AUTORITÉ
DE SÛRETÉ
NUCLÉAIRE

ASN REPORT

on the state of nuclear safety
and radiation protection in France in **|2020|**

The French Nuclear Safety Authority presents its report on the state of nuclear safety and radiation protection in France in 2020.

This report is required by Article L. 592-31 of the Environment Code.

It was submitted to the President of the Republic, the Prime Minister and the Presidents of the Senate and the National Assembly and transmitted to the Parliamentary Office for the Evaluation of Scientific and Technological Choices, pursuant to the above-mentioned Article.

THE FRENCH NUCLEAR SAFETY AUTHORITY

Roles
Operations
Key figures

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

On behalf of the State, ASN ensures the oversight of nuclear safety and radiation protection 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 oversight that is recognised by the citizens and regarded internationally as a benchmark for good practice.

ROLES

REGULATING

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

AUTHORISING

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

MONITORING

ASN is responsible for ensuring compliance with the rules and requirements applicable to the facilities and activities within its field of competence. Since the Energy Transition for Green Growth Act of 17 August 2015, ASN's roles now include protecting ionising radioactive sources against malicious acts. Inspection is ASN's primary monitoring activity. More than 1,500 inspections were thus performed in 2020 in the fields of nuclear safety and radiation protection.
ASN has graded enforcement and penalty powers (formal notice, administrative fines, daily fines, ability to carry out seizure, take samples or require payment of a guarantee, etc.). The administrative fine is the competence of the Administrative Enforcement Committee within ASN, which complies with the principle of the separation of the examination and sentencing functions.

INFORMING

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

IN EMERGENCY SITUATIONS

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

REGULATION AND MONITORING OF DIVERSIFIED ACTIVITIES AND FACILITIES

Nuclear power plants, radioactive waste management, fabrication and reprocessing of nuclear fuel, 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:
- 56 nuclear reactors(*) producing 70% of the electricity consumed in France, as well as the Flamanville EPR reactor under construction;
- about 80 other facilities participating in civil research activities, radioactive waste management activities or "fuel cycle" activities;
- more than thirty or so facilities which have been finally shut down or are being decommissioned;
- several thousand facilities or activities using sources of ionising radiation for medical, industrial or research purposes;
- several hundred thousand shipments of radioactive substances performed annually in France.

EXPERT SUPPORT

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

* *As at 30 June 2020.*

OPERATIONS

THE COMMISSION

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

Bernard DOROSZCZUK Chairman	Sylvie CADET-MERCIER(*) Commissioner	Géraldine PINA JOMIR Commissioner	Lydie ÉVRARD(*)(**) Commissioner	Jean-Luc LACHAUME(*) Commissioner
from 13 November 2018 to 12 November 2024	from 21 December 2016 to 9 December 2023	from 15 December 2020 to 9 December 2026	from 10 March 2017 to 9 December 2023	from 21 December 2018 to 9 December 2026
APPOINTED BY the President of the Republic	APPOINTED BY the President of the Republic	APPOINTED BY the President of the Republic	APPOINTED BY the President of the Senate	APPOINTED BY the President of the National Assembly

** The Environment Code, modified by Act 2017-55 of 20 January 2017, introducing the general status of the independent administrative Authorities and the independent public Authorities, provides for the renewal of half of the ASN Commission, other than its Chairman, every 3 years. Decree 2019-190 of 14 March 2019 (codifying the provisions applicable to BNIs, the transport of radioactive substances and transparency in the nuclear field) sets out the relevant interim provisions and modified the duration of the mandates of three Commissioners.*

*** By Decree of the President of the Republic dated 21 April 2021, Laure Tourjansky was appointed Commissioner for the remainder of the mandate of Lydie Évrard, called to other duties.*

Impartiality

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

Independence

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

Competencies

The Commission takes decisions and issues opinions, which are published in ASN's *Official Bulletin*. The Commission defines ASN's oversight policy. The Chairman appoints the ASN inspectors. The Commission decides whether to open an inquiry following an incident or accident. Every year, it presents Parliament with the *ASN Report on the State of Nuclear Safety and Radiation Protection in France*. Its Chairman reports on ASN activities to the competent committees of the National Assembly and of the Senate and to the Parliamentary Office for the Evaluation of Scientific and Technological Choices. The Commission defines ASN's external relations policy at national and international level.

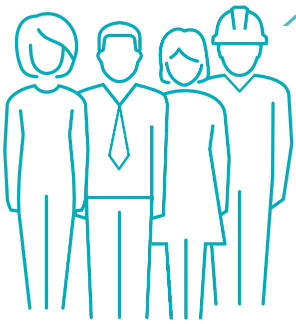
THE DEPARTMENTS

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

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

**** Administrative region headed by a Prefect.*

KEY FIGURES IN 2020



PERSONNEL

529 staff members

of which

85% management

47% women

320 inspectors

€65.77M budget for ASN (programme 181)

€83M budget for the IRSN devoted to technical expertise for ASN

BUDGET

ASN ACTIONS(*)

9 plenary meetings and **3** virtual consultations of the Advisory Committees of Experts

24,886 inspection follow-up letters available on *asn.fr* as at 31 December 2020

198 technical opinions sent to ASN by the IRSN

1,573 inspections including 320 performed remotely

1,651 individual licenses issued for facilities or activities

INFORMATION(*)

9 press conferences

67 information notices

Nearly **600** replies to queries from the public and stakeholders

** These figures take account of the impact of the Covid-19 pandemic on some ASN activities.*

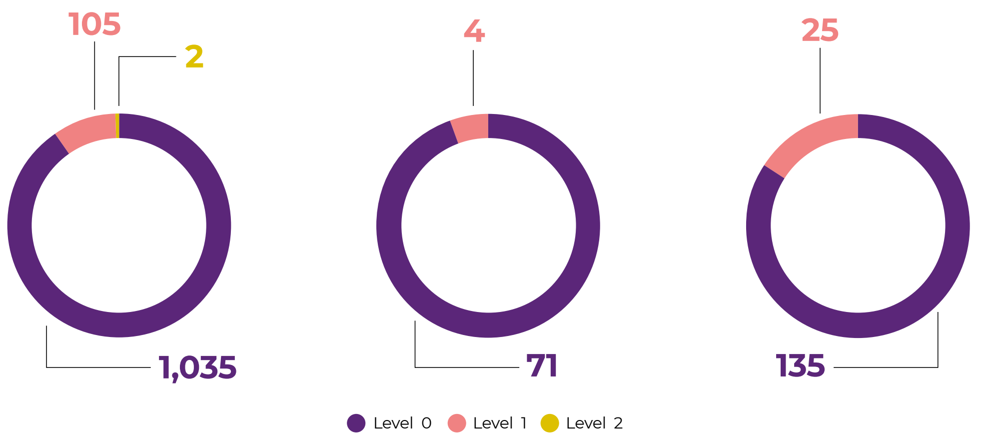
KEY FIGURES IN 2020

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

1,142
events in the Basic Nuclear Installations

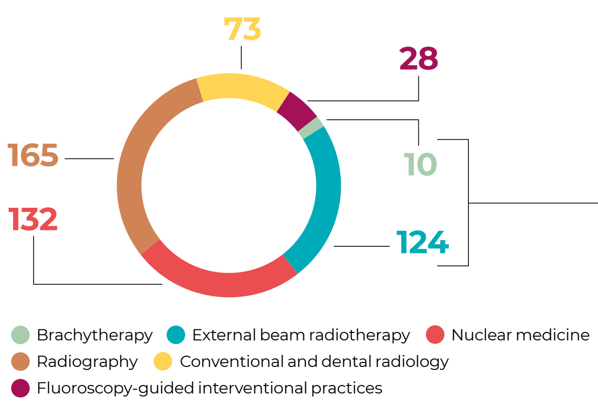
75
events in the transport of radioactive substances

160
events in small-scale nuclear facilities (medical and industrial)



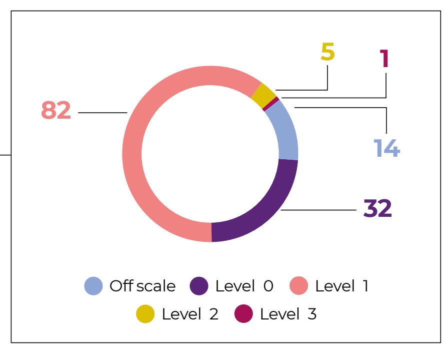
NUMBER OF SIGNIFICANT EVENTS IN THE MEDICAL FIELD(*)

532
significant events per area of exposure



134
significant events in external beam radiotherapy and brachytherapy

according to the rating on the ASN-SFRO scale



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

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

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

ASN ORGANISATION CHART

On 2 March 2021

COMMISSION

Chairman
Bernard Doroszczuk

Commissioners
Sylvie Cadet-Mercier
Jean-Luc Lachaume
Lydie Évrard
Géraldine Pina Jomir

Head of Private Office
Sylvie Rodde

GENERAL DIRECTORATE

Director General
Olivier Gupta

Deputy Directors General
Julien Collet
Daniel Delalande
Anne-Cécile Rigail

Chief inspector
Christophe Quintin

Director of Private Office
Vincent Cloître

Ethics Officer
Alain Dorison

DEPARTMENTS

NUCLEAR POWER PLANTS
Rémy Catteau

NUCLEAR PRESSURE EQUIPMENT
Corinne Silvestri

WASTE, RESEARCH FACILITIES AND FUEL CYCLE
Christophe Kassiotis

TRANSPORT AND SOURCES
Fabien Féron

IONISING RADIATION AND HEALTH
Carole Rousse

ENVIRONMENT AND EMERGENCY SITUATIONS
Olivier Rivière

LEGAL AFFAIRS
Olivia Lahaye

INFORMATION, COMMUNICATION AND DIGITAL USAGES
Céline Acharian

INTERNATIONAL RELATIONS
Luc Chanial

OFFICE OF ADMINISTRATION
Brigitte Rouède

MANAGEMENT AND EXPERTISE OFFICE
Adeline Clos

REGULATION AND OVERSIGHT SUPPORT MISSION
Julien Husse

REGIONAL DIVISIONS

(1) **BORDEAUX**
Regional representative: Alice-Anne Médard
Regional head: Simon Garnier

(2) **CAEN**
Regional representative: Olivier Morzelle
Regional head: Adrien Manchon

(3) **CHÂLONS-EN-CHAMPAGNE**
Regional representative: Hervé Vanlaer
Regional head: Mathieu Riquart

(4) **DIJON**
Regional representative: Jean-Pierre Lestoille
Regional head: Marc Champion

(5) **LILLE**
Regional representative: Laurent Tapadinhas
Regional head: Rémy Zmyslony

(6) **LYON**
Regional representative: Jean-Phlippe Deneuvy
Regional head: Caroline Coutout

(7) **MARSEILLE**
Regional representative: Corinne Tourasse
Regional head: Bastien Lauras

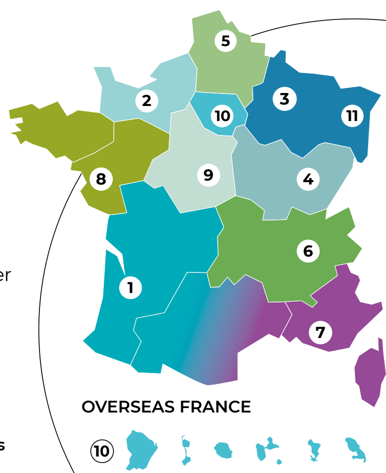
(8) **NANTES**
Regional representative: Annick Bonneville
Regional head: Émilie Jambu

(9) **ORLÉANS**
Regional representative: Hervé Brûlé
Regional head: Arthur Neveu

(10) **PARIS**
Regional representative: Agathe Baltzer (p.i.)
Regional head: Agathe Baltzer

(11) **STRASBOURG**
Regional representative: Hervé Vanlaer
Regional head: Pierre Bois

For BNI oversight only, the Caen and Orléans divisions hold responsibility for the Brittany and Île-de-France regions respectively. The Paris division intervenes in overseas France.



Competence
Independence
Rigour
Transparency

asn.fr
info@asn.fr

SUMMARY

ADVICE TO THE READER

- **The control of small-scale nuclear facilities (medical, research and industry, transport) is presented in chapters 7, 8, 9.**
- **Only regulatory news for the year 2020 is present in this report. All the regulations can be consulted on *asn.fr*, under the heading "Réglementer".**

EDITORIAL BY THE COMMISSION

THE NUCLEAR STAKEHOLDERS ADAPT TO AN UNPRECEDENTED SITUATION

“Learning lessons from this situation to strengthen a culture of anticipation and precaution”

From left to right:*
Jean-Luc LACHAUME, Commissioner; **Lydie ÉVRARD,** Commissioner; **Bernard DOROSZCZUK,** Chairman; **Sylvie CADET-MERCIER,** Commissioner; **Géraldine PINA JOMIR,** Commissioner

** To ensure compliance with health restrictions, the members of the Commission were photographed separately.*

Montrouge, 02 March 2021

The year 2020 was profoundly marked by the crisis caused by the Covid-19 pandemic. ASN considers that the level of nuclear safety and radiation protection achieved remained satisfactory and that those responsible for nuclear activities were able to adapt and cope with the situation.

In early 2021, the health crisis is still not over and prudence is required with regard to the lessons to be learned, in an uncertain and changing context.

ASN considers that this situation raises systemic questions which could apply, in the same terms, in the event of a nuclear crisis. This notably concerns trust in scientific expertise and in the authorities by the population and the conditions determining the acceptability of the restrictive population protection measures.

More generally, ASN considers that the first analyses of the problems encountered during this health crisis confirm the absolute need, which it has regularly underlined, to strengthen the culture of anticipation and precaution among all those concerned by nuclear matters.

Proven adaptability by the stakeholders, but vigilance to be maintained

In the context of an unprecedented crisis, the ability of all the stakeholders to adapt was a key point for nuclear safety and radiation protection. It proved to be satisfactory. On the one hand the licensees continued with the activities crucial to supplying the country with electricity, while maintaining a high level of safety in their installations. On the other, those in charge of nuclear activities, notably in the medical sector, demonstrated great reactivity and adapted their organisation to ensure that the health situation was managed and the provision of health care remained uninterrupted.

However, the postponement of numerous activities in the spring of 2020, combined with new restrictions in the autumn, created a considerable amount of pressure, which will last well beyond 2020. The rescheduling of unit outages to take account of electricity production needs in the winter and the domino effect that this has for the coming years, is leading to operational constraints for the NPPs, strain on the management of unit outages and contractor mobilisation, and demands particular vigilance with regard to the regulatory requirements. In the medical field, long-term management of the health crisis is raising questions regarding patient radiation protection in some centres, owing to the lack of availability or the overwork of the medical professionals. In this context, ASN remains attentive to the steps taken to ensure the nuclear safety and radiation protection of the activities, whether material, organisational, or human.

Finally, ASN is committed to learning all long-term lessons from the management of this crisis, on the one hand regarding its own oversight, in particular concerning the complementary nature of on-site and remote inspections, and on the other regarding the conditions for maintaining a collective approach internally, as this is a key factor in the quality and robustness of its decision-making process.

Industrial capacity to be mobilised

Over the coming five years, the nuclear sector will have to cope with a significant increase in the volume of work that is absolutely essential to ensuring the safety of the facilities in operation.

Starting in 2021, four to five of EDF's 900 Megawatts electric (MWe) reactors will undergo major work as a result of their fourth ten-yearly outages. This workload will inevitably be compounded by the essential work needed to increase spent fuel storage capacity, as well as that linked to priority operations involved in the conditioning of legacy waste and the dismantling of installations.

All of this work will significantly increase the industrial workload of the sector, with particular attention required in certain segments that are under strain, such as mechanical and engineering, at both the licensees and the contractors. The prospect of increased work on the existing NPP fleet is a point demanding particular attention, but it should also be an opportunity for the nuclear sector which, in the past, lacked projects capable of maintaining its skills.

In the current context of the health and economic crises, ASN considers that the State and the ordering customers should pay particular attention to maintaining the industrial capacity of the key players in the sector, notably when they are also encountering difficulties in other high-tech sectors, such as aeronautics.

Results in terms of rigour, skills and quality expected as of 2021

A year ago, ASN drew attention to the need to reinforce skills, professional rigorousness and quality within the nuclear sector.

The measures initiated in 2020 under EDF's Excell plan and within the French Nuclear Energy Industry Group (GIFEN) reflect a real collective engagement on these issues. The correct performance of operations "first time round", the rapid detection and processing of any non-compliances, the evaluation of the maturity of the various phases of projects and the search for greater standardisation of equipment and of work programmes are key points in these approaches.

ASN considers that the goals of skills enhancement, notably regarding welding, as well as of increased rigorousness in project management and monitoring of activities, are steps in the right direction.

ASN will be attentive to ensuring that these goals lead to tangible results starting in 2021, notably for those installations under construction, such as the Flamanville EPR reactor, but also for work linked to the fourth periodic safety review of the 900 MWe reactors.

Safety improvements opening up the prospect of continued operation of the 900 MWe reactors

The objectives set for the fourth periodic safety review of the 900 MWe reactors are ambitious. They were defined in the light of the safety objectives defined for the third generation reactors, in particular the EPR. They will make the installations more robust to natural hazards and reduce the radiological consequences in the event of an accident, notably one with core melt.

In order to achieve these goals, EDF has proposed numerous modifications to the installations, notably to improve the safety of the spent fuel pool, reduce the risk of core melt and limit releases in the event of a severe accident. Following the generic phase of the periodic safety review, ASN considers that implementation of the modifications proposed by EDF leads to significant improvements in the safety of the installations. ASN prescribes the implementation of the major safety improvements planned by EDF, along with certain additional provisions it considers necessary to achieve the safety review objectives.

Deployment of the modifications proposed by EDF and the additional provisions prescribed by ASN will be implemented in two stages, to favour satisfactory management by the licensee and easier assimilation by the operating teams. ASN ensured that most of the safety improvements are deployed during the first phase, that is during the reactor's ten-yearly outage.

ASN considers that these safety improvements open up the prospect for continued operation of the 900 MWe reactors for a further 10 years following their fourth periodic safety review.

By 2031, EDF will have carried out the specific phase of the fourth periodic safety review of each of the 900 MWe reactors. The provisions proposed by EDF will then lead to a public inquiry. ASN will then submit for public consultation the draft requirements it considers to be necessary for continued operation of each of the reactors.

