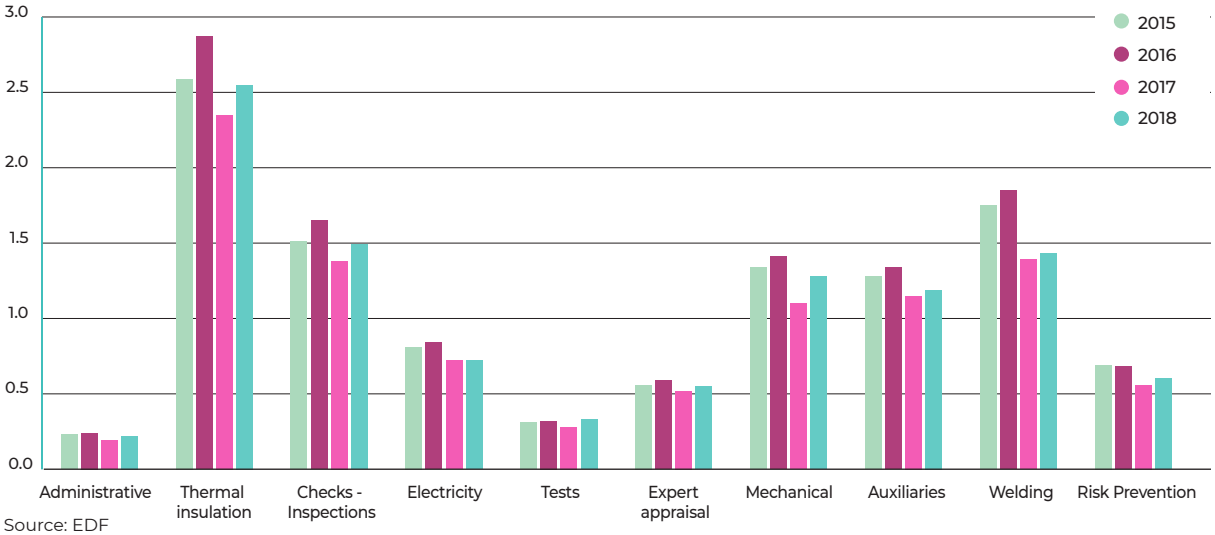
Graph 6



Source: EDF

Evolution of mean individual dose according to categories of workers in NPPs

Graph 7



Source: EDF

This oversight is carried out during inspections (specifically on the topic of radiation protection, one to two times per year and per site, during reactor outages, following incidents, or occasionally in the EDF head office departments and engineering centres), and during the review of files concerning occupational radiation protection (significant events, design, maintenance or modification files, EDF documents implementing the regulations, etc.) with the support of IRSN when necessary.

Periodic meetings are held with EDF as part of the technical dialogue with the licensee. They enable ASN to check the progress of technical or organisational projects being run to improve radiation protection.

• Significant contamination events

Two significant contamination events were notified in 2018 in the NPPs operated by EDF. These events, which led to exposure greater than one quarter the regulation limit per square centimetre of skin, were rated level 1 on the INES scale. They concern:

- contamination of the skin of the neck of a worker assigned to maintenance work in the Cruas-Meysse NPP;
- contamination of the skin under the beard of a worker assigned to maintenance work in the Tricastin NPP.

2.7.2 _ Evaluation of personnel radiation protection

The collective dose on all the reactors increased in 2018 by comparison with 2017 (Graph 5), as did the average dose received by workers for one hour of work in a controlled zone. However, these values remain lower than those recorded in 2015 and 2016. The doses received by the workers are broken down as shown below in Graphs 5 and 6.

Graph 6 shows the breakdown of the workers in terms of whole body external dosimetry. It can be seen that the dosimetry for 77% of the exposed workers is less than 1 mSv for the year 2018, 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 2018.

Graph 5 shows the trend in the collective dose received by NPP workers over the past ten years. Despite a slight increase in the collective dose received in 2018 by comparison with 2017, this Graph shows a trend towards stabilisation of the average collective dose per reactor over the past few years.

Graph 7 shows the trend in whole body average individual dosimetry according to the worker categories in NPPs. The most exposed worker categories in 2018 are personnel in charge of thermal insulation, monitoring, inspection and welding and mechanical work.

ASN considers that in 2018 the way the NPPs deal with radiation protection varies, notably with regard to control of radiological cleanness within the facilities and the steps taken to prevent the risk of contamination.

In the light of these findings, ASN carries out tightened checks on the implementation of the action plans required to correct these situations on the reactors concerned.

ASN considers that, on the whole, the radiation protection situation of the NPPs in 2018 should be improved on the following points:

- a lack of radiation protection culture on the part of certain outside contractors was fond by the ASN inspectors on several sites. Steps are required to reinforce monitoring and to develop exchanges between the various EDF entities and outside contractors concerning the protective measures to be taken;
- control of industrial radiography worksites remains fragile. ASN in particular identifies several events concerning shortcomings in signage or involving the presence of workers in the exclusion zones. Progress is required in the preparation of the worksites, more specifically multiple contractor activities, the optimisation of signage and the quality of the installation walkdowns carried out when preparing these worksites;
- the dosimetry optimisation approach must be reinforced, more particularly the exhaustiveness of the risk assessments for the work and their reassessment following unforeseen events;
- greater rigorousness is required in the administrative management of sources;

- control of radiological zoning is progressing, although greater vigilance is required regarding the removal of signs by unauthorised staff.

The prevalence of organisational shortcomings means that ASN is taking specific inspection measures to look at the links between the services competent in radiation protection and the other contributors to worker radiation protection, whether inside or outside EDF (see "Tightened inspections" box).

In several NPPs, ASN observes the positive impact of allocating "zone managers" and the position of worker radiation protection supervisor during reactor outages.

2.8 _ Labour Law in the nuclear power plants

2.8.1 _ Monitoring Labour Law in the nuclear power plants

ASN carries out labour inspectorate duties for the 58 reactors in operation (spread over the 19 NPPs), the eight reactors undergoing decommissioning and the EPR under construction at Flamanville. The number of people working in an NPP varies between 800 and 2,000 employees. The total number of staff assigned to all the nuclear sites is about 24,000 for the employees of EDF, and 23,000 for the employees of the subcontractors, which more specifically take part in maintenance during reactor outages.

The role of the labour inspectorate is to ensure that the Labour Code as a whole is applied by the employers, whether EDF or its contractors.

The labour inspectorate takes part in the integrated vision of regulation and oversight sought by ASN and it sees its monitoring work as being linked to other activities to monitor and oversee the safety of facilities and radiation protection.

As at 31 December 2018, for its labour inspectorate duties, ASN's staff was as follows:
- 16 labour inspectors, 4 of whom were 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

With regard to occupational health and safety, the ASN labour inspections more specifically covered the following topics in 2018:
- The use of electrical installations. The inspections carried out on this topic on various sites led EDF to adopt an approach designed to restore compliance.
- The worksites with asbestos risks. The labour inspectors are particularly vigilant with regard to preventing the risk of inhalation of these fibres during their inspections and had to remind personnel of the regulations on several occasions.
- The conformity of working equipment and more specifically lifting gear. The collective measures taken in 2016 and 2017 led EDF to implement a compliance plan for this equipment. This plan is being closely monitored by the labour inspectors.
- The fire and explosion hazards, for which the ASN inspectors revealed non-conformities. ASN provides coordinated monitoring 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).

Occupational accident inquiries are systematically held in the event of serious accidents or near-accidents. Three fatal accidents, caused by cardiac problems, unfortunately took place in 2018.

• International subcontracting and provision of services

Steps were taken in 2018 regarding the monitoring of notifications and the conditions for the secondment of staff from foreign companies, notably on the Flamanville EPR reactor construction site. In July 2018, ASN thus took part in action organised by the anti-fraud operational committee of the Manche *département*, coordinated by the Cherbourg District Court.

• Criminal and administrative procedures in progress

With regard to illegal work, ASN closely monitors the criminal proceedings instigated in previous years, more specifically through regular contacts with the Public Prosecutor's offices.

With regard to health and safety, the actions of the ASN labour inspectorate led in 2018 to the initiation of three criminal procedures against EDF or contractors concerning the electrical risk and the lack of suitable individual protection equipment for work in a confined space.

A labour inspection concerned the incorporation of the EDF code of ethics into the in-house regulations of its NPPs. This inspection led to administrative decisions by the labour inspectorate requiring withdrawal from the internal regulations of the facilities concerned of the parts of the code of ethics which contradicted the provisions of the Labour Code.

2.8.2 _ Health and safety assessment, professional relations and quality of employment in the NPPs

Certain occupational risk situations are still worrying and must be significantly improved: risks linked to work equipment and more particularly to lifting gear, the explosion risk and electrical risks. The labour inspectorate still observes situations in which the risk linked to the presence of asbestos is not systematically considered prior to the work, in order to avoid accidental exposure.

Finally, progress is still required in the management of multiple contractors working simultaneously (quality of prevention plans in particular) and the use of subcontracting and the secondment of foreign employees.

2.9 _ Lessons learned from the accident in the Fukushima Daiichi NPP

After the Fukushima Daiichi NPP accident, ASN issued a set of resolutions dated 5 May 2011 asking the licensees of major nuclear facilities to perform stress tests.

ASN issued a position statement on the conclusions of these stress tests on 3 January 2012, which was itself subject to a European peer review, as part of the European stress tests, in April 2012.

On the basis of the opinions of the Advisory Committee and the conclusions of the European stress tests, ASN issued a series of resolutions dated 26 June 2012 requiring that EDF implement:
- a "hardened safety core" of material and organisational measures which, in the event of an extreme external hazard, are designed to:
  - prevent an accident with fuel melt, or limit its progression,
  - limit large-scale radioactive releases,
  - enable the licensee to carry out its emergency management duties;

- a local emergency centre allowing emergency management of the nuclear site as a whole in the event of an extreme external hazard;
- a Nuclear Rapid Intervention Force (FARN) which, using mobile means external to the site, can intervene on a nuclear site in a pre-accident or accident situation;
- a range of corrective measures or improvements, notably the acquisition of additional communication and radiological protection means, the implementation of additional instrumentation, extensive consideration of internal and external hazard risks, improvement of the way in which emergency situations are taken into account.

In addition to its requests, ASN issued a range of resolutions dated 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".

Generally speaking, ASN's requests are part of a continuing process to improve safety with regard to the targets set for the 3rd generation reactors and aim in addition to be able to cope with situations far beyond those normally considered for this type of installation.

These requests are issued in application of the defence-in-depth approach and as such concern measures to prevent and mitigate the consequences of an accident, based on both additional fixed means and external mobile means planned for all the installations on a site beyond their initial design basis.

Given the nature of the required work, the licensee must carry out studies for the design, construction and installation of new equipment, which first require lead times and then require a schedule to optimise their implementation on each NPP. In addition, when 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 nuclear power plants.

So that the improvements needed as a result of the lessons learned from the Fukushima Daiichi NPP accident are made as rapidly as possible, while taking account of the constraints inherent in the engineering of these major works, EDF intends to implement these improvements in three phases.

• Phase 1 (2012-2015)
Deployment of temporary or mobile measures to enhance protection against the main situations of total loss of the heat sink or electrical power supplies.

At the end of 2015, EDF had deployed the provisions of phase 1, which is now completed. More particularly, connection means were installed so that, in the event of an emergency, the mobile systems can be connected to provide water. In particular, the FARN, which is one of the main emergency management measures, was deployed. Since 31 December 2015, the FARN teams have the capacity for simultaneous intervention on all the reactors of a site in less than 24 hours (up to six reactors in the case of the Gravelines site).

• Phase 2 (2015-2021)
Deployment of certain final design and organisational means that are robust to extreme hazards, in order to deal with the main situations of total loss of the heat sink or of electrical power supplies beyond the baseline safety requirements in force. The most important measures are:

- installation of a large-capacity ultimate backup diesel-generator set, requiring the construction of a dedicated building;
- setting up of an ultimate water source;
- creation of an ultimate water make-up system for each reactor and each spent fuel pool;
- reinforcement of the earthquake resistance of the containment venting filter;
- construction on each site of a local emergency centre capable of withstanding extreme external hazards (functionally independent in an emergency situation).

On the various sites, EDF has begun to implement a large part of the permanent measures recalled above, more particularly the construction of the ultimate back-up diesel generator sets. ASN is inspecting the performance of the work.

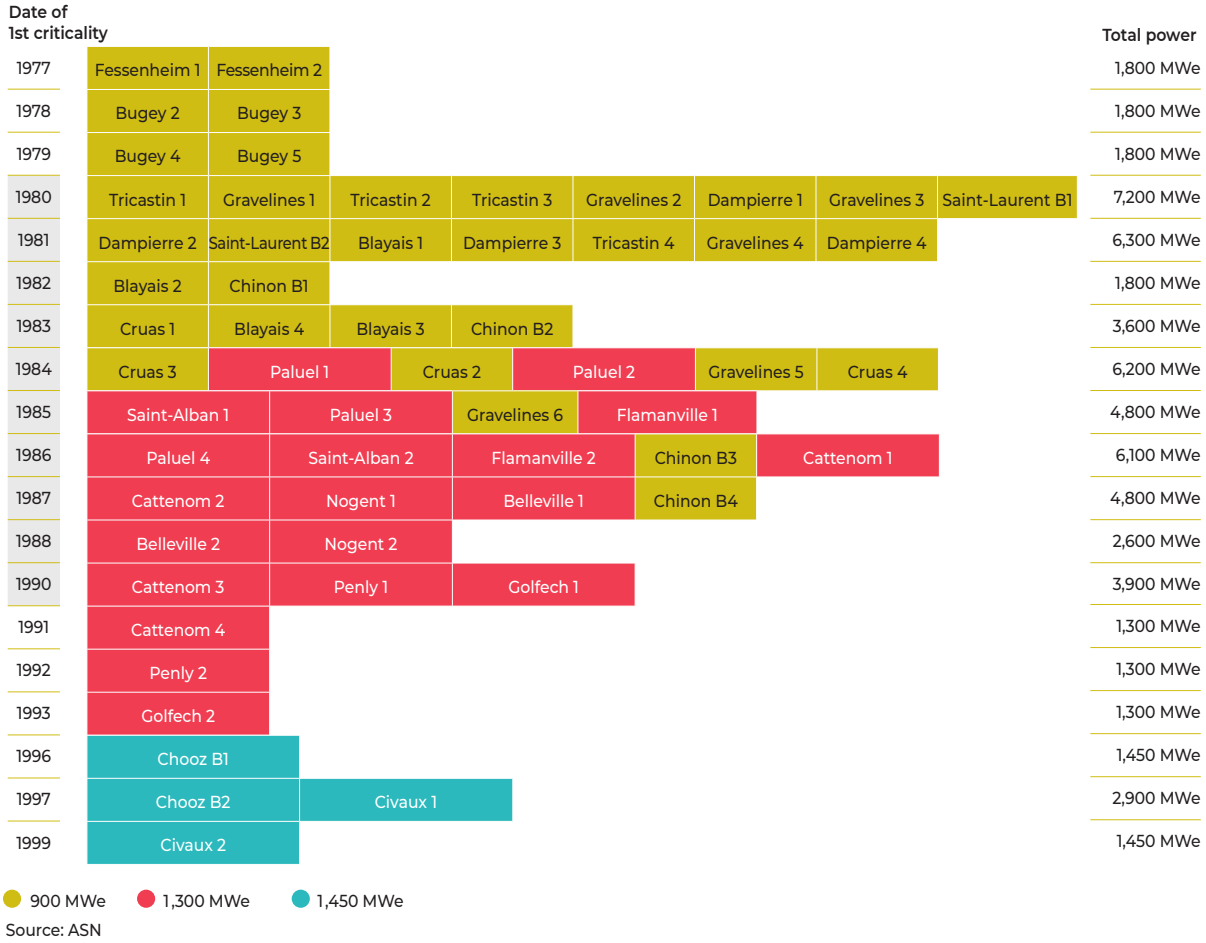
Postponed commissioning of ultimate backup diesel-generator sets (DUS)

In its resolutions of 26 June 2012, issued further to the conclusions of the stress tests performed in the wake of the Fukushima Daiichi NPP accident, ASN instructed EDF to deploy an additional means of electrical power supply before 31 December 2018, so that if the other on-site and off-site electricity sources are lost, the systems and components belonging to the "hardened safety core" can be supplied with power. In response to these requirements, EDF began the construction of ultimate backup diesel-generator sets (DUS).

EDF informed ASN that for 54 reactors, it was impossible to meet the 31 December 2018 deadline for deployment of these ultimate back-up diesel generating sets. 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 ultimate back-up diesel generating sets owing to the technical difficulties encountered by EDF. 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.

Chronology of first criticality of the French nuclear power reactors at the end of 2018



Source: ASN

• Phase 3 (as of 2019)

This phase will supplement phase 2, notably to be able to deal with external hazards. 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.

With a view to the implementation of the "hardened safety core" and in particular the provisions of phases 2 and 3, ASN is examining the design hypotheses of the material provisions and is checking that the solutions proposed by EDF are able to meet the safety targets set.

On the basis of the files transmitted by EDF and the studies carried out, ASN asked its Advisory Committee for Reactors (GPR) to submit its opinion on the more important points of these files. To date, three meetings of the GPR have been held:

- the GPR was consulted on 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 _ NPP operating life extension

2.10.1 _ The age of NPPs

The NPPs currently in service in France were built over a relatively short period of time: 45 nuclear power reactors representing nearly 50,000 MWe, or three-quarters of the power output by all French nuclear power reactors, were commissioned between 1980 and 1990, and seven reactors, representing 10,000 MWe, between 1991 and 2000. In December 2018, the average ages of the reactors, calculated from the date of initial reactor criticality, were as follows:

- 37 years for the thirty-four 900 MWe reactors;
- 31 years for the twenty 1,300 MWe reactors;
- 21 years for the four 1,450 MWe reactors.

2.10.2 _ The periodic safety review

• The principle of the periodic safety review

The periodic safety reviews of nuclear power reactors comprise the following two parts:

- A check on the condition and conformity of the facility: this step aims to evaluate the situation of the facility with respect to the rules applicable to it. It is based on a range of inspections and tests in addition to those performed in real-time. These verifications can comprise checks on the initial design studies as well as field inspections of the equipment, or even ten-yearly tests such as the containment tests. Any deviations detected during these investigations are then restored to conformity within a time-frame commensurate with their potential consequences. Ageing control is also incorporated into this part of the review.
- The safety reassessment: this step aims to improve the level of safety in the light of the experience acquired during operation, changing knowledge, the requirements applicable to the more recent facilities and international best practices. Following these reassessments, EDF identifies the modifications it intends to make to its facilities in order to reinforce their safety.

• The review process for the EDF nuclear power reactors

In order to benefit from the standardisation of the NPP reactors operated by EDF, these two parts of the review are first the subject of a generic design programme for a given plant series (900 MWe, 1,300 MWe or 1,450 MWe reactors). The results of this programme are then implemented on each of the nuclear power reactors on the occasion of its 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 outage inspections of its reactors. In accordance with the provisions of Article L. 593-19 of the Environment Code, following this 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 the parts specified in the Decree of 2 November 2007.

• The ASN analysis

The guidelines of the generic programmes proposed by EDF to verify the status of the facility and reassess safety are the subject of an ASN position statement issued following consultation of the GPR and possibly of the Advisory Committee for Nuclear Pressure Equipment (GPESPN). On this basis, EDF carries out safety reassessment studies and defines the modifications to be made.

Following consultation of the Advisory Committees at the end of the periodic safety review generic phase, ASN issues a position statement on the results of the reassessment studies and on the modifications envisaged by EDF that aim to improve safety.

ASN informs the Minister responsible for Nuclear Safety of its analysis of the review conclusions report for each nuclear power reactor, mentioned in Article L. 593-19 of the Environment Code and can issue new binding requirements regarding its continued operation.

The Energy Transition for Green Growth Act 2015-992 of 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 thirty-fifth year of operation of a nuclear power reactor. Five years after submitting the periodic safety review report, the licensee also submits an interim report on the condition of these equipment items, in the light of which ASN may supplement its requirements.

• The main challenges in controlling ageing

Like all industrial facilities, nuclear power plants are subject to ageing. ASN ensures that, in line with its general operating and maintenance strategy, EDF takes account of ageing-related phenomena in order to maintain a satisfactory level of safety in the installations for their operating lifetime.

To understand the ageing of an NPP, apart from simply the time elapsed since its start-up, a certain number of factors must be taken into account, in particular the existence of physical phenomena that can degrade the characteristics of the equipment, depending on its function or conditions of use.

• Deterioration of replaceable items

Equipment ageing is the result of phenomena such as the hardening of certain steels under the effect of irradiation or temperature, the swelling of certain concretes, 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 vessel (see point 2.2) and the containment (see point 2.3) are closely monitored in order to ensure that they are ageing as anticipated and that their mechanical properties remain within limits allowing their satisfactory behaviour.

• Equipment or component obsolescence

Before it is installed in the NPPs, some equipment undergoes a qualification process designed to ensure that it is able to perform its functions in the stress and atmosphere conditions corresponding to the accident situations in which it would be required. The availability of spares for this equipment is heavily dependent on changes in the industrial network of suppliers, with the cessation of manufacture of certain components or the closure of the manufacturing company, potentially leading to supply difficulties. Prior to installing these parts, EDF must check that the new spares that are different from the original parts do not compromise the qualification of the equipment on which they are to be installed. Given the length of this procedure, the licensee must anticipate these needs well in advance.

• The nuclear power reactors ageing control process

The approach adopted by EDF to control the ageing of its facilities is based on three key points:

- Anticipate ageing in the design: in the design and during manufacture of components, the choice of materials and the installation arrangements must be tailored to the intended operating conditions and take into account the kinetics of known or presumed deterioration processes.
- Monitor the actual condition of the facility: during operation, degradation phenomena other than those considered in the design can be discovered. The periodic 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 early.
- Repair, renovate or replace equipment: given the operating constraints liable to be generated by such routine or exceptional maintenance operations, especially when they can only be performed during NPP reactor outages, EDF must seek to anticipate them, to take account of the time needed to procure new components, the time required to prepare for and carry out the work, the risk of obsolescence of certain components and the loss of technical skills on the part of the workforce.

At the request of ASN, EDF established a methodology for controlling 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 control 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 the extent to which account has been taken of ageing for a group of similar reactors. Subsequently, on the occasion of the third periodic safety review on each nuclear power reactor, a summary file specific to the reactor is produced in order to demonstrate control of the ageing of the equipment and the reactor's ability to continue to operate for the ten-year period following its third ten-yearly outage inspection.

With a view to the possible continued operation of the nuclear power reactors beyond their fourth periodic safety review, EDF intends to continue with such an approach, which will be extended to all systems, structures and components important for controlling not only radiological risks, but also conventional ones.

2.10.3 _ The periodic safety reviews in progress on NPPs

• 900 MWe reactors

The third periodic safety review

In July 2009, ASN adopted a position statement on the generic aspects of the continued operation of the 900 MWe reactors beyond 30 years. ASN did not identify any generic elements compromising EDF's ability to ensure the safety of the 900 MWe reactors up until the next periodic safety review. 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 conclusion report for the reactor submitted by EDF.

In 2018, Gravelines NPP reactor 6 and Cruas-Meysse NPP reactor 2 incorporated the improvements resulting from their periodic safety review as part of their ten-yearly outage inspection, meaning that 32 out of the thirty four 900 MWe reactors have carried out their third periodic safety review.

In 2018, ASN also sent the Minister responsible for Nuclear Safety its analysis of the review conclusions reports for the Bugey 3 reactor. On the basis of this analysis, ASN has not identified any element that would compromise EDF's ability to satisfactorily control the safety of this 900 MWe reactor until the next periodic safety review. Pursuant to Article L.593-19 of the Environment Code, ASN took this opportunity to issue additional requirements designed to reinforce the safety of this reactor.

The fourth periodic safety review

The fourth periodic safety review for the 900 MWe reactors is dealt with in a specific thematic sheet (see the introduction to this report).

• 1,300 MWe reactors

The second periodic safety review

In 2006, ASN gave a favourable opinion to the generic aspects of continued operation of the 1,300 MWe reactors up to their third periodic safety review, provided that the modifications decided on during this review were effectively implemented.

The twenty 1,300 MWe reactors have now all undergone their second periodic safety review and have incorporated the improvements resulting from the review.

Pursuant to Article L.593-19 of the Environment Code, ASN in 2014 sent its position statement on the continued operation of the two Saint-Alban reactors, Cattenom reactors 2 and 3, the two Nogent-sur-Seine reactors and Penly reactor 1 and took this opportunity to issue additional requirements designed to reinforce the safety of these nuclear power reactors. It is currently preparing its position regarding the continued operation of the other 1,300 MWe reactors.

The third periodic safety review

In early 2015, ASN issued a position statement on the generic aspects of the continued operation of the 1,300 MWe reactors beyond thirty years of service. ASN considers that the steps taken or being envisaged by EDF to assess the condition of its 1,300 MWe reactors and control their ageing up until the fourth periodic safety review are acceptable. ASN also considers that the modifications identified by EDF during this study phase will help to significantly improve the safety of these installations. These improvements in particular concern reinforcing protection of the facilities against hazards, reducing releases of radioactive substances in the event of an accident, with or without core melt, and preventing the risk of uncovering of the fuel assemblies stored in the spent fuel pit or during handling.

Further to the conclusions of the generic phase of this review, ASN intends to issue additional generic binding requirements in 2019 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/Saint-Maurice NPP, Paluel NPP reactors 1, 2 and 3 and Cattenom NPP reactors 1 and 2 carried out their third ten-yearly outage inspection between 2015 and 2018. These third ten-yearly outage inspections for the 1,300 MWe reactors will continue until 2024.

• 1,450 MWe reactors

The first periodic safety review

The generic studies and modifications associated with the first periodic safety reviews of the 1,450 MWe reactors were the subject of an ASN position statement in 2012, which in particular requested additional work by EDF to demonstrate the adequacy either of the studies carried out, or of the modifications made to the installations during their first ten-yearly outage inspection, in order to comply in full with the objectives set in the periodic safety review.

The first ten-yearly outage inspections took place between 2009 and 2012.

Following the additional work performed by EDF, ASN issued a position statement on the continued operation of the two Chooz NPP reactors and the two Civaux NPP reactors. On this occasion, it issued additional binding requirements to reinforce the safety of these reactors, more particularly requiring the processing of a deviation affecting the water reserves of the secondary system and the performance of modifications to improve control of the fuel storage pool drainage, explosion and high outdoor temperature risks.

The second periodic safety review

In 2011, EDF transmitted its orientation proposals for the generic studies programme for the periodic safety review of the 1,450 MWe reactors. After consulting the GPR in 2012, EDF supplemented its generic studies programme with a number of measures and clarified some of its proposals. In February 2015, ASN ruled on the orientations of the second periodic safety review of the 1,450 MWe reactors. It more specifically considers that the safety objectives to be considered for the second periodic safety review of the 1,450 MWe reactors must be defined in the light of the objectives applicable to the new nuclear power reactors and asked EDF to study the measures liable to comply with this requirement as rapidly as possible, so that they can be implemented as of the second periodic safety review of the 1,450 MWe reactors.

The second ten-yearly outage inspections for the 1,450 MWe reactors are scheduled to start in 2019 with the Chooz B2 reactor and will run until 2022.

Ageing control

With a view to continued operation beyond the fourth periodic safety review of the 900 MWe NPP reactors, EDF intends to reuse the ageing control approach applied since the third periodic safety review of its reactors, while reinforcing its equipment renovation and replacement projects. Ageing control, in particular for irreplaceable items whose integrity is vital for safety (such as the reactor pressure vessel – see point 2.2 – and its containment – see point 2.3), and obsolescence management, are essential for maintaining a satisfactory level of safety.

Having considered in 2013 and then in 2016 that the steps taken or planned by EDF – more particularly to identify the various degradation modes for this equipment, implement the corresponding countermeasures and incorporate operating experience feedback – were on the whole satisfactory, ASN, with the support of IRSN, again examined the ageing and obsolescence control approach and in March 2018 obtained the opinions of the GPR and the 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 control 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 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 outage inspection. Steps 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 outage inspections) are consistent with the ageing assessments.

The improvements identified for the processing of obsolescence are such as to guarantee its satisfactory and long-term processing.

The programme of additional investigations defined by EDF and the planned procedures for processing the results are considered 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.

In addition, the issue of ageing control was the subject of the first Topical Peer Review stipulated 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. This Directive requires a peer review, every six years, of a technical aspect relating to the nuclear safety of their nuclear facilities. The procedures of this review are defined by ENSREG (European Nuclear Safety Regulators Group) (see chapter 6, point 2.2).

With regard to EDF's nuclear reactors, this review confirmed that the ageing control approach, accompanied by an extensive R&D programme, is appropriate, more particularly given the requirements of the international standards. A national action plan will be drafted in response to the conclusions of this review, notably with regard to the inspections of buried piping and the need for an ageing control programme during the lengthy construction phases of new facilities and prolonged reactor outage periods.

2.11 _ Flamanville EPR

The EPR is a pressurised water reactor based on a design which is an evolution of the design of the reactors currently in service in France, enabling it to comply with 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 about ten years during which no nuclear reactors were built in France, EDF submitted an application in May 2006 to the Ministers responsible for Nuclear Safety and Radiation Protection for the creation of a 1,650 MWe EPR type reactor on the Flamanville site, already equipped with two 1,300 MWe reactors.

The Government authorised its creation by Decree 2007-534 of 10 April 2007, following ASN's favourable opinion, subsequent to its examination of the application. This Decree was modified in 2017 to extend the time allowed for commissioning of the reactor.

After issue of this Creation Authorisation Decree and the building permit, construction of the Flamanville EPR reactor began in September 2007. The first pouring of concrete for the buildings in the nuclear island began in December 2007. Since then, the civil engineering (structural) work has continued and is now almost completed.

EDF plans to load fuel and start-up the reactor at the end of 2019. ASN however observes that some welds on the main secondary systems need to be repaired (see p. 15) and that a significant percentage of the start-up tests are still to be carried out.

2.11.1 _ Examination of authorisation applications

• The partial commissioning authorisation for the Flamanville EPR reactor for the introduction of steam containing tritium

On 26 July 2018, ASN authorised EDF to use steam containing tritium from Flamanville NPP reactors 1 and 2, in addition to or in place of other sources of steam production present on the site (auxiliary and temporary boilers), for preparation for and performance of the hot tests. The introduction of tritium into the facility requires an authorisation referred to as the "partial commissioning authorisation" pursuant to Article 20 of the Decree of 2 November 2007 concerning BNIs and the regulation and oversight of the nuclear safety of the transport of radioactive substances. This authorisation is limited to the period corresponding to the time needed to perform these tests. It states that ASN consent is required prior to initial pressurisation of the main secondary systems, on which certain welds contain flaws.

• Examination of the commissioning authorisation application and the partial commissioning authorisation application for the Flamanville 3 reactor to allow arrival of fuel

In March 2015, EDF sent ASN its commissioning authorisation application, including the safety analysis report, the general operating rules, a study of waste management in the facility, the on-site emergency plan, the decommissioning plan and an update of the facility's impact assessment. Following a preliminary examination, ASN considered that all the documents required by the regulations were indeed present, but it considered that additional demonstrations were needed to enable ASN to rule on a possible commissioning authorisation. ASN however initiated technical examination of the subjects for which most of the information was available, although it did submit some requests on certain points. At the same time, EDF sent a partial commissioning application for the facility, to allow the arrival of fuel on the site.

In June 2017, ASN received updated versions of the commissioning and partial commissioning authorisation application files. Some elements still need to be provided before ASN is able to issue a position statement on the commissioning authorisation application files. In 2018, ASN notably issued requests for additional data regarding the general operating rules.

ASN also obtained the opinion of the Advisory Committee for Reactors (GPR) on 4 and 5 July 2018 concerning the safety analysis report for the Flamanville EPR. This meeting was more particularly devoted 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 parallel with its examination of the partial commissioning authorisation application file relating to the use of steam containing tritium, ASN on 28 September 2018 updated its 2010 resolutions defining the limits and procedures for environmental discharge of liquid and gaseous effluents for the nuclear power reactors on the Flamanville site.

2.11.2 _ Monitoring of construction, start-up tests and preparation for operation

ASN is faced by numerous challenges when checking construction, start-up tests and preparation for the operation of the Flamanville EPR. They concern:

- checking the quality of equipment manufacturing and installation construction in a manner commensurate with the safety, radiation protection and environmental protection issues, in order to be able to rule on the ability of the installation to meet the defined requirements;
- ensuring that the various stakeholders learn the lessons from the construction and start-up testing phase, including the upstream phases (selection and monitoring of contractors, construction, procurement, etc.) which will enable the as-built installation to comply with the safety case for the duration of the project;

- ensuring that the start-up tests programme is complete, that the tests are correctly performed and that the deviations brought to light are dealt with;
- ensuring that the licensee take the necessary steps so that the teams in charge of operating the installation after commissioning are well-prepared.

To do this, ASN has set binding requirements regarding the design, construction and start-up tests for the Flamanville NPP EPR reactor and for operation of the two reactors 1 and 2 close to the construction site. As this is a nuclear power reactor, ASN is also responsible for labour inspectorate duties on the construction site. Finally, ASN oversees the manufacture of the NPE that will form part of the primary and secondary systems of the nuclear steam supply system. The main steps taken by ASN in 2018 are described below.

• Oversight of the construction, assembly and test activities on the Flamanville EPR reactor site

In 2018, ASN carried out twenty inspections on the Flamanville EPR reactor construction site to monitor construction, the performance of the start-up tests and the preparedness of the teams who will be in charge of operating the reactor. These in particular concerned the following technical topics:

- mechanical assembly activities, notably concerning the secondary systems of the NSSS, the main primary system protection valves, the nuclear auxiliary systems, the containment mechanical penetrations, the effluent treatment systems and the equipment necessary for operation of the backup electricity generating sets. In 2018, ASN notably checked the compliance of the main secondary systems (see introduction to this report), following EDF's notification of two significant safety events;
- the electrical systems installation activities, including cable connections in the buildings;
- preservation of equipment and structures present on the construction site until commissioning of the reactor. Owing to the postponements announced by EDF, ASN ensures that EDF continues to pay particular attention to defining and complying with the requirements relating to the preservation of the equipment already installed and the structures already built, notably taking account of water filling of systems for the hydrotests and start-up tests;
- continuation of start-up tests, in particular during the first tests of the installation as a whole. 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 pays particular attention to the organisation put into place to guarantee that the tests are representative and traceable;

"Air" testing of the fuel loading machine

- the environmental impact of the construction site, in particular the management of buried waste discovered on the site in 2017, preparation for operation, taking account of the management of conventional and nuclear waste, control of environmental risks and the consideration of the new binding requirements issued by ASN regarding water intake and discharges for the Flamanville reactors;
- the radiation protection of workers during radiographic inspection of welds;
- preparations for operation by the EDF entity that will be in charge of operating the Flamanville EPR after its start-up. This entity currently comprises more than 400 staff. With a view to reactor commissioning, EDF is continuing with a process of gradual transfer of responsibility for the operation of the structures, systems and components from the entity in charge of reactor construction and start-up operations to the entity in charge of its future operation. Through its oversight, ASN verifies that the future operating staff take advantage of operating experience and best practices employed in EDF's NPPs and that they correctly assimilate the working of the equipment during reactor construction and systems start-up tests. ASN also ensures that these preparations for operation are completed before actual commissioning of the reactor.

Furthermore, given the importance of the start-up tests in the facility's safety case, ASN carried out a tightened inspection on this topic in October 2018.

• Oversight of the Flamanville EPR engineering activities

In 2018, ASN focused its inspections in the EDF engineering departments on the topics of managing the deviations encountered and advance preparation for the operations phase. In 2018, ASN therefore carried out inspections in the EDF engineering departments responsible for the detailed design studies of the Flamanville NPP EPR reactor, on the topic of equipment qualification, management of deviations and the modifications to be implemented after commissioning of the installation.

• Labour inspectorate duties on the Flamanville EPR reactor construction site

The actions carried out by the ASN labour inspectors in 2018 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 2018, the ASN labour inspectors also initiated and carried out a number of checks on the regulatory provisions governing transnational secondment of workers.

• Oversight of NPE design for the Flamanville EPR reactor

During the course of 2018, ASN continued to assess the conformity of manufacture of the NPE for the main primary and secondary systems.

Having observed inadequate justification and incomplete design files for this equipment, more specifically with regard to the risk assessments, choice of materials and in-service inspectability of the equipment, ASN held numerous technical meetings with Framatome (formerly Areva NP) in 2013 and 2014 to define the additional data to be provided. Framatome began a revision of all technical design documentation for this equipment in 2015, completing it in 2018.

Authorisation for commissioning and operation of the Flamanville EPR reactor vessel

At the end of 2014, Framatome revealed an anomaly in the chemical composition of the steel used in the Flamanville EPR reactor pressure vessel closure and bottom heads, which could impair its ability to withstand crack propagation. Together with EDF, Framatome initiated a test programme to demonstrate that the mechanical strength of the steel is sufficient in all operating situations, including accident situations. Framatome transmitted its technical conclusions to ASN in December 2016.

Based on an assessment of the files transmitted by Framatome and the additional technical data supplied by EDF, carried out by its nuclear pressure equipment department and its technical support organisation, IRSN, on the opinions of its Advisory Committee for Nuclear Pressure Equipment and of the High Council for the Prevention of Technological Risks, and the observations collected by the public consultation, ASN issued its opinion on this anomaly on 10 October 2017. It indicated that, with certain reservations, it considered that this anomaly did not compromise the commissioning of the reactor pressure vessel.

As the commissioning and operation of the Flamanville EPR reactor pressure vessel also required ASN authorisation, notably with regard to compliance with other requirements applicable to the vessel as a whole, Framatome submitted an application in this respect on 13 July 2018, which was then supplemented following requests from ASN. ASN examined this application, drawing on the conclusions of its 2017 opinion. It also verified compliance with the technical and regulatory requirements other than those concerning the chemical composition of the steel of the reactor vessel closure and bottom heads.

On the basis of the conclusions of this examination, ASN authorised the commissioning and operation of the Flamanville EPR reactor pressure vessel on 9 October 2018, subject to the performance of a test programme to monitor thermal ageing, plus specific inspections during operation of the facility. As the current state of knowledge does not enable the feasibility of these inspections to be confirmed for the vessel closure head, ASN set a service life limit at end of 2024 for the existing vessel closure head.

The organisations approved for assessment of NPE conformity are authorised by ASN to assist it with the examination of this design documentation.

• Oversight of NPE manufacturing for the Flamanville EPR reactor

During the course of 2018, ASN continued to assess the conformity of manufacture of the Nuclear Pressure Equipment (NPE) for the main primary and secondary systems, equipment manufacturing having now been completed.

ASN and the organisations it approves are reviewing the technical documentation and the monitoring of the on-site NPE assembly operations.

The conformity of the equipment intended for the Flamanville EPR is also evaluated in the light of operating experience feedback from the assembly and testing performed on other EPR type reactors such as those of Taishan (China) and Olkiluoto (Finland). ASN asks Framatome to identify and implement the necessary corrective measures based on this operating experience feedback. This is notably the case with the cracks detected on the seating surfaces of certain valves and vibrations detected on the pressuriser expansion line.

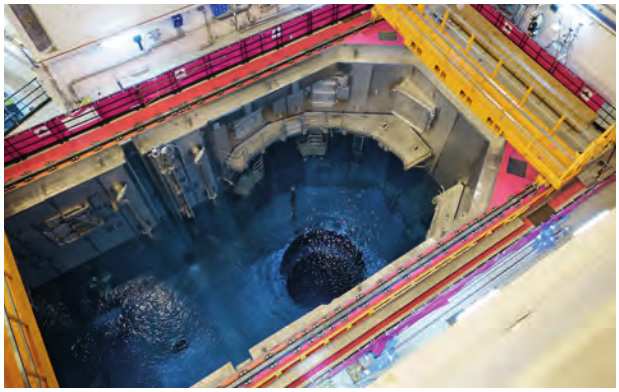
With the support of the organisations it has duly mandated, ASN is also examining the handling of deviations identified by the review of the manufacturing files for the components forged at the Creusot Forge plant and installed on the Flamanville EPR reactor.

In 2018, ASN carried out six inspections of EDF and its manufacturer Framatome concerning the assembly of the NSSS and the preparation of the hydrotests and three inspections of approved inspection organisations or entities mandated by ASN to monitor these activities. In addition, these inspection organisations or entities themselves carried out several thousand inspections in 2018 on all the nuclear pressure equipment of the Flamanville EPR reactor (see point 2.2.2).

• Certification of compliance for Flamanville EPR reactor nuclear pressure equipment

At the end of the design and manufacturing checks and if they prove to be satisfactory in the light of the regulatory requirements, ASN issues certification of NPE compliance. During the course of 2017 and 2018, ASN issued the very first certificates. The compliance evaluation of the other NPE or level N1 nuclear assemblies will continue in 2019.

ASN also authorised the commissioning and operation of the reactor vessel in 2018 (see box).



Filling of the reactor building cavity for the functional tests with vessel open

2.11.3 _ Evaluation 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 preparations for operations is on the whole satisfactory.

Despite the improvements to the traceability of test conditions and results, EDF must further adapt its practices regarding the performance of start-up tests, so that they are carried out in the planned conditions and so that their actual representativeness is correctly documented.

The inspections carried out on equipment qualification also reveal inadequate traceability of qualification reservations until such time as they are lifted. EDF is required to complete the qualification process on this point. Finally, major shortcomings in EDF monitoring of outside contractors were revealed during assembly and inspection of the main secondary systems. ASN therefore asked that the review of the quality of the Flamanville 3 EPR reactor equipment be extended to include a broader scope of equipment and subcontractors, while adapting the depth of the review to the specific implications concerned. In 2019, ASN will continue its oversight of these topics, more specifically on preparation for operations, start-up tests and the compliance work on the main secondary systems.

2.12 _ Studies on reactors of the future

• EPR new model and 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), currently 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 type reactors at Flamanville 3, Olkiluoto 3, Taishan 1 and 2 and Hinkley-Point C, along with operating experience feedback from existing reactors. Moreover, the design of this reactor aims to incorporate all the lessons learned from the Fukushima Daiichi NPP accident. This more specifically entails reinforcing the design against natural external hazards and consolidating the independence of the installation and the site in an accident situation (with or without core melt) until such time as the off-site emergency services can intervene.

ASN examined the Safety Options Dossier (DOS) for the EPR NM with the support of IRSN during the course of 2017, taking account of the recommendations of Guide No. 22 on the design of pressurised water reactors. At the request of ASN, the GPR met in January 2018 to examine this dossier. EDF also forwarded to ASN its decision to upgrade the technical configuration of the EPR NM to a new version, called EPR 2, which incorporates some of the conclusions of the examination of the DOS for the EPR NM. ASN will be issuing a position statement on the proposed safety options in early 2019.

ASN inspection – Reactor building: preparation for the containment hydrotest – March 2018

• 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 plant and delivered to their installation site. A French SMR project involving EDF, Technicatome, CEA and Naval Group is currently at the feasibility studies 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 looking at the development of fourth generation nuclear reactors, notably within the framework of the Generation IV International Forum (GIF). For their promoters, the main challenge for fourth generation reactors is to allow sustainable development of nuclear energy while optimising the use of natural resources, reducing the production of radioactive waste, improving nuclear safety and offering greater protection against security, proliferation and terrorism risks. For those promoting them, the industrial deployment of fourth generation reactors is envisaged in France no earlier than the middle of the 21st century.

3 Outlook

In 2019, ASN actions in the field of the oversight of NPPs will more specifically concern the following topics.

• The periodic safety reviews

2019 will be marked by the first ten-yearly outage inspections associated with the fourth periodic safety review of the 900 MWe reactors and the second periodic safety review of the 1,450 MWe reactors. ASN will provide specific oversight of these reactor outages, during which EDF will carry out a significant part of the conformity checks and implement a large part of the modifications associated with the review.

In 2019, ASN will also complete most of the examinations of the generic studies carried out by EDF as part of the fourth periodic safety review of the 900 MWe reactors, with a view to an ASN position statement at the end of 2020. ASN will notably take account of the comments made by the public during the consultation launched in 2018 on the steps proposed by EDF to address the objectives of this review.

ASN will also finalise the generic examination of the third periodic safety reviews of the 1,300 MWe reactors and will adopt binding requirements applicable to all the reactors, in order to reinforce their safety.

• Lessons learned from the Fukushima Daiichi NPP accident

In 2019, EDF will continue to deploy the phase 2 modifications defined after the accident which struck the Fukushima Daiichi NPP (see point 2.9).

Monitoring the implementation of the material and organisational measures enabling EDF to justify satisfactory control of the basic safety functions in extreme situations will remain a priority for ASN.

• Compliance of the facilities with their baseline design, construction and operating requirements

Following on from its action taken in 2017 and 2018, ASN will continue with its tightened inspections in the field, wherever operating experience feedback shows that EDF needs to further improve its knowledge of the actual state of its facilities. In addition to monitoring EDF's ability to correct the nonconformities found on the reactors in service, as rapidly as possible, ASN will check that the steps taken by EDF actually prevent deviations from occurring. In this respect, the first 1,450 MWe and 900 MWe nuclear power reactors deploying the safety improvements corresponding to their second and fourth periodic safety reviews respectively, will be the subject of particular vigilance on the part of ASN.

• Monitoring of the Flamanville EPR reactor

ASN will continue to monitor the installation of equipment, the preparations 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 nuclear pressure equipment most important for safety.

• Monitoring of nuclear pressure equipment

Monitoring of nuclear pressure equipment was marked by two major events in recent years: the detection of major carbon segregation problems in certain forged components and the discovery of irregularities that could be construed as falsifications within the Creusot Forge plant.

In 2019, ASN will continue with the measures it undertook in previous years. It will in particular continue to check the performance of the review of all the components manufactured in the past by the Creusot Forge plant. It will ensure that this review process is seen through to completion for the forged and cast components, in order to assess all the irregularities which could have affected past production and analyse the consequences regarding the safety of the facilities.