Flamanville EPR, a complex project facing numerous setbacks

ASN remains vigilant with regard to the Flamanville EPR, a complex project facing numerous setbacks. The extensive test programme conducted with a view to reactor commissioning showed that, on the whole, the systems performance requirements are met, but it also revealed deviations, some of which entail installation modifications. On the basis of the tests performed on the fuel pool safety systems and the inspections it carried out, ASN authorised the arrival of nuclear fuel on the Flamanville EPR reactor site in October 2020 and it is being stored in this pool.

The inspection of the EPR equipment has already revealed numerous deviations from the required level of quality. ASN therefore asked EDF to perform a quality review of the Flamanville EPR reactor equipment. With regard to the secondary circuits (main steam lines and steam generator feedwater lines), more than a hundred welds are concerned by deviations. EDF plans to repair some of these welds and justify maintaining others as-is. The repair processes were defined by EDF and are undergoing specific testing and mock-ups for qualification of the processes. ASN gives its approval prior to each implementation step. ASN examination of the files justifying maintaining the welds as-is includes an analysis of the consequences of the deviation with respect to non-compliance with the post-weld heat treatment temperatures.

ASN is particularly attentive to operating experience feedback from the EPR reactors in Finland and China, which highlights certain subjects requiring specific investigation and examination. It notably concerns the stress corrosion on the pilot valves of the EPR reactor at Olkiluoto (Finland), as well as the anomalies on the power distributions in the EPR cores in Taishan (China).

A decisive period for decisions on the management of radioactive materials and waste

Following the public debate held in 2019 to prepare for the next edition of the National Radioactive Materials and Waste Management Plan (PNGMDR), the Minister in charge of ecology and the ASN Chairman set out the guidelines for this next edition, in a resolution dated 21 February 2020.

ASN's involvement in the drafting of the plan, which had already been queried in 2018 by its peers during an International Atomic Energy Agency (IAEA) mission, also led to questions being raised during the public debate. With the agreement of the Ministry for Ecological Transition, ASN has decided to cease its role as co-owner of the plan, which constitutes a management policy document that is the responsibility of the Government.

ASN has refocused its action on evaluation and oversight of the radioactive materials and waste management routes, to ensure that they are safe. In preparation for the fifth PNGMDR, ASN thus issued a number of opinions, concerning very low level waste, low level long-lived waste, radioactive materials and high level long-lived waste. One key issue emerged: reinforcing the anticipation culture.

Concerning waste management, the previous plans led to the development of numerous studies and the sharing of a large amount of data and information with the stakeholders, so that the possible solutions, their advantages and their drawbacks could be inventoried. The aim now is to make tangible progress in the implementation of these routes. If no choices or decisions are made in the 5 year period covered by the next PNGMDR, no management route will be operational in the coming 20 years and our country will be unable to meet the capacity needs for disposal of the waste generated by the decommissioning of facilities and by completion of the legacy waste retrieval and conditioning operations.

With regard to materials, ASN's opinion set out the principles which should underpin this anticipation culture. Thus, reuse of a material could be considered to be plausible if the existence of an industry for use of this material is realistic within a time-frame of about thirty years, and if this reuse concerns volumes consistent with the stocks of material held now and foreseeable in the future. For the more distant future, long-term storage in safe conditions must be anticipated, along with the possible management of the radioactive substance as waste. In any case, if there are no prospects for use within a time-frame of about a century, the substance shall be reclassified as waste.

Decommissioning and management of legacy waste: large-scale projects falling behind schedule

Decommissioning operations are large-scale projects, from the technical and organisational viewpoints, which take place over lengthy periods of time, on installations which are constantly changing. The nuclear safety and radiation protection issues must therefore be periodically reassessed.

The observations made for a number of years now show that postponing the decommissioning of old facilities makes the operations considerably more complex and leads to major delays with regard to the planned schedules.

In 2020, ASN issued binding requirements concerning the next steps in the specific operations involved in the decommissioning of the six first-generation gas-cooled reactors, and asked that decommissioning files incorporating the new decommissioning scenario be submitted by 2022. It also found clear delays in implementation of the waste management and decommissioning strategy for the legacy facilities of the Alternative Energies and Atomic Energy Commission (CEA), for which ASN and the Defence Nuclear Safety Authority (ASND) issued a ruling in 2019. It observed improvements at Orano, albeit too slow, in the legacy radioactive waste retrieval and conditioning operations.

Overall, ASN continued with its examination of the steps taken by the licensees to manage their complex projects, which it considers to be essential if decommissioning is to be able to progress satisfactorily.

Organisational and technical failings still the cause of avoidable events in the medical sector

Even in the context of the health crisis, radiation protection in the medical field remained at a satisfactory level. There were very few level 2 or 3 significant Radiation Protection Events (ESR) but they were nonetheless avoidable (laterality error, dose fractionation error). The occurrence of these ESR reveals organisational and technical failings, recalling the importance of a radiation protection culture. The control of high-tech devices remains delicate, on the one hand for their handling and on the other during the implementation of new procedures. Adequate training time is essential for their appropriation by the teams and thus avoid incorrect setting of software parameters and standardisation of procedures would also help reduce the risk of transmitting incorrect data.

Preparing for and supporting technological innovation in the medical field

To prepare for the expansion of the therapeutic indications of radiopharmaceutical drugs marked with lutetium-177 and the increase in the number of patients who will benefit accordingly in France, ASN asked the Advisory Committee for Radiation Protection of Health Professionals, the Public and Patients for Medical and Forensic Applications of Ionising Radiation (GPMED) to update the conditions for the possession and administration of these drugs by the nuclear medicine units.

This anticipation approach, conducted jointly with the stakeholders (including the French Society for nuclear medicine) and the French National Agency for Medicines and Health Products Safety led, in 2020, to the nationwide distribution of and access to this class of drugs, while guaranteeing good conditions of radiation protection for the patients, the professionals concerned and the environment (management of contaminated effluents).

From post-accident preparedness to the development of a precautionary culture

In a letter dated 18 June 2020, the Prime Minister tasked ASN with continuing to lead the work of the Steering Committee for the post-accident phase of a nuclear accident (Codirpa) for a period of 5 years. After focusing primarily on the consequences of an accident affecting a nuclear power plant, Codirpa will thus deal with the cases of accidents leading to radioactive releases in the marine environment, as well as accidents that could lead to releases of alpha emitting radionuclides, which require appropriate management. Having learned the lessons from emergency situations, Codirpa will also expand its actions to contribute to the development of a radiation protection culture. This culture requires greater involvement of regional players and the population living near the nuclear facilities in the preparation of the response plans and the exercises and in crisis management.

ASN considers that the lessons learned from the health crisis and the work of the Codirpa, with the support of local partners, will be key factors in achieving progress in a precautionary culture.

International relations maintained in appropriate formats

In 2020, ASN maintained its international cooperation activities in various appropriate formats. After the cancellation, or the postponement sine die of all the major international events in the spring of 2020, exchanges were set up in virtual formats, notably to share the lessons learned from health crisis management. In certain exceptional cases, these postponements meant that it was impossible to fully meet certain obligations. This was the case of the peer review, scheduled by the Convention on Nuclear Safety and carried out under the aegis of IAEA. Although the current situation is a major obstacle to exchanges, in particular the informal exchanges which represent a significant part of international cooperation, contacts are nonetheless being maintained thanks to the pre-existing dynamics and ASN's involvement in the virtual events being organised.

EDITORIAL BY THE DIRECTOR GENERAL

“2020, from uncertainty to accelerated transformation”

Olivier GUPTA

Montrouge, 2 March 2021

In 2020, the health crisis was a real test for each and every one of us.

ASN and the sector it regulates were also faced with unprecedented challenges. Our institution coped and showed its resilience.

This crisis was a powerful accelerator of the transformations already under way, but also, owing to the inventiveness that it demanded, it was the starting point for new regulation and oversight practices.

Finally, this crisis reminded all players of the importance of preparedness and precaution, which have already been two ASN priorities for a number of years.
ASN will be drawing the relevant conclusions in its next multi-year strategic Plan.

The health crisis, the importance of robust operation at ASN

When the first lockdown was announced, little time was left for preparation, but it was essential that ASN guarantee the continuity of its activities, so that other problems in the short or long term did not further compound the health crisis. The nuclear power plants continued to operate, so their regulation and oversight therefore had to continue. In the medical field, numerous hospital centres required urgent adaptations of their licenses so that they could utilise equipment (mainly scanners) to diagnose patients suffering from Covid-19. Finally, the examination and preparation of decisions concerning important subjects had to be continued, as any delay would have led to a blockage in the longer-term.

This was possible because the digital transformation plan, launched in 2017, was already well advanced (ASN already had resources that were essential for remote-working on a large scale). It was also because the ASN personnel demonstrated exceptional commitment and continued to carry out their duties to the best of their abilities, despite sometimes difficult remote-working conditions. Finally, this is because they form a closely-knit entity.

I wish to pay tribute to them, simply by citing two examples, because it is thanks to them that the draft generic position statement on the continued operation of the 900MWe reactors could be submitted for consultation, on-time, and that several opinions were published regarding the National Radioactive Materials and Waste Management Plan. It is thanks to them that on-site inspections were able to resume rapidly. In total, over the year, nearly 2,600 man-days will have been spent conducting field inspections.

To my mind, this commitment and these results are the fruit of a robust common culture and a collectively shared vision of the issues, of a management method that promotes accountability, combining stringency and goodwill, and a permanent and always constructive social dialogue.

The field of activity which suffered the most from the crisis was naturally that of international relations. However, certain activities were able to continue remotely: with ASN as Chair, the WENRA association thus reached a new milestone in publishing “reference levels”, that is harmonised safety requirements for research reactors, an area not hitherto covered by its work. The WENRA also proposed a subject which was selected for the next European level topical peer review: this concerns management of fire risks, an important subject and one that concerns all nuclear facilities.

> “The ASN personnel demonstrated exceptional commitment, and continued to carry out their duties to the best of their abilities, despite sometimes difficult remote-working conditions.”

The health crisis, an accelerator of change in regulation and oversight practices

The exceptional nature of the situation led ASN to experiment with new ways of carrying out its duties, some of which will be adopted permanently.

It is clear that remote-working was a shot in the arm for ASN's digital transformation, owing to the increased use of videoconferencing, digital archival and dematerialisation in general.

New remote-inspection practices in particular were put into place. While first of all seen as a stop-gap pending the implementation of health protocols, they proved their worth as a complement to on-site inspections: possibility of remote-access to certain licensee databases, as well as to the state of the reactors; possibility of examining documents by devoting more time than would be possible on-site. These new forms of inspection are not intended to take the place of a presence in the field, which remains essential for understanding the issues linked to a nuclear facility or activity, examining the condition of premises and equipment, observing the performance of work and understanding the interactions between the persons involved. They do however enable the inspectors' presence in the field to be optimised, so that they can then focus on what cannot be inspected remotely.

The health crisis, a factor in ASN strategic thinking

Even if it profoundly marked the year 2020 and will probably do the same in 2021 as well, the health crisis did not call into question the guidelines of ASN's current strategy, which are still valid and for which work is continuing: enhance the use of a graded approach; improve coordination of technical examinations, enhance the effectiveness of our actions in the field; consolidate our operation; consolidate the French and European approach through international action.

However, this crisis requires that all stakeholders, including our institution, take a fresh look at preparedness and precaution. It helps highlight the fundamental questions regarding which ASN has for several years been asking for decisions, notably in order to avoid eventual blockages in the long term: margins needed to ensure both nuclear safety and the security of the power grid; decisions to be taken for long-term safe management of radioactive waste; boosting the skills of the sector.

Consideration of ASN's future strategic Plan will begin at the end of 2021. In this regard, several questions could be examined:

- for greater efficiency in public action, the methods whereby ASN can work with the various stakeholders, to ensure that, once identified, potential blockages are correctly anticipated;

> "The future strategic Plan will make it possible to determine a vision for the regulation and oversight of nuclear safety and radiation protection that is tailored to the new challenges..."

- interaction with the other oversight players in related fields, in order to reach optimal decisions, in other words, which take account of all issues regarding the protection of persons and the environment;
- any adjustments to be made to ASN's regulation and oversight policy, so that it can be adapted to the context and to the challenges of the coming decade;
- ASN's inspection procedures: apart from the already mentioned example of the balance between remote inspections and field inspections performed by ASN, the role to be played by the approved organisations carrying out inspections on behalf of ASN should be mentioned;
- the steps to be taken to consolidate ASN's independence, notably in terms of operations;
- the resources that ASN will need in the coming years to carry out its duties, in both quantitative, but above all qualitative terms. The growing complexity of the questions to be dealt with means that the need to hire experienced personnel or those with rare skills must be identified far upstream.

This work is all the more important as it will enable a healthy perspective to be gained in relation to a situation that remains dominated by the health crisis. It will make it possible to determine a vision for the regulation and oversight of nuclear safety and radiation protection that is tailored to the new challenges. As ASN marks the fifteenth anniversary of its transformation to an independent administrative Authority, it will also be an opportunity to measure how far it has come.

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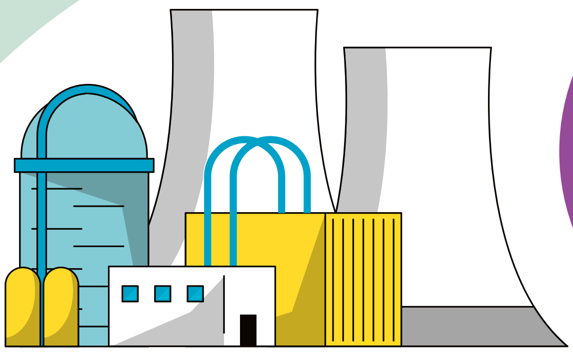
I must repeat my thanks to the ASN teams for their exceptional commitment throughout the year. I also particularly wish to thank our partners, especially the IRSN, and the members of the groups advising ASN or collaborating in its work: all have stood side by side with us in these difficult times and, without them, we would not have been able to make the progress that we did.

The health crisis is not over. The ASN teams know that much will still be expected of them in 2021, given the scale of the challenges ahead. They will do all they can to live up to the responsibilities entrusted to them and be worthy of the trust placed in them.

THE IMPACT OF COVID-19

An unprecedented stress test on the organisation of nuclear safety and radiation protection

The measures taken during the health emergency period severely affected nuclear activities. The licensees of the Basic Nuclear Installations (BNIs) activated their activity continuity plan and adapted their organisation in order to maintain the level of safety in the installations and guarantee compliance with the regulatory requirements. The medical nuclear players also had to deal with an unprecedented health situation. During this period, ASN adapted its oversight methods, notably by developing remote-inspections for certain subjects.



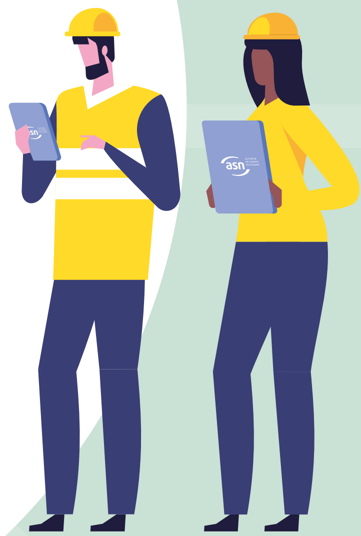
The licensees and activity managers demonstrated **a good level of adaptability**

Satisfactory management of the health crisis

- **Maintaining the required level of safety**
- **Implementing an activity continuity plan**

Organisational adaptability: continued preparation of the files required by ASN, by means of remote-working, efficient measures to ensure the permanent availability of qualified operating personnel on the sites.

Operational adaptability: continued performance of the priority activities considered to be essential (monitoring, safety checks), postponement or cancellation of non-essential activities, satisfactory compliance with the applicable requirements regarding nuclear safety and radiation protection, etc.



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ASN maintains links with the licensees and nuclear activity managers

ASN was vigilant with regard to the steps taken **to ensure the nuclear safety and radiation protection of the activities**

- **In the medical field**

  Exchanges on organisational changes regarding patient care, in the light of the health and radiation protection constraints.

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- **For the nuclear installations**

  Regular contacts with the licensees concerning the steps taken to adapt to the health context: check on the suitability of the adaptations selected.

  Postponement of deadlines for the transmission of certain documents, pursuant to the Health Emergency Act.

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This crisis was an opportunity to innovate **and develop new inspection methods**

Adaptation of operation and ASN oversight methods

- **In the medical field**

  Adaptation of examination and licensing procedures in the context of the health emergency to allow the use of equipment or premises not normally covered by the licenses for the possession and utilisation of radioactive sources: scanners in nuclear medicine or radiotherapy units, radiation protected rooms or brachytherapy rooms, used to accommodate persons suffering from Covid-19.

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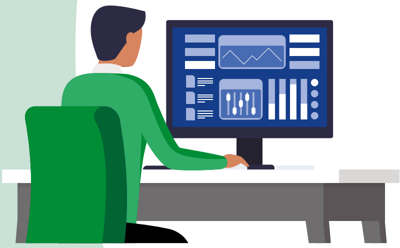
- **For the inspections carried out by ASN**

  Relaxation of the inspections programme in the medical field (check on the ability of the departments to host the inspection).

  Rapid resumption of inspections on-site as soon as adequate health measures are finalised.

  Organisation of remote-inspections instead of, and then in addition, to on-site inspections.

  Adaptation of the inspection programme to the context, so that inspections on important subjects were carried out in 2020.



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ASN **ASSESSMENTS**

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

ASN ASSESSMENTS **PER LICENSEE**

EDF

The Nuclear Power Plants (NPPs) in operation

ASN considers that the year 2020 was on the whole satisfactory in terms of operating safety in the EDF NPPs. Operational rigorousness in particular made progress. The particular context created by the health crisis may have contributed to these good results. ASN does however observe that the step backwards seen in 2019 with regard to worker radiation protection was further accentuated in 2020. A strong reaction from EDF is expected on this point.

Managing the consequences of the health crisis

ASN considers that EDF correctly managed the changes to its organisations made necessary by the health measures linked to the Covid-19 pandemic.

The travel restrictions put in place by the Government in the spring of 2020 at first severely reduced EDF's ability to carry out scheduled maintenance work during the reactor refuelling outages. Faced with this situation, EDF decided to extend the expected duration of all the scheduled outages and to postpone certain others. ASN made sure that the maintenance and outage operations were pushed back by EDF in compliance with the applicable safety rules.

EDF also had to adopt measures to guarantee the safety of the installations, while complying with the health rules on the sites. Some of these changes in fact had safety benefits. This is particularly the case with the steps taken to limit contacts with the control operators, which created a calmer atmosphere in the control rooms.

EDF keeps ASN regularly informed during the health crisis, which enabled ASN to maintain precise monitoring of the situation in each NPP.

Operation

ASN observes that the vast majority of NPPs made progress in 2020 with respect to the rigorousness of monitoring in the control room and control of the installations. In most cases, this progress was accompanied by a clear reduction in the number of unauthorised excursions from the operating range and the number of failures to comply with the operating control rules. The organisational changes and activity postponements resulting from the health crisis may have been a contributory factor to this improvement.

In 2020, on the majority of NPPs, ASN did however observe an increase in the number of significant events. An analysis of their causes reveals that inappropriate documentation was used by the control team or that this documentation was incorrectly used.

In 2020, ASN observed a good level of familiarity with the control procedures in an accident situation, but again found that certain actions cannot be performed within the required times, or even cannot be carried out at all owing to the configuration of the facilities. These cases were however fewer in number than in 2018 and 2019.

The organisation put into place on the sites to manage skills, qualifications and training remained on the whole satisfactory in 2020.

As in 2019, the ASN inspections focusing on the organisation and emergency resources confirmed that the organisation, preparedness and management principles for emergency situations covered by an on-site emergency plan have been correctly assimilated.

The analyses conducted by the sites further to significant events are generally appropriate and the identification of organisational causes is progressing. However, as in 2019, the analysis of the root causes fails to adequately call into question the organisation and still all too often leads to relatively unambitious corrective measures.

The conformity of the facilities

In 2020, ASN found that the management of deviations affecting the installations continued to improve. More specifically, EDF further improved its ability to correct deviations rapidly, even if efforts are still needed on this point.

However, as in previous years, ASN considers that the actual compliance of the facilities with the rules applicable to them needs to be significantly improved. The year 2020 was again marked by the detection of deviations affecting equipment that call into question its ability to fulfil its function in an accident situation. Some of these deviations date back to the construction of the reactors, others were created when implementing modifications to the facilities, including recently, or result from ageing or insufficient maintenance of the facilities. 2020 brought to light earthquake resistance defects on electrical power sources, back-up equipment and reactor cooling systems. EDF must continue the targeted inspection actions it has been gradually deploying over the last few years, but must also broaden their scope.

The inspections prescribed by ASN in 2019 on the electrical supply sources, in particular the emergency diesel generator sets, enabled the seismic resistance defects on 37 reactors to be detected and corrected. This event was rated level 2 on the International Nuclear and radiological Event Scale (INES) for certain reactors.

Maintenance

In general, the organisation in place in the NPPs for carrying out large-scale maintenance work was satisfactory in 2020, even in a situation made more difficult by the Covid-19 pandemic. In a context of a heavy maintenance workload, due in particular to the continued operation of the reactors and the *Grand Carénage* major overhaul programme, ASN has in the past regularly drawn EDF's attention to the persistence of an excessively high number of maintenance quality deficiencies. Over the last few years EDF has taken steps to reduce their occurrence.

However, in 2020, ASN still found areas for improvement with regard to reactor maintenance, such as the consideration of various hazards, the preparation of activities or the traceability of the work carried out. Faults in the management of the activities are also still caused by the procurement of non-conforming spare parts.

In the past, ASN regularly noted EDF's difficulty in ensuring appropriate and proportional monitoring of subcontracted activities, whether the activities are performed on-site or at the suppliers of goods and services. This being said, in 2020 ASN confirms the improvement observed in 2019 in the technical oversight of contractor operations and monitoring, particularly through the use of computerised tools recently deployed in the NPPs.

Environmental protection

EDF's organisation for controlling the detrimental effects and impact of the NPPs on the environment needs to be improved on most sites. ASN considers that the licensee needs to raise its level of vigilance on these topics even further.

In 2020, ASN observed improved adoption by the sites of the methodical analysis of microbiological hazards and efforts made to improve the containment of hazardous liquid substances on certain sites. However, ASN considers that corrective measures are still needed with respect to pollution prevention and waste management. Despite a few occasional weaknesses, EDF has shown a good level of control over its management process for effluent discharges.

Worker radiation protection and occupational safety

ASN observes that the step backwards observed in worker radiation protection in 2019, was accentuated in 2020. The analysis of significant events in particular all too often shows inadequate perception of the radiological hazards and an inappropriate radiation protection culture. ASN considers that EDF must give radiation protection real meaning in order to unite the operators in dealing with the true issues and challenges.

In 2020, the occurrence of accidents fell significantly in EDF's NPPs. The particular context created by the health crisis may have contributed to these results. EDF has continued with implementation of improvement measures regarding the main risks for workers further to inspections by the ASN labour inspectors. However, certain hazard situations must be significantly improved. These concern the hazards linked to work equipment and more particularly to lifting gear, the explosion and fire hazard and electrical hazards.

Continued operation of the reactors

The ambitious modifications EDF plans making to the facilities and the operational methods within the framework of the reactor periodic safety reviews are significantly improving the safety of the facilities. EDF is deploying considerable engineering resources for these reviews. As in previous years, ASN observes that these engineering capacities are saturated.

ASN considers that all the provisions specified by EDF and those that it itself stipulates, open up the prospect of continued operation of the 900 Megawatts (MWe) of electrical power reactors for the ten years following their fourth periodic safety review. Implementation of this review on each reactor will include specific inspections and will take account of the particularities of each installation.

In 2020, EDF continued to carry out the fourth ten-yearly outages of its 900MWe reactors, with the first of them being of a reactor on the Bugey site. As of 2021, the pace of these ten-yearly outages will accelerate, with several being performed every year. ASN will be attentive to EDF's capacity for deploying the resources needed to perform these operations in satisfactory conditions.

Individual NPP assessments

The ASN assessments of each NPP are detailed in the Regional Overview in this report.

With regard to safety, the NPPs of Saint-Alban and, to a lesser extent, Civaux and Cattenom stood out favourably in 2020. For the Cattenom NPP, the progress observed will need to be confirmed, as 2020 saw very little maintenance work carried out. ASN is maintaining the reinforced monitoring put into place on the Flamanville NPP in 2019. The Gravelines, Nogent-sur-Seine and Golfech NPPs also under-performed in 2020.

With regard to radiation protection, only the Civaux NPP stood out positively. ASN considers that several NPPs had under-performed. This is particularly the case with the NPPs of Dampierre-en-Burly and Flamanville and, to a lesser extent, those of Golfech, Chooz, Nogent-sur-Seine, Gravelines and Blayais.

With regard to environmental protection, the NPPs of Paluel, Nogent-sur-Seine, Saint-Laurent-des-Eaux, Chooz and Saint-Alban stood out positively. On the other hand, the NPPs of Belleville and Dampierre and, to a lesser extent, those of Blayais and Gravelines, had under-performed.

The Flamanville EPR reactor under construction

ASN considers that the organisation put into place to receive and store the fuel assemblies is satisfactory on the Flamanville EPR site. This led to authorisation for arrival of the fuel on the site in 2020.

The preparation for and performance of weld repairs on the main secondary systems are also taking place in good conditions. ASN will continue with its oversight of these activities in 2021 and will be vigilant to ensuring that adequate resources and organisational measures are in place for a greater volume of repairs simultaneously.

The organisation for performance of the start-up tests is satisfactory, but EDF must ensure that these tests are proven to be representative and that the results analysis is exhaustive.

However, ASN considers that EDF must significantly add to the programme of additional inspections scheduled as part of the quality review of equipment other than pressure equipment. This programme had been requested by ASN in 2018 due to serious shortcomings in EDF's monitoring of its contractors.

NPPs being decommissioned and waste management facilities

ASN considers that the level of safety of the facilities being decommissioned and of waste management is on the whole satisfactory, even though the progress of the decommissioning work slowed down considerably in 2020.

For the EDF facilities undergoing decommissioning from which the fuel has already been removed, nuclear safety consists in controlling the containment of the radioactive substances. With regard to the first-generation reactors (Gas-Cooled Reactor series, see chapter 13), the vast majority of these substances are situated in the currently contained reactor vessels which are not undergoing any decommissioning operations that could put them back into suspension. EDF will thus have to manage the ageing of these facilities, while seeking to shorten the decommissioning time-frame for the reactor vessels, in order to minimise safety risks.

Progress with the decommissioning of the Chooz A and Superphénix reactors is in line with the schedules set out in their decrees. ASN however considers that the Superphénix emergency management organisation needs to be improved.

The issues that EDF has to address concern radiation protection of the workers and waste management. On these points, it has implemented measures to counteract the difficulties with managing the alpha radiation hazard, which is more particularly present in the Chooz A installation. However, the effectiveness of these action plans could not be evaluated in 2020, owing to the reduction in activity as a result of the health crisis. Furthermore, EDF is regularly confronted with the problem of asbestos in the equipment to be dismantled, causing it to suspend the work in order to establish appropriate protective measures and remove the asbestos.

In accordance with ASN's request, EDF reinforced the organisation of the Fessenheim decommissioning project and made the required additions to the installations decommissioning preparations, following its final shutdown in 2020. EDF also submitted the Fessenheim decommissioning file to the Minister in charge of nuclear matters at the end of the year. ASN observes common failings in some decommissioning or review files submitted by EDF. They do not always have the required level of detail to allow an evaluation of the safety and radiation protection consequences of the envisaged operations.

ORANO

ASN considers that the level of safety in the facilities operated by Orano remained on the whole at a satisfactory level in 2020. In the context of the health crisis, Orano maintained most of its activities, while adapting its organisation to guarantee the required level of safety.

The facilities operated by Orano are located on the sites of La Hague, Tricastin and Marcoule. They present significant implications for safety but of different types, both chemical and radiological.

The organisation of the Orano group is mainly decentralised, which leads to differences in practices between each site. These differences could be exacerbated by the restructuring of the group, carried out at the end of 2020, which split the licensee Orano Cycle into three separate companies responsible for the production of enriched uranium (Orano Chimie-Enrichissement), the reuse of materials derived from spent fuel (Orano Recyclage), and the decommissioning of nuclear facilities (Orano Démantèlement). In 2021, ASN will examine the long-term acceptability of the organisation defined by Orano, in which a part of the operational responsibility of the licensee of facilities undergoing decommissioning, such as the operation of sensitive equipment, is delegated to another entity of the group.

Managing the consequences of the health crisis

ASN considers that Orano correctly managed the changes to its organisations made necessary by the health measures linked to the Covid-19 pandemic and regularly informed ASN of the measures adopted. Orano to a large extent maintained its activities during the health emergency period, in accordance with the applicable nuclear safety and radiation protection requirements. Orano also maintained certain decommissioning activities with major safety implications.

Risk control

Orano is continuing its efforts to boost rigorousness in containing radioactive substances and is dealing satisfactorily with containment breaches that may occur in operating conditions on certain installations. Similarly, radiation protection issues are taken very seriously by Orano in its installations where they are the greatest. In 2020, Orano reported a worker contamination event, temporarily rated level 2 on the INES scale, pending the results of in-depth studies. Its analysis showed that the radiation protection instructions had been correctly followed by the licensee and it did not call into question the pertinence of its radiation protection provisions. It therefore led to research work to gain a clearer understanding of the behaviour of certain plutonium particles.

With regard to waste management, ASN observes that greater rigorousness is needed in all the Orano group's Basic Nuclear Installations (BNIs), with regard to the procedures for dropping off waste at the various collection points in the installation.

ASN observes major inadequacies regarding the fire hazard and excessively slow improvement within the BNIs of the Orano group on this subject. The licensee must improve its incident response instructions, so that they are more appropriate and operational, and carry out periodic exercises to test them. 2020 was in particular marked by a fire in a complete building on the La Hague site, regarding which the operating experience feedback would appear to have been examined in insufficient depth. On this site, ASN finds that the measures to prevent the flow and environmental dispersal of radioactive or hazardous liquid substances, including those liable to result from actions taken to combat a possible incident, must still be improved. On the Tricastin site, control of the fire hazard was the subject of enforcement measures by ASN in 2020. ASN observes that improvements have been made.

Orano demonstrated a proactive approach to its performance of the stress tests further to the Fukushima Daiichi NPP accident. Orano has completed the construction of virtually all the complementary resources resulting from these stress tests. These are resources designed to help cope with extreme situations in its facilities, particularly water make-up resources and new emergency response buildings that are robust to extreme hazards. Only the emergency control post in the Melox plant is still to be completed.

Monitoring of outside contractors

In 2020, ASN observed that outside contractor monitoring practices in the BNIs of the Orano group still need to be improved. The group must continue and reinforce the efforts made on this subject, notably by improving the means of monitoring and its organisation.

Legacy waste retrieval and conditioning, decommissioning and waste management

Large quantities of legacy waste at La Hague are not stored in accordance with current requirements and present major safety risks. The retrieval and conditioning of this legacy waste determines the progress of decommissioning in the definitively shut down plants. ASN observes significant delays in the Orano legacy waste retrieval and conditioning projects. The complexity of this waste retrieval and conditioning, for shipment to approved routes, meant that Orano had to revise its retrieval and processing scenarios several times and announced significant postponement, sometimes for decades, of the deadlines to which it was committed. Thus, in 2019, ASN initiated a procedure to monitor the management of these projects, assisted by the General Directorate for Energy and Climate (DGEC). In this procedure, ASN asked Orano to make structural improvements to its organisation and to the management of these projects. In 2020, Orano presented improvements to its organisation and to its project management, which should lead to more robust management, notably by taking account of operating experience feedback and adopting a project maturity evaluation table. However, this approach needs to be taken further and supplemented in order to lead to better evaluation of the time-frame for Retrieval and Conditioning of legacy Waste (RCD) and decommissioning, so that Orano can announce firm dates that will actually be met. ASN will continue with its monitoring of the management of these projects in 2021. It will make a more complete evaluation of the progress made, by examining the integrated schedules that are to act as the basis for the revision of ASN resolution 2014-DC-0472 of 9 December 2014 concerning the binding requirements to be met by Orano concerning these retrieval operations.

ASN considers that the completion of vitrification of the legacy solutions of fission products from UP2-400 and the production of the first drums of waste from silo 130 are satisfactory. This progress means significant improvements in the safety of these ageing facilities, owing to the reduction in the source term. ASN however urges the licensee to achieve the industrial retrieval rate for the waste from silo 130, without delay.

CEA

ASN considers that the safety of the facilities operated by the Alternative Energies and Atomic Energy Commission (CEA) remains on the whole satisfactory, at a time of reduced activity. The safety issues concern on the one hand the continued operation of the facilities, designed in accordance with old safety standards, and on the other, the decommissioning of the definitively shut down facilities and the retrieval and conditioning of legacy waste, as well as the management of its radioactive waste and materials with no identified use. ASN considers that there are nonetheless weaknesses at the CEA, notably with regard to the organisation for the management of emergency situations and to safety-related projects which span several years.

Safety organisation and management

ASN considers that the CEA's organisation has been constantly changing for a number of years, with a further major modification in 2020. In the light of these changes, ASN considers that the CEA must remain attentive to ensuring that all the safety-related aspects are properly taken into account at all levels of the organisation and are led by people with the necessary resources, skills and authority. ASN is expecting the CEA to provide operating experience feedback regarding the latest organisational changes and rapidly propose a strategic vision of safety management for the coming years.

ASN considers that the implementation of "major safety commitments", managed at the highest level and enabling the most important nuclear safety and radiation protection issues to be monitored, is on the whole satisfactory. It will be necessary to ensure that the reduction in resources allocated to the CEA has no impact on compliance with other commitments, particularly those that are governed by ASN requirements.

Managing the consequences of the health crisis

The restrictions put in place by the Government in the spring of 2020 led the CEA to shut down most of its BNIs and make them safe. This interruption in operations, the restrictions placed on travel and the unavailability of certain contractors meant that, after analysis, the CEA was unable to carry out certain periodic checks and maintenance operations on schedule. Monitoring and the essential safety inspections were however maintained and the CEA conducted safety analyses in order to define the actions to be taken before resuming its activities. The CEA learned lessons from the first lockdown and in November 2020 maintained certain activities felt to be priorities by the operational divisions, along with maintenance and all inspections and periodic tests.

The CEA's regular reporting to ASN during the health crisis was satisfactory.

Installations in operation

Faced with the ageing of its facilities in operation and the uncertainty surrounding the projects to replace some of them, the CEA developed a medium/long-term strategy in 2019 concerning the utilisation of its experimental civil nuclear research facilities and its waste and material management facilities. The first conclusions show the need to streamline and optimise the existing facilities, along with significant renovation work and even the construction of new facilities. ASN considers that this prioritisation is legitimate from the safety standpoint and that the CEA must use it to identify clear action plans and precisely formalise the options it has taken (abandoning or optimising operation, work to be undertaken, etc.).

Facilities undergoing decommissioning

In 2019, ASN and the Defence Nuclear Safety Authority (ASND) underlined the in-depth and pertinent review by the CEA of its decommissioning and radioactive waste and materials management strategy, its prioritisation of operations, the human resources allocated and the efficiency of its organisation, while examining the resources devoted to these operations.

In 2020, the Authorities found that this strategy had substantially changed, with numerous postponements, scope reductions or even some projects being abandoned. Certain deadlines were pushed back by several decades, with no adequate justification, even though they concern ordinary decommissioning projects, based on sound operating experience feedback (notably the decommissioning of the research reactors). A number of responses to structural requests from ASN and ASND regarding this decommissioning strategy were sent belatedly in 2020. These responses will need to be clarified in 2021 and additional exchanges between the CEA and the Authorities will be needed in order to improve oversight of the management of decommissioning and RCD projects that are priorities in terms of safety.

With regard to control of the processing of its effluents and the management of its waste, its spent fuels and its materials, along with the corresponding transport operations, implementation of the strategy is expected within the time-frame announced by the CEA; the Authorities drew the CEA's attention to the need for particular vigilance on these points in 2019, in particular for the unique installations, the unavailability of which could weaken the process as a whole. Firm answers to the Authorities' questions regarding the financial resources allocated to these cross-cutting projects, the credibility of the performance time-frames and the progress made have yet to be received.