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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 cycle plants are part of the Orano Cycle (formerly Areva NC) or EDF (Framatome, formerly Areva NP) 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 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 ex-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. *Transuranic elements are chemical elements heavier than uranium.*
2. *Storage is temporary, while disposal is final.*

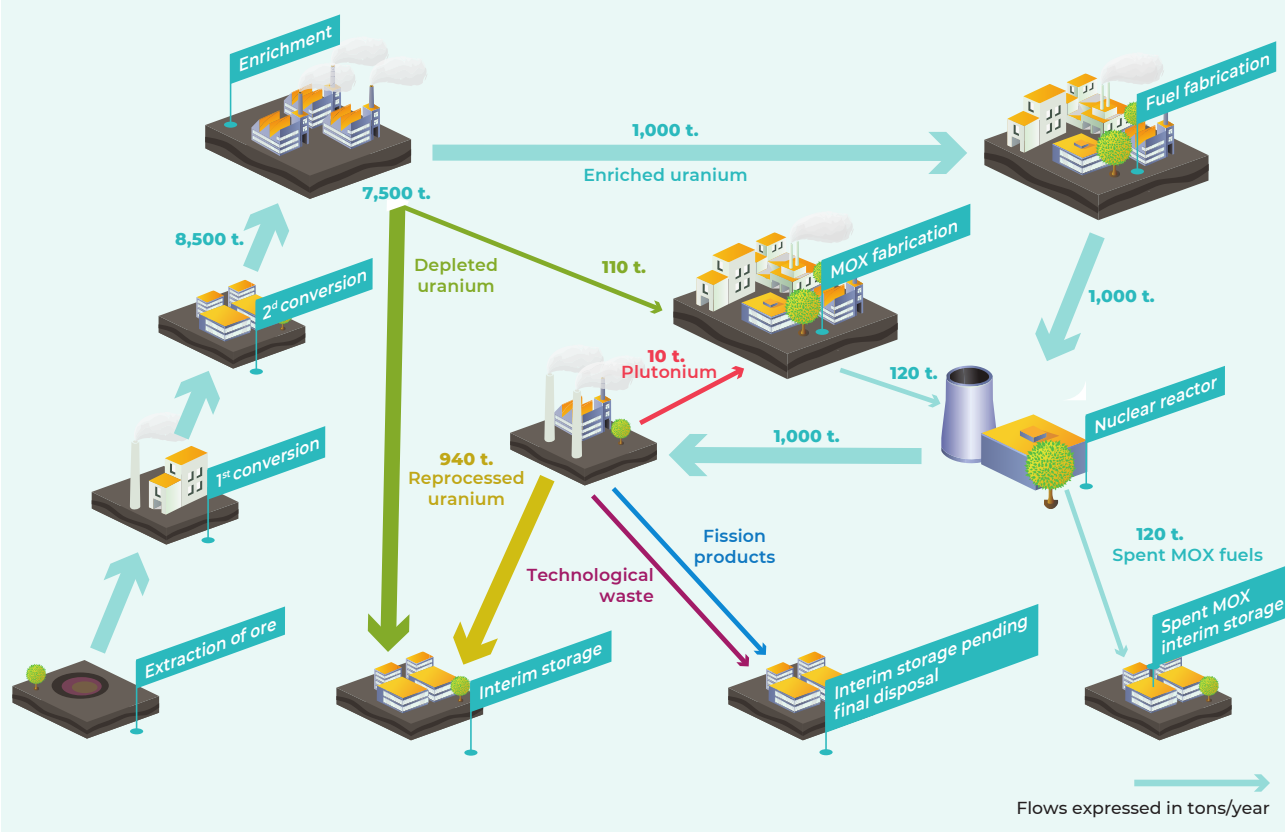
Fuel cycle industry movements in 2018

Table 1

INSTALLATION	MATERIAL PROCESSED			PRODUCT OBTAINED (1)		PRODUCT SHIPPED (2)	
	ORIGIN	MATERIAL PROCESSED	TONNAGE HEAVY METAL	PRODUCT OBTAINED (1)	TONNAGE HEAVY METAL	DESTINATION	TONNAGE HEAVY METAL
Orano Cycle (ex-Comurhex)	DBNI Marcoule	Uranyl Nitrate	0	U_3O_8	0	DBNI Pierrelatte	0
	ICPE Malvési	UF_4	1,387	UF_6	30	Orano Cycle (Tricastin uranium-bearing material storage yard)	30
Orano Cycle (TU5)	Orano Cycle La Hague	Uranyl nitrate	765	U_3O_8	813	Orano Cycle (Tricastin uranium-bearing material storage yard)	813
Orano Cycle (W)	Orano Cycle (Tricastin enrichment company)	UF_6 depleted	6,206	U_3O_8	4,953	Orano Cycle (Tricastin uranium-bearing material storage yard)	4,953
	Orano Cycle (enrichment business unit)		431		343		343
Orano Cycle (GB II)	Conversion	UF_6	10,069	UF_6 depleted	8,538	Orano Cycle (W)	8,538
				UF_6 enriched	1,368	Fuel manufacturers	1,368
Framatome plants in Romans-sur-Isère	Germany	UO_2 rods based on natural and depleted uranium	1.6	Assemblies based on natural uranium	1.5	EDF	2.1
	Orano Cycle (Eurodif production)	UF_6 based on natural and depleted uranium	1.5				
	BNFL (United Kingdom)	UF_6 (based on enriched natural uranium)	16	Assemblies based on enriched natural uranium	742	China	127
	Urenco (United Kingdom)		123			EDF	617
	Orano Cycle (Eurodif production)		574				
	United States	Uranium	0.4		0.6		0.5
Orano Cycle (Melox)	Orano Cycle Lingen (Germany)	UO_2 depleted	90	Fuel elements MOX	80	EDF	76
	Orano Cycle La Hague	PuO_2	8.4			EPZ (Netherlands)	2
Orano Cycle La Hague	Fuels reprocessed in the La Hague plant						
	• EDF • EPZ (Netherlands)	UOX and MOX	1,009	Uranyl nitrate	1,003	Orano Cycle Tricastin	765
				PuO_2	11.6	Orano Cycle (Melox)	9
	Fuels stored in the La Hague plant pools						
	• EDF • EPZ (Netherlands) • CEA (Orphée)	Spent fuel elements	1,117	-	-	-	-

(1) The products obtained may be shipped or stored in the facility concerned.
(2) The shipped products may have been produced in previous years.

Fuel cycle diagram



1.1 — The front-end fuel cycle

To produce fuels that can be used in the reactors, the uranium ore must undergo a number of chemical transformations, from the preparation of the "yellow cake" through to conversion into uranium hexafluoride (UF_6), the form required for enrichment. These operations take place primarily on the 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);
- 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 BNI (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, enabling it to reprocess all the uranyl nitrate ($UO_2(NO_3)_2$) produced by the Orano Cycle plant at La Hague, converting it into U_3O_8 (a stable solid compound able to guarantee safer uranium storage 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).

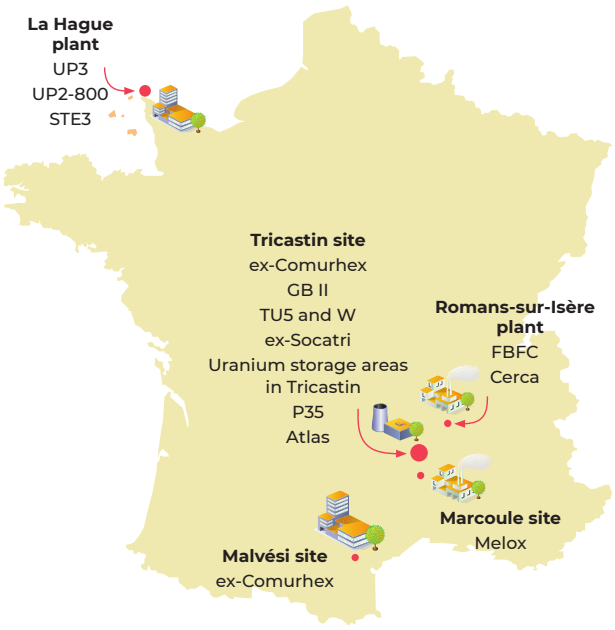
Controlled facilities classified as ICPEs are included within its perimeter and dedicated to the fluorination of UF_4 into UF_6, so that it can be subsequently enriched in the GB II plant. Each year, they produce about 14,000 tonnes of UF_6 from the UF_4 coming from the Orano Cycle facility in Malvési. 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.

Installations of the fuel cycle in operation or undergoing decommissioning



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.

This laboratory meets the most recent safety requirements. The building chosen for the siting of Atlas is thus more robust to external hazards than the laboratory buildings it is replacing. ASN authorised the commissioning of Atlas on 7 March 2017. After validation of the start-up tests, Orano began operation of two of the three infrared analysis benches and UF_6 sub-sampling benches in 2018. In accordance with the commissioning license, Orano produced a summary of the start-up tests, a review of acquired operating experience and updated its baseline safety requirements in 2018.

• 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 P179, 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 being commissioned 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 plant

The reprocessing plants comprise several industrial units, each of which performs a specific operation. There are thus the reception and storage installations for spent fuel, facilities for shearing and dissolving it, for chemical separation of fission products, uranium and plutonium, for purification of the uranium and plutonium and for treatment of effluents and conditioning of waste.

When they arrive in the plants, the spent fuel assemblies in their transport casks are unloaded either under water in the spent fuel pool, or dry, in a leaktight, shielded cell. The assemblies are then stored in pools for cooling.

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

The nitric acid solution comprising the dissolved radioactive substances is then processed in order to extract the uranium and plutonium and leave the fission products and other transuranic elements.

After purification, the uranium is concentrated and stored in the form of uranyl nitrate $UO_2(NO_3)_2$. It is intended for conversion in the TU5 facility on the Tricastin site into a solid compound (U_3O_8), called "reprocessed uranium".

After purification and concentration, the plutonium is precipitated by oxalic acid, dried, calcined into plutonium oxide, packaged in sealed containers and placed in storage. 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. 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 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.

In 2015, ASN asked EDF to conduct an overall review of the "Cycle Impact" file by 2016. In June 2016, EDF submitted the "Cycle Impact 2016" file for the period 2016-2030: this file, which was 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 by 2040, on the basis of various energy mix evolution 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 to design and build 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 evolution 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.

The Government is currently preparing the "Multi-annual Energy Plan" (MEP), which is updated every five years. The functioning of the nuclear fuel cycle could evolve according to the orientations thus defined. 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.

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 to enable its review to continue in 2019.

• 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. Subsequent design difficulties however led Orano Cycle in 2018 to request more time before submitting the authorisation application for this unit required by ASN. ASN will examine the acceptability of this request in 2019.

• 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. In 2017, it transmitted the safety options file for this project. This project, for which the location has not yet been specified by EDF, should allow storage of spent fuels for which reprocessing or disposal can only be envisaged in the long-term future. The envisaged operating life for this storage facility is about a century.

ASN asked EDF to supplement its file in June 2017. Once the additional data was received, ASN reviewed the acceptability of this file and asked IRSN to conduct an expert assessment and analysis of this subject. It also wished to obtain the opinion of the Advisory Committee, which met on 20 December 2018 to examine these safety options. ASN will issue an opinion in 2019.

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 (powder, liquid or crystals).
- 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.

In addition to the inspections carried out on each facility, ASN checks the fuel cycle facilities, paying particular attention to the following subjects:

- the safety cases produced by the licensee to justify the operation of the nuclear facilities or modifications to them;
- the organisation of the licensees;
- the quality of operations in the various BNIs;
- fuel cycle consistency;
- operating experience feedback within the fuel cycle BNIs (see chapter 3, point 3.3.1).

When the facilities undergo a substantial modification or are finally shut down, ASN is responsible for reviewing these modifications and proposes the draft decrees in support of these changes to the Government. ASN also establishes binding requirements for these main steps. Finally, ASN also reviews the safety files specific to the operations of each BNI.

For each facility, ASN regulates the organisation and means chosen by the licensee to enable it to assume its responsibilities in terms of nuclear safety, radiation protection, emergency management in the event of an accident and protection of nature, the environment and public health and safety. ASN 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 Cycle and Framatome designed and implemented new means to deal with extreme situations in their facilities in a very short period of time.

ASN authorised the licensees of the Romans-sur-Isère and Tricastin sites to update the On-site Emergency Plans for the BNIs, in 2016 and 2017 respectively, so that the specific hardened safety core provisions for emergency management could be incorporated into them. More specifically, the Local Emergency Command Posts (PCD-L) on these 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 NPP.

With regard to the La Hague site, Orano Cycle completed replacement of the Moulinets dam valves at the end of 2018 so ensure that this structure was robust enough to provide large-scale water reserves in an extreme situation. Orano Cycle is also completing installation of fixed water recirculation pumps under each storage pool so that water can be recycled and a minimum level of water maintained above the fuel assemblies in the event of a leak. These works are scheduled for completion in April 2019. In August 2018, ASN authorised Orano Cycle to take new organisational measures to remedy the consequences of extreme hazards on its La Hague site. The site's new PCD-L emergency command post building, which is designed to withstand these hazards, is today operational.

On the Marcoule site, Orano Cycle has begun the construction of its new emergency building, designed to withstand extreme hazards, and it should be completed in 2019.

ASN considers that the progress of the post-Fukushima work is on the whole satisfactory at Orano Cycle and Framatome.

2.3 — Periodic safety reviews of fuel cycle facilities

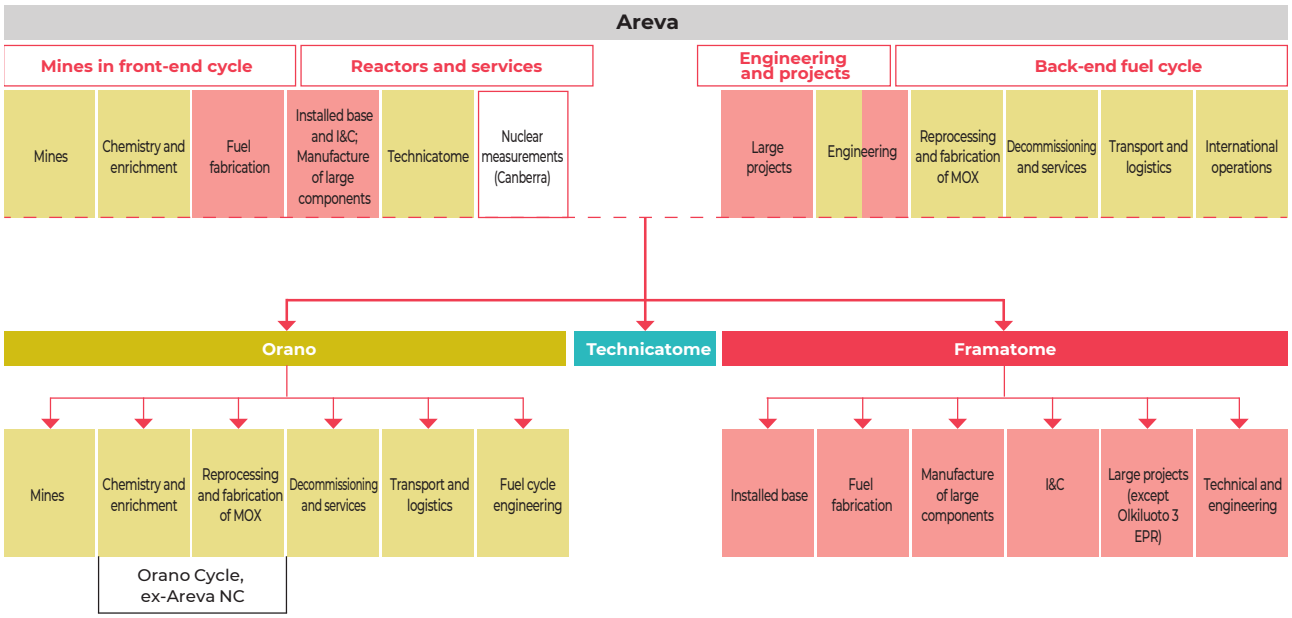
Since the publication of the Decree of 2 November 2007, all the BNI licensees must carry out periodic safety reviews of their facilities at least every ten years. These exercises were carried out gradually on the fuel cycle facilities. The first one concerns BNIs 151 (Melox) and 138 (Socatri) and identified 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.

These reviews show the importance of an *in situ* verification of the conformity of the Elements Important for Protection (EIP) 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. Orano Cycle has defined an approach for selecting the equipment to be monitored that is in principle acceptable. However, ASN's 2018 inspection of its implementation shows that this approach is in fact inadequately deployed by Orano Cycle.

In the context of the faster than anticipated corrosion of the fission products evaporators-concentrators and other equipment in the La Hague plant, the control of ageing is a priority issue for ASN with regard to the back-end cycle facilities, which will be the subject of dedicated inspections and increased vigilance in the examination of the ongoing periodic safety reviews.

Schematic diagram of the reorganisation of Areva in 2018



Excluding ENR and Areva Med
Excluding support functions

2.4 — Organisation of the nuclear fuel cycle facility licensees

The year 2018 was marked by the reorganisation of the Areva group. Its nuclear fuel conversion, enrichment, reprocessing activities and its fabrication of fuel containing plutonium are now merged within Orano Cycle, while the enriched uranium nuclear fuel fabrication activities are grouped within Framatome, which is owned by several industrial groups and EDF, which now holds a majority stake. During this process, Orano Cycle and Framatome demonstrated considerable transparency with respect to ASN, regularly presenting the decisions in progress and any residual uncertainties. This transparency illustrates the positive trend observed by ASN in recent years with regard to its high-level relations with these industrial stakeholders.

During the course of 2018, ASN carried out several inspections in the head office departments of these groups.

Framatome and Orano Cycle signed agreements for management of their inter-dependence, notably in the field of emergency management and Operating Experience Feedback (OEF). Generally speaking, ASN notes that the pooling of expertise, emergency management and OEF resources, through joint coordination of networks on transverse safety, environment and industrial risk topics, is now operational and enables each group to maintain the technical and organisational capacity it needs to carry out its duties as licensee.

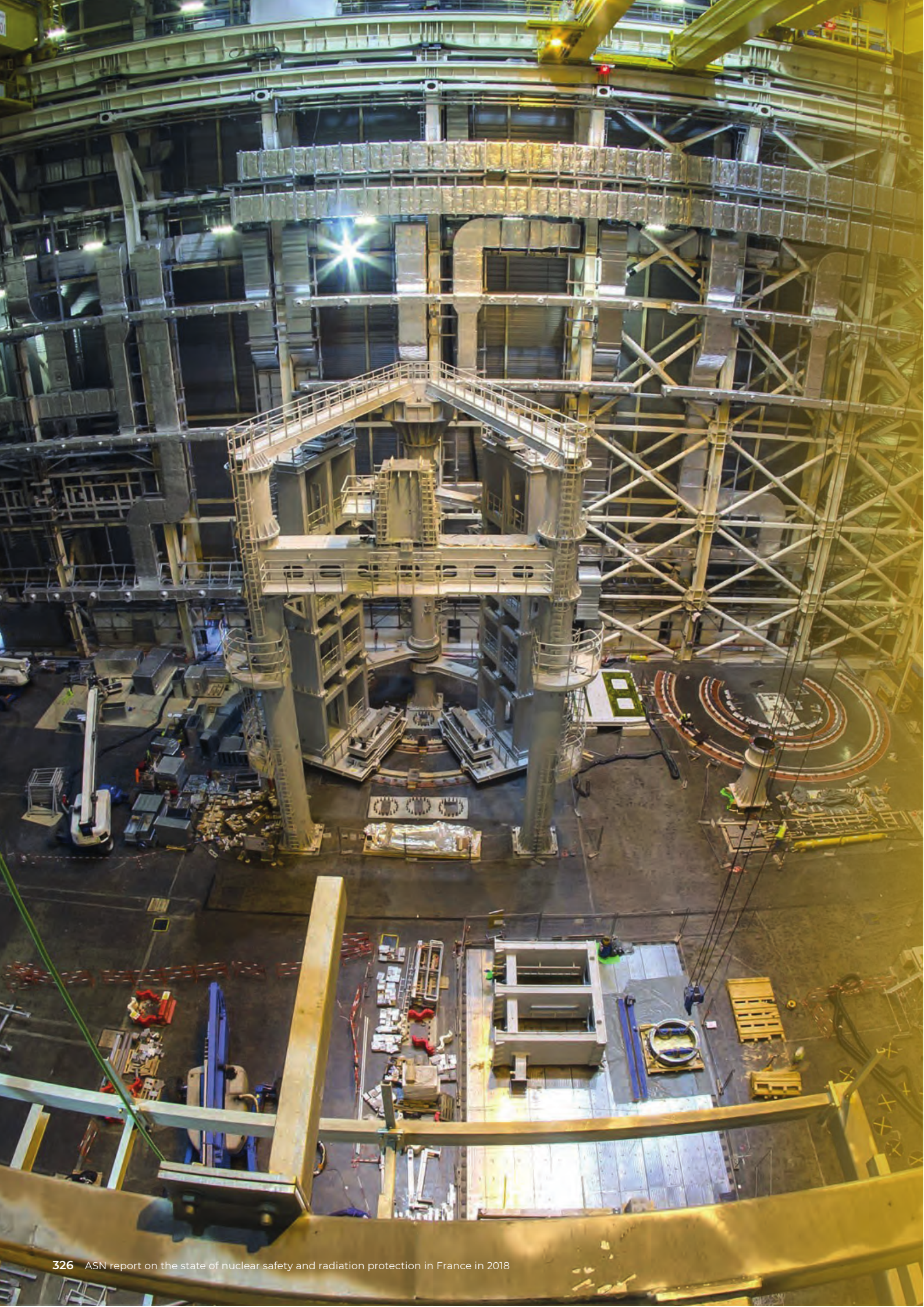
ASN found that significant changes have been made within Orano, notably with regard to the deployment of the 2017-2020 safety-environment policy linked to the strategic plan and the priorities set by the general management. In this respect, the new organisation of the Group, which separated its independent safety organisation from its central operational safety department, is a step in the right direction.

2.5 — Particular regulatory actions conducted in consultation with the Defence Nuclear Safety Authority (ASND)

The upcoming declassification of the Tricastin DBNI to a BNI will mean that ASN will take over responsibility for oversight of these facilities. Together with the 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.



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Nuclear research and miscellaneous industrial facilities

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Nuclear research and miscellaneous industrial facilities

Nuclear research or industrial facilities differ from the 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. Some of these facilities also produce radionuclides for medical uses. 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.

Each research reactor is a specific facility, for which ASN adapts its regulation and oversight to the particular risks and detrimental effects.

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 (thimbles) 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), and the High-Flux Reactor – RHF (BNI 67) operated by the Max von 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 will be shutting down the Orphée reactor permanently at the end of 2019. It will then be decommissioned.

• "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 PWR type nuclear power reactor, the experiments enable ageing studies to be performed on the materials and components subjected to a high neutron flux. After irradiation, the samples undergo destructive examination, notably in the research laboratories, in order to fully 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.

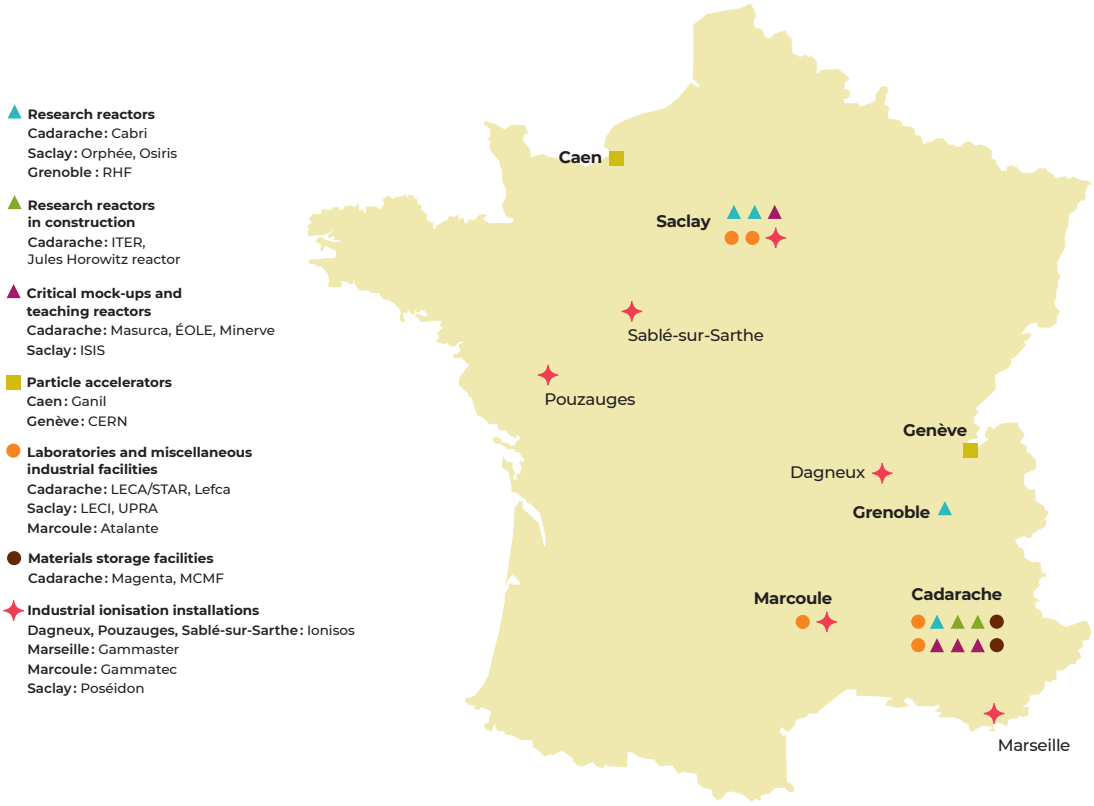
The power of these reactors varies from a few tens to a hundred MWth. These reactors operate in cycles of about 20 to 30 days.

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.

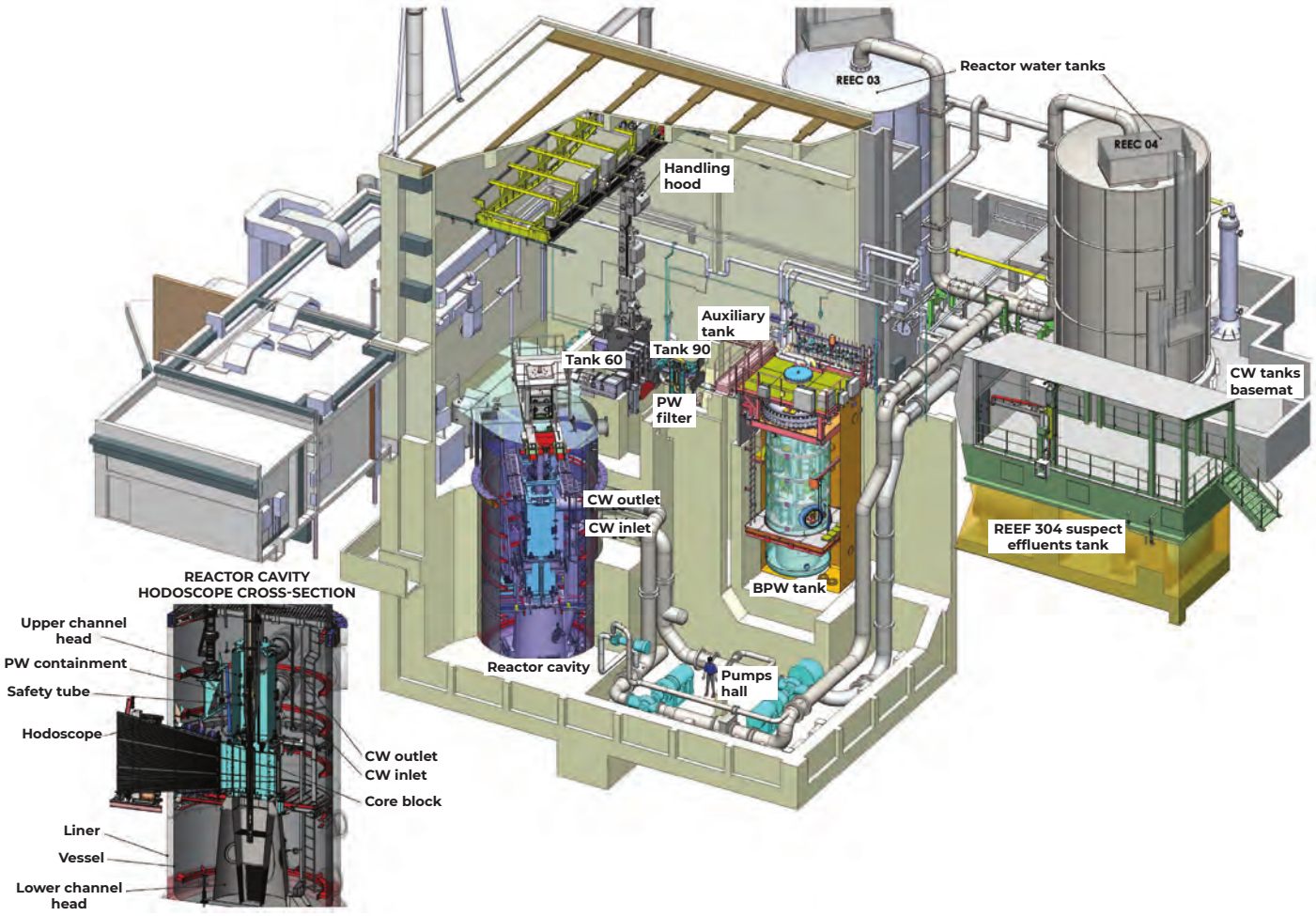
• Critical mock-ups

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.

Research facilities in France



Cabri, "test" reactor



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 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 radionuclides 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 chain reaction 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 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, the world leader in radiopharmaceuticals.

1.2.2 _ Particle accelerators

Some particle accelerators are Basic Nuclear Installations: 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.

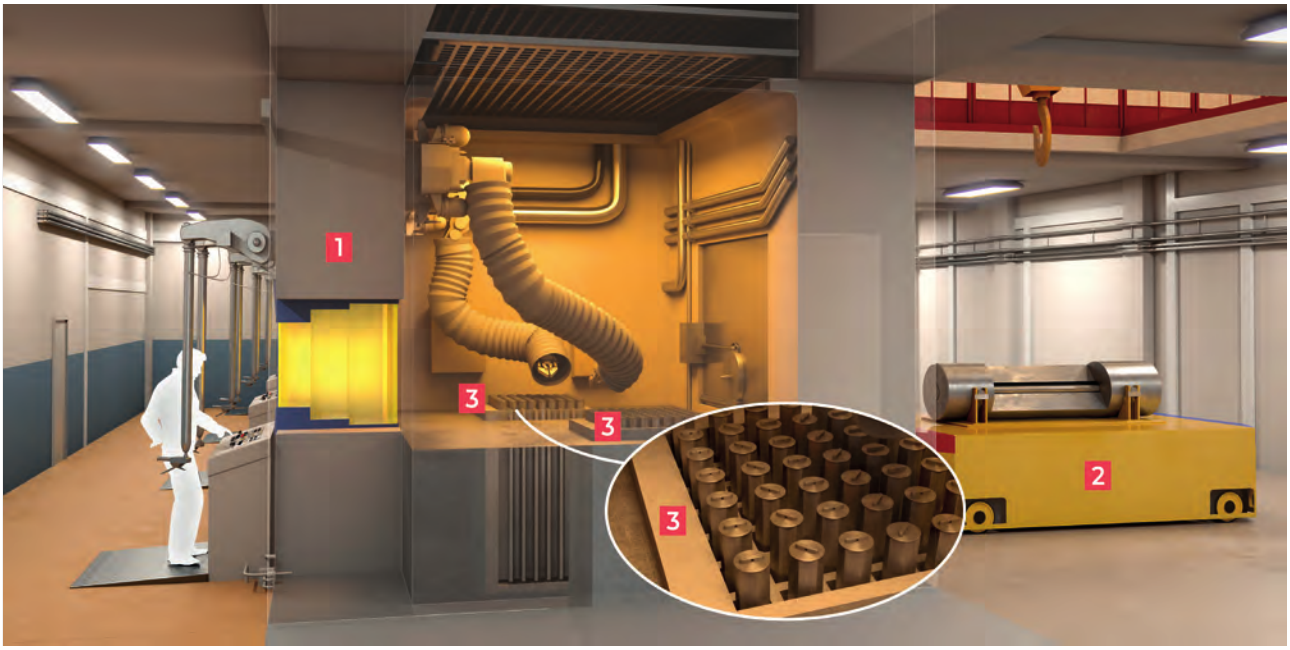
• The Ganil

The Large National Heavy Ion Accelerator (Ganil, BNI 113), located in Caen, carries out fundamental and applied research work, more particularly in atomic 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 facilities, 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, agri-food 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 and is now empty.

• 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 today ageing and CEA may wish to replace them for safety reasons or to obtain tools that are better-suited to its research needs.

CEA's future projects concern:

- **The Mosaïc laboratory**: CEA is envisaging the construction of a new laboratory, called Mosaïc, to replace the LECA laboratory. In 2018, CEA informed ASN that studies had started to define the safety options for this new facility.
- **The Zephyr critical mock-up**: CEA is envisaging the construction of a new critical mock-up called Zephyr (Zero Power Experimental PHYsics Reactor) which would incorporate the functions of ÉOLE and Minerve, as well as those of Masurca, the experimental reactors that have now been permanently shut down. The purpose of this facility is to carry out appropriate experiments to validate core physics computing tools for reactors in service and for future projects.

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 proportionate to the scale of the risks and detrimental effects presented by the facility. In this respect, ASN has divided the facilities it regulates into three categories, from 1 to 3 in descending order of 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 reinforced on those with the highest risks, in terms of the inspections and the scope of 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 allow an appraisal of the situation of the facility with respect to the rules applicable to it and to update the assessment of the risks or detrimental effects, 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.

For facilities which had not yet undergone such a review, the Decree of 2 November 2007 required that the licensees submit their first periodic safety review report no later than November 2017. CEA thus carried out 16 periodic safety reviews and transmitted the review reports to ASN on 1 November 2017.

ASN implemented an examination method commensurate with the issues in the facilities: some facilities merit particular attention owing to the risks they present, while others, with lesser risks, are the subject of appropriate inspections and investigations.

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.

In 2018, 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 CEA has now better assimilated the problems relating to the review, thanks to the implementation on each site of a transverse organisation specifically devoted to these processes.

ASN will be attentive to the correct performance of the works identified in the periodic safety reviews. For CEA, it finds that several projects concerning the refurbishment of facilities or new facility projects, mentioned in the periodic safety review reports, were subsequently redefined or simply abandoned for budgetary reasons. In certain cases, ASN could thus be required to restrict the operating conditions, or even request the shutdown of certain facilities.

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.

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 RHF reactor (ILL) 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 2018, 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 (CIS Bio), 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 construction 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. ASN points out that given the delays observed in the construction of the new emergency management buildings for the Saclay and Cadarache centres, the compensatory measures proposed by CEA must be rapidly operational.

Finally, of the thirty other 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 Gammaster irradiator and the irradiators of the Ionisos group.

3 The nuclear safety of research and miscellaneous industrial facilities

For each facility, the 2018 results are detailed in the introduction to this report per region and accompanied by the corresponding ASN assessment. Some licensees of research or miscellaneous industrial facilities only operate from one to three facilities.

CEA 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 storage facilities.

CEA has finally shut down several 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. During the periodic safety reviews, it identified the need to carry out work in numerous facilities, to enable them to continue to function.

ASN will be attentive to the correct performance of the works identified in the periodic safety reviews. It thus observes that CEA sometimes makes undertakings for each dossier, although it is not always able to ensure that the human or financial resources are actually available. This can subsequently lead to certain undertakings not being met. ASN thus observed delays in the availability of new emergency management buildings, designed to take account of the lessons learned from Fukushima, for the Saclay and Cadarache centres. The compensatory measures proposed by CEA will need to be rapidly operational. ASN remains vigilant with respect to compliance with CEA's schedule of commitments, the completeness of the dossiers transmitted, the quality of the answers to requests and compliance with the requirements.

The regulations stipulate that the licensee must in particular have the technical skills needed to perform its activities. To ensure this, CEA defines and implements an Integrated Management System (IMS) ensuring that the requirements concerning the protection of interests are systematically taken into account in any decision concerning its nuclear facilities. This IMS specifies the steps taken with regard to organisation and to resources, 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 CEA aims to check the IMS implementation procedures. ASN also monitors CEA's organisation for managing the resources needed for performance of these activities. It checks that the organisational and human aspects have been correctly taken into account at the various stages in the lifetime of a facility (design, modification, final shutdown and decommissioning, etc.). To do this, ASN carries out inspections in the nuclear facilities or, more occasionally, in the head office departments. It also periodically examines a review of the entire CEA management system. The next CEA review is scheduled for 2019.

ASN's overall assessment of the nuclear safety of the facilities operated by CEA is also presented in the introduction. Finally, the assessment of the decommissioning and waste management strategy is presented in chapters 13 and 14.

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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 (BNI). These activities include removal of the radioactive materials and waste still present in the installation and disassembly of the equipment, components and facilities used during operation. The licensee 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 2018 in France, 36 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 2018, ASN was examining 16 decommissioning files for definitively shut down facilities whose decommissioning has not yet been prescribed or whose decommissioning conditions have been substantially changed.

2018 was marked by ASN's examination of the files to justify the change of EDF's decommissioning strategy for the Gas-Cooled Reactors (GCR) and the joint examination by the Defence Nuclear Safety Authority (ASND), of the CEA and Orano's decommissioning and waste management strategy files.

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 objects when handling large components on worksites situated at height, fires or burns during hot work in the presence of combustible materials, anoxia when working in confined areas, instability of partially dismantled structures, chemical risks during decontamination operations, etc.

One of the major challenges in the decommissioning of an installation is linked to the very large volumes of waste produced compared with the operational waste. The scale and the difficulties must be assessed as early as possible in the life of the installation (from the design stage if possible) in order to ensure safe decommissioning in as short a time frame as possible.

Smooth running of the decommissioning operations is thus governed by the availability of appropriate management routes for all the types of waste likely to be produced. When the availability of the final waste disposal outlets on the stated dates is called into question, the licensees must, with due caution, organise the facilities necessary for the interim storage of their waste pending opening of the corresponding disposal 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 4.1).

ASN promotes the French decommissioning doctrine on the international scene

Since 2014, the International Atomic Energy Agency (IAEA) recognises two possible decommissioning strategies for nuclear facilities following final shutdown:

- Deferred dismantling: the parts of the installation containing radioactive materials are maintained or placed in a safe state for several decades before actual decommissioning operations begin (the "conventional" parts of the installation can be decommissioned as soon as the installation is shut down).
- Immediate dismantling: decommissioning is started as soon as the installation is shut down, without a waiting period, although the decommissioning operations can extend over a long period of time.

The IAEA considers that immediate dismantling should be favoured.

A third strategy called "safe enclosure" (or entombment), which consists in placing the parts of the installation containing radioactive substances in a reinforced containment structure for a period that enables a sufficiently low level of radiological activity to be reached with a view to releasing the site, is no longer considered acceptable by the IAEA, but may be justified in exceptional circumstances.

Today, in accordance with the IAEA position, French policy aims to ensure that BNI licensees adopt a strategy of decommissioning in the shortest possible time frame.

ASN observes that some western countries recognise deferred dismantling as the reference strategy. ASN observes more recently that the IAEA position of not accepting "safe enclosure" is called into question by some countries, essentially for financial reasons.

ASN internationally promotes - in its bilateral relations and in the international and European working groups - the French approach which fosters decommissioning through to complete clean-out, within as short a time frame as possible, in order to not place the financial burden on future generations.

The French waste management policy does not provide for release thresholds for very low level radioactive waste, but requires that it be managed *via* a specific route to guarantee grouping and traceability. This policy is based on the zoning of the waste from the installations, which is often established conservatively by the licensees for operational reasons. Consequently, the decommissioning of the old installations of the CEA and the first-generation plants of Orano (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, 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

1.2.1 _ Immediate dismantling

Many factors can influence the choice of one decommissioning strategy rather than another: national regulations, social and economic factors, financing of the operations, availability of waste disposal routes, decommissioning techniques, qualified personnel, personnel present during the operating phase, exposure of the personnel and the public to ionising radiation resulting from the decommissioning operations, etc. Consequently, practices and regulations differ from one country to another.

Decommissioning in the shortest time frame possible is a core principle in the regulations applicable to BNIs (Order of 7 February 2012 setting the general rules relative to basic nuclear installations). It has been included in the doctrine established by ASN for BNI decommissioning and delicensing since 2009 and has been taken up at legislative level in Act 2015-992 of 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:

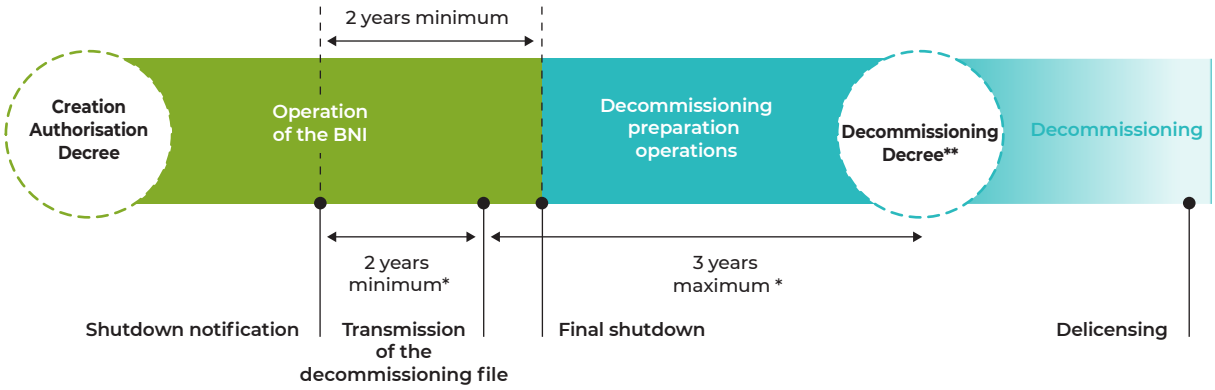
- The licensee prepares the decommissioning of its installation from the design stage.
- The licensee anticipates decommissioning and sends its decommissioning application file before it stops operating the installation.
- The licensee has financial resources to finance decommissioning, covering its anticipated expenses by dedicated assets.
- The decommissioning operations are carried out "in as short a time as possible" after shutting down the installation, a time frame which can vary from a few years to a few decades, depending on the complexity of the installation.

1.2.2 _ Complete clean-out

The decommissioning and post-operational clean-out operations for a nuclear installation must lead to the elimination of any radioactive substances resulting from the activation or deposition phenomena, and any migration of contamination in the structures of the installation premises or the ground of the site.

The structure clean-out operations are defined on the basis of the prior updating of the facility's waste zoning plan which identifies the areas in which the waste produced is, or could be, contaminated or activated. As work progresses (for example after cleaning the surfaces of a room using appropriate methods), the "possible nuclear waste production areas" are downgraded to "conventional waste areas".

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.

Pursuant to the provisions of Article 8.3.2 of the Order of 7 February 2012, "*the final state reached on completion of decommissioning must be such that it prevents the risks or adverse effects that the site may represent for the interests mentioned in Article L. 593-1 of the Environment Code, in view of the projections for reuse of the site or buildings and the best post-operational clean-out and decommissioning methods available under economically acceptable conditions*".

In this context, ASN recommends, in accordance with its decommissioning doctrine, that the licensees deploy decommissioning and clean-out practices taking into account the best scientific and technical knowledge available at the time and under economically acceptable conditions, with the aim of achieving a final status in which all the hazardous and radioactive substances have been removed from the BNI. This is the reference approach according to ASN. Should it be difficult to apply this approach due to the nature of the contamination, ASN considers that the licensee must go as far as reasonably possible in the clean-out process. Whatever the case, the licensee must provide technical or economic 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 decommissioning must be as low as reasonably possible. ASN therefore considers that the defining of thresholds is not reasonable. An exposure leading to an effective annual dose of 300 microsieverts for the public (i.e. one third of the annual dose limit of 1 millisievert for the public) is only acceptable after demonstrating the integration of an optimisation process, in accordance with the IAEA texts on the unconditional release of a site contaminated by radioactive substances.

In 2016, ASN thus updated and published a technical guide 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. ASN also published in 2016 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 and therefore the framework under which it is authorised must change since the Creation Authorisation Decree 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 after consultation with ASN. This decree sets out, among other things, the main decommissioning steps, the decommissioning end date and the final state.

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 above illustrates the corresponding regulatory procedure.

The licensee must demonstrate in its decommissioning file that the decommissioning operations will be carried out in as short a time frame as possible.

The decommissioning phase may be preceded by a 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 (production of radiological maps, collection of pertinent data (operating history) with a view to decommissioning, etc). For example, the fuel in a nuclear reactor can be removed during this phase.

ASN shall ensure that the licensee remains compliant with its operating baseline requirements until the decree authorising major decommissioning operations is issued. ASN recommends that the licensee inform the Local Information Committee (CLI) of the planned work in the decommissioning preparation phase, regularly inform the CLI of the progress of operations and present the results once they are completed.

As part of its oversight duties, ASN monitors the implementation of the decommissioning operations as directed by the decommissioning decree.

The Environment Code requires – as is the case for all other basic nuclear installations – 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 excavation, 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 amended 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. 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 packaging 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.

An agreement signed between ASN and the General Directorate for Energy and Climate (DGEC) whereby ASN monitors the long-term costs, defines:
- the conditions in which ASN produces the opinions it is required to issue pursuant to Article 12 of the above-mentioned Decree of 23 February 2007, on the consistency of the strategies for decommissioning and management of spent fuels and radioactive waste;
- the conditions in which the DGEC can call on ASN expertise pursuant to Article 15 of the same Decree.

2 ___ Situation of nuclear facilities undergoing decommissioning - specific challenges

In 2018, 36 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 manage during decommissioning and 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.

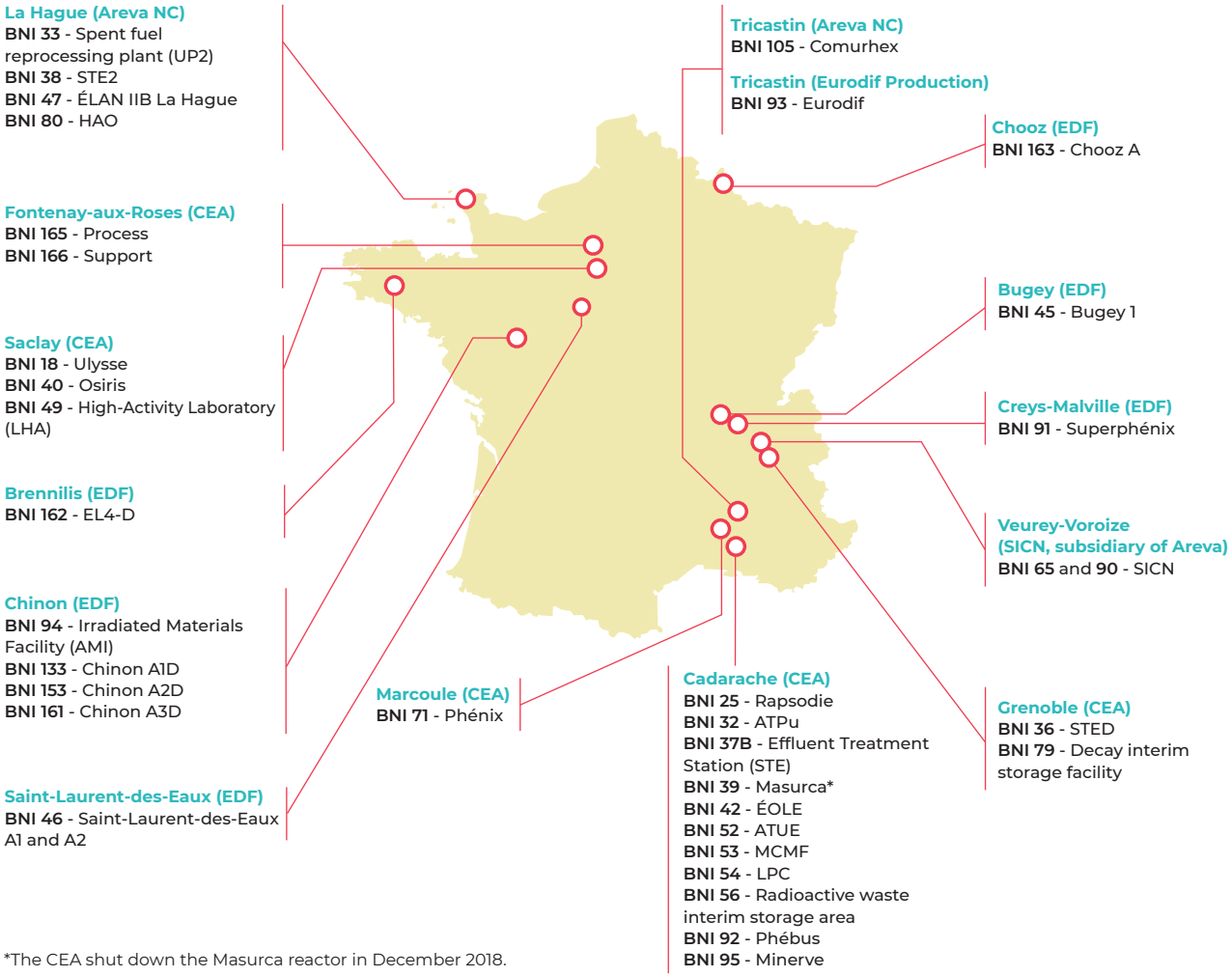
2.1 _ Nuclear power reactors

2.1.1 _ Pressurised Water nuclear power Reactors (PWR)

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 time frames specified in the Decree.