Radioactive waste management

The operation of radioactive waste management support facilities is satisfactory. In 2020, ASN observed improvements in the zoning, signage and tidiness of the collection areas for these wastes. The CEA must however remain vigilant as to compliance with the storage times for certain waste in its facilities. ASN also underlines the implementation of a new organisation in 2020 devoted to the management of radioactive waste which will eventually allow improved communication and greater sharing of resources, with harmonisation of practices among the CEA centres.

Finally, ASN notes that the provisions of the protocol between the National Radioactive Waste Management Agency (Andra) and the CEA regarding Andra's monitoring of the CEA waste packages liable to be disposed of in *Cigéo* are overly restrictive of Andra's scope of action and therefore fail to fully meet the provisions of ASN resolution 2017-DC-0587.

The conformity of the facilities

As in 2019, ASN observes the efforts made to improve the conformity of the facilities during the periodic safety reviews, notably an improvement in the scheduling of the compliance work designed to secure the commitments made by the CEA.

However, even if the CEA has supplied most of the additional studies for correct assessment of the conformity of its facilities, ASN notes that not all of the weaknesses identified in the safety review reports, submitted since the end of 2017, have as yet undergone compliance work. This situation is particularly noteworthy for facilities in which activities have ceased and with low potential safety implications. Even if the CEA attributes these delays to the health context in 2020, ASN observes that the postponements can be up to several years.

Management of deviations

The management of deviations within the CEA facilities is on the whole satisfactory. In 2020, the CEA continued to deploy a monitoring tool common to all the centres, and also modified its ranking of deviations, including a third level, to allow graded processing more compatible with the actual issues. No significant event exceeded level 1 on the INES scale. The analysis of their causes regularly reveals a technical deficiency (related to ageing or obsolescence) or an organisational or human cause (related to incorrect transposition of safety requirements in the operational documentation or to activity scheduling). ASN notes that the events are correctly dealt with in the facilities. The CEA must however modify its organisation so that the analysis of the generic nature of a significant event, carried out by the head office departments, is more robust and more operational (consultation of the CEA centres and top-down and bottom-up information). In addition, for the analysis of the organisational causes, improved traceability in the significant event reports is required. Finally, ASN underlines the quality of the experience feedback sheets produced by the head office departments for the centres and the nuclear facilities. It encourages the CEA to take measures to ensure that the actions defined in these sheets are effectively applied in the BNIs.

Change management

For many years now, the CEA has applied a change management system that is on the whole satisfactory, particularly through the quality of the files submitted to ASN when applying for authorisations for noteworthy changes. ASN also observes that the changes made in the field do effectively correspond to the information provided by the CEA in its authorisation applications.

Maintenance and the scheduling of periodic inspections and tests

Maintenance work and the scheduling of the periodic inspections and tests, their performance and their monitoring within the CEA facilities are on the whole satisfactory. As these operations are generally subcontracted, the CEA must remain attentive to the level of technical competence. Moreover, ASN still observes disparities between the facilities on these two subjects. In addition, the traceability of the inspections performed must be further improved. ASN also expects the CEA to implement a harmonised ageing and obsolescence management strategy for all its facilities, because, for the facilities as a whole, ageing is often only managed through the periodic inspections and tests.

Outside contractors

ASN observes that the CEA's monitoring of outside contractors has been stepped up over the last few years, particularly by following monitoring plans and appointing the CEA personnel to specifically monitor the subcontracted activities. ASN notes the need for the CEA to reinforce the monitoring of the chain of outside contractors, particularly its contractors' subcontractors. Finally, there are still disparities in the quality of this monitoring between the facilities operated by the CEA and this needs to be remedied.

Risk control and emergency management

ASN observes significant delays in the construction of the emergency management buildings for the Cadarache, Marcoule and Saclay centres, designed to take account of the lessons learned from Fukushima Daiichi NPP accident.

The CEA's emergency organisation and resources still need to be significantly improved, in order to make up the delay in meeting the current requirements. The national organisation in particular needs to be reinforced, paying very close attention to the coordination between the national level, the sites and the facilities. ASN notes that the teams in the field are engaged and motivated in the performance of emergency exercises. Coordination between the local security force and the facilities of the CEA centres is improving, particularly as regards keeping the intervention plans and instructions up to date.

ASN finally considers that the CEA must continue its efforts to improve protection against the fire hazard. Management of the technical devices (fire doors and dampers, detection systems, etc.), must be improved and fire loads limited, particularly on worksites.

Personnel radiation protection

Within the various the CEA centres, radiation protection is on the whole dealt with satisfactorily. For all the centres, the identification of items and activities important to protection, management of measuring instrument ageing and the monitoring of outside contractors (handling of deviations, traceability and application of the ALARA (As Low As Reasonably Achievable) approach need to be improved.

Environmental protection

For the year 2020, control of the detrimental effects and impact of the CEA facilities on the environment is on the whole satisfactory. The action plans implemented in 2020 regarding non-conformities identified in the management of non-radioactive liquid effluents from certain facilities at Cadarache, are satisfactory. ASN does however consider that the CEA must continue with implementation of actions on several subjects associated with control of environmental impacts, in particular for its Cadarache site, such as the ageing of its industrial liquid effluents network and the compliance work need on the piezometers network.

Individual facility assessments

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

The Jules Horowitz research reactor currently under construction

The Jules Horowitz Reactor (RJH), which was authorised in 2009, is currently under construction. The worksite contingencies, such as the management of safety-related deviations, are handled satisfactorily. In view of the extension of the construction period and of the time required to commission the reactor, the CEA must address issues of project management, maintaining its technical skills over time and the conservation of equipment already manufactured and possibly installed, before it is commissioned. In 2020, the project governance changed, with no reduction in the resources allocated to safety.

ANDRA

Andra is the only licensee operating radioactive waste disposal BNIs in France. ASN considers that the operation of Andra's waste disposal BNIs is satisfactory. Andra is a dynamic player investing heavily in public information and in consultation.

Operation of Andra's existing facilities

ASN considers that safety and radiation protection in the facilities operated by Andra are satisfactory. In 2020, Andra's service continuity efforts during the lockdowns and its regular reporting to ASN on the conditions of operation in the facilities should be underlined. ASN considers that the measures adopted enabled a satisfactory level of monitoring to be maintained.

ASN observes that the number of significant events reported for the Aube repository (CSA) since 2018 remains at a very low level in 2020 (no significant event in 2018 and 2019, and just one in 2020). It has concerns regarding Andra's reporting of events.

ASN also considers that certain components of Andra's safety approach need to be improved, notably so that defence in depth can be better taken into account in the classification of certain elements or activities important for protection.

Organisation dedicated to the *Cigéo* project creation authorisation file

In 2020, ASN observes a further postponement in the announced date for the submission of the creation authorisation application for the *Cigéo* deep geological disposal project. It considers that the calendar must be stabilised, in order to identify the consequences of any postponement in the commissioning of *Cigéo* on the entire management route.

The technical exchanges between ASN and Andra continued in 2020 on the subject of the work identified during examination of the safety options file prior to the creation authorisation application.

ASN considers that the consultation regarding *Cigéo* is primarily the responsibility of the project manager. It observes that Andra is exemplary on this point, having brought in the National Public Debates Commission, which appointed guarantors for this process, and regularly informing ASN.

ASN considers that the principle of incremental development envisaged by Andra for the *Cigéo* repository needs to be clarified, in particular by identifying any nuclear safety justification data that would be provided after the creation authorisation application.

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

ASN ASSESSMENTS **BY AREA OF ACTIVITY**

THE MEDICAL SECTOR

2020 was marked by the Covid-19 pandemic, which considerably disrupted the health care system and required that the health care facilities adapt their patient care procedures to ensure compatibility with the two-fold radiation protection and health constraints. ASN therefore adapted its oversight procedures, by opting for remote-inspections whenever necessary. ASN considers that on the basis of the inspections carried out in 2020, the state of radiation protection in the medical sector is comparable to that of 2019. However, the significant radiation protection events reported are a reminder of the need for regular evaluation of practices and reinforcement of the radiation protection culture.

In radiotherapy, the inspections confirm that the safety fundamentals are in place (equipment verifications, medical staff training, quality and risk management policy) and that quality assurance initiatives are progressing satisfactorily. However, the risk analyses are not updated sufficiently to take account of organisational or technical changes. The occurrence of events, such as laterality or fractionation errors, which sometimes have serious health consequences, shows that there are still organisational deficiencies. The inspections carried out in 2020 did however reveal that the radiation protection conditions had significantly improved in the centres which had received formal notice from ASN or which had undergone reinforced monitoring over the course of the previous years.

In brachytherapy, occupational radiation protection and the management of high-level sealed sources are considered satisfactory on the whole, but this level must nevertheless be maintained through a continuous training effort. Increased attention must be given to the security of access to these sources.

In nuclear medicine, the radiation protection of patients and medical staff in the nuclear medicine units inspected is satisfactory. Progress is however still required in terms of optimisation of practices and the efforts made in occupational training in worker radiation protection must be maintained. The events reported underline the fact that the radiopharmaceuticals administration process must be regularly evaluated, to ensure that it is correctly managed, in particular for therapeutic procedures.

In the area of fluoroscopy-guided interventional practices, and as in previous years, ASN finds that the measures taken are still insufficient to improve the radiation protection of patients and professionals, more particularly for surgical procedures performed in operating theatres. Events are still being reported to ASN with the dose limits for the extremities of interventional practitioners being exceeded. 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. Considerable work is still needed to raise the awareness among all professionals if a radiation protection culture is to be developed among medical and paramedical professionals, notably those working in the operating theatres. Continuous training of professionals, practitioners in particular, and the intervention by the medical physicist to optimise the radiation protection aspect of the procedures, are the two key areas for managing the doses delivered to the patients during interventional procedures.

In computed tomography, diagnostic examinations contribute very substantially to the collective dose received by the public, as medical imaging is the leading source of artificial exposure of the public to ionising radiation. The medical justification remains insufficiently traceable. During its inspections, ASN observes a lack of traceability of this justification and difficulties encountered by the professionals in implementing it. The lack of training on the part of the requesting physicians, or of use of the *Guide to good medical examination practices*, and the lack of justification protocols for the most common procedures, partly explain why this justification principle is not always followed. In addition, the lack of availability of other diagnostic procedures (MRI, ultrasonography) and of health professionals, limits the extent to which irradiating procedures can be replaced by non-irradiating procedures.

THE INDUSTRIAL AND RESEARCH SECTOR

Among the nuclear activities in the **industrial sector**, industrial radiography and more particularly gamma radiography, are priority sectors for ASN oversight owing to their radiation protection implications. ASN considers that the risks are addressed to varying extents depending on the companies, even though worker dosimetric monitoring is generally carried out correctly. If the risk of incidents and the doses received by the workers are on the whole well managed by the licensees when this activity is performed in a bunker in accordance with the applicable regulations, ASN is still concerned by the observed shortcomings in the signage of the operations area during on-site work, even if a slight improvement on this point is observed by comparison with 2019. ASN also recalls the need for regular maintenance and periodic checks on the correct working of the safety systems integrated into the bunkers, so that they represent an effective line of defence against unintentional exposure. More generally, ASN considers that the ordering parties should give priority to industrial radiography services in bunkers and not on the worksite.

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 advance 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.

The actions carried out in recent years have led to improvements in the implementation of radiation protection within the research laboratories. The most notable improvements concern the conditions of waste and effluent storage, more particularly the setting up of pre-disposal inspection procedures; nevertheless, progress is still needed on this point, particularly with a view to the retrieval of unused "legacy" sealed radioactive sources. In addition, the registration and analysis of events which could lead to accidental or unintentional exposure of persons to ionising radiation, notably as a result of insufficient traceability of the radioactive sources being held, are still not systematic enough, even if progress is being observed.

With regard to the **veterinary uses of ionising radiation**, ASN can see the result of the efforts made by veterinary bodies over the past few years to comply with the regulations, notably in conventional radiology activities on pets. For practices concerning large animals such as horses, or performed outside veterinary facilities, ASN considers that the implementation of radiological zoning 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 2020, the safety of transport of radioactive substances is on the whole satisfactory. Although a few transport operations – mainly by road – did suffer incidents, these must be put into perspective with the 770,000 transport operations carried out each year. They did not lead to any dispersal of radioactive substances into the environment. In 2020, ASN observed significant exposure, beyond the regulation dose limits, of three drivers carrying radiopharmaceutical products.

The number of significant events relating to the transport of radioactive substances on the public highway (75 events reported to ASN in 2020) is slightly down on the 2019 figures, even if the number of events rated level 1 on the INES scale remains stable. The events mainly comprise:

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

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

With regard to transport operations involved in the "fuel cycle" and, more generally, for BNIs, ASN considers that the consignors must further improve how they demonstrate that the contents actually loaded into the packaging comply with the specifications of the package model approval certificates and the corresponding safety files. This more specifically concerns transports relating to research facilities or the removal of legacy radioactive waste.

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

At a time when the uses of radionuclides in the medical sector are generating a high volume of transport traffic, progress is still needed in familiarity with the regulations applicable to these transport operations and the arrangements made by certain hospitals or nuclear medicine centres for the shipment and reception of packages. ASN considers that the radiation protection of carriers of radiopharmaceutical products, who are significantly more exposed than the average worker, needs to be improved. This is moreover illustrated by the three cases in which the individual exposure limit for workers was exceeded. An inspection carried out at the end of 2020 at one of the main forwarding agents (the Isovital company) used by the manufacturers of radiopharmaceutical products, also sometimes as a carrier, brought to light a number of deficiencies in the performance of its activities.

NOTABLE EVENTS 2020

Conditions for the continued operation of the 900 MWe reactors

ASN has completed its examination of the generic phase of the 4th periodic safety review of the 900 MWe reactors. ASN considers that all the provisions specified by EDF and those that it itself requires, open up the prospect of continued operation of the 900 MWe reactors for the ten years following their 4th periodic safety review.

Tricastin Nuclear Power Plant (NPP)

In France, the authorisation to create a nuclear facility is issued by the Government, after consulting ASN. This authorisation is issued without time limit. An in-depth examination, called the "periodic safety review", is performed every 10 years to evaluate the conditions for the continued operation of the installation for the next 10 years.

EDF's 32 reactors of 900 MWe are the oldest reactors in operation in France. Their 4th periodic safety review is of particular significance, because their design postulated an operating lifetime of 40 years. Their continued operation beyond this period requires the updating of design studies and equipment replacements.

ASN underlines the ambitious objectives of the 4th periodic safety review of the 900 MWe reactors and the substantial work carried out by EDF in the generic phase. It also underlines the scale of the modifications planned by EDF, the implementation of which will bring about significant safety improvements.

The periodic safety review determined a roadmap for the specified safety improvements

These improvements more particularly concern **control of the risks associated with hazards (fire, explosion, flooding, earthquake, etc.), the safety of the spent fuel storage pool and the management of core meltdown accidents.**

In its resolution 2021-DC-0706 of 23 February 2021, ASN required the implementation of the major safety improvements planned by EDF, along with additional measures it considers necessary to achieve the objectives of the periodic safety review. This resolution closes the "generic" phase of the periodic safety review, which concerns the studies and modifications of the installations common to all the 900 MWe reactors, as they are all based on a similar design.

The measures planned at the generic stage of the periodic safety review and those that will be defined in the studies specific to each site, will have to be applied on each reactor with a view to its continued operation. ASN asks EDF to carry out the majority of the safety improvements before submitting the periodic safety review concluding report, and in practice during the 10-yearly outage of each reactor. The other improvements shall be carried out within a maximum of 5 years after submitting this report. This time is increased to 6 years for the first reactors, that is: Tricastin 1 and 2, Bugey 2, 4 and 5, Gravelines 1 and Dampierre 1.

This phased approach is linked to the scale of the works on each reactor, which will moreover be carried out concurrently on several 900 MWe reactors. It takes account of the ability of industry to conduct the works with the required standard of quality and the associated operator training necessary so that they can familiarise themselves with these changes.

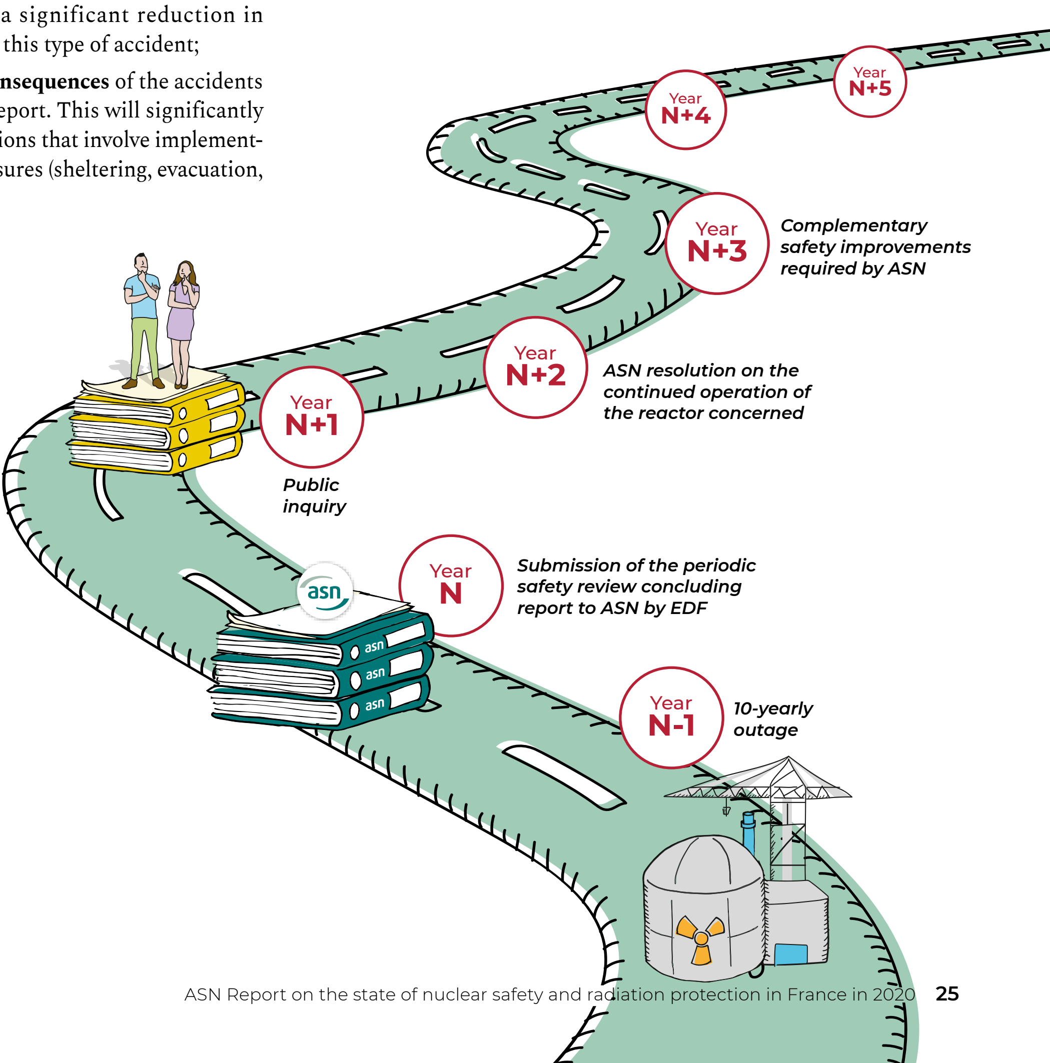
ASN underlines the ambitious objectives of the 4th periodic safety review of the 900 MWe reactors and the substantial work carried out by EDF during the generic phase

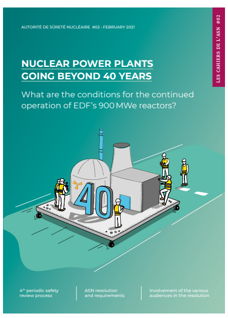
ASN asked EDF to report annually on the actions implemented to meet the requirements and their deadlines, and also on the industrial capacity of both itself and its suppliers to complete the modifications to the facilities on schedule. ASN asks that this information be made public.