PWR decommissioning benefits from experience feedback from numerous projects across the world and the design of these

Installations definitively shut down or in the process of decommissioning as at 31 December 2018



*The CEA shut down the Masurca reactor in December 2018.

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.

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, the EL4-D heavy water reactor on the Brennilis site, and the sodium-cooled fast breeder reactors Phénix and Superphénix.

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 powers of these reactors are relatively high (all greater than 250 MWth), 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 LLW-LL disposal is envisaged.

Decommissioning of the EL4-D reactor (prototype heavy water reactor) has been hindered, firstly due to the lack of prior experience in the decommissioning techniques to use, and secondly due to unforeseen setbacks in the commissioning of the storage facility dedicated to the most highly active 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 these 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 1960's, were dedicated to R&D to support 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, such as 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 as accurately as possible the waste and the radiological status of the facility 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 in themselves 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.

ASN inspection at the AMI irradiated materials facility - June 2018

2.2.2 _ Research reactors

Six experimental reactors are in definitive shut down status in 2018: Rapsodie (sodium-cooled fast neutron reactor), Masurca (critical mock-up), Minerve, Phébus, Osiris ("pool" type reactors), ÉOLE (water reactor) and Ulysse (training reactor). They are all in the decommissioning preparation phase, except for Ulysse, whose decommissioning is to be completed in 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 1960's to 1980's, 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. Thus, the maintaining of 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.

There is a considerable amount of decommissioning experience feedback for the research reactors, given the decommissioning of numerous similar installations in France (Siloé, Siloette, Harmonie, Triton, the Strasbourg university reactor) and abroad. Their dismantling time frames span about ten years.

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 very low-level waste, which must be stored then disposed of *via* an appropriate route.

2.3 _ The front-end nuclear fuel cycle facilities

Four front-end nuclear fuel cycle facilities are in shutdown status. Two facilities (BNI 65 and 90), whose decommissioning is almost complete, constitute the former nuclear fuel manufacturing plant of Veurey-Voroize, operated by the *Société industrielle du combustible nucléaire* (Orano group). Two facilities situated on the Tricastin site, one specialising in uranium enrichment by gaseous diffusion (BNI 93), the other in uranium conversion (BNI 105) are in the decommissioning preparation phase.

The only radioactive materials used in these plants were uranium-bearing substances. One of the particularities of these facilities therefore 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. Nevertheless, the fact that uranium alone is present facilitates the characterisation of the state of the facility at the start of the decommissioning operations.

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. The industrial processes involved the use of large quantities of toxic chemical substances (uranium, chlorine trifluoride and hydrogen fluoride, for example) and the containment of these chemical substances is an important issue on 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 supporting plants, 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, most of the waste generated by the first reprocessing plant was stored in bulk. 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 storage facilities. They will span several decades and are a prerequisite to the decommissioning of these facilities, whereas the decommissioning of the plant's process facilities is continuing with more conventional techniques.

2.5 — The support facilities (storage, effluent and waste processing)

The availability of the "support" facilities (for the storage of waste and materials, waste packaging, effluent treatment, etc.) governs the performance of the waste retrieval and packaging, decommissioning and clean-out operations. These facilities must not only be available at the right time, but also be appropriate for the quantities and types of waste or effluents they will be required to treat.

Many of these facilities, most of which were commissioned in the 1960's and whose standard of safety does not comply with current best practices, have been shut down. They have not always been replaced by new facilities.

Old storage facilities were not initially designed to allow the removal of the 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 complicated and will extend over several decades. The waste must then be packaged and stored under safe conditions. New packaging and storage facilities are thus planned or under construction. The packaging and storage must be carried out without adversely affecting the suitability of the waste for subsequent disposal in the planned facilities. It is therefore necessary for the licensees to undertake an ambitious development programme relative to the packaging of low and intermediate-level long-lived waste.

Initially, almost every site had an Effluent Treatment Station (STE) which also packaged the resulting concentrates. The ageing of the facilities or the shutdown of the effluent-producing facilities led to the shutdown of these STEs. Examples include the 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 the tanks.

With respect to the needs to treat the effluents from facilities undergoing decommissioning and in operation, there are significant uncertainties regarding the required capacities due to the lack of forecasting of the production of intermediate and high-level liquid waste and to the decommissioning processes used (dry or wet processes). Historically, low-level and intermediate-level liquid effluents were packaged in a bituminous matrix. This organic matrix can be used to package a wide physical-chemical and radiological spectrum of waste, but it deteriorates over time due to the radiation and produces hydrogen. The new processes aim to package effluents in a mineral matrix by cementation. Due to the difficulty in guaranteeing the quality of the matrix under all conditions, they do not - at this stage of their development allow the packaging of such a wide range of waste.

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 decommission, 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.

Schematic of retrieval and packaging of the waste from silo 130

- The difficulty in accessing the waste was not taken into consideration in the design (trenches, concrete-lined pits, cramped premises, etc.), necessitating the costly construction of infrastructures in conformity with current safety practices and leading to long retrieval time frames 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.

3 — ASN actions concerning research facilities: 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 and the inspections and depth of examinations conducted by ASN to be proportional to the risks present at the facility.

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 as substantial reinforcement work on a facility undergoing decommissioning as on a facility in operation, provided that the decommissioning is effectively carried out and leads to a reduction in the hazard sources in short time frames.

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 on their installations, including those 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 reinforcing of emergency management means on centres that often also have facilities in operation (see introduction to the report and chapters 11 and 12).

For civil facilities undergoing decommissioning, the main challenges concern the La Hague site facilities. The licensee has put in place operational provisions for extinguishing a fire in silo 130 following a "hardened safety core" earthquake[1]. Silo 115 must also be further protected against fire risk and ASN has asked the licensee to study measures to speed up implementation of this programme.

Integration of the lessons learned from the Fukushima accident for the facilities presenting more limited risks shall be assessed by ASN at 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

Licensees of basic nuclear installations conduct periodic safety review of their facilities, even if they have been definitively shut down and are undergoing decommissioning. This 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 drawbacks of the facility, taking into account the condition of the facility, acquired operating experience, changes in knowledge and the rules applicable to similar facilities.

For facilities whose final shutdown is announced, the safety review provides the opportunity to prepare for decommissioning by detailing the decommissioning plan, which must be regularly updated during the life of the facility. In this case the aim of the safety review is to ascertain the acceptability of the safety of the changes in the facilities resulting from the decommissioning work, of the quantities and nature of the radionuclides and other hazardous substances present in the facility, as well as the nature of the ageing of the facility. The ageing assessment is carried out with respect to the envisaged decommissioning completion time, and must take into account margins to allow for decommissioning project contingencies. For facilities in which the radioactive substance removal and decommissioning times are well under control, it may be acceptable not to apply the same requirements as on recent facilities that are in operation.

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 require particular attention due to the risks they present; for others presenting a lower level of risk, the extent of the inspections and examinations is adapted accordingly.

In 2018, ASN continued the examination of the safety review conclusion reports of some thirty facilities undergoing decommissioning. This examination in 2018 of the reports received in 2017 revealed no major deficiencies in the documents, but ASN nevertheless did have to request additional information or technical supporting evidence for the majority of the files in order to continue their examination.

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 chapter 14.

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 levels of detail of the submitted reports. More specifically, the EDF triennial report did not provide sufficient information for ASN to adopt a position. EDF does not present its expenses 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 of these facilities not being 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 cleaning 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. In 2018, as in 2017, ASN noted a lack of detail in the information provided by EDF and the need to assess the impact should the facilities required for decommissioning not be available on the projected date. ASN also noted little change in the structural clean-out and contaminated soil management procedures with respect to the three-yearly reports submitted in 2016. Lastly, ASN considers that the licensees must supplement the expenses evaluation by including the cost of the decommissioning preparation operations.

1. Earthquake considered for the equipment forming the "hardened safety core" of the facilities. The term "hardened safety core" was defined after the Fukushima NPP accident to identify the ultimate equipment controlling the vital safety functions in an extreme situation (earthquake, winds, tornado, extreme flooding, etc.).

4 Assessment of the nuclear safety of facilities undergoing decommissioning

4.1 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 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 for consistency with the regulatory framework and the guidelines of the PNGMDR (French National Radioactive Material and Waste Management Plan). ASN examines with particular attention the defences against unforeseen events on a waste management facility and the plausibility of the time frames 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 practise govern the sustainability of the decommissioning strategy.

In 2019, ASN will adopt a position on the decommissioning and waste management strategies of the CEA and Orano and on the file justifying the change of decommissioning strategy for the EDF Gas-Cooled Reactors. The context and the preliminary conclusions of these examinations are detailed below.

4.1.1 Assessment of EDF's decommissioning strategy

The first decommissioning strategy for definitively shut down EDF reactors was transmitted in 2001 at the request of ASN. This strategy has been updated regularly, 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. These updates did not call into question either the decommissioning scenarios or the pace of decommissioning.

In March 2016, EDF informed ASN of a complete change of decommissioning strategy for its Gas-Cooled Reactors (changing to "in air" instead of "under water" decommissioning, and changing the first reactor to be decommissioned from Bugey 1 to Chinon A2), resulting in their decommissioning being pushed back by several decades. This strategy is now based on the operation of an industrial demonstrator for about ten years to qualify the reactor pressure vessel decommissioning procedure. Once qualification is confirmed, EDF proposes completely decommissioning the pressure vessel of a first reactor (Chinon A2) before starting decommissioning of the pressure vessels of the five other reactors.

In June 2016, ASN heard EDF on this strategy and asked that the files justifying this change be submitted. ASN received these files in March 2017 and December 2017, and they have been the subject of substantial technical discussion between EDF and ASN. In December 2017, ASN inspected the organisation and integration of safety and radiation protection in the decommissioning studies and strategy. This inspection shows that the request for proposals process for the Bugey "under water" decommissioning studies was rigorous and effectively took into account the questions of nuclear safety and radiation protection. The inspectors have noted that the decision to change strategy seems to have been taken in order to share the industrial risk with the possible service providers, and for financial reasons.

ASN considers that waiting for one reactor to be completely decommissioned before starting all the others, resulting in their decommissioning being pushed back by several decades, is unacceptable and has asked EDF to study possible ways of optimising the GCR decommissioning schedule.

4.1.2 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 difficult-to-characterise nature of the 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. Moreover, the WRP work is highly complex.

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 to the facilities to decommission. Orano's personnel and technical resources must be increased to meet the deadlines for these projects.

ASN and ASND have mobilised substantial expertise to examine this file and will adopt a position on the strategy in 2019.

The "major commitments" of the CEA as at 31 December 2018

Table 1

SITE	BNI	ACTION	DEADLINE
Marcoule	71 (Phénix)	Transmit the NOAH commissioning file for decommissioning of Phénix	2nd half 2021
	177 (Diadem)	Transmit the commissioning file	Waiting for a new deadline proposal (previously 1st half of 2019). Late, given stopping of the works in 2018
Saclay	35 (Stella)	Recovery of effluents from tank MA500	New proposed deadline of 1st half 2020 (previously 2nd half 2018) further to experience feedback on the pace of cementation. Currently being examined by ASN
	56 (Storage area)	Complete recovery of stainless steel packages from pit 6	2nd half year 2022
	72 (ZGDS)	Remove fuels from pool and block storage	2nd half year 2022
	72 (ZDGS)	Eventually stop accepting routine production of radioactive waste from Saclay. Then initiate the post-operational clean-out and decommissioning process	2nd half year 2022
Fontenay-aux-Roses	165-166 (Process-Support)	Remove from BNI 166 the LLW/ILW/HLW organic effluents resulting from R&D work in BNI 165	1st half 2019

4.1.3 _ Assessment of the CEA's decommissioning strategy

About twenty of the BNIs or individual DBNI installations operated by the CEA are currently in final shutdown status or undergoing decommissioning. This figure has been rising for the last few years and will continue to do so in the coming decade.

The main challenge for the CEA is to ensure the decommissioning of the definitively shut down facilities, to retrieve and package the legacy waste and to manage its radioactive waste and materials that have no identified use.

ASN wanted the CEA issues presenting the greatest risks to be subject to more rigorous tracking through a steering aid implemented at the CEA's highest level. The CEA has proposed a list of "major commitments" essentially concerning decommissioning and waste management projects. This enables the priority actions to be tracked. At the end of 2018, CEA presented ASN with the update of its "major commitments" (see Table 1). Discussions between the CEA and ASN are continuing in order to integrate additional commitments in 2019, such as removal in the medium term of the source term of the ÉOLE-Minerve, Osiris-ISIS, Orphée or Phébus installations, removal of specific wastes, etc.

Until the end of the 2000's, the CEA's strategy was to conduct all of the BNI decommissioning operations concurrently as soon as they were in final shut down status and with as short as possible time frames. Due to the combined effect of the number of facilities involved and the extent of the delays in work progress, the CEA has in some cases been obliged to keep radioactive substances stored on the sites, sometimes in large quantities.

This situation led ASN, jointly with ASND, to ask the CEA in July 2015 to conduct an overall review of the decommissioning strategy for its facilities, the prioritisation of the operations, the human resources and the efficiency of the organisational structures and the appropriateness of the financial resources devoted to these operations. The two authorities also asked the CEA to present its management strategy for radioactive materials and waste.

The CEA submitted the conclusions of its review in December 2016.

The number and complexity of the operations to carry out in all the nuclear facilities operated by the CEA has led priorities being defined based chiefly on safety analyses. The majority of the top priority operations concern the retrieval and packaging of legacy waste stored in the DBNI of Marcoule, under ASND oversight. The top priority operations for the civil facilities concern BNI 72 in Saclay and BNI 56 in Cadarache. These are projects that aim to reduce the "potential source term", which is currently high. The CEA has also committed to including in the highest priority tasks the operations made necessary by contamination of the soils.

In the majority of cases, mostly on account of its human and financial resources, the CEA is moving towards "two-stage" decommissioning of each facility, removing as much of the potential source term as possible in the first stage, then, in the second stage - after a time lapse which may be long - completing the decommissioning operations.

ASN and ASND have mobilised substantial expertise to examine this strategy and will adopt a position on the file in 2019.

4.2 _ Assessment of the nuclear safety of EDF's facilities undergoing decommissioning

The nuclear safety of EDF facilities undergoing decommissioning is on the whole satisfactory. ASN nevertheless notes the exceeding of the deadlines for the main decommissioning operations of all the Gas-Cooled Reactors and the Brennilis reactor.

Following the events concerning the internal contaminations of workers on the sites of Saint-Laurent-des-Eaux A in 2016 and Chooz A in 2017, EDF put in place an action plan which aims at better controlling the risks due to the presence of

radionuclides emitting "alpha" radiation. This is one of the main decommissioning risks, and it should get greater, more specifically with decommissioning of the Gas-Cooled Reactors and the Chooz A reactor vessel.

ASN notes that the technical dialogue with the teams in charge of the NPPs undergoing decommissioning and waste management is sometimes difficult. As a general rule, ASN considers the EDF files to be either insufficiently detailed (as is the case with EDF's triennial reports on the long-term expenses, with the general operating rules relative to waste management and certain studies submitted under the PNGMDR), or incomplete (e.g. certain environmental analyses are missing in the periodic safety reviews). This means that ASN has to make numerous demands for additional information, which delays the decision-making process and can ultimately have an impact on the decommissioning or waste management project time frames. ASN expects EDF to provide technical information that enables the risks and drawbacks in its files to be assessed as soon as they are received.

4.3 _ Assessment of the nuclear safety of the CEA's facilities undergoing decommissioning

The main challenge for the CEA is to ensure the decommissioning of the definitively shut down facilities, to retrieve and package the legacy waste and to manage its radioactive waste and materials that have no identified use. In the defining of its decommissioning strategy (see point 4.1.3), the CEA has defined a new organisation to manage the decommissioning of its facilities, which in principle seems suitable. It should lead to tangible progress in the management of the decommissioning projects and compliance with deadlines.

The CEA has reviewed the safety of the majority of its facilities and submitted the corresponding review reports at the end of 2017. These reports are currently being examined. Due to the significant duration of the decommissioning operations, ASN may request priority reinforcement work to maintain the safety of these facilities. Lastly, ASN will be particularly attentive to the maintaining of appropriate monitoring, maintenance and operating measures over time.

4.4 _ Assessment of the nuclear safety of Orano's facilities undergoing decommissioning

The Orano facilities undergoing decommissioning are mainly situated on the La Hague and Tricastin sites. The inspections carried out by ASN in 2018 underlined the need to step up the rigour and safety of the worksites, the monitoring of outside contractors and the management of waste. The licensee must improve operating rigour and the level of safety of some older facilities presenting safety risks until the radioactive substances stored in them have been removed.

ASN notes, particularly at La Hague, significant delays in the various legacy waste retrieval and packaging and decommissioning projects, leading to failure to meet the set regulatory deadlines. Some delays are linked to Orano having given priority to the plants in operation, to changes in scenario and the need to review design studies. ASN has asked Orano to increase its project management capacities in order to successfully move forward with the WRP and decommissioning operations.

Appendix

List of basic nuclear installations undergoing decommissioning or delicensed as of 31 December 2018

INSTALLATION LOCATION	BNI	TYPE OF INSTALLATION	COMMISSIONED	FINAL SHUTDOWN	LAST REGULATORY ACTS	CURRENT STATUS
IDE Fontenay-aux-Roses (FAR)	(Former BNI 10)	Reactor (500 KWth)	1960	1981	1987: Removed from BNI list	Decommissioned
Triton FAR	(Former BNI 10)	Reactor (6.5 MWth)	1959	1982	1987: removed from BNI list and classified as ICPE	Decommissioned
ZOÉ FAR	(Former BNI 11)	Reactor (250 kWth)	1948	1975	1978: removed from BNI list and classified as ICPE	Confined (Museum)
Minerve FAR	(Former BNI 12)	Reactor (0.1 kWth)	1959	1976	1977: Removed from BNI list	Dismantled at FAR and reassembled at Cadarache
EL2 Saclay	(Former BNI 13)	Reactor (2.8 MWth)	1952	1965	Removed from BNI list	Partially decommissioned, remaining parts confined
EL3 Saclay	(Former BNI 14)	Reactor (18 MWth)	1957	1979	1988: removed from BNI list and classified as ICPE	Partially decommissioned, remaining parts confined
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

INSTALLATION LOCATION	BNI	TYPE OF INSTALLATION	COMMISSIONED	FINAL SHUTDOWN	LAST REGULATORY ACTS	CURRENT STATUS
RM2 FAR	(Former BNI 59)	Radio-metallurgy	1968	1982	2006: Removed from BNI list	Integrated into BNI 165 and 166
LCAC Grenoble	(Former BNI 60)	Fuels analysis	1975	1984	1997: Removed from BNI list	Decommissioned
LAMA Grenoble	(Former BNI 61)	Laboratory	1968	2002	2017: Removed from BNI list	Cleaned-out
STEDs FAR	(Former BNI 73)	Radioactive waste decay storage	1971	2006	2006: Removed from BNI list	Integrated into BNI 166
ARAC Saclay	(Former BNI 81)	Fabrication of fuel assemblies	1981	1995	1999: Removed from BNI list	Cleaned-out
LURE	(Former BNI 106)	Particle accelerators	From 1956 to 1987	2008	2015: Removed from BNI list	Cleaned out - institutional controls (***)
IRCA	(Former BNI 121)	Irradiator	1983	1996	2006: Removed from BNI list	Cleaned out - institutional controls (**)
FBFC Pierrelatte	(Former BNI 131)	Fuel fabrication	1990	1998	2003: Removed from BNI list	Cleaned out - institutional controls (**)
Miramas uranium warehouse	(Former BNI 134)	Uranium-bearing materials warehouse	1964	2004	2007: Removed from BNI list	Cleaned out - institutional controls (**)
SNCS Osmanville	(Former BNI 152)	Ioniser	1983	1995	2002: Removed from BNI list	Cleaned out - institutional controls (**)
Ulysse Saclay	18	Reactor (100 kWth)	1967	2007	2014: Final shutdown and decommissioning decree	Decommissioning in process
Rapsodie Cadarache	25	Reactor (40 MWth)	1967	1983		Preparation for decommissioning
ATPu Cadarache	32	Fuel fabrication plant	1962	2003	2009: Final shutdown and decommissioning decree	Decommissioning in process
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
EOLE	42	Reactor (1 kWth)	1965	2017		Preparation for decommissioning

INSTALLATION LOCATION	BNI	TYPE OF INSTALLATION	COMMISSIONED	FINAL SHUTDOWN	LAST REGULATORY ACTS	CURRENT STATUS
Bugey 1	45	Reactor (1,920 MWth)	1972	1994	2008: Final shutdown and decommissioning decree	Decommissioning in process
Saint-Laurent-des-Eaux A1	46	Reactor (1,662 MWth)	1969	1990	2010: Decommissioning Decree	Decommissioning in process
Saint-Laurent-des-Eaux A2	46	Reactor (1,801 MWth)	1971	1992	2010: Decommissioning Decree	Decommissioning in process
ÉLAN IIB La Hague	47	Manufacture of caesium-137 sources	1970	1973	2013: Decommissioning Decree	Decommissioning in process
High Activity Laboratory (LHA) Saclay	49	Laboratory	1960	1996	2008: Final shutdown and decommissioning decree	Decommissioning in process
ATUE Cadarache	52	Uranium processing	1963	1997	2006: Final shutdown and decommissioning decree	Decommissioning in process
MCMF	53	Storage of radioactive substances	1968	2017		Preparation for decommissioning
LPC Cadarache	54	Laboratory	1966	2003	2009: Final shutdown and decommissioning decree	Decommissioning in process
SICN Veurey-Voroize	65 and 90	Fuel fabrication plant	1963	2000	2006: Final shutdown and decommissioning decree	Delicensing 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
Comurhex Tricastin	105	Uranium chemical transformation plant	1979	2009		Preparation for decommissioning
Chinon A1D (Former Chinon A1)	133 (Former BNI 5)	Reactor (300 MWth)	1963	1973	1982: Chinon A1 confinement decree and creation of the Chinon A1 D storage BNI	Partially decommissioned, remaining parts confined Integrated in BNI. Preparation for complete decommissioning

INSTALLATION LOCATION	BNI	TYPE OF INSTALLATION	COMMISSIONED	FINAL SHUTDOWN	LAST REGULATORY ACTS	CURRENT STATUS
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
Chooz AD (Former Chooz A)	163 (Former BNI 1, 2, 3)	Reactor (1,040 MWth)	1967	1991	2007: Final shutdown and decommissioning decree	Decommissioning in process
Procédé FAR	165	Grouping of former research installations (BNI 57 and 59) concerning reprocessing processes	2006	2006	2006: Final shutdown and decommissioning decree	Decommissioning in process
Support FAR	166	Grouping of former installations (BNI 34 and 73) for packaging and treating waste and effluents	2006	2006	2006: Final shutdown and decommissioning decree	Decommissioning in process

* Attila: reprocessing pilot located in a unit of BNI 57
** Passive institutional controls
*** Active institutional controls.