ASN considers that the measures planned by EDF, supplemented by the replies to the requirements formulated by ASN, will make it possible to achieve the periodic safety review objectives and bring the level of safety of the 900 MWe reactors close to that of the most recent reactors (third generation), in particular:

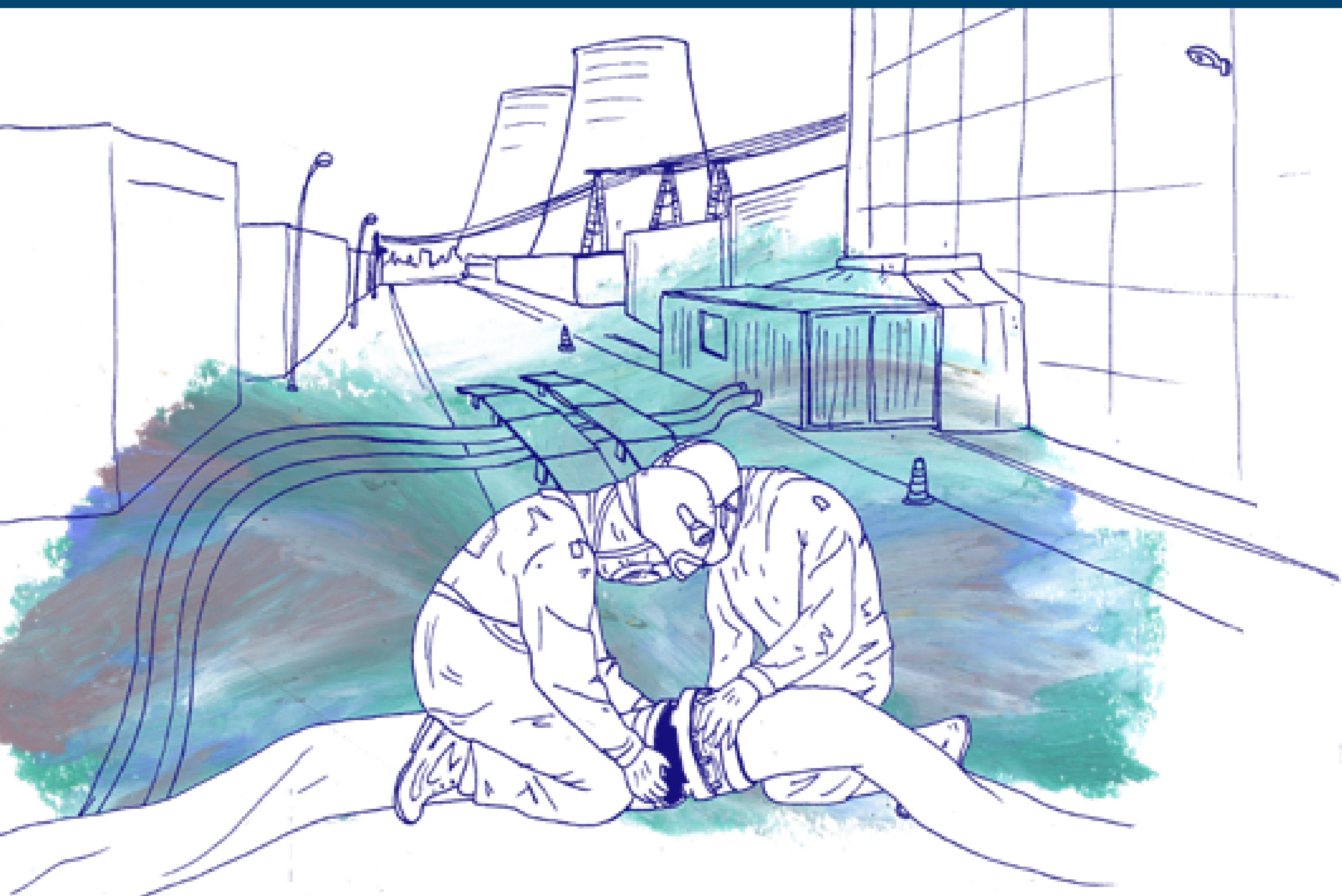
- **by checking, across a broad perimeter, the conformity of the reactors with the safety rules** that apply to them;
- **by improving the way potential hazards** (earthquake, flooding, explosion, fire, etc.) are taken into account. The reactors will also be able to cope with more severe hazards than those hitherto considered;
- **by reducing the risk of accident with core melt** and mitigating any consequences of this type of accident. These provisions will thus lead to a significant reduction in environmental releases during this type of accident;
- **by limiting the radiological consequences** of the accidents studied in the safety analysis report. This will significantly reduce the occurrence of situations that involve implementing population protection measures (sheltering, evacuation, taking iodine tablets);
- **by improving the provisions for managing accident situations affecting spent fuel pools.**

The public was involved throughout the generic phase of this review. More specifically, the measures set out by EDF underwent consultation from September 2018 to March 2019, under the aegis of the High Committee for Transparency and Information on Nuclear Safety. ASN also posted its draft resolution on its website for public consultation between 3 December 2020 and 22 January 2021. Subsequent to this consultation, it modified or clarified certain provisions of its resolution. This is the case, for example, with certain studies required by ASN, for which the completion deadlines have been brought forward. ASN has also pushed back some deadlines on account of specific industrial and operating constraints when this was acceptable from the safety standpoint. ASN also explained its position regarding the deployment schedule for the modifications resulting from the periodic safety review and its requirements with regard to deviations detected during the 10-yearly outage.

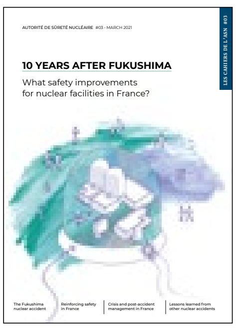




[Read online *Le cahier de l'ASN #02* on french-nuclear-safety.fr]



Safety improvements made to nuclear facilities in France



Read online *Le cahier de l'ASN #03* on french-nuclear-safety.fr

The Fukushima Daiichi NPP accident highlighted the need to reinforce the resilience of nuclear facilities and organisations in the face of extreme situations. Extensive work was started at the national, European and international levels to learn the relevant lessons. Ten years later, how has the safety of nuclear facilities in France improved?

Stress tests

This French approach was part of two framework: on the one hand, at the request of the French Prime Minister (referral to ASN of 23 March 2011), the performance of a nuclear safety audit of the French civil nuclear facilities in the light of what happened in Fukushima Daiichi; on the other, at the request of the European Council (meeting of 24 and 25 March 2011), the performance of stress tests (*see chapters 10, 11, 12 and 13*).

To ensure that the European and French frameworks were consistent, **the French specifications for the stress tests (ECS) were drawn up on the basis of the European specifications**, drafted by Western European Nuclear Regulators' Association (WENRA). One particularity of the French approach however was that it concerned all facilities and not simply nuclear power reactors.

The approach consisted in **evaluating the margins available in the facilities in situations beyond those considered in the safety studies**. To do this, scenarios resulting from extreme natural hazards (flooding, earthquake), or the total loss of systems important for safety, such as electrical power supply or cooling systems, were studied. The approach also covered the management of severe accidents that could result from these scenarios.

Examination of these evaluations led **ASN, as of 2012, to set binding requirements for the licensees of the nuclear facilities with the highest potential safety implications** (CEA, EDF, Orano) in order to:

- **define a "hardened safety core"** of material and organisational measures aimed at preventing a severe accident or limiting its spread, mitigating large-scale radioactive releases and enabling the licensee to perform its extreme crisis management duties;
- **implement a range of corrective actions or improvements** (notably additional water make-up and electricity supply means, additional instrumentation, improved management of emergency situations, etc.) and, for EDF, a Nuclear Rapid Intervention Force (*Force d'Action Rapide Nucléaire* – FARN), enabling outside resources to be brought to a damaged NPP;
- **study additional modifications and resources** to deal with extreme situations (*see chapters 10, 11, 12 and 13*).

ASN then made additional demands to clarify certain provisions regarding the "hardened safety core".

ASN's demands are part of a continuous process to improve safety and aim to be able to cope with situations far beyond those considered in the safety studies. This "defence in depth" approach stands out on the international stage in the scope and scale of the resulting modifications.

For 22 lower priority facilities operated by CEA, EDF, CIS bio international and the International Thermonuclear Experimental Reactor (ITER), the evaluations were submitted in September 2012 and have been examined.

Finally, for the thirty or so facilities with lesser potential safety implications[1], a schedule for submission of the stress test reports during the periodic safety reviews was deployed until 2020.

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1. *Operated by French radioactive waste management agency (*Agence nationale pour la gestion des déchets radioactifs *– Andra), EDF, Ganil, Ionisos and Steris.*

Large-scale works, phased over a period of time

The improvement approach was regulated by binding ASN requirements and phased over a period of time owing to its scope and scale:

- first of all, **rapid reinforcement using mobile resources** (pumps, electricity generating sets, means of communication);
- then, **over the past ten years, the gradual deployment of additional mobile or fixed resources** to ensure water make-up, electrical power supplies and enable management of a crisis;
- finally, for the Basic Nuclear Installations (BNIs) on which the potential safety implications so warrant, the **gradual installation of a "hardened safety core" which is an additional line of defence** designed to prevent and mitigate large-scale releases in an extreme situation, as well as lasting effects in the environment.

Improvements already effective **today**

- **Deployment of mobile and then, gradually, fixed resources,** to guarantee resilient management of a situation in which electrical power or cooling systems are lost.
- **Reinforced emergency organisation** at the licensees; reinforcement of the existing emergency centres or the creation of bunkerised emergency centres.
- **Reduction in the quantities of radioactive substances in a number of laboratories and former plants:** rationalisation of storage of waste and materials, shutdown of old facilities, such as Comurhex.
- **Changes in French doctrine for managing the consequences of a nuclear accident,** more particularly by simplifying the response through actions that are more appropriate and more easily understood by the population.

Tomorrow, even more robust installations and organisations

- Within the framework of the periodic safety reviews, **continue to deploy the "hardened safety core" in the NPPs.**
- **Complete the construction of new bunkerised emergency rooms** for those installations not as yet equipped (EDF, CEA).
- Within the framework of the Steering Committee for management of the post-accident phase (Codirpa) **continue to work on the precautionary culture and the population protection measures** in the event of an accident.

Protecting and assisting the population following a nuclear accident

The Steering Committee for management of the post-accident phase (Codirpa) is a pluralistic group headed by ASN, the role of which is to propose changes to the Government concerning the national strategy for protection of the population and reconstruction following a nuclear accident. This Committee was created in 2005 at the request of the Prime Minister, who specified its mandate, and consists of experts and representatives of Government departments and civil society. Its work is made public on the ASN website.

Improving protection of the population by learning the lessons from the accident at the Fukushima Daiichi NPP

Between 2014 and 2019, the Codirpa proposed changes to post-accident doctrine to take account of the lessons learned from the accident that struck the Fukushima Daiichi NPP in Japan. These proposals, accepted by the Prime Minister in June 2020, will be implemented in the next update of the Major nuclear or radiological accident national response plan.

The principal recommendation consists in simplifying the post-accident zoning which underpins the population protection measures:

- **To protect the population from the external exposure risk**[1], a population evacuation perimeter (uninhabitable zone) would be put into place. The consumption and sale of foodstuffs produced in this zone would be prohibited.
- **To limit exposure of the population to the risk of contamination through consumption**, a non-consumption perimeter for fresh local produce[2] would be defined. First of all, this perimeter will be defined on the basis of the largest of the population protection perimeters (sheltering, ingestion of iodine, etc.) determined during the emergency phase.
- **With regard to the marketing of local agricultural produce**, a regional approach per production sector would be adopted. Checks prior to marketing will be adopted, to guarantee compliance with the maximum permitted levels[3] of radioactive contamination defined at European level for the sale of foodstuffs.

This zoning approach would be accompanied by protective measures adopted in the national plan (decontamination, etc.) taking account of the scale of the accident, the result of measurements and the perception of the situation by the population.

1. External exposure corresponds to the exposure resulting from radioactive sources situated outside the organism.
2. Produce from gardens or from open-air market gardens and fruit orchards, as well as products taken from the natural environment (such as mushrooms, berries and wild game) and the marine environment (shellfish, notably in seashore fishing zones).
3. Council regulation (Euratom) 2016/52 of 15 January 2016 setting the maximum permitted levels for radioactive contamination for foodstuffs and animal feedstuffs after a nuclear accident or in any other radiological emergency situation.

Between 2014 and 2019, the Codirpa proposed changes to post-accident doctrine to take account of the lessons learned from the Fukushima Daiichi disaster

Targeted support for the various categories of post-accident management players

To meet the demand for support from the local players, the Codirpa proposed various solutions:

- a website (in french only) to raise awareness of post-accident situations. This site enables elected officials, health professionals, associations, education personnel and economic players to access documents and information of use for preparing or managing life in a region contaminated by a nuclear accident;
- **a practical guide** intended for the inhabitants of a region contaminated by a nuclear accident;
- **frequently asked questions/answers** drawn up with and for health professionals (publication in 2021).

This information work will be continued on a long-term basis.

Download the practical guide (in french only) on asn.fr

The challenges for the coming period

The Prime Minister's mandate of 18 June 2020 sets the objectives for Codirpa for the period 2020-2024, with the following main priorities:

- **management of the consequences of an accident occurring in a facility other than an NPP** ("fuel cycle" plants, waste storage site, transport accident, etc.);
- **the impact of a radioactive release in the aquatic environment;**
- **the contamination mitigation and waste management strategy;**
- **the role of the local stakeholders** in developing a safety and radiation protection culture around nuclear sites.

Codirpa

A pluralistic structure

About a hundred participants in the Codirpa plenary meetings, since 2013:

- **33** persons from the administration
- **19** experts
- **17** persons representing the licensees
- **16** persons from associations
- **4** international representatives

From 29 October 2014 to 29 October 2019:

- **10** plenary meetings
- **61** meetings
- **7** working groups and 4 sub-groups:
  - **Waste**
  - **Long-term releases**
  - **Water**
  - **Involvement of stakeholders**
    - Health local group
    - Health experts group
    - Population guide
    - Website
  - **Overhaul of doctrine**
  - **Codirpa orientation**
  - **Food**

Bugey GCR reactor

Gas-Cooled Reactor decommissioning strategy

EDF's first-generation nuclear reactors are Gas-Cooled Reactors (GCRs), which operate using natural uranium as a fuel. This operation differs from that of Pressurised Water Reactors – PWR (*see chapter 10*), which form the entirety of the current French NPP fleet and operate with enriched uranium.

The first GCR reactor was commissioned at Chinon in 1963. A total of six reactors of this type were built in France: at Chinon (Chinon A1, A2 and A3), Saint-Laurent-des-Eaux (Saint-Laurent A1 and A2) and Bugey (Bugey 1). These reactors were shut down between 1973 and 1994, as this technology was replaced by the PWR. The fuel, which represented virtually the entire safety risk in these installations, has been removed. **However, some of these installations were only partially decommissioned before being placed under surveillance**, pending final dismantling. The pertinence of immediate dismantling of nuclear installations was in fact only recognised by all players in the early 2000s. Since then, this notion became law in 2015, with the Environment Code now requiring "dismantling as rapidly as possible".

A change in decommissioning strategy

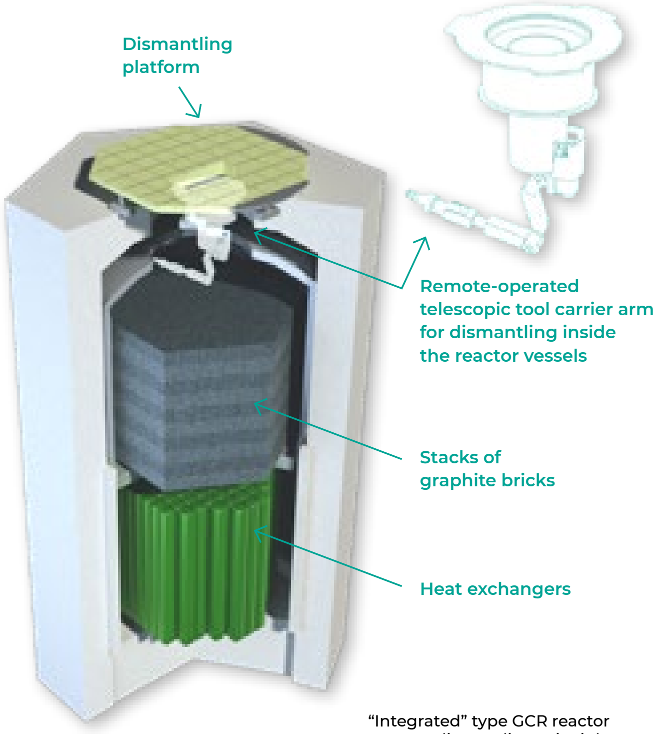
EDF has not as yet provided any demonstrations such as to permit authorisation of the next stages in the decommissioning of the Chinon A1 and A2 reactors. The other four GCR reactors (Bugey 1, Chinon A3, Saint-Laurent A1 and A2) have received decommissioning authorisation, in accordance with a scenario set out by EDF in the early 2000s. **This scenario was to fill the reactor core (or vessel) with water in order to perform the decommissioning operations**, to reduce the ionising radiation risks. EDF initially planned to complete decommissioning of these reactors in 2024, 2027 and 2031 respectively.