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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 a 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 issue 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 prepared this public debate in collaboration with this special committee.

In 2018, ASN gave its opinion on the safety options file submitted by Andra in 2016 for the deep geological repository project, *Cigéo*. This opinion underlines that these safety options constitute significant progress and it sets out the additional justifications that will be necessary for a future creation authorisation application.

Lastly, in 2018, ASN and ASND –the Defence Nuclear Safety Authority– continued examining the decommissioning and waste management strategy files of the CEA (Alternative Energies and Atomic Energy Commission) and Orano, received in 2016. ASN and ASND will give their opinions on these files in 2019.

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 conditioning.

The types of radioactive waste differ widely in their radioactivity (specific activity, nature of the radiation, half-life) and their form (scrap metal, rubble, oils, etc.).

Two main parameters can be used to assess the radiological risk that radioactive waste represents: firstly the activity, which contributes to the toxicity of the waste, and secondly the half-life of the radionuclides present in the waste which determines the required waste containment time. A distinction is therefore made between very low, low, intermediate and high-level waste on the one hand and, on the other hand, very short-lived waste (whose activity level is halved in less than 100 days) resulting mainly from medical activities, short-lived waste (chiefly containing radionuclides whose activity level is halved in less than 31 years) and long-lived waste (which contains a large quantity of radionuclides whose activity level is halved in more than 31 years).

Each type of waste requires the implementation of an appropriate and safe management solution in order to control the risks it represents, particularly the radiological risk.

1.1 — 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 or small-scale nuclear activities, other than those linked to National Defence

Classification of radioactive waste

Table 1

	Very short lived waste containing radionuclides with a half-life of < 100 days	Short lived waste in which the radioactivity comes mainly from radionuclides with a half-life ≤ 31 years	Long lived waste containing mainly radionuclides with a half-life > 31 years
Hundreds Bq/g — **Very-low-level (VLL)**	**Management by radioactive decay on production site** then disposal via disposal routes dedicated to conventional waste	**Recycling or dedicated surface disposal** (disposal facility of the industrial centre for collection, storage and disposal (Cires) in the Aube *département*)	
Millions Bq/g — **Low-level (LL)**		**Surface repository** (Aube repository (CSA))	**Near-surface disposal** (being studied pursuant to the Act of 28 June 2006)
Intermediate level (IL)			
Billions Bq/g — **High level (HL)**	Not applicable(1)	**Deep geological disposal** (planned pursuant to the Act of 28 June 2006)	

(1) There is no such thing as high level, very short-lived waste.

which are overseen by ASND and those relative to Installations Classified for Protection of the Environment (ICPE), which are placed under the oversight of the Prefects.

1.1.1 _ Management of radioactive waste in BNIs

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 (NPP) 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. 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 in nuclear medicine, biomedical or industrial research creates solid and liquid waste: small laboratory equipment used to prepare sources, medical equipment used for administration, remains from meals (uneaten foodstuffs, containers, cutlery) served to patients who have received injections for diagnostic or therapeutic purposes, etc. Radioactive liquid effluents also come from source preparation as well as from patients who eliminate the administered radioactivity by natural routes.

The diversity of waste from small-scale nuclear activities, the large number of establishments producing it and the radiation protection issues involved, have led the public authorities to regulate the management of the waste produced by these activities.

• Management of disused sealed sources considered as waste

Sealed sources are used for medical, industrial, research and veterinary applications (see chapters 7 and 8). Once they have been used, and if their suppliers do not envisage their reuse in any way, they are considered to be radioactive waste and must be managed as such.

The management of sealed sources considered as waste, and their disposal in particular, must take into consideration the dual constraint of concentrated activity and a potentially attractive appearance in the event of human intrusion after loss of the memory of a disposal facility. This dual constraint therefore limits the types of sources that can be accepted in disposal facilities, especially surface facilities.

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. 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 are 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[1] relative to waste storage facilities, coming under Sections 2760 of the ICPE nomenclature, are satisfied;
- in Cires[2] (Industrial centre for grouping, storage and disposal) intended for the disposal of very low-level 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 radionuclides of natural origin:
- Villeparisis in Île-de-France, authorised until 31 December 2020, for an annual capacity of 250,000 tonnes, all wastes combined;
- Bellegarde in Occitanie, authorised until 4 February 2029, for an annual capacity of 250,000 tonnes all wastes combined until 2018 and 105,000 tonnes beyond this;
- Champteussé-sur-Baconne in Pays de la Loire, authorised until 2049, for an annual capacity of 55,000 tonnes, all waste combined;
- Argences in Normandie, authorised until 2023, for an annual capacity of 30,000 tonnes, all waste combined.

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 conducting a periodic assessment and defining the prospects for the radioactive substance management policy. It also increases the missions of Andra. Finally, it prohibits the disposal in France of foreign waste by providing for the adoption of rules specifying the conditions for the return of waste resulting from the reprocessing in France of spent fuel and waste from abroad.

This framework was amended in 2016 with the publication of the Ordinance 2016-128 of 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 re-qualify materials as radioactive waste;
- reinforce the existing administrative and criminal penalties and provide for new penalties in the event of noncompliance with the applicable provisions regarding 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 was 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 the licensees to conduct waste management studies setting out the licensee's targets for limiting the volume and the radiological, chemical and biological toxicity of the waste produced in its facilities and to reduce, by recycling and treating this waste, the final disposal volume reserved for ultimate waste. This study shall consider the installations' waste management routes through to disposal.

ASN resolution 2015-DC-0508 of 21 April 2015 relative to the waste management study and the assessment of the waste produced in the BNIs details the provisions of the Order of 7 February 2012, particularly concerning:
- the content of the waste management study, which must be submitted when a BNI is commissioned and kept up to date throughout its operation;
- the procedures for drawing up and managing the waste zoning plan;
- the content of the annual waste management assessment which each installation must transmit to ASN.

1. Circular of 25/07/06 relative to classified installations – Acceptance of technologically enhanced or concentrated natural radioactivity in the waste disposal centres.
2. Installation subject to licensing under the system of Section 2797 of the ICPEs.

ASN Guide No. 23 presents the conditions of application of this resolution with regard to the drawing up and modification of the waste zoning plan.

1.2.2 _ Legal framework for the management of radioactive waste produced by activities authorised under the Public Health Code

Article R. 1333-16[3] of the Public Health Code states that the management of effluents and waste contaminated by radioactive substances originating from all nuclear activities that involve 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 conditioning facilities to enable them to be accepted in existing or planned disposal centres;
- a study of the requirements in terms of interim storage facilities;
- optimised technical and economic planning of the acceptance and elimination of disused sealed sources in the light of the availability of processing, storage and disposal facilities and transport constraints.

Furthermore, Decree 2015-231 of 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 (Aube *département*) for waste from small producers other than nuclear power plants. ASN considers that the approach adopted by Andra will be sufficient to meet the duties entrusted to it under Article L. 542-12 of the Environment Code and that this must be continued.

Nevertheless, the tritiated solid waste must be managed with the waste from 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 ITER. 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 study 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 EPR reactors 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.
- Scenario SR3 takes up the hypotheses of scenario SR1, but with renewal of the reactor fleet only by EPRs, which implies reprocessing of the spent ENU[4] fuels only and no reprocessing of spent MOX[5] and ERU[6] 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 input data for the PNGMDR.

3. Former Article R. 1333-12, modified by the Decree 2018-434 of 4 June 2018.
4. Enriched Natural Uranium.
5. MOX (mixed oxide) fuel is a nuclear fuel based on a mixture of oxides of uranium and plutonium.
6. Enriched Reprocessed Uranium.

1.2.4 _ The National Radioactive Material and Waste Management Plan (PNGMDR)

Article L. 542-1-2 of the Environment Code, amended by the abovementioned Ordinance 2016-128 or 10 February 2016, defines the objectives of the PNGMDR:

- draw up the inventory 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 DGEC of the Ministry responsible for Energy and by ASN on the basis of the work of a pluralistic working group chiefly comprising 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 issue – 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 respectively the prescriptions of the Environment Code and the studies to conduct in the coming years. There are 83 such studies, each with a coordinator and a completion deadline.

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 2017 and 2018, ASN kept track of the progress of the PNGMDR 2016-2018 work, more specifically through its participation in the PNGMDR working group.

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 option 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 OPECST (Parliamentary Office for the Evaluation of Scientific and Technological Choices) for evaluation before being made public.

(see p. 20 of this report).

1.3 _ Long-term management of waste - existing or projected disposal facilities

1.3.1 _ Very-low-level waste

Very low-level (VLL) waste comes essentially from the operation, maintenance and decommissioning of nuclear facilities. It consists mainly of inert waste (rubble, soil, sand) and metal waste. Its specific activity is usually less than 100 Bq/g and can even be below the detection threshold of certain measuring devices.

Cires, the industrial centre for collection, storage and disposal, includes a facility for the disposal of VLL waste. This facility, which has ICPE status, has also been operational since August 2003.

At the end of 2018, Cires contained 376,153 m^3 of VLL waste, which represents 57.9% of its authorised regulatory capacity (650,000 m^3). 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

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 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.

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Cires without changing its ground coverage area and, subject to these conditions being favourable, filing 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.

ASN considers moreover that the management of VLL waste in France must continue to be based on the place of origin of the waste (areas in which the produced waste is or could be contaminated or activated) and guarantee its traceability, by means of specific routes, from production to disposal. ASN also considers that the possibilities of recycling very-low-level materials within the nuclear sector must be studied exhaustively before considering other outlets. These positions are formalised in ASN opinion 2016-AV-0258 of 18 February 2016.

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 p. 52 and 65).

The quantity of LL/ILW-SL waste produced as at the end of 2018 was 917,000 m^3 and, according to the national inventory established by Andra, it 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 _ Low-level long-lived waste management

Low-level long-lived waste (LLW-LL) initially comprised two main categories: graphite waste resulting from the operation of the Gas-Cooled Reactor (GCR) nuclear power plants, and radium-bearing waste, from the radium industry and its offshoots. Other types of waste 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. Some waste that will be produced by the Orano Cycle Malvési plant as from 1 January 2019 is also included in this waste category.

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 2013-2015 PNGMDR required the various actors involved to carry out studies (characterisation and waste treatment

possibilities, geological investigations on a site identified by Andra, design studies and preliminary safety analyses) so that in 2016 the State can specify guidelines for the management of LLW-LL waste. Thus, the holders of LLW-LL waste have made progress in the characterisation of their waste and in the processing possibilities, particularly with regard to graphite waste and some types of bituminised waste. More specifically, the radiological inventory of the chlorine-36 and iodine-129 in this waste has been downwardly revised to a considerable extent.

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 will have to detail more specifically 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, IRSN, Andra, the LLW-LL waste producers and representatives of civil society was thus set up in Autumn 2018.

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. ASN will examine this study in 2019.

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 storage facilities 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.

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 vitrified waste 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 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 within the framework of 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 main 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 at least the next twenty years. 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 justify 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. ASN will adopt a position on Andra's analyses in 2019.

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 conditioned 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 for creating a reversible deep geological repository for HL and ILW-LL radioactive waste are detailed in Act of 25 July 2016.

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.

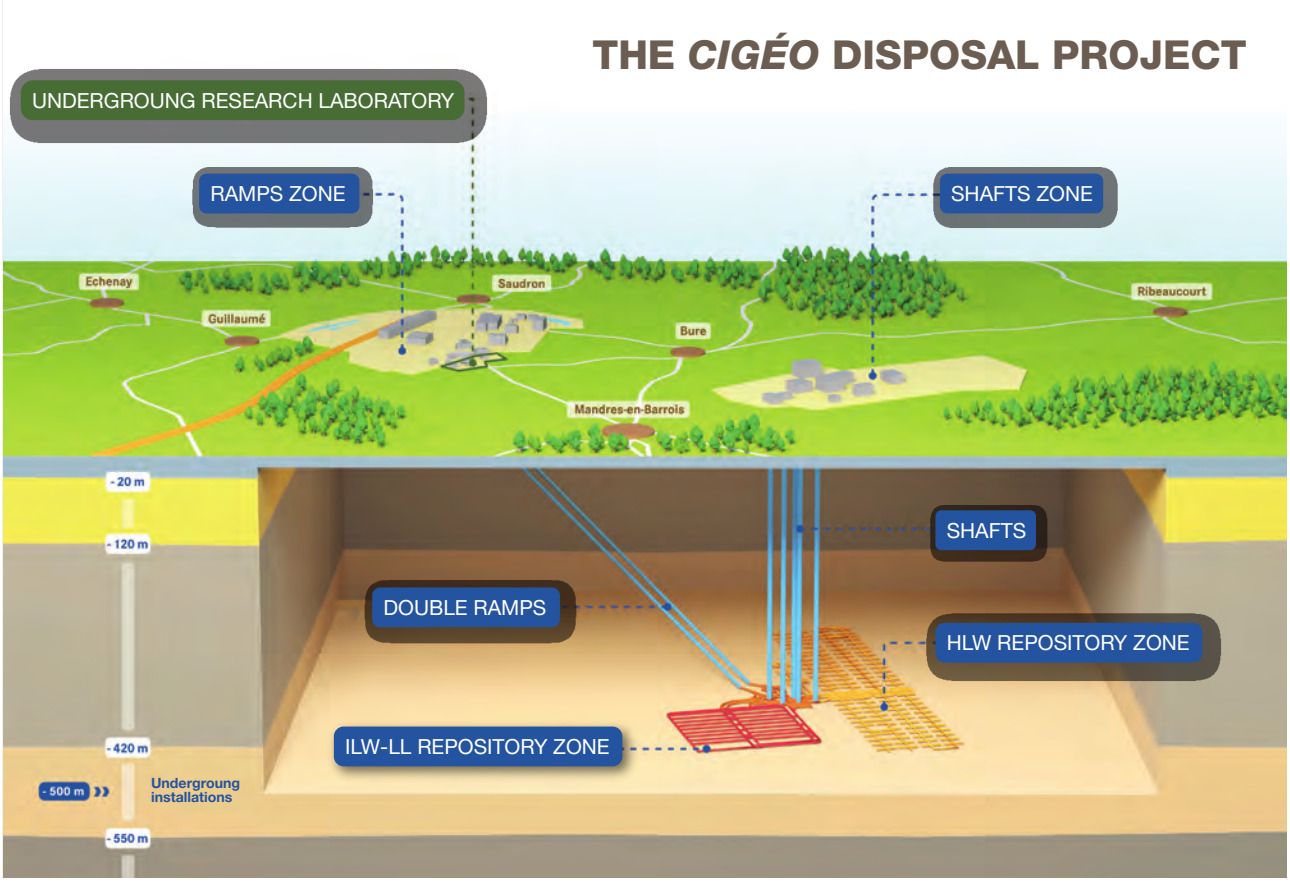
The Decree of 23 February 2017 relative to the provisions of the PNGMDR details certain principles applicable to *Cigéo*, and more particularly in Articles D. 542-88 to D. 542-96 of the Environment Code. Article D. 542-90 stipulates in particular that "*The inventory to be considered by the French National 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

Schematic diagram of the *Cigéo* repository showing the surface and underground facilities



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 (see box below).

• 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 Chapter II of the Decree of 2 November 2007 relative to BNIs, and 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 early 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 (DOS)

The filing of a DOS marks the start of a regulatory process[7]. 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 follow-up 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 (see box). 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, studies to modify the design in order to rule out the risk of runaway exothermal reactions should be carried out. 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).

The Minister responsible for Energy, jointly with ASN, decided that an independent multidisciplinary assessment drawing on international practices should be conducted on this issue. This assessment is in progress and its conclusions are expected in mid-2019. ASN will ensure that Andra can take the conclusions into account in its creation authorisation application.

• From the DOS 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 and a creation authorisation application. ASN and IRSN make regular progress assessments with Andra to check that the key issues identified in the examination of the previous 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 disposal cells.

In September 2018, an Internet resources platform dedicated to the deep geological disposal project[8] 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, NGOs, association and citizens. These documents illustrate the technical and societal issues relating to the *Cigéo* project.

ASN's opinion on the *Cigéo* DOS

General observations

ASN considers that:

- The project has on the whole reached satisfactory technological readiness at the DOS stage:
  - Detailed understanding of the Meuse/Haute-Marne site has been acquired, confirming the suitability of the chosen area.
  - Considerable knowledge has been compiled concerning the various components of the repository.
  - The disturbances that could affect the host rock and those that will occur during the transients (thermal, hydraulic, mechanical, etc.) that will result from the construction of the repository have been properly identified. The results presented tend to indicate that their extent should be limited, given the thickness of the host rock.
  - The principles adopted in the safety approach are consistent with the ASN safety guide of 2008 and the recommendations made by the international bodies.
- It is documented and supported and has made significant progress with respect to the files of 2005 and 2009.

Safety options to supplement

Additions are required for the facility's creation authorisation application with regard to:

- the radioactive waste inventory;
- the bituminised waste packages and control of the fire risks;
- certain subjects which could lead to design changes:
  - justification of the repository architecture;
  - dimensioning of the facility to withstand hazards;
  - monitoring and surveillance of the facility;
  - post-accident situations.

In the public debate relative to the next PNGMDR, the question of *Cigéo* governance[9] was identified as requiring closer examination, particularly with regard to the implementation of reversibility and the objectives of the pilot industrial phase.

• 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).

7. *Article 6 of the Decree of 2 November 2007 stipulates that* "any person who plans to operate a BNI can, before initiating the creation authorisation procedure provided for by Article 29 of Act 2006-686 of 13 June 2006, ask ASN for an opinion on all or part of the options it has chosen to ensure the safety of that installation. ASN, through an opinion rendered and published under the conditions determined by ASN, indicates the extent to which the safety options presented by the applicant are appropriate for preventing or limiting the risks for the interests mentioned in I of Article 28 of the Act of 13 June 2006, given the prevailing technical and economic conditions. It may indicate the additional studies and justifications that will be required for a prospective creation authorisation application. It can set a validity period for its opinion. This opinion is communicated to the applicant and to the Ministers responsible for Nuclear Safety".
8. *www.cigeo.gouv.fr*
9. *It will be formalised when the* Cigéo *creation authorisation application is filed.*

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 chemical treatment process to separate the cladding and the fission products. The hulls and end-pieces are then compacted to reduce their disposal footprint.

Socodei's melting and incineration facility 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 the metal waste is melted down.

The radioactive effluents can also be concentrated by evaporation, like the operations carried out in Agate (BNI 171), with this same aim of volume reduction.

• Conditioning

Radioactive waste conditioning 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 conditioning operations are sometimes carried out in the facilities in which they are to be stored, which will be the case for the LL/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.

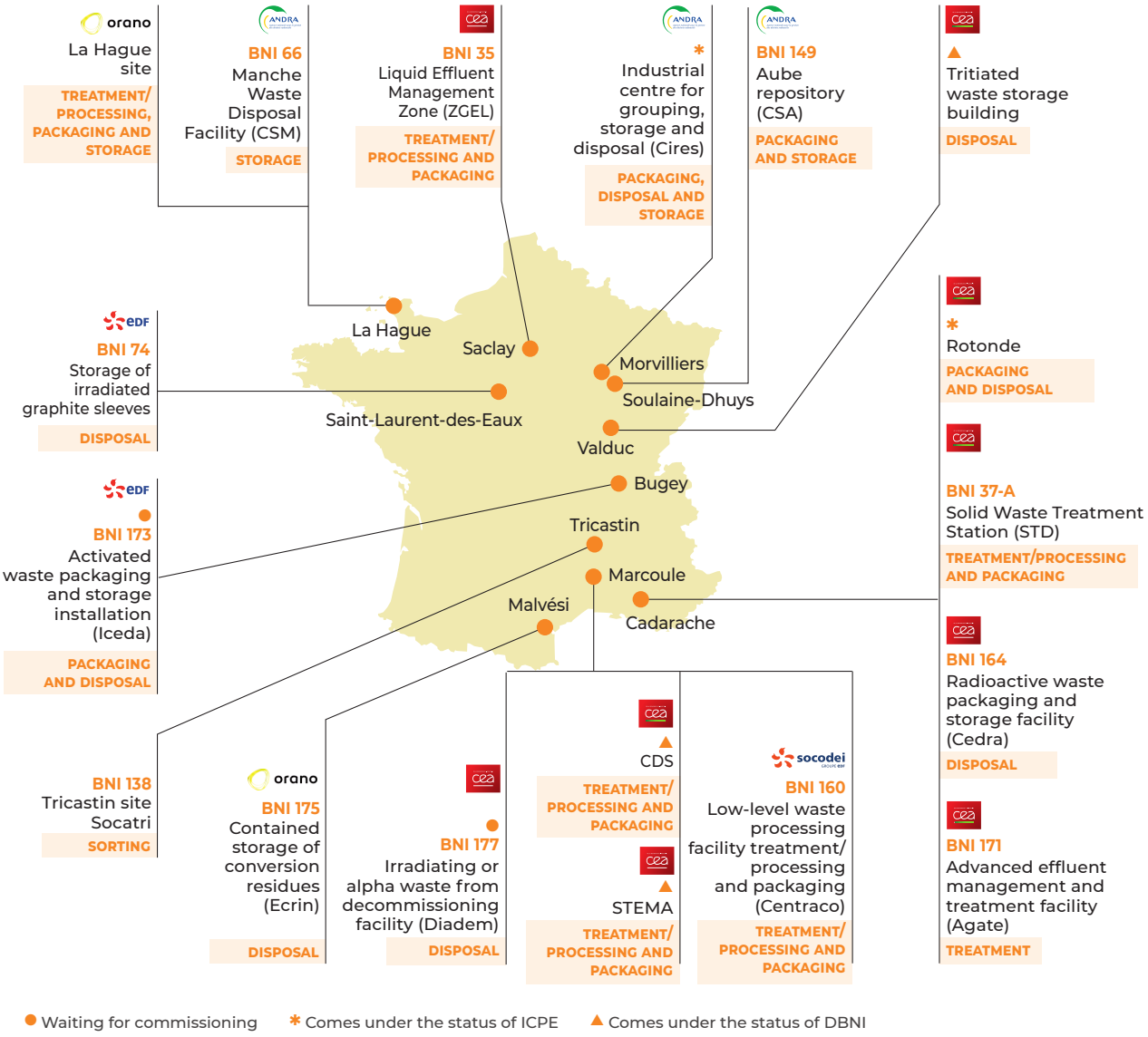
Some facilities (see opposite) are specifically dedicated to the storage of radioactive waste, such as Écrin, commissioned in 2018, and Cedra. This will also be the case with Iceda and Diadem once these facilities enter service. As for the CSD-C and CSD-V packages, they are stored directly in various 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.

The main support facilities for radioactive waste management



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, conditioning 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 conditioning. 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 conditioning 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 waste acceptance criteria of the disposal facility that is to receive the packages. Andra delivers an approval formalising its agreement on the package manufacturing process and the quality of the packages. Andra verifies the conformity of the packages with the delivered approvals by means of audits and monitoring actions on the package producers' premises and on the packages received at its facilities.