ASN duly notes the difficulties encountered with continued dismantling "under water" and [....] it will study the safety of the "in air" operations planned and the corresponding deadlines

Given the major technical difficulties (tightness of the reactor vessel and treatment of the contaminated water), but also technological progress which has identified other solutions, remote-operation in particular, EDF in 2016 announced that the "**under water" dismantling scenario was no longer the reference solution**, resulting in a change in strategy. EDF thus opted for an "**in air" dismantling scenario, eliminating the problems linked to the use of water**. This change also entailed a significant postponement in the dismantling operations on these reactor vessels. EDF felt that the feasibility of certain complex operations (such as cutting very thick concrete or the use of tools attached to an articulated arm required to descend to a depth of 20 metres) needed to be validated with an industrial demonstrator, followed by complete dismantling of one reactor vessel before beginning dismantling of the other five vessels. Given the results of the studies conducted, EDF has also significantly increased the time needed to decommission a reactor.

ASN duly notes the difficulties encountered with continued dismantling "under water" and, via the decommissioning files for the GCR reactors, it will study the safety of the "in air" operations planned and the corresponding deadlines. After examining a number of substantiation files, holding a hearing of EDF and carrying out inspections on the subject, ASN considers that the production of an industrial demonstrator for this new dismantling technique is relevant, notably in order to qualify the tools for use in harsh conditions. However, ASN considers that waiting for the end of decommissioning of a first reactor vessel and analysis of the lessons learned – which would not happen until about 2060-2070 – before starting to decommission the other reactor vessels, is not acceptable with regard to the obligation of dismantling within the shortest possible time-frame.

After consultation of the public, the ASN resolutions of March 2020 ordered EDF to submit a file requesting changes to the existing decommissioning decrees for the Bugey 1, Saint-Laurent A1 and A2 and Chinon A3 reactors and to submit the decommissioning files for those reactors which did not already have one (Chinon A1 and Chinon A2), no later than the end of 2022. ASN also stated that EDF must in particular shorten the decommissioning time-frame set out in its 2016 strategy, in order to meet the legislative obligation for dismantling in as short a time as possible for each reactor.



"Integrated" type GCR reactor dismantling principle

ASN also instructed EDF to submit a report on the activities of the industrial demonstrator, the construction of which began in the fourth quarter of 2020. ASN also instructed EDF to carry out decommissioning of the rooms and equipment situated around the vessel, which has already been authorised and remains unchanged. Only the reactor vessel decommissioning operations have been revised and prove to be more complex than initially envisaged. The other decommissioning operations shall therefore be carried out as soon as possible. EDF shall regularly inform ASN of the progress of its studies and work.

Finally, in order to make the reactor decommissioning schedule more reliable, **ASN asked EDF to choose robust waste management routes which could**, if necessary, lead to the creation of new waste storage facilities.

The main guidelines of the fifth Plan

Planning Act 2006-739 of 28 June 2006 on the sustainable management of radioactive materials and waste stipulated the periodic drafting of a National Radioactive Materials and Waste Management Plan (*Plan national de gestion des matières et déchets radioactifs* – PNGMDR). In concrete terms, the PNGMDR gives a detailed inventory of radioactive materials and waste management routes, whether operational or to be deployed, and then makes recommendations or sets targets to develop these routes.

CEA's Cedra facility in Cadarache

The production of the 5th edition of the PNGMDR was, for the first time, preceded by a public debate, organised by the National Public Debates Commission (CNDP). The debate was held between April and September 2019 under the aegis of a special public debates commission (CPDP) and enabled the public to express their opinions on the main topics related to the management of radioactive materials and waste. In November 2019, the CNDP and the CPDP published their conclusions following this debate.

On 21 February 2020, the Ministry in charge of energy and ASN published their decision as a result of the public debate. This decision specifies the main outlines of this 5th edition for each management route. It more specifically makes provision for a process including greater involvement by the stakeholders in the production of the subsequent editions.

In the light of the conclusions of the public debate, **ASN, together with the Ministry for Ecological Transition** (**MTE**), **decided to no longer be co-owner of the next PNGMDR**. The Government will henceforth be the sole signatory to the Plan.

ASN nonetheless continues to be involved and, jointly with the MTE, co-chairs the PNGMDR working group. This pluralistic group meets several times a year to monitor the implementation of the plan.

ASN analysed the studies specified in the Order of 23 February 2017, for the purposes of the 2016-2018 edition of the PNGMDR, and in 2020 and 2021, it issued **six opinions for each of the main management routes. A seventh opinion should be published in the second third of 2021**.

Classification of radioactive wastes and corresponding management routes

CATEGORY	VERY SHORT LIVED WASTE	SHORT LIVED WASTE	LONG LIVED WASTE
Very Low Level (VLL)	VSL Management by radioactive decay	VLL Surface disposal (Industrial centre for collection, storage and disposal)	
Low Level (LL)		LL/ILW-SL Surface disposal (Aube and Manche waste repositories)	LL-SL Near-surface disposal being studied
Intermediate Level (IL)			ILW-LL *Cigéo* geological disposal project
High Level (HL)	Not applicable		HL

These opinions, which can be consulted on *asn.fr*, is ASN's contribution to the production of the next edition of the PNGMDR, emphasising the main nuclear safety and radiation protection issues. They more particularly draw the Government's attention to the following.

First of all, ASN stresses the importance of planning ahead when defining the management options for radioactive materials and waste, so that **concrete prospects for safe and lasting management of all types of waste for the 2035/2040 time-frame can be defined**.

More specifically:

- the need for the **nuclear licensees to use all necessary means for retrieval and conditioning of legacy** intermediate and high level waste, giving priority to safety aspects;
- the need for the **producers to implement an ambitious programme to characterise bituminous waste packages**, which is essential in order to develop the demonstration that some or all of the bituminous waste packages could be disposed of in the *Cigéo* facility without prior processing and with a high level of safety;
- the lack of credibility in the prospects for transmutation on an industrial scale of the waste already conditioned in the *Cigéo* reference inventory. If studies were to continue on the subject, **they should cover the radioactive substances currently categorised as materials, or the waste produced by a future fleet of reactors**;
- the need to **plan ahead for storage needs. More specifically, the construction of additional spent fuel storage capacity** is a strategic issue for the overall safety of the nuclear installations. As EDF chose the option of a centralised EDF fuel storage pool, ASN considers that it must submit a creation authorisation application as soon as possible;
- the fact that the recoverable nature of the material must be assessed, taking account of the time-frames within which industrial solutions for using these materials will be available, and the volume of material concerned. ASN considers that it is essential that **a substantial quantity of depleted uranium be requalified as waste, as of now**;
- the need for the next multi-year energy plan to **define reprocessing prospects beyond 2040**.

ASN also highlights the need to **involve all the stakeholders concerned**, notably the representatives of the regions involved or liable to be involved, via multicriteria and multi-player analyses, in particular for the choice of management of very low level waste, low level/long-lived waste, legacy waste locations for radioactive waste, mining processing residues and uranium mine waste rock.

Finally, ASN recalls that the management of very low level waste should in principle be based on the origin of the waste and guarantee its traceability, by means of specific routes. However, the recovery of certain types of waste, which will be produced in large volumes, is encouraged. ASN notably recommends the creation of a specific oversight framework for continuation of the metals recycling facility project.

In 2021, the MTE will oversee the drafting of this 5th Plan, it environmental assessment and the public consultation. **ASN will then issue an opinion on the draft regulatory produced by the MTE**.

The Plan will then be made public and transmitted to the Parliamentary Office for the Evaluation of Scientific and Technical Choices for its opinion.

MINISTÈRE DE LA TRANSITION ÉCOLOGIQUE
Liberté Égalité Fraternité

For the production of the 5th edition of this Plan, the Ministry for Ecological Transition (MTE) chose to rely on an orientations commission, chaired by an independent qualified person, and consisting of radioactive waste producers, licensees of management facilities for this waste, environmental protection associations and national elected officials and representatives from the local authorities. It issues opinions on each topic debated, which will be taken into account in the drafting of the next plan.

REGULATORY NEWS

The health situation meant that 2020 was marked by particular activity in terms of standards.

In addition, a number of ASN orders and resolutions resulting from Decrees transposing Council Directive 2013/59/Euratom of 5 December 2013 laying down Basic Standards for health protection against the dangers arising from exposure to ionising radiation were published in 2020.

NATIONAL NEWS

1.1 Acts and Ordinances

Act 2020-1525 of 7 December 2020 *accelerating and simplifying public actions*, known as the "*ASAP Act*", was published in the *Official Journal of the French Republic (JORF)* on 8 December 2020.

The main objectives of the ASAP Act are to eliminate administrative commissions (Articles 1 to 24), to decentralise individual administrative decisions (Articles 25 to 33), to simplify procedures applicable to companies (Articles 34 to 66), various simplification measures (Articles 67 to 139) and to eliminate "over-transposition" of certain European Directives into French law (Articles 140 to 149).

Three provisions in particular are of direct interest to ASN:
- the first concerns the frequency of the updating of the National Radioactive Materials and Waste Management Plan (PNGMDR) which goes from 3 to 5 years;
- the second concerns maintaining the National review board for financing the cost of decommissioning of Basic Nuclear Installations (BNIs) and the management of Spent Fuels and Radioactive Waste (CNEF). In carrying out its role of evaluating the adequacy of the provisions made for the cost of decommissioning BNIs, the CNEF will be able to consult the Prudential Supervision and Resolution Authority (ACPR);
- finally, the third allows improved "dissemination of the information transmitted to the Departmental Council for the Environment and for Health and Technological Risks (CODERST)": the documents transmitted to the members of this body for the matters it is examining will be made public. With regard to nuclear subjects, this obligation will apply when, at the request of ASN, the Prefect refers draft requirements to the CODERST concerning water intake and effluent discharges for a BNI or when ASN informs the CODERST of a project concerning unnecessary equipment within the perimeter of a BNI.

Moreover, the ASAP Act modifies numerous provisions concerning Installations Classified for Protection of the Environment (ICPE). They will apply to the unnecessary ICPEs located within the perimeter of a BNI:
- Article 34 modifies the conditions for the application of new rules and binding requirements for ICPE projects being examined;
- Article 44 modifies the conditions for public consultation regarding certain projects with an environmental impact;
- Article 56 enables the Prefect to authorise certain construction work to be carried out in advance, before the environmental authorisation is issued.

Articles 34, 44 and 56 of the ASAP Act were referred to the Constitutional Council and declared to be in compliance with the Constitution (Constitutional Council decision 2020-807-DC of 3 December 2020).

Act 2020-1672 of 24 December 2020, concerning the European Prosecutor's Office, environmental justice and specialised criminal justice, published in the *JORF* on 26 December 2020.

This Act, which deals with the creation of the "European Prosecutor's Office" (Part I), the role of which will be to investigate and prosecute fraud concerning the budget of the European Union and other offences harming the financial interests of the European Union, also comprises provisions concerning specialised criminal justice (Part II), aiming in particular to improve the fight against environmental delinquency. Regional centres specialising in environmental damage are thus created (in addition to the two national Public Health centres in Marseille and Paris which already exist), for graded treatment of environmental offences. They will be based in each Court of Appeal and will have civil and criminal competence. It also creates a judicial convention of public interest (known as the "Environmental Convention"), a new judicial means of implementing environmental compensation or reparation mechanisms in cases with major financial implications brought against legal persons, to ensure a rapid judicial response.

Ordinances dealing with the health state of emergency

The health crisis led the Government to adopt exceptional measures. ASN adapted its working methods to take account of these measures, revising its inspection programme as part of its oversight duty, but also by implementing measures concerning the management of due dates, deadlines and administrative procedures during the health emergency period, as set out in successive ordinances on procedural deadlines (see Ordinance 2020-306 of 25 March 2020 *relative to the extension of expired dates during the health emergency period and the adaptation of procedures during this same period*, modified by Ordinance 2020-427 of

15 April 2020 *containing various provisions concerning deadlines to deal with the Covid-19 epidemic* and Ordinance 2020-560 of 13 May 2020 *setting the deadlines applicable to various procedures during the health emergency period*).

The purpose of the provisions of these Ordinances was to guarantee the continuity of the administration's actions, while ensuring the regularity of the procedures and protection of the public.

Ordinance 2020-306 of 25 March 2020 comprised a Part I devoted to the general provisions concerning the extension of deadlines and a Part II devoted to administrative deadlines and procedures.

Article 1 of the Ordinance determined the "legal protection period", that is the period considered when determining whether or not a deadline fell within the scope of the Ordinance.

The other provisions of the Ordinance set the nature of the deadlines concerned and the way in which their calculation was affected.

This "legal protection period" began on 12 March 2020 and ended on 23 June 2020, at midnight.

The Ordinance, published on 26 March 2020, was therefore retroactive, because it applied to current deadlines or those which expired on 12 March 2020.

The Ordinance first of all made provision for postponement of the deadline for certain procedures or formalities. Thus the due dates by which procedures or formalities, etc., had to be completed, which should have been between 12 March and 23 June 2020, were extended as of the end of this period for the legally allowed duration, within a maximum of two months.

The Ordinance did not therefore cancel the performance of a procedure or formality due within the legal protection period, but simply meant that the procedure performed within the additional time allocated was not considered to be late.

For example, an application for renewal of an authorisations or submission of a review report, which should have taken place between 12 March and 23 June 2020, was to be completed no later than 23 August 2020 in order to be considered as having been done on-time.

The Ordinance also stipulated that the authorisations and approvals in force, which would expire between 12 March and 23 June 2020, were extended until 23 August 2020, unless terminated or modified beforehand by ASN.

For example, the authorisations issued pursuant to the Public Health Code, which expired during this period, were thus automatically extended until 23 August 2020.

The Ordinance then comprised provisions which suspended or postponed certain procedural deadlines. This suspension of deadlines did not however suspend examination of the applications themselves, nor ASN's ability to issue administrative documents.

This possibility was however reserved for cases in which no public consultation or participation procedure is required, provided that the deadlines set for completion of these procedures were also suspended or postponed.

Finally, the deadlines set by the administration, pursuant to the law and the regulations, for any person to carry out inspections and works or to comply with requirements of whatsoever nature were also suspended, from 12 March 2020 to 23 June 2020.

These are deadlines set by individual resolutions, binding requirements, formal notices (etc.).

The starting point for deadlines of the same type which should have begun to run during this same period was postponed until the end of said period.

One provision included the possibility of an exception to the principle of deadline suspension, by a decree setting categories of documents, procedures and obligations for which, with a view to protection of the fundamental interests of the Nation, security, protection of individual and public health, preservation of the environment and protection of children and the young, the deadlines were restored.

For example, the deadlines regarding certain inspection obligations for pressure equipment and nuclear pressure equipment, were restarted as of 3 April 2020.

1.2 Decrees and Orders

1.2.1 Radiation protection

TEXTS ISSUED PURSUANT TO THE PUBLIC HEALTH CODE

▸ Ban on the addition of radionuclides

The Order of 25 May 2020 granting an exemption to the ban on the addition of radionuclides set out in Article R. 1333-2 of the Public Health Code, for the addition of krypton-85 and thorium-232 in certain discharge lamps grants an exemption to the Dr Fischer Europe SAS, Lumileds France SAS, Osram Lighting, Signify France and Tungsram Lighting SAS on the ban on the addition of radionuclides, for the addition of krypton-85 and thorium-232 to certain discharge lamps.

▸ Radon

The Order of 26 October 2020 regarding the communication of the results of analysis of the integrated radon measurement devices and the corresponding data to the Institute for Radiation Protection and Nuclear Safety (IRSN) implements Article R. 1333-31 of the Public Health Code. It defines the nature of the data to be communicated by the accredited organisations for analysis of passive integrated radon measurement devices to the IRSN and specifies the data transmission procedures.

▸ Waters intended for human consumption

The Order of 6 April 2020 modifying the Order of 5 July 2016 concerning the conditions for the approval of laboratories for the sampling and health checks on waters adapts the provisions of the Order of 5 July 2016 as amended, concerning the conditions for the issue of the approval by the Ministry for Health, regarding the measurement of radon-222 in waters until 31 December 2020.

TEXTS ISSUED PURSUANT TO THE LABOUR CODE

The Order of 28 January 2020 modifying the Order of 15 May 2006 as amended concerning the conditions for the demarcation and signage of monitored and controlled zones, called "demarcated zones" in the light of exposure to ionising radiation, brings the provisions of the Order of 15 May 2006 into line with the provisions of the Labour Code regarding the demarcation of zones for ionising radiation reasons. The provisions that contradicted the Labour Code or were redundant, were thus deleted. This is notably the case with the provisions relating to:

- the exposure levels used to define the zones and the transfer of radioactive materials, which are now set in the Labour Code;
- the conditions for access to the zone and the health and safety rules in the regulated zones which were deleted to take account of the new provisions of the Labour Code and those which exist in common law.

The entry into force of the modified Order rendered applicable all the provisions of the Labour Code regarding demarcation of zones.

The Order of 23 October 2020 regarding measurements taken for the assessment of risks and checks on the effectiveness of the prevention means put into place for the protection of workers against the risks from ionising radiation is implemented pursuant to Article R. 4451-51 of the Labour Code. It specifies the methods for taking measurements for risk assessment. The Order reorganises the procedures and the conditions for performance of technical inspections, henceforth called "verifications", by making them proportional to the scope of the implications for worker radiation protection. An accredited organisation is only required at commissioning of the installation and the working equipment, as well as after any major modification of them liable to affect the health and safety of the workers. Finally, the employer may use the company's own resources for the periodic verifications, notably by or under the supervision of its Radiation Protection Advisor.

1.2.2 Basic Nuclear Installations

The Order of 7 February 2012 setting the general rules concerning Basic Nuclear Installations ("BNI Order")

Revision work on this Order began in 2019 and continued in 2020 with the drafting of proposals for changes to the Order. Proposals were made taking account of feedback from application of the Order over the previous 6 years and the observations and proposed changes from the licensees.

All the stakeholders will be consulted on the draft modifying Order.

1.2.3 The security of radioactive sources

The Order of 24 June modifying the Order of 29 November 2019 relating to the protection of sources of ionising radiation and batches of radioactive sources of categories A, B, C and D against malicious acts, postponed the initial application deadlines by 6 months, because of the first health emergency period and in particular the legal protection period created on this occasion.

1.2.4 Transport of radioactive substances

The Order of 29 May 2009 relating to the Transport of Dangerous Goods by land ("TMD Order") was modified by the Order of 10 December 2020 creating exemptions to certain provisions of the Order of 29 May 2009 relating to the transport of dangerous goods by land so that, in addition to incorporating amendments to the international regulations and updating obsolete regulatory or technical references, a dematerialised procedure is introduced to appoint Safety Advisors for the Transport of Dangerous Goods (CSTMD – Article 6 of the TMD Order).

The Order of 25 November 2020 modified the Order of 6 February 2019 relating to the appointment of the body tasked with organising the initial examinations and renewal of the certificate for the Safety Advisor for Transport of Dangerous Goods by road, rail or inland waterway. Under 1.8.3.12.5 of the ADR Book, the examination leading to issue of the safety advisor certificate, organised by the competent authority or by an examining body appointed by it, may be carried out in part or in full, by means of an electronic examination. As technology has progressed rapidly in recent years, gradual dematerialisation of the safety advisor examination for the transport of dangerous goods is introduced. This dematerialisation will eventually allow:

- an increase in the number of examination sessions per year, offering a wider choice of examination locations, thus obviating the need for long journeys;
- an on-line registration, giving the candidate a greater choice of examination dates and locations;
- a significant reduction in the time needed to transmit the results.

The Order of 17 November 2020 amended the regulation appended to the Order of 18 July 2000 regulating the Transport and Handling of dangerous goods in Seaports (RPM). The modification of the RPM represents an in-depth update of the provisions and references of the applicable texts in the case of a temporary stay by class 7 materials and objects. This update refers to both international texts (International Maritime Dangerous Goods Code – IMDG Code), and national provisions (Labour Code, Public Health Code, specific Orders, and their implementing texts).

1.3 ASN resolutions

1.3.1 Radiation protection

ASN resolution 2020-DC-0694 of 8 October 2020 relating to the qualification of physicians or dental surgeons performing procedures using ionising radiation for medical or research purposes involving humans, to the qualifications required to be appointed coordinating physician for a nuclear activity for medical purposes or to request an authorisation or registration as a natural person

Article L. 1333-18 of the Public Health Code states that *"ionising radiation may only be used on the human body for medical diagnostic, therapeutic treatment, screening, prevention or biomedical research purposes"*. Article R. 1333-68 of this Code specifies that the examinations and procedures using ionising radiation for medical purposes are performed by physicians and dental surgeons who can justify the required competence and by radiographers intervening under their own responsibility.

ASN's resolution clarifies the definition of certain qualifications:

1. of the physician or dental surgeon performing procedures using ionising radiation for medical or research purposes involving humans;
2. the physician coordinating the steps taken to ensure radiation protection of the patients (Article R. 1333-131 of the Public Health Code);
3. the natural person responsible for a nuclear activity for medical purposes, in other words a physician who reports a nuclear activity to ASN or a physician who requests ASN authorisation for radiotherapy, nuclear medicine or computed tomography.

This resolution repeals ASN resolution 2011-DC-0238 of 23 August 2011 relative to qualifications as defined in Article R. 1333-45 of the Public Health Code, required for persons responsible for a nuclear activity for medical purposes.

1.3.2 Pressure equipment

ASN resolution 2020-DC-0688 of 24 March 2020 concerning the qualification of organisations tasked with the inspection of nuclear pressure equipment

This resolution sets out the procedures for the qualification of organisations working in the field of nuclear pressure equipment inspection, whether with regard to manufacturing aspects or to in-service monitoring. It recognises the NF EN ISO/IEC 17020 "Conformity assessment – Requirements for the operation of various types of bodies performing inspection" and NF EN ISO/IEC 17021 "Requirements for bodies providing audit and certification of management systems" standards, supplemented by the specific requirements of Appendix 2, assuming compliance with the guarantees in terms of organisation, independence and competence, as set out in Articles L. 557-31 and R. 557-4-2 of the Environment Code. Appendix 1 sets out the process to be followed by a body applying for qualification or renewal, appendix 2 sets out the specific requirements to be obtained to obtain this qualification.

This resolution repeals resolution 2007-DC-0058 of 8 June 2007.

It entered into force on 2 July 2020, after publication of its approval Order of 25 May 2020 in the *Official Journal*.

1.4 The professional guides approved by ASN

Guide No. 30 relative to policy for the management of risks and detrimental effects of nuclear installations and the licensees' integrated management system

ASN Guide No. 30 comprises the ASN recommendations for application:

- of Articles L. 593-6 and R. 593-63 of the Environment Code, as well as Part II of the Order of 7 February 2012 as amended setting out the general rules relative to BNIs;
- Articles L. 593-6-1 and R. 593-9 to R. 593-13 of the Environment Code, regulating the use of outside contractors by BNI licensees.

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

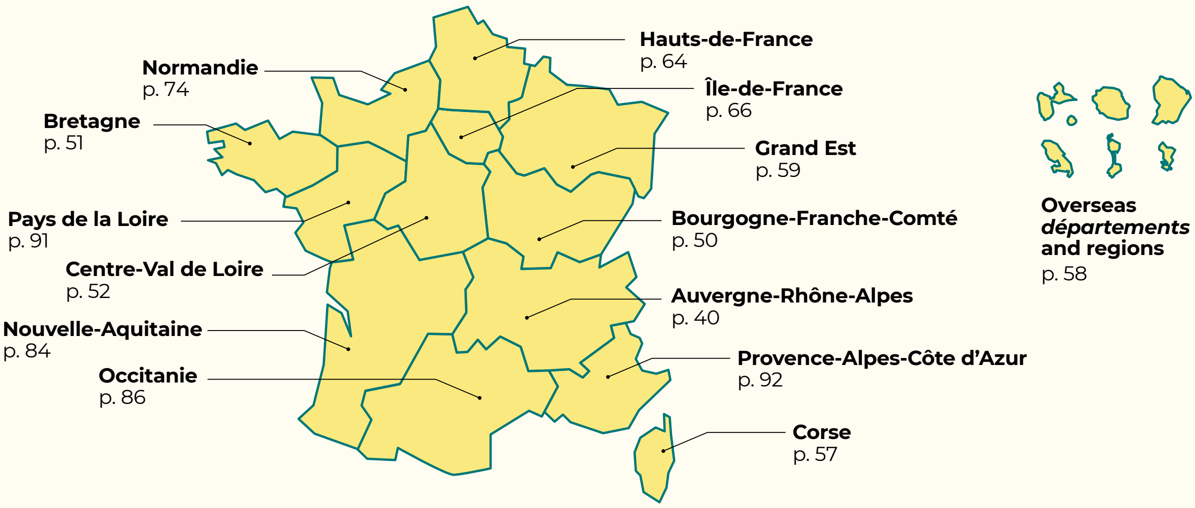
This Guide is part of the work to integrate into the French regulatory framework a number of positions adopted by Western European Nuclear Regulators Association (WENRA), in particular the "reference levels" for the existing reactors.

The recommendations set out in this Guide are the result of several years of work by ASN and were the subject of technical exchanges with the French licensees. The guide was the subject of a public consultation on the ASN website in December 2019.

Regional overview

of nuclear safety and radiation protection

ASN, the French Nuclear Safety Authority, has 11 regional divisions through which it carries out its regulatory duties 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 2020, the ASN regional divisions totalled 231 employees, including 175 inspectors.



Under the authority of the regional representatives (see chapter 2), the ASN regional divisions carry out on-the-ground inspections of the Basic Nuclear Installations (BNIs), of radioactive substance transport operations and of small-scale nuclear activities; they examine the majority of the licensing applications submitted to ASN by the persons/entities responsible for nuclear activities within their regions. The regional divisions check application within these installations of the regulations relative to nuclear safety and radiation protection, to pressure equipment and to Installations Classified for Protection of the Environment (ICPEs). They ensure the labour inspection in the Nuclear Power Plants (NPPs).

In radiological emergency situations, the ASN regional divisions check the on-site measures taken by the licensee to make the installation safe and assist the Prefect of the *département*, who is responsible for protection of the population. To ensure emergency situation preparedness, they help draw up the emergency plans established by the Prefects and take part in the periodic exercises.

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

This section presents ASN's oversight action in the BNIs of each region and its assessment of nuclear safety and radiation protection.

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

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

MEDICAL FIELD > 07
RESEARCH AND INDUSTRY > 08
TRANSPORT > 09

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.

In 2020, ASN carried out 293 inspections in the Auvergne-Rhône-Alpes region, comprising 96 inspections in the Bugey, Saint-Alban, Cruas-Meysse and Tricastin Nuclear Power Plants (NPPs), 81 inspections in plants and installations undergoing decommissioning, 101 inspections in small-scale nuclear activities and 15 inspections in the radioactive substance transport sector.

ASN also carried out 32 days of labour inspections in the four NPPs and on the Creys-Malville site.

In the exercise of its oversight duties, ASN drew up three violation reports and gave one nuclear activity manager formal notice to comply with the regulations.

In 2020, ASN was notified of 30 significant events rated level 1 on the International Nuclear and Radiological Event Scale (INES scale), of which 28 occurred in BNIs and 2 in small-scale nuclear activities.

Furthermore, one event was rated level 2 on the ASN-SFRO scale (scale specific to radiation protection events affecting patients undergoing a radiotherapy procedure).

BUGEY SITE

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

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

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

Bugey nuclear power plant

Reactors 2, 3, 4 and 5 in operation

ASN considers that the overall performance of the Bugey NPP with regard to nuclear safety, radiation protection and environmental protection is in line with ASN's general assessment of EDF plant performance. The NPP has satisfactorily controlled the impact of the sanitary crisis due to the Covid-19 pandemic, particularly with regard to monitoring and operation of the facilities, maintaining the emergency organisation and waste management.

ASN considers that the nuclear safety performance of the NPP remains contrasted, despite being in line with the general assessment of the EDF plants. The weaknesses observed in 2019 concerning compliance with the operating technical specifications, the implementation of error-reduction practices and the configuring of the systems persisted in 2020. Furthermore, lack of rigour was observed regarding monitoring in the control room and the identification and processing of deviations. On the other hand, ASN notes improvements in the monitoring of service providers, application of the operating and maintenance baseline requirements, and control of integrity of the first barrier which consists of the fuel assembly cladding. The four reactors of the Bugey NPP were shut down in 2020 for scheduled maintenance and partial refuelling. Quite apart from the health crisis situation, ASN considers that further progress is necessary in the control of outages, with improvements required notably in the management of conformity deviations, the scheduling and preparation of maintenance activities and activity quality assurance. The Bugey NPP reactors 2 and 4 were shut down in January and November 2020 respectively for their fourth ten-yearly outage, which is a part of the fourth periodic safety review.

With regard to radiation protection, ASN considers that the Bugey NPP's performance is in line with the general assessment of the EDF plants. Implementation of the radiation protection optimisation process during the reactor outages is satisfactory. Weaknesses are nevertheless observed in the radiological cleanliness of the facilities.

ASN considers that the environmental protection performance of the NPP is in line with its general assessment of the EDF plants. Waste management is considered satisfactory on the whole. The management of liquid containment, especially the prevention of the risks of leakage of buried structures (pipes and conduits) carrying radioactive and chemical fluids, has improved. However, the control of conformity of the ultimate structures contributing to environmental protection must be improved and deviations affecting them must be addressed with the same rigour as those relating to nuclear safety. Lastly, improvements are required in the management of emergency situations relating to the environment.

With regard to occupational health and safety, ASN's inspections also confirmed EDF's compliance with its commitments. ASN notes the significant work undertaken by the NPP to remedy the deviations concerning safety and the inspection of scaffolding. With regard to worker protection in response to the health crisis, ASN noted that as of March 2020 the site had put in place appropriate protection measures, which evolved as knowledge progressed. Improvements are expected of EDF in the demonstration of conformity of the ventilation of premises where there is a specific pollution risk and facilities situated in identified explosion-risk areas.

Reactor 1 undergoing decommissioning

Bugey 1 is a graphite-moderated GCR. 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" GCR, whose heat exchangers are situated inside the reactor vessel beneath the reactor core.

In March 2016, in view of the technical difficulties encountered, EDF announced a complete change of decommissioning strategy for its definitively shut down reactors. In this new strategy, the planned decommissioning scenario for all the reactor pressure vessels involves decommissioning "in air" rather than "under water" as initially envisaged. Through ASN Chairman's resolution CODEP-CLG-2020-021253 of 3 March 2020, in the context of EDF's change of decommissioning strategy, ASN instructed EDF to complete, by 2024 at the latest, decommissioning of the buildings and equipment which are not necessary for the decommissioning of the reactor pressure vessel.

In 2020, ASN authorised the creation of a new effluents storage facility at the Bugey 1 reactor to replace the old station, which will be put out of service, decommissioned and cleaned out.

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.

THE INSTALLATIONS AND ACTIVITIES TO REGULATE COMPRISES:

- **4 Nuclear Power Plants (NPPs) operated by EDF:**
  - Bugey (4 reactors of 900 MWe),
  - Saint-Alban (2 reactors of 1,300 MWe),
  - Cruas-Meysse (4 reactors of 900 MWe),
  - Tricastin (4 reactors of 900 MWe);
- **the nuclear fuel fabrication plants operated by Framatome in Romans-sur-Isère;**
- **the "nuclear fuel cycle" plants operated by Orano on the Tricastin industrial platform;**
- **the Operational Hot Unit (BCOT) at Tricastin, operated by EDF;**
- **the High Flux Reactor (RHF) operated by the Laue-Langevin Institute in Grenoble;**
- **the Activated waste packaging and storage facility (Iceda) under construction on the Bugey nuclear site and the Bugey Inter-Regional Warehouse (MIR) for fuel storage operated by EDF;**
- **reactor 1 undergoing decommissioning at the Bugey NPP operated by EDF;**
- **the Superphénix reactor undergoing decommissioning at Creys-Malville and its auxiliary installations, operated by EDF;**
- **the Ionisos irradiator in Dagneux;**
- **the CEA (French Alternative Energies and Atomic Energy Commission) reactors and plants in Grenoble, waiting to be delicensed;**
- **the CERN international research centre located on the Swiss-French border;**
- **small-scale nuclear activities in the medical sector:** p. 206
  - 22 external-beam radiotherapy departments,
  - 6 brachytherapy departments,
  - 23 nuclear medicine departments,
  - 130 facilities using fluoroscopy-guided interventional procedures,
  - 148 scanners within 115 facilities,
  - some 10,000 medical and dental radiology devices;
- **small-scale nuclear activities in the veterinary, industrial and research sectors:** p. 238
  - one synchrotron,
  - about 700 veterinary practices (surgeries or clinics),
  - 34 industrial radiology agencies,
  - about 600 users of industrial equipment,
  - about 70 research units;
- **activities associated with the transport of radioactive substances;** p. 266
- **ASN-approved laboratories and organisations:**
  - 3 organisations and 7 agencies approved for radiation protection controls.

On 28 July 2020 ASN authorised the commissioning of Iceda and regulated operation of the facility through requirements relative to the operating range, the maximum storage durations for radioactive waste, the defining of criteria for activating the on-site emergency plan, the content of the end-of-startup file, compliance with waste package qualification heights, and the conditions of reception of source rods from Chooz A. The first activated waste package was received in late September.

ASN has also set the time frame within which EDF shall submit the end-of-startup file, as provided for in Article R. 593-34 of the Environment Code.

Activated waste packaging and interim storage facility

The Activated waste packaging and interim storage facility (Iceda), which constitutes BNI 173, is intended for the packaging and storage of various categories of radioactive waste on the Bugey site (Ain *département*). It is designed to receive, package and store:

- low-level long-lived (LLW-LL) graphite waste from the dismantling of the Bugey 1 reactor, which is destined – after interim storage – for near-surface disposal in a facility whose concept is still being studied;
- activated metallic intermediate-level long-lived waste (ILW-LL) from the operation of the in-service power plants, for example parts which have spent time near the reactor core, such as control rod clusters, destined for deep geological disposal after interim storage;
- some low-level or intermediate-level short-lived waste (LL/ILW-SL), called "deferred transfer" waste, intended for above-ground disposal but requiring a period of radioactive decay ranging from several years to several decades before being accepted at the Aube repository (BNI 149), operated by the French national agency for radioactive waste management (Andra).

Inter-Regional Warehouse

MIR, the inter-regional warehouse (BNI 102) operated by EDF at Bugey, is a storage facility for fresh nuclear fuel intended for the nuclear power plant fleet in operation.

MIR presented a satisfactory overall level of safety in 2020, a year in which its activities were greatly restricted to allow the renovation of the main handling crane in particular. ASN nevertheless wants to see tightened operational monitoring of the activities. The periodic safety review of the facility is in progress, as are the stress tests requested by ASN following the Fukushima Daiichi NPP accident.

Saint-Alban nuclear power plant

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

ASN considers that the performance of the Saint-Alban NPP with regard to nuclear safety, radiation protection and environmental protection stands out positively in comparison with the general assessment of EDF plant performance. The NPP has satisfactorily managed the impact of the sanitary crisis due to the Covid-19 pandemic, particularly with regard to monitoring and operation of the facilities, maintaining the emergency organisation and waste management.