• Waste packages intended for projected disposal facilities

With regard to disposal facilities currently being studied, the waste acceptance criteria have of course not yet been defined. Andra therefore cannot issue approvals to govern the production of packages for LLW-LL, HLW 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 "conditioning 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 conditioning operations.

• Checks and inspections

Alongside Andra's surveillance of approved packages, ASN checks that the licensee correctly applies the requirements of the approval and has a satisfactory command of the packaging processes. For waste packages intended for disposal facilities still being studied, ASN is particularly attentive to ensuring that the packages comply with the conditions of the issued conditioning 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. The latter resolution, for example, dated 23 March 2017, addresses the conditioning of radioactive waste and the conditions of acceptance of the radioactive waste packages in the disposal basic nuclear installations. 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 its website.

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 WENRA which aims to harmonise nuclear safety practices in Europe by defining "reference safety levels" which must be transposed into the national regulations of its member countries. In this respect, the WGWD (Working Group on Waste and Decommissioning) is tasked with developing reference levels for the management of radioactive waste and spent fuel, 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 conditioning of radioactive waste. In 2018, ASN presented the way in which the WENRA safety reference levels for waste packaging were set out in the French regulations. ASN will have to provide a few further substantiations in 2019, but WENRA considers that the large majority of the safety requirements are already present in the French regulations. ASN also tracks the transposition of the reference levels in the 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 ENSREG (European Nuclear Safety Regulators Group) group 2 which is responsible for subjects relative to radioactive waste management. A meeting of this working group was organised in Paris in 2018, along with a visit to the CEA Fontenay-aux-Roses facilities to illustrate the waste management issues on a site undergoing decommissioning.

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 the French procedure, the coherence of its policy, the quality of the regulatory framework 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.

European Directive 2011/70 establishing a community framework for the responsible and safe management of spent fuel and radioactive waste moreover requires that

The ARTEMIS missions

The ARTEMIS (Integrated Review Service for Radioactive Waste and Spent Fuel Management, Decommissioning and Remediation) missions are organised by the IAEA service in charge of radioactive waste and spent fuel management, decommissioning and post-operational clean-out, thus enabling foreign experts to give their opinion on the French system with regard to the IAEA safety guides and technical recommendations and terms of best practices.

The peer review held in France from 15 to 24 January 2018 focused on the legislative, regulatory and organisational framework for the management of radioactive waste; the PNGMDR (French National Plan for Radioactive Materials and Waste Management); the French national inventory of radioactive waste and the estimates concerning the future quantities of radioactive waste; the safety requirements for the facilities intended for radioactive waste management, and the provisions regarding the informing and participation of the public prior to their licensing, particularly for the *Cigéo* deep geological disposal project; the funding mechanisms for the management of spent fuel and radioactive waste; the measures taken to ensure and maintain a high level of skill and expertise in the various organisations involved in radioactive waste management.

The conclusions of the January 2018 review underline that France has established a radioactive waste management framework that covers all the issues and presents numerous strong points, particularly in terms of maintaining and developing the skills of the main waste management actors and continuous improvement of waste management in the successive national plans.
The international experts also made nine suggestions, presented in a report, the French version of which is posted on line on the website of the Ministry for Ecological and Solidarity-based Transition. They concern, for example, the identification of possibilities for optimising the management of low-level short-lived waste and very-low-level waste.

These peer reviews serve to improve the French radioactive waste management system thanks to the sharing of experience. They also foster the establishing of far-reaching, internationally-recognised common rules for radioactive waste management and the protection of persons and the environment.

each European Union country's programme on these themes be assessed by a peer review. In France, this international assessment was held from 15 to 24 January 2018 as part of an ARTEMIS mission organised by the IAEA (see box). 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 in IAEA actions, particularly concerning the deep geological disposal of radioactive waste.

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 their situation 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 five 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, conditioning and waste package storage facility on the La Hague site;
- one BNI operated by Andra: BNI 149, the Aube radioactive waste repository (CSA: BNI 149).

Two additional periodic safety review reports should be submitted to ASN in 2019. They concern the Saint-Laurent-des-Eaux storage silos (BNI 74) and the Manche waste repository (CSM: BNI 66).

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 conditioning 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 Aube (CSA) and Manche (CSM) above-ground radioactive waste repositories operated by Andra are BNIs and are therefore obliged to undergo 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 assumption 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 different stages of progress (for the CSM, the licensee is drawing up studies, for the CSA, ASN is examining the report), thus highlight the need to move forward in the knowledge of the long-term impacts associated with the toxic chemicals contained in the waste, and on the knowledge 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 ensure control of the adverse effects of the facility over the long term, such as through the installation of the cover which contributes to the final containment of the disposal concrete blocks. 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 and to preserve the site memory for future generations.

2.3 _ CEA's waste management strategy and its assessment by ASN

• Types of waste produced by the CEA

The CEA operates diverse installations covering all the activities associated with the nuclear cycle, ranging from laboratories and plants involved in research on the fuel cycle to experimental reactors.

The CEA also carries out numerous decommissioning operations.

Consequently, the types of waste produced by the CEA are varied and include more specifically:

- waste resulting from operation of research facilities (protective garments, filters, metal parts and components, liquid waste, etc.);
- waste resulting from legacy waste retrieval and conditioning projects (cement-, sodium-, magnesium- and mercury-bearing waste);
- waste resulting from final shutdown and decommissioning of the facilities (graphite waste, rubble, contaminated soils, etc.).

The contamination spectrum of this waste is also wide with, in particular, the presence of alpha emitters in activities relating to fuel cycle research and beta-gamma emitters in operational waste from the experimental reactors.

The CEA has specific facilities for managing this waste (treatment, conditioning 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 treatment, conditioning 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 conditioning 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.

Very significant increases in the projected duration of decommissioning operations declared by the CEA after the review of 2012, along with the quantity, the non-standard and difficult-to-characterise nature of certain substances or waste that will be either removed from storage or produced during the decommissioning operations, led ASN and ASND to jointly ask the CEA to conduct an overall review of its decommissioning and radioactive materials and waste management strategies for the next fifteen years. The CEA report was received in December 2016 and is currently being examined by ASN and ASND in order to have an overall view of the subject and establish a joint position of the oversight authorities on CEA's strategy. ASN will issue an opinion on this strategy in 2019.

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 issue 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 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, Areva submitted to ASN and ASND a file presenting the decommissioning and waste management strategy for the group's installations in France and its practical application on the La Hague and Tricastin sites. This file, for which additional elements were received in 2017, is currently being examined. ASN will give an opinion on this strategy in 2019. The last review of Areva's waste management strategy dates back to 2005 and only focused on the Areva NC La Hague site.

• The issues and implications

The main issues relating to the management of waste 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, conditioning 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. On the Tricastin site, the storage conditions in certain facilities which do not meet current safety requirements must be improved.
- Defining solutions for waste conditioning, in particular for 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 conditioning deadlines is a particularly important aspect, which requires the development of characterisation programmes to demonstrate the feasibility of the chosen conditioning processes and to identify sufficiently early the risks that could significantly affect the project. If necessary, when the feasibility of the defined conditioning cannot determined within times compatible with the prescribed deadlines, the licensee must plan for an alternative solution, such as 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 MLW-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 conditioning solutions that necessitate the development of new processes, particularly for the following IL-LL waste:
- the sludge from the La Hague STE2 facility;
- the alpha-emitting technological waste which comes primarily from the La Hague and Melox plants and is not suitable for above-ground disposal.

For other types of IL-LL waste resulting from the WRP operations, Orano is examining the possibility of adapting existing processes (compaction, cementation, vitrification). Part of the associated conditioning 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 HL and IL-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 IL-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 conditioned 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.

• The issues and implications

The main issues related to the EDF waste management strategy concern:
- The management of legacy waste. The management of legacy waste primarily concerns structural waste (graphite sleeves) from the graphite-moderated gas-cooled reactor fuels. This waste could be disposed of in a repository for LLW-LL waste (see point 1.3.4). It is stored primarily in semi-buried silos at Saint-Laurent-des-Eaux. Graphite waste is also present in the form of stacks in the gas-cooled reactors currently being decommissioned. In accordance with the PNGMDR, EDF is reassessing the activity of this waste and must submit its conclusions in 2019.
- 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. In a letter of 5 May 2011, ASN asked EDF to implement a more rigorous policy for managing its storage capacity for substances before their disposal or treatment (see chapter 11). More specifically with regard to waste, EDF must for example ensure that the available packaging containers can meet the disposal needs.

3 Assessment of the nuclear safety of the facilities operated by Andra

Andra is the only licensee operating radioactive waste disposal BNIs in France. This public agency, which became independent of the CEA and more generally of the waste producers by virtue of the "Bataille Act" of 1991, was assigned the long-term management of radioactive waste. The Act of 28 June 2006 consolidates Andra's mandate for the design and operation of radioactive waste disposal facilities. The Agency is thus tasked more specifically with the design and setting up of a reversible deep geological repository for high-level and intermediate-level long-lived waste and seeking a solution for low-level long-lived waste.

ASN considers that the licensee's organisation and technical resources are appropriate for the operation of the existing facilities and that they are operated satisfactorily.

At the end of 2018, ASN conducted an inspection of Andra's central services to assess the internal procedures for examining the files for the approval of the LL/ILW-SL waste packages and their acceptance by the CSA repository, and the packaging agreements for the HL and ILW-LL packages ultimately destined for *Cigéo*. This inspection also provided the opportunity to assess the licensee's organisation for monitoring the package production activities carried out on the waste producers' premises, which are intended to guarantee the quality of the packages intended for the disposal facilities. It has been noted that the internal technical organisation for examining and monitoring LL/ILW-SL waste packages has improved considerably over the last ten years. In this respect, Andra should be able to fully commission a package inspection facility at the CSA in 2019, which will allow independent inspections, whether destructive or not (core sampling, manual inventory, measurement of tritium degassing, etc.), to be carried out, thereby significantly increasing its inspection capacities, both quantitatively and qualitatively. With regard to the examination of the packaging agreements, the existing procedures must be improved in order to guarantee greater process reliability. Lastly, ASN expects a ramping up of the system deployed by Andra for monitoring the producers of HL and LL/ILW-LL waste packages, given that progress in development of the *Cigéo* project allows more precise preliminary acceptance specifications for the waste to be defined.

The last periodic safety review of the CSA carried out in 2017 highlights the facility's compliance with its baseline requirements. This review gave Andra the opportunity to reassess control of the fire risks and to undertake an action plan that significantly improves management of the fire risk during the facility operating phase. With regard to the control of earthquake-related risks, the ongoing examination will aim to determine the risk level to adopt as the design basis for the CSA "support" facilities (excluding disposal structures), particularly those accommodating the waste packaging processes. Lastly, gaining better insight into the long-term impacts associated with hazardous substances emerges as an area to focus on for the next periodic safety review.

Greater efforts are expected for the CSM. The impact study will have to be reviewed to take into account the regulatory changes in this area and the improved knowledge of the hydrogeological context of the site. Furthermore, ASN considers that Andra must rapidly define the technical principle to adopt to place the facility in its long-term configuration, particularly by improving the repository cover. ASN is also attentive to the continued progress of the work to preserve the memory of the facility, useful not only for the licensee during the monitoring and surveillance phase, but also for future generations once the facility is delicensed.

Lastly, ASN has evaluated Andra's provisions for the long-term expenses of decommissioning and waste management and concludes that they are satisfactory. Andra adopts reasonably conservative assumptions for the various scenarios for placing the disposal facilities in their long-term configuration and for their monitoring and surveillance.

4 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-Côtes 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 understanding of the environmental and health impact of the former uranium mines and their surveillance;
- manage the mining waste rock (better identify the uses and reduce impacts if necessary);
- reinforce information and consultation.

• 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 uranium ore treatment residue disposal areas;
- 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. This study is currently being examined by ASN.

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.

• Management of reused mining waste rock

Most of the mining waste rock has remained on the site where it was produced (mine in-fill, redevelopment work or spoil heaps). Nonetheless, 1 to 2% of the mining waste rock may have been used as backfill, in earthworks or for road beds in public places situated near the mining sites. Although the reuse of waste rock in the public domain has been traced since 1984, knowledge of reuses prior to 1984 remains incomplete. ASN and the Ministry responsible for the Environment, in the framework of the action plan drawn up further to the Circular of 22 July 2009, asked Orano Mining to inventory the mining waste rock reused in the public domain in order to verify compatibility of the uses and to reduce the impacts if necessary.

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 millisieverts per year (mSv/year) on the basis of a radiological impact study.

Within the framework of the PNGMDR 2016-2018, an assessment of the actions taken to inventory mining waste rock in the public domain was submitted by Orano in January 2018 and will be examined by ASN in 2019.

All these operations are under the administrative surveillance of the Prefect, on the basis of proposals from the Regional Directorate for the Environment, Planning and Housing (Dreal). ASN assists the Prefects with regard to the radiation protection of workers and the public and the review of the management routes. In this context it encourages the complete clean-out of the sites when this is technically possible and asks that any other procedure implemented be justified with regard to this reference strategy. Furthermore, the Dreal is particularly attentive to cases that could lead to human exposure, especially to radon. Lastly, it ensures that the actions are carried out with complete transparency, by involving the local players as much as possible, and that the information relating to these actions is preserved so that the future use of these sites can be managed.

The ASN regional divisions participate in the former uranium mining site monitoring commissions which comprise representatives of the State, local authorities, environmental protection associations and Orano Mining.

5 Management of sites and soils polluted by radioactive substances

A site contaminated by radioactive substances is defined as any site, whether abandoned or in operation, on which natural or artificial radioactive substances have been or are employed or stored in conditions such that the site may constitute a hazard for health and the environment.

Contamination by radioactive substances can result from industrial, craft, medical or research activities involving radioactive substances. It can concern the places where these activities are carried out, but also their immediate or more remote vicinity. The activities concerned are generally either nuclear activities as defined by the Public Health Code, or activities concerned by 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 are: radium extraction for medical and para-pharmaceutical needs, from the early 20th century up to the end of the 1930s; the manufacture and application of luminescent radioactive paint for night vision and the industries working ores such as monazite or zircons. Sites contaminated by radioactive substances are managed on a case-by-case basis, which necessitates having a precise diagnosis of the site.

Article L.125-6 of the Environment Code provides for the State to create soil information sectors 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 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[10] of the Ministry responsible for the Environment dedicated to contaminated sites and Soils.

In October 2012, ASN finalised its doctrine specifying the fundamental principles it has adopted for the management of sites contaminated by radioactive substances. In the event that, depending on the characteristics of the site, this procedure would be difficult to apply, it is in any case necessary to go as far as reasonably possible in the remediation process and to provide elements, whether technical or economic, proving that the remediation operations cannot be taken further and are compatible with the actual or planned use of the site.

The ASN doctrine defines the measures to take if complete remediation is not achieved. ASN considers moreover that the stakeholders and audiences concerned must be involved as early as possible in the process to rehabilitate a site contaminated by radioactive substances.

ASN also points out that in application of the "polluter-pays" principle written into the Environment Code, those responsible for the contamination finance the operations to rehabilitate the contaminated site and to remove the waste resulting from these operations. If the responsible entities default, Andra, on account of its public service remit and by public requisition, ensures the rehabilitation of radioactive contaminated sites.

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.

Since the publication of Decree 2018-438 of 4 June 2018, 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).

The commission met four times in 2018, particularly to address monitoring of the management of ongoing polluted site decontamination work, such as the Champlay and Isotopchim sites, and those of the Radium Diagnosis Operation.

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 installations inspectors to give its opinion on the clean-out objectives of a site.

10. *www.georisques.gouv.fr/dossiers/pollution-des-sols-sis-et-anciens-sites-industriels*

The ASN regional divisions accompanying the Prefect's offices in the management of contaminated sites and soils and of the former uranium mines

Former uranium mines

In the Nouvelle-Aquitaine region, the Bordeaux division took part in the assessment of the radiation protection results and actions proposed by Orano Mining for the final stoppage of the work on the sites of Henriette (Haute Vienne *département*), La Védrenne (Corrèze *département*) and Montmassacrot (Haute Vienne *département*). ASN is attentive to the proper assessing of the risks of radiological exposure linked to radon, to mining waste rock and ore treatment residues. If the exposure is likely to exceed the regulatory reference levels, ASN makes proposals to preserve of the memory of these sites through soil information sectors or active institutional controls.

In Bretagne, Orano Mining carried out an environmental pollution assessment in 2018 to assess the effects of the sludge and radiologically-marked sediments situated downstream of the former mining sites.

Soils contaminated by radioactive substances

The ASN Dijon division is particularly attentive to land in the Bourgogne-Franche-Comté region polluted by residues from the treatment of uranium-bearing ores situated in the municipality of Gueugnon (Saône et Loire *département*). ASN participates in the monitoring of the radiological remediation work which Orano Mining began in September 2016 on a first site accommodating a dwelling house. The work carried out so far has remediated two-thirds of the land to a high standard and restored a situation close to the natural radiological state. In 2018, Orano Mining conducted the studies necessary for completion of the remediation work. ASN moreover contributed in August 2018 to the reinforcing of environmental monitoring around the disposal facility situated on the municipality of Gueugnon, which contains waste from a uranium ore treatment plant. The perimeter of this facility has moreover been widened to include contiguous land polluted by ore treatment residues.

The reuse of mining waste rock

ASN also assists the Dreals which are tasked with assessing Orano Mining's proposals for remedying the radiological anomalies resulting from the reuse of mining waste rock in the public domain. All the sites in the Bretagne and Pays de Loire regions which necessitated priority work (where the annual effective dose exceeded 0.6 mSv/year) were treated in 2018. In Bretagne, the ASN Nantes division has checked achievement of the remediation targets by taking samples during a joint inspection with the Dreal. In the Pays de Loire region, Orano Mining has also carried out the work requested by the Prefect to reduce the radon of anthropogenic origin in the buildings or dwelling houses concerned. A new radon screening campaign was undertaken during winter 2018/2019 to assess its effectiveness. In the Bourgogne-Franche-Comté region, the Dijon division issued an opinion on the work envisaged by Orano Mining in the Saône-et-Loire and Nièvre *départements*.

The sites contaminated by radioative substances

ASN is called upon by the Dreals to contribute to the identification, securing and monitoring of the decontamination of sites contaminated by radioactive substances of artificial or natural origin.

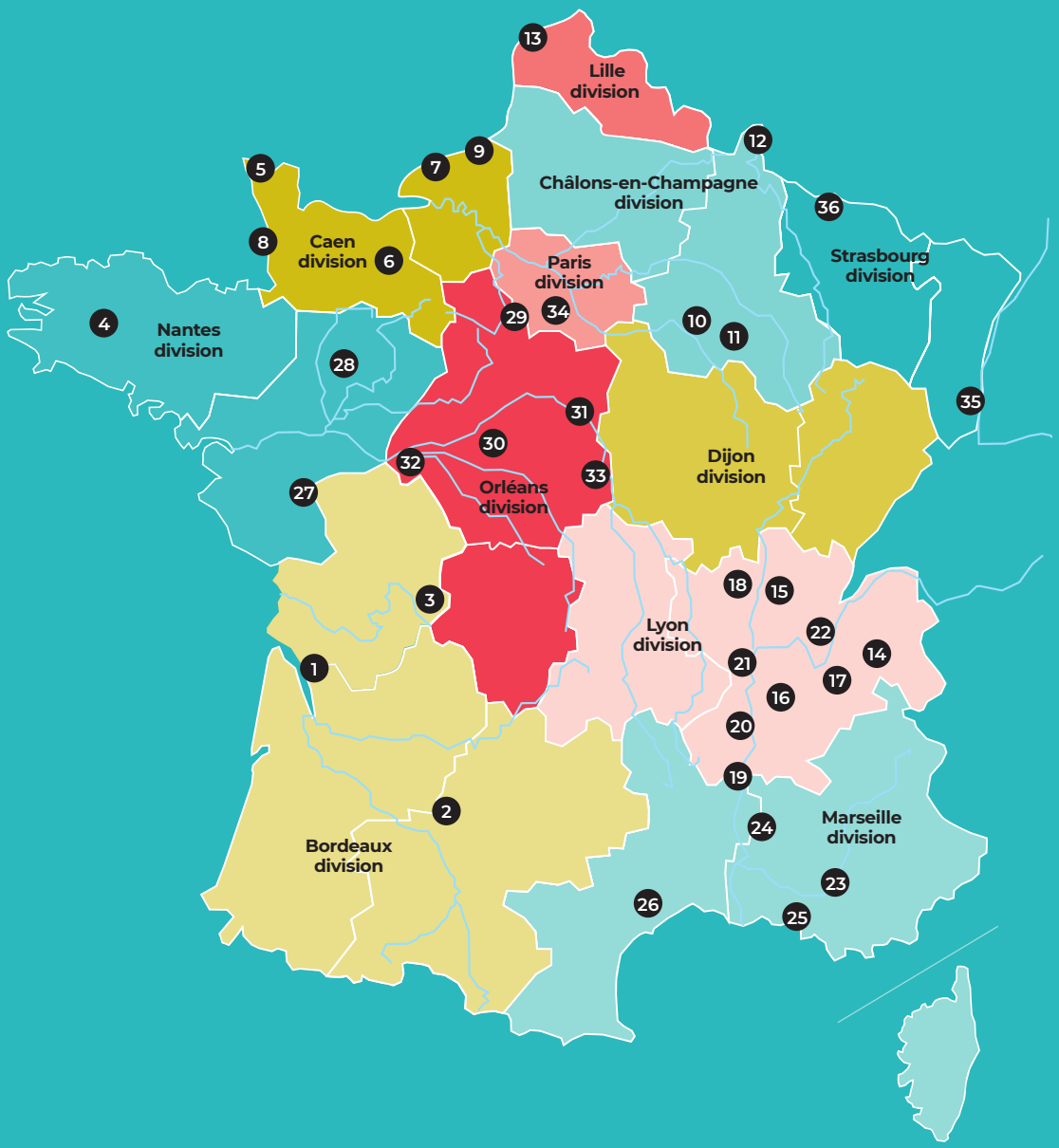
These can be former production sites of radium –or tritium– based luminescent paint for the watchmaking industry, or sites on which radioluminescent devices were used. In the Bourgogne-Franche-Comté region, the ASN Dijon division keeps track of the radiological clean-out of a former watchmaking factory in the Haut-Doubs area which began in 2014. In 2018, it contributed to the drafting of a Prefectural Order authorising the last phases of this work. In July 2018, radioactive watchmaking objects were discovered in a vocational training high school in Morteau (Doubs *département*). At the request of the Prefect and with the technical support of IRSN, ASN intervened to conduct the radiological characterisation of the premises and assess the health risks for the exposed persons. IRSN estimated that the doses involved were extremely low and would have no impact on the health of the persons who frequented the premises. The identified radioactive objects were placed in safe keeping pending their removal by Andra. A low level of radiological contamination by tritium was detected in a storage room, which has now been decontaminated. Lastly, recommendations were made to the head of the school so that in the future radioactive objects can be detected before they enter the premises, and to heighten pupil and staff awareness of these risks.

In the Provence-Alpes-Côte d'Azur region, the Marseille division of ASN monitors the steps taken on two radium-contaminated sites in Bandol (Var *département*) to make them secure and start their decontamination. The Marseille division also monitors the decontamination work which began in 2015 on a storage site situated in Cuers-Pierrefeu (Var *département*) containing radioluminescent devices for the aeronautical industry. In June 2018, the site owner put out a request for proposals for the sorting, characterisation and packaging of the radioactive waste with a view to its retrieval by Andra.

Other sites have been contaminated as a result of research activities involving the use of radioactive substances. This is the case for example in Occitanie, Provence-Alpes-Côte d'Azur and Corse.

The Marseille division monitors the sites of Oraison (Alpes-de-Haute-Provence *département*), Pech Rouge (Aude *département*) and San Giuliano (Haute Corse *département*) on which experiments on the transfer of radioactivity to plants were carried out by INRA (French National Institute of Agricultural Research). Studies have been requested to assess the consequences of the radiological contamination of these sites, considering different future use scenarios. The Marseille division will examine them and given an opinion on the proposed management options. In the Alpes de Haute-Provence *département*, the Marseille division in 2018 also monitored the measures taken by Andra to render secure the Ganagobie site, where radioactive waste resulting from the activities of the company Isotopchim is still present.

Sites regulated by the ASN regional divisions



— BORDEAUX DIVISION

1 ▲ Blayais 2 ▲ Golfech 3 ▲ Civaux

— CAEN DIVISION

4 ▲ Brennilis 5 ■ La Hague 6 ● Caen 7 ▲ Paluel
8 ▲ Flamanville 9 ▲ Penly

— CHÂLONS-EN-CHAMPAGNE DIVISION

10 ▲ Nogent-sur-Seine 11 ■ Soulaines-Dhuys 12 ▲ Chooz

— LILLE DIVISION

13 ▲ Gravelines

— LYON DIVISION

14 ○ ● Grenoble 15 ▲ ○ Bugey 16 ■ Romans-sur-Isère
17 ■ Veurey-Voroize 18 ○ Dagneux 19 ▲ ■ ○ Tricastin
20 ▲ Cruas-Meysse 21 ▲ Saint-Alban/Saint-Maurice
22 ○ ▲ Creys-Malville

— MARSEILLE DIVISION

23 ○ ● Cadarache 24 ▲ ■ ○ ● Marcoule 25 ○ Marseille
26 ○ Malvési

— NANTES DIVISION

27 ○ Pouzauges 28 ○ Sablé-sur-Sarthe

— ORLÉANS DIVISION

29 ● Saclay 30 ○ ▲ Saint-Laurent-des-Eaux
31 ▲ Dampierre-en-Burly 32 ▲ ○ Chinon
33 ▲ Belleville-sur-Loire 34 ● Fontenay-aux-Roses

— STRASBOURG DIVISION

35 ▲ Fessenheim 36 ▲ Cattenom

Type of installation

▲ Nuclear power plant
■ Factory
● Research installations
■ Disposal of waste
○ Others

APPENDIX

List of Basic Nuclear Installations as at 31 December 2018

List of Basic Nuclear Installations as at 31 December 2018

To regulate all civil nuclear activities and installations in France, ASN has set up a regional organization comprising 11 regional divisions based in Bordeaux, Caen, Châlons-en-Champagne, Dijon, Lille, Lyon, Marseille, Nantes, Orléans, Paris and Strasbourg.

The Caen and Orléans divisions are responsible for BNI regulation in the Bretagne (Brittany) and Ile-de-France regions respectively. The Paris division oversees the overseas regions and the *département* of Mayotte, while the Marseille division oversees radiation protection and radioactive substance transport in the Corse 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 ASN opinion. Their design, construction, operation and decommissioning are all regulated.

The following are BNIs:
1. Nuclear reactors;
2. Large installations for the preparation, enrichment, fabrication, treatment or storage of nuclear fuels or the treatment, storage or disposal of radioactive waste;
3. Large installations containing radioactive or fissile substances;
4. Large particle accelerators;
5. Deep geological repositories for radioactive waste.

With the exception of nuclear reactors and the possible future deep geological repositories for radioactive waste, which are all BNIs, Decree 2007-830 of 11 May 2007 relative to the nomenclature of Basic Nuclear Installations sets the threshold for entry into the BNI System for each category.

For technical or legal reasons, the concept of a Basic Nuclear Installation can cover a number of different physical situations: for example in a nuclear power plant, each reactor may be considered as a separate BNI, or a given BNI might in fact comprise two reactors. Similarly, a fuel cycle plant or a CEA centre can comprise several BNIs. These different configurations do not alter the regulatory conditions in any way.

The following are subject to the BNI System:
- facilities under construction, provided that they are the subject of a Creation Authorisation Decree;
- facilities in operation;
- facilities shut down or undergoing decommissioning, until they are delicensed by ASN.

As at 31 December 2018, there were 126 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.

SITE NAME	NAME AND LOCATION OF THE INSTALLATION	LICENSEE	TYPE OF INSTALLATION	BNI
LOCATION OF INSTALLATIONS REGULATED BY THE BORDEAUX DIVISION				
❶ Blayais	BLAYAIS NUCLEAR POWER PLANT (reactors 1 and 2) 33820 Saint-Ciers-sur-Gironde	EDF	Reactors	86
❶ Blayais	BLAYAIS NUCLEAR POWER PLANT (reactors 3 and 4) 33820 Saint-Ciers-sur-Gironde	EDF	Reactors	110
❷ Golfech	GOLFECH NUCLEAR POWER PLANT (reactor 1) 82400 Golfech	EDF	Reactor	135
❷ Golfech	GOLFECH NUCLEAR POWER PLANT (reactor 2) 82400 Golfech	EDF	Reactor	142
❸ Civaux	CIVAUX NUCLEAR POWER PLANT (reactor 1) BP 1 - 86320 Civaux	EDF	Reactor	158
❸ Civaux	CIVAUX NUCLEAR POWER PLANT (reactor 2) BP 1 - 86320 Civaux	EDF	Reactor	159
LOCATION OF INSTALLATIONS REGULATED BY THE CAEN DIVISION				
❹ Brennilis	MONTS D'ARRÉE EL4D 29530 Loqueffret	EDF	Reactor	162
❺ La Hague	SPENT FUEL REPROCESSING PLANT (UP2-400) 50107 Cherbourg	Orano Cycle	Transformation of radioactive substances	33
❺ La Hague	EFFLUENT AND SOLID WASTE TREATMENT STATION (STE2) AND SPENT NUCLEAR FUELS REPROCESSING FACILITY (AT1) 50107 Cherbourg	Orano Cycle	Transformation of radioactive substances	38
❺ La Hague	ELAN IIB FACILITY 50107 Cherbourg	Orano Cycle	Transformation of radioactive substances	47
❺ La Hague	MANCHE WASTE REPOSITORY (CSM) 50440 Digulleville	Andra	Disposal of radioactive substances	66
❺ La Hague	HAO (HIGH LEVEL OXIDE) FACILITY 50107 Cherbourg	Orano Cycle	Transformation of radioactive substances	80
❺ La Hague	REPROCESSING PLANT FOR SPENT FUEL ELEMENTS FROM LIGHT WATER REACTORS (UP3 A) 50107 Cherbourg	Orano Cycle	Transformation of radioactive substances	116
❺ La Hague	REPROCESSING PLANT FOR SPENT FUEL ELEMENTS FROM LIGHT WATER REACTORS (UP2-800) 50107 Cherbourg	Orano Cycle	Transformation of radioactive substances	117
❺ La Hague	LIQUID EFFLUENT AND SOLID WASTE TREATMENT STATION (STE3) 50107 Cherbourg	Orano Cycle	Transformation of radioactive substances	118
❻ Caen	NATIONAL LARGE HEAVY ION ACCELERATOR (GANIL) 14021 Caen Cedex	G.I.E. GANIL	Particle accelerator	113
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❼ Paluel	PALUEL NUCLEAR POWER PLANT (reactor 2) 76450 Paluel	EDF	Reactor	104
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❼ Paluel	PALUEL NUCLEAR POWER PLANT (reactor 4) 76450 Paluel	EDF	Reactor	115
❽ Flamanville	FLAMANVILLE NUCLEAR POWER PLANT (reactor 1) 50340 Flamanville	EDF	Reactor	108
❽ Flamanville	FLAMANVILLE NUCLEAR POWER PLANT (reactor 2) 50340 Flamanville	EDF	Reactor	109
❽ Flamanville	FLAMANVILLE NUCLEAR POWER PLANT (reactor 3 - EPR) 50340 Flamanville	EDF	Reactor	167
❾ Penly	PENLY NUCLEAR POWER PLANT (reactor 1) 76370 Neuville-lès-Dieppe	EDF	Reactor	136

SITE NAME	NAME AND LOCATION OF THE INSTALLATION	LICENSEE	TYPE OF INSTALLATION	BNI
❾ Penly	PENLY NUCLEAR POWER PLANT (reactor 2) 76370 Neuville-lès-Dieppe	EDF	Reactor	140
	LOCATION OF INSTALLATIONS REGULATED BY THE CHÂLONS-EN-CHAMPAGNE DIVISION			
❿ Nogent-sur-Seine	NOGENT-SUR-SEINE POWER PLANT (reactor 1) 10400 Nogent-sur-Seine	EDF	Reactor	129
❿ Nogent-sur-Seine	NOGENT-SUR-SEINE POWER PLANT (reactor 2) 10400 Nogent-sur-Seine	EDF	Reactor	130
⓫ Soulaines-Dhuys	AUBE WASTE REPOSITORY (CSA) 10200 Bar-sur-Aube	Andra	Radioactive waste surface repository	149
⓬ Chooz	CHOOZ B NUCLEAR POWER PLANT (reactor 1) 08600 Givet	EDF	Reactor	139
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⓬ Chooz	ARDENNES NUCLEAR POWER PLANT CNA-D (CHOOZ A) 08600 Givet	EDF	Reactor	163
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⓭ Gravelines	GRAVELINES NUCLEAR POWER PLANT (reactors 1 and 2) 59820 Gravelines	EDF	Reactors	96
⓭ Gravelines	GRAVELINES NUCLEAR POWER PLANT (reactors 3 and 4) 59820 Gravelines	EDF	Reactors	97
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⓮ Grenoble	HIGH FLUX REACTOR (RHF) 38041 Grenoble Cedex	Max von Laue Paul Langevin Institute	Reactor	67
⓮ Grenoble	DECAY INTERIM STORAGE FACILITY (STD) 38041 Grenoble Cedex	CEA	Storage of radioactive substances	79
⓯ Bugey	BUGEY NUCLEAR POWER PLANT (reactor 1) BP 60120 - 01150 Saint-Vulbas	EDF	Reactor	45
⓯ Bugey	BUGEY NUCLEAR POWER PLANT (reactors 2 and 3) BP 60120 - 01150 Saint-Vulbas	EDF	Reactors	78
⓯ Bugey	BUGEY NUCLEAR POWER PLANT (reactors 4 and 5) BP 60120 - 01150 Saint-Vulbas	EDF	Reactors	89
⓯ Bugey	BUGEY INTER-REGIONAL WAREHOUSE (MIR) BP 60120 - 01150 Saint-Vulbas	EDF	Storage of new fuel	102
⓯ Bugey	ACTIVATED WASTE PACKAGING AND STORAGE INSTALLATION (ICEDA) 01150 Saint-Vulbas	EDF	Packaging and interim storage of radioactive substances	173
⓰ Romans-sur-Isère	NUCLEAR FUELS FABRICATION UNITT (FBFC) 26104 Romans-sur-Isère	Framatome	Fabrication of radioactive substances	98
⓰ Romans-sur-Isère	NUCLEAR FUELS FABRICATION UNI (CERCA) 26104 Romans-sur-Isère	Framatome	Fabrication of radioactive substances	63
⓱ Veurey-Voroize	NUCLEAR FUELS FABRICATION PLANT 38113 Veurey-Voroize	SICN	Fabrication of radioactive substances	65
⓱ Veurey-Voroize	PELLET FABRICATION FACILITY 38113 Veurey-Voroize	SICN	Fabrication of radioactive substances	90
⓲ Dagneux	DAGNEUX IONISATION PLANT Z.I. Les Chartinières - 01120 Dagneux	Ionisos	Utilisation of radioactive substances	68

SITE NAME	NAME AND LOCATION OF THE INSTALLATION	LICENSEE	TYPE OF INSTALLATION	BNI
⑲ Tricastin	TRICASTIN NUCLEAR POWER PLANT (reactors 1 and 2) 26130 Saint-Paul-Trois-Châteaux	EDF	Reactors	87
⑲ Tricastin	TRICASTIN NUCLEAR POWER PLANT (reactors 3 and 4) 26130 Saint-Paul-Trois-Châteaux	EDF	Reactors	88
⑲ Tricastin	GEORGES BESSE PLANT FOR URANIUM ISOTOPE SEPARATION BY GASEOUS DIFFUSION (EURODIF) 26702 Pierrelatte Cedex	Orano Cycle	Transformation of radioactive substances	93
⑲ Tricastin	URANIUM HEXAFLUORIDE PREPARATION PLANT (COMURHEX) 26130 Saint-Paul-Trois-Châteaux	Orano Cycle	Transformation of radioactive substances	105
⑲ Tricastin	URANIUM CLEAN-UP AND RECOVERY FACILITY (IARU) 26130 Saint-Paul-Trois-Châteaux	Orano Cycle	Factory	138
⑲ Tricastin	TU5 and W FACILITIES BP 16 - 26701 Pierrelatte	Orano Cycle	Transformation of radioactive substances	155
⑲ Tricastin	TRICASTIN OPERATIONAL HOT UNIT (BCOT) BP 127 - 84504 Bollène Cedex	EDF	Nuclear maintenance	157
⑲ Tricastin	GEORGES BESSE II PLANT FOR CENTRIFUGAL SEPARATION OF URANIUM ISOTOPES (GB II) 26702 Pierrelatte Cedex and 26130 Saint-Paul-Trois-Châteaux	Orano Cycle	Transformation of radioactive substances	168
⑲ Tricastin	AREVA TRICASTIN ANALYSIS LABORATORY (ATLAS) 26700 Pierrelatte	Orano Cycle	Laboratory for the utilisation of radioactive substances	176
⑲ Tricastin	TRICASTIN URANIUM-BEARING MATERIAL STORAGE YARD 26700 Pierrelatte	Orano Cycle	Storage of radioactive materials	178
⑲ Tricastin	P35 26700 Pierrelatte	Orano Cycle	Storage of radioactive materials	179
⑳ Cruas-Meysse	CRUAS-MEYSSE NUCLEAR POWER PLANT (reactors 1 and 2) 07350 Cruas	EDF	Reactors	111
⑳ Cruas-Meysse	CRUAS-MEYSSE NUCLEAR POWER PLANT (reactors 3 and 4) 07350 Cruas	EDF	Reactors	112
㉑ Saint-Alban/ Saint-Maurice	SAINT-ALBAN/SAINT-MAURICE NUCLEAR POWER PLANT (reactor 1) 38550 Le Péage-de-Roussillon	EDF	Reactor	119
㉑ Saint-Alban/ Saint-Maurice	SAINT-ALBAN/SAINT-MAURICE NUCLEAR POWER PLANT (reactor 2) 38550 Le Péage-de-Roussillon	EDF	Reactor	120
㉒ Creys-Malville	SUPERPHENIX REACTOR 38510 Morestel	EDF	Reactor	91
㉒ Creys-Malville	FUEL STORAGE FACILITY (APEC) (Creys-Malville) 38510 Creys-Mépieu	EDF	Storage of radioactive substances	141

LOCATION OF INSTALLATIONS REGULATED BY THE MARSEILLE DIVISION

㉓ 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
㉓ Cadarache	CABRI 13115 Saint-Paul-lez-Durance Cedex	CEA	Reactor	24
㉓ Cadarache	RAPSODIE 13115 Saint-Paul-lez-Durance Cedex	CEA	Reactor	25
㉓ Cadarache	PLUTONIUM TECHNOLOGY FACILITY (ATPu) 13115 Saint-Paul-lez-Durance Cedex	CEA	Fabrication or Transformation of radioactive substances	32
㉓ Cadarache	SOLID WASTE TREATMENT STATION (STD) 13115 Saint-Paul-lez-Durance Cedex	CEA	Transformation of radioactive substances	37-A
㉓ Cadarache	EFFLUENT TREATMENT STATION (STE) 13115 Saint-Paul-lez-Durance Cedex	CEA	Transformation of radioactive substances	37-B

SITE NAME	NAME AND LOCATION OF THE INSTALLATION	LICENSEE	TYPE OF INSTALLATION	BNI
23 Cadarache	MASURCA 13115 Saint-Paul-lez-Durance Cedex	CEA	Reactor	39
23 Cadarache	ÉOLE 13115 Saint-Paul-lez-Durance Cedex	CEA	Reactor	42
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23 Cadarache	ENRICHED URANIUM AND PLUTONIUM WAREHOUSE (MCMF) 13115 Saint-Paul-lez-Durance Cedex	CEA	Storage of radioactive substances	53
23 Cadarache	CHEMICAL PURIFICATION LABORATORY (LPC) 13115 Saint-Paul-lez-Durance Cedex	CEA	Transformation of radioactive substances	54
23 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
23 Cadarache	SOLID RADIOACTIVE WASTE STORAGE YARD 13115 Saint-Paul-lez-Durance Cedex	CEA	Storage of radioactive substances	56
23 Cadarache	PHÉBUS 13115 Saint-Paul-lez-Durance Cedex	CEA	Reactor	92
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23 Cadarache	LABORATORY FOR RESEARCH AND EXPERIMENTAL FABRICATION OF ADVANCED NUCLEAR FUELS (LEFCA) 13115 Saint-Paul-lez-Durance Cedex	CEA	Utilisation of radioactive substances	123
23 Cadarache	CHICADE BP 1 - 13115 Saint-Paul-lez-Durance Cedex	CEA	R&D laboratory	156
23 Cadarache	CEDRA 13115 Saint-Paul-lez-Durance Cedex	CEA	Packaging and interim storage of radioactive substances	164
23 Cadarache	MAGENTA 13115 Saint-Paul-lez Durance Cedex	CEA	Reception and shipment of nuclear materials	169
23 Cadarache	EFFLUENT ADVANCED MANAGEMENT AND PROCESSING FACILITY (AGATE) 13115 Saint-Paul-lez Durance Cedex	CEA	Packaging and interim storage of radioactive substances	171
23 Cadarache	JULES HOROWITZ REACTOR (JHR) 13115 Saint-Paul-lez Durance Cedex	CEA	Reactor	172
23 Cadarache	ITER 13115 Saint-Paul-lez-Durance Cedex	International organisation ITER	Nuclear fusion reaction experiments with tritium and deuterium and deuterium plasmas	174
24 Marcoule	PHÉNIX 30205 Bagnols-sur-Cèze	CEA	Reactor	71
24 Marcoule	ATALANTE 30200 Chusclan	CEA	R&D laboratory and study of actinides production	148
24 Marcoule	NUCLEAR FUELS FABRICATION PLANT (MELOX) BP 2 - 30200 Chusclan	Orano Cycle	Fabrication of radioactive substances	151
24 Marcoule	CENTRACO 30200 Codolet	Socodei	Radioactive waste and effluent processing	160
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24 Marcoule	DIADEM 30200 Chusclan	CEA	Storage of solid radioactive waste	177
25 Marseille	GAMMASTER IONISATION PLANT 13323 Marseille Cedex 14	Synergy Health Marseille	Ionisation installation	147
26 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
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28 Sablé-sur-Sarthe	SABLÉ-SUR-SARTHE IONISATION PLANT Z.I. de l'Aubrée - 72300 Sablé-sur-Sarthe	Ionisos	Ionisation installation	154
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29 Saclay	ARTIFICIAL RADIONUCLIDES PRODUCTION FACILITY (UPRA) 91191 Gif-sur-Yvette Cedex	CIS Bio International	Fabrication or transformation of radioactive substances	29
29 Saclay	LIQUID EFFLUENT MANAGEMENT ZONE (STELLA) 91191 Gif-sur-Yvette Cedex	CEA	Transformation of radioactive substances	35
29 Saclay	OSIRIS-ISIS 91191 Gif-sur-Yvette Cedex	CEA	Reactors	40
29 Saclay	HIGH-ACTIVITY LABORATORY (LHA) 91191 Gif-sur-Yvette Cedex	CEA	Utilisation of radioactive substances	49
29 Saclay	SPENT FUEL TEST LABORATORY (LECI) 91191 Gif-sur-Yvette Cedex	CEA	Utilisation of radioactive substances	50
29 Saclay	SOLID RADIOACTIVE WASTE MANAGEMENT ZONE (ZGDS) 91191 Gif-sur-Yvette Cedex	CEA	Storage and packaging of radioactive substances	72
29 Saclay	POSEIDON IRRADIATION FACILITIES 91191 Gif-sur-Yvette Cedex	CEA	Utilisation of radioactive substances	77
29 Saclay	ORPHÉE 91191 Gif-sur-Yvette Cedex	CEA	Reactor	101
30 Saint-Laurent-des-Eaux	SAINT-LAURENT-DES-EAUX NUCLEAR POWER PLANT (reactors A1 and A2) 41220 La Ferté-Saint-Cyr	EDF	Reactors	46
30 Saint-Laurent-des-Eaux	IRRADIATED GRAPHITE SLEEVE STORAGE SILOS 41220 La Ferté-Saint-Cyr	EDF	Storage of radioactive substances	74
30 Saint-Laurent-des-Eaux	SAINT-LAURENT-DES-EAUX NUCLEAR POWER PLANT (reactors B1 and B2) 41220 La Ferté-Saint-Cyr	EDF	Reactors	100
31 Dampierre-en-Burly	DAMPIERRE-EN-BURLY NUCLEAR POWER PLANT (reactors 1 and 2) 45570 Ouzouer-sur-Loire	EDF	Reactors	84
31 Dampierre-en-Burly	DAMPIERRE-EN-BURLY NUCLEAR POWER PLANT (reactors 3 and 4) 45570 Ouzouer-sur-Loire	EDF	Reactors	85
32 Chinon	IRRADIATED MATERIAL FACILITY (AMI) 37420 Avoine	EDF	Utilisation of radioactive substances	94
32 Chinon	CHINON INTER-REGIONAL WAREHOUSE (MIR) 37420 Avoine	EDF	Storage of new fuel	99
32 Chinon	CHINON NUCLEAR POWER PLANT (reactors B1 and B2) 37420 Avoine	EDF	Reactors	107
32 Chinon	CHINON NUCLEAR POWER PLANT (reactors B3 and B4) 37420 Avoine	EDF	Reactors	132
32 Chinon	CHINON A1 D 37420 Avoine	EDF	Reactor	133
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32 Chinon	CHINON A3 D 37420 Avoine	EDF	Reactor	161
33 Belleville-sur-Loire	BELLEVILLE-SUR-LOIRE NUCLEAR POWER PLANT (reactor 1) 18240 Léré	EDF	Reactor	127

SITE NAME	NAME AND LOCATION OF THE INSTALLATION	LICENSEE	TYPE OF INSTALLATION	BNI
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34 Fontenay-aux-Roses	SUPPORT 92265 Fontenay-aux-Roses Cedex	CEA	Effluent treatment and waste storage installation	166

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36 Cattenom	CATTENOM NUCLEAR POWER PLANT (reactor 1) 57570 Cattenom	EDF	Reactor	124
36 Cattenom	CATTENOM NUCLEAR POWER PLANT (reactor 2) 57570 Cattenom	EDF	Reactor	125
36 Cattenom	CATTENOM NUCLEAR POWER PLANT (reactor 3) 57570 Cattenom	EDF	Reactor	126
36 Cattenom	CATTENOM NUCLEAR POWER PLANT (reactor 4) 57570 Cattenom	EDF	Reactor	137

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ASN report on the state of nuclear safety and radiation protection in France in 2018

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Publishing director: Bernard Doroszczuk, Chairman of ASN
Editor: Marie-Christine Bardet
Editorial staff: Fabienne Covard
Iconographer: Olivier Javay

ISSN 1967 – 5127

Printer number: 14028-5-2019 – **Legal deposit:** May 2019
Production: BRIEF
Printing: Imprimerie Fabrègue

Find the Abstract Report
on the state of nuclear safety and radiation protection
in France in 2018 on

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