With regard to nuclear safety, ASN notes that the Saint-Alban NPP maintained its good performance in 2020, which is at a higher level than ASN's general assessment of the EDF power plants. Despite this, ASN noted that some events indicate that compliance which the operating technical specifications needs to be improved.

Concerning maintenance, only reactor 1 was scheduled for a refuelling and maintenance outage and ASN considers that the planned activities were on the whole well managed by EDF. During this outage, EDF finished integrating the modifications stemming from the third ten-yearly outage of the reactor. The Ultimate Backup Diesel generator sets (DUS) were also commissioned within the deadlines set by ASN.

With regard to worker radiation protection, ASN considers that the operational results were satisfactory. Although the availability of radiation protection equipment and the monitoring of entry points to work sites involving a contamination risk have improved, ASN found that the quality of the estimated dosimetric evaluations for EDF employees must be improved. Lastly, ASN is still waiting for improved compliance with work site access rules and the wearing of the requisite protective equipment.

ASN considers that the environmental protection performance of the Saint-Alban NPP stands out positively compared with the general standard of EDF plant performance and is stable with respect to the preceding years. The organisation defined and implemented by EDF to meet the regulatory requirements concerning the monitoring of discharges and the environment is found to be satisfactory.

The results concerning health and safety at work are also satisfactory. ASN notes in particular that no serious accidents occurred during the reactor 1 maintenance outage. Nevertheless, ASN observes a relatively high accident rate during this outage. With regard to worker protection in response to the health crisis, ASN noted that as of March 2020 the site had put in place appropriate protection measures, which evolved as knowledge progressed.

Cruas-Meysse nuclear power plant

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

ASN considers that the overall performance of the Cruas-Meysse NPP has improved and is on the whole in line with its general assessment of the EDF plants in the areas of nuclear safety, radiation protection and environmental protection.

The impact of the health crisis associated with the Covid-19 pandemic was managed satisfactorily by the NPP and the planned nuclear safety measures were maintained.

ASN considers that the nuclear safety performance of the Cruas-Meysse NPP is in line with ASN's general assessment of EDF plant performance. ASN notes that the site has improved its compliance with operating technical specifications and prevention of reactor trips. Nevertheless, in 2020 ASN observed shortcomings in compliance with the authorised reactor operating ranges. With regard to maintenance and work associated with the reactor outages, ASN considers that, despite the health crisis, the Cruas-Meysse NPP on the whole adequately managed the planned schedule and quality of the activities.

In the area of radiation protection, ASN considers that the performance of the Cruas-Meysse NPP is in line with its general assessment of the EDF plants, and maintains the assessment it made in 2019. Shortcomings nevertheless persist in the radiological cleanliness of the facilities and control of the contamination risk during reactor outage periods.

As far as environmental protection is concerned, ASN considers that the performance of the Cruas-Meysse NPP is also in line with the general assessment of the EDF plants and improving with respect to the preceding years. The improvement actions implemented to meet the regulatory requirements are bearing fruit. Lastly, waste management has been improved, even though ASN still notes a lack of rigour in operational application of the new organisation put in place to manage waste on storage areas and to prepare for its shipment.

The site's results in occupational health and safety are satisfactory. With regard to worker protection in response to the health crisis, ASN noted that as of March 2020 the site had put in place appropriate protection measures, which it adapted as knowledge progressed. The ASN inspections confirmed compliance with the commitments made by the site, leading to an improvement in the prevention of vital risks. The vigilance and efforts must nevertheless be maintained regarding risks relating to the use of chemical products and to lifting activities.

TRICASTIN SITE

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

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, radiation protection and environmental protection is in line with ASN's general assessment of EDF plant performance. The NPP has satisfactorily managed the impact of the sanitary crisis due to the Covid-19 pandemic, particularly with regard to monitoring and operation of the facilities, maintaining the emergency organisation and waste management.

ASN considers that the nuclear safety performance of the NPP remains contrasted, despite being in line with the general assessment of the EDF plants. The weaknesses observed in 2019 concerning compliance with the operating technical specifications, the implementation of error-reduction practices and the configuring of the systems persisted in 2020. Furthermore, difficulties were observed in the performance of the periodic tests. On the other hand, ASN notes improvements in the control of fire risks and the integrity of the first barrier made up by the fuel assembly cladding, despite one notable foreign-object related event when a screw was found in the reactor 4 pressure vessel during its refuelling. Regarding maintenance, the 4 reactors of the Tricastin NPP were shut down in 2020 for scheduled maintenance and partial refuelling. In the context of the health crisis, ASN considers that further progress is necessary in 2021 in the control of outages for scheduled maintenance and partial refuelling, with improvements required in particular in the management of conformity deviations, the scheduling and preparation of maintenance activities and quality assurance.

With regard to radiation protection, ASN considers that the NPP's performance is in line with the general assessment of the EDF plants and has improved with respect to 2019. Control of subcontracted activities in the area of radiation protection improved throughout the year 2020. Weaknesses are nevertheless still observed in the radiological cleanliness of the installations and the implementation of the radiation protection optimisation procedure during reactor outages, with difficulties in establishing accurate and appropriate dosimetric estimates.

ASN considers that the environmental protection performance of the NPP is in line with its general assessment of the EDF plants and has improved in comparison with preceding years. Control of liquid containment has improved. With regard to the control of activities relating to discharges and environmental monitoring, occasional deviations were observed in 2020, and ASN wants to see a return to a nominal effluent treatment situation after the difficulties encountered in recent years in the systems for evaporation treatment of radioactive effluents. Lastly, waste management is on the whole satisfactory, despite a persistent lack of rigour in the monitoring of the quantities of radioactive waste stored in the packaging auxiliaries building.

ASN considers that the occupational safety results for the site are satisfactory. ASN notes that no serious accidents occurred in 2020 and that the accident rate, particularly during the reactor outages, was kept under control. With regard to worker protection in response to the health crisis, ASN noted that as of March 2020 the site had put in place appropriate protection measures, which evolved as knowledge progressed.

THE "NUCLEAR FUEL CYCLE" FACILITIES

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, which became Orano Chimie-Enrichissement on January 2021 and is called Orano hereinafter.

The site comprises:

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

Following the inspections it conducted in 2020, ASN considers that the level of safety of the Orano facilities on the Tricastin site has remained stable. The industrial commissioning of new facilities with reassessed safety standards displayed contrasting results in 2020. ASN has checked the tests and the start of commissioning of the new waste treatment unit "Trident", and the results are considered satisfactory. The results are less clear-cut for the Philippe Coste conversion plant however, where ASN has noted difficulties in the monitoring of the crystalliser replacement work and the corrective actions required for pollution prevention.

In 2019, ASN authorised the application of a new version of the On-site Emergency Plan (PUI), adapted to the new organisation of the site, under the responsibility of Orano as sole licensee. This new organisation was inspected by ASN during a tightened inspection carried out on a Sunday along with an unannounced emergency exercise. The organisation is considered satisfactory on the whole, but ASN has requested several operational improvements.

The campaign of unannounced inspections that ASN carried out simultaneously in BNIs 93, 105, 138, 155, 168 and 178 in 2020 showed that pollution prevention and the control of accidental spillages is generally satisfactory, except in the conversion plants. ASN also conducted several inspections in 2020 focusing on the organisation of Orano's platform on the Tricastin site for managing its significant modifications. ASN noted that this organisation needs to be better harmonised on the site, but that the internal inspection body handles the modification files with greater efficiency.

In 2021, ASN will ensure that Orano continues to deploy its action plans to improve safety management in order to further harmonise the practises of the BNIs on the platform. Lastly, in 2021 ASN plans engaging itself with the Defence Nuclear Safety Authority (ASND) in a new phase of delicensing of a significant proportion of the DBNIs.

Orano 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 plant in La Hague to be processed for conversion into U_3O_8 (a stable solid compound that can guarantee storage of the uranium under safer conditions than in liquid or gaseous form). Once converted, the reprocessed uranium is 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 II plant, to stabilise it as U_3O_8.

ASN considers that the facilities situated within the perimeter of BNI 155 are operated with a satisfactory level of safety. The new unit of the W plant, called EM3, commissioned in mid-2018 and having necessitated hardware modifications in 2019, now functions nominally.

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

THE IMPACT OF COVID-19

ASN has noted that the Covid-19 pandemic has not disrupted the normal operation of the plants in service. The licensee managed to maintain safety and radiation protection both in the production units and on the BNI construction or modification worksites. During the first lockdown of the pandemic, all the facility decommissioning worksites were stopped, resulting in the year's targets falling behind schedule.

More generally, the licensee must maintain its efforts to increase its operating rigour, particularly through the detection and effective management of deviations.

Orano uranium fluorination plants

Pursuant to the ASN requirement, the oldest fluorination facilities were shut down definitively in 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.

The decommissioning of BNI 105 is now authorised by Decree 2019-1368 of 16 December 2019. The main issues associated with decommissioning concern the risks of dissemination of radioactive substances, of exposure to ionising radiation and of criticality, on account of the residual uranium-bearing substances present in some items of equipment. ASN expects the licensee to make the necessary efforts to repackage the packages containing radioactive and hazardous substances stored on areas 61 and 79 within the set deadlines.

ASN also inspected the upgrading of the process core of the Philippe Coste plant, whose facilities are classified Seveso high threshold and replace those of BNI 105 (formerly Comurhex). The main units of this plant were commissioned in 2019 and revealed design defects. The second fluorine production unit underwent tests with a view to gradual commissioning until the end of 2020.

For the Philippe Coste plant the year 2020 was thus marked by a "major shutdown" during which, among other things, all the crystallisers were replaced further to design defects which had led to degraded operating conditions for several months and to compensatory measures. ASN notes that the licensee conducted the analysis and resolved these technical difficulties efficiently. ASN verified that the process core had been properly upgraded but nevertheless detected a lack of supervision and monitoring of the crystalliser replacement work. Commissioning of the Philippe Coste plant's unit 68 for treating non-uranium-bearing effluents has again been postponed until 2021, on account of an inappropriate initial design.

Lastly, ASN notes that the year 2020 was marked by high production expectations of the Philippe Coste plant in a context where the licensee had to cope with difficulties due to the defects in its new facilities and the design obsolescence of the old facilities still in service. Through its oversight actions ASN observed that this context led to a reduction in the control of risks in the management of nonconformities and technical problems. This context also led to the reporting of numerous events significant for the environment.

In 2021, ASN will be attentive firstly to the conditions of commissioning of the new fluorine production unit and the effluent treatment unit of the Philippe Coste plant, and secondly to the repackaging and processing of the uranium-bearing materials present in BNI 105 in preparation for its decommissioning.

Georges Besse I enrichment plant

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

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

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

The decommissioning issues particularly concern the large volume of very low level waste (VLLW) produced, including 160,000 tonnes of metal waste. In 2020, ASN monitored firstly the licensee's preliminary studies and operations to determine the procedures for cutting up the components, and secondly the supervision of the effluent transfers and the materials still to be removed.

In 2020, ASN checked the effective operation of the facility for hydraulic containment and treatment of the alluvial water table polluted with perchloroethylene and trichloroethylene and considers the results satisfactory.

The main residual risk of BNI 93 is now associated with the UF_6 containers in the storage yards, which are still attached to the perimeter of the facility. These yards should ultimately be attached to the Tricastin uranium storage yards (BNI 178).

Georges Besse II enrichment plant

The Georges Besse II plant, BNI 168, became the site's new enrichment facility following the shutdown of Eurodif. It uses the centrifuge process to separate uranium isotopes.

The standard of safety of the plant's facilities in 2020 was satisfactory. The technologies utilised in the facility enable high standards of safety, radiation protection and environmental protection to be reached. ASN considers that the licensee is proactive in the detection of deviations from its baseline requirements and duly meets the commitments made to ASN.

Deterioration of the rail tracks of the external UF_6 cylinder handling gantry cranes obliged the licensee to stop using them since October 2020 and to use other handling equipment to move the cylinders. ASN will check that these gantry cranes are repaired in 2021, as they enhance the safety of the cylinder handling operations.

Despite an ambitious action plan deployed in 2019 and 2020, the licensee must continue its search for the causes of the significant losses of refrigerant to the atmosphere. Several facility modification applications authorised in 2020 will be implemented in 2021 and ASN will keep a close watch to ensure their safe application.

Maintenance, effluent treatment and waste packaging facilities

The effluent treatment and uranium recovery facility, constituting BNI 138 (formerly Socatri), ensures the treatment of liquid effluents and waste, as well as maintenance operations for various BNIs. ASN considers that the licensee's efforts to improve the level of operational safety and operating rigour must be continued, particularly regarding prevention of the fire risk. In effect, shortcomings – some of them significant – were identified during two inspections on this theme in 2020.

Decree 2019-113 of 19 February 2019 authorised substantial modifications to the BNI, notably to create "Trident", a facility for treating the site's waste. In 2020, ASN inspected the end of the fitting out work in this facility and its tests. ASN issued the commissioning authorisation and "Trident" gradually began operational service in September 2020.

In 2021, ASN will be attentive firstly to the operation of the Trident facility, and secondly to the continuation of the licensee's actions to increase operating rigour, including prevention of the fire risk.

Tricastin uranium-bearing material storage yards and P35

Following the delicensing of part of the Pierrelatte DBNI by decision of the Prime Minister, the Tricastin uranium-bearing materials storage yards (BNI 178) have been created. This facility groups the uranium storage yards and the new emergency management premises of the Tricastin platform. Following on from the Pierrelatte DBNI delicensing by decision of the Prime Minister, the "P35" facility (BNI 179) has been created. This facility comprises ten uranium storage buildings. ASN registered BNI 178 in December 2016 and BNI 179 in January 2018, and made sure, with ASND, of the continuity of oversight of the nuclear safety of these facilities.

The overall level of safety of BNIs 178 and 179 operated by Orano was satisfactory in 2020. Progress has been made in the upkeep and cleanliness of the facilities. The licensee still has to process several legacy packages for which control of ageing has not been demonstrated. This point is one of the subjects of the analysis of the periodic safety review concluding report for BNIs 178 and 179 that ASN carried out in 2020. As a general rule, the licensee must improve its compliance with the deadlines for sending ASN replies to follow-up letters and submitting significant event reports, and with the deadlines for commitments made to ASN for the correction of deviations and the updating of its safety baseline requirements. With regard to the emergency management building and equipment, the licensee has improved its internal operating rules aiming to guarantee operation of the emergency centre and the various mobile emergency equipment items.

New uranium storage facility project

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

Tricastin analysis laboratory

Authorised by Decree 2015-1210 of 30 September 2015 and commissioned in May 2017, the Tricastin analysis laboratory, Atlas, constitutes BNI 176. The facility represents a significant improvement in safety compared with the old laboratories it replaces.

Two of the three UF_6 analysis and sampling benches have been functioning since February 2018 following validation of the preliminary test results. The start-up of the last bench, which will finalise the complete commissioning of the facility, was planned for 2019. However, major difficulties were encountered in sealing the bench in 2019 and 2020, which led ASN to conduct regular inspections on this subject.

As a general rule, ASN has noted a significant improvement in the licensee's deviation management and is now waiting for it to safely finalise the installation operations of the third UF_6 sampling bench and to improve the management of the ventilation system downtimes.

Tricastin Operational Hot Unit

The Tricastin Operational Hot Unit (BCOT) constitutes BNI 157. Operated by EDF, it was intended for the maintenance and storage of equipment and tooling, fuel elements excluded, originating from contaminated systems and equipment of the nuclear power reactors.

In a letter dated 22 June 2017, EDF declared final shutdown of the BCOT in June 2020. The storage and maintenance operations shall now be carried out on the Saint-Dizier maintenance base.

The last operating activity consists in finishing cutting up the used fuel cluster guide tubes from the PWR's operated by EDF. ASN considers that the level of safety of the BCOT is on the whole satisfactory. In 2021, ASN will be attentive to the rate of the fuel cluster guide tube cutting-up operations and to the planned removals of massive parts and obsolete tooling.

ROMANS-SUR-ISÈRE SITE

Framatome operates two BNIs on its Romans-sur-Isère site in the Drôme *département*, namely the plant fabricating fuel elements for research reactors (BNI 63) and the plant fabricating nuclear fuel for the PWRs (BNI 98).

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).

BNI 63 includes building F 2, which houses the "uranium zone" in which compacted powder cores placed in aluminium frames and plates are produced. The licensee has undertaken to replace this uranium zone by a new uranium zone called "NZU", in order to improve more specifically the containment of the premises, the process and the prevention of risks in the event of an extreme earthquake. The NZU construction work began in late 2017 and must accommodate the current activities of the uranium zone of building F 2 before 31 December 2022. This is because as from that date, which is stipulated in ASN resolution 2019-DC-0670 of 4 June 2019 relative to the periodic safety review of BNI 63, the presence of radioactive material in the uranium zone of building F2 shall be prohibited. Construction of the NZU continued in 2020, with the production of the new storage compartments for uranium-bearing materials and the glove boxes. The safety report update and the new operating rules associated with the NZU should be submitted in the first quarter of 2021.

A request for a modification of the Order of 22 June 2000 governing water intakes, discharges and environmental monitoring of the Romans-sur-Isère nuclear site was also submitted to ASN in July 2020. This request follows on from several changes, including in particular the modification of the Decree authorising creation of BNI 98 to increase its production capacity, the stopping of certain activities, the taking into account of the changes made to the liquid effluent treatment facilities, and the changeover from continuous discharging of liquid effluents to discharging into tanks. This file is currently being examined with a view to the preparation of two ASN resolutions: the first stipulating the requirements relative to the conditions of effluent discharge, water intakes and consumption and environmental monitoring, the second stipulating the environmental discharge limits.

Lastly, because the buildings of BNIs 98 and 63 are closely interlinked on the same site, a request to unite the two BNIs was submitted in 2020 and is currently being examined. In the last quarter of 2020 Framatome also filed a request for a substantial modification to BNI 98 so that it can increase its production of enriched reprocessed uranium.

Three significant events relating to control of the criticality risk and rated level 1 on the INES scale were reported in 2020. Particular vigilance remains essential with regard to the presence of radioactive material within the BNI 98 plants.

The sampling inspections in 2020 confirmed satisfactory accomplishment of the work carried out in summer 2020 in the F2 facility of BNI 63 and monitoring of qualification of the Protection Important Components (PIC) of the Geode unit (new waste conditioning facility) of BNI 98. It was observed that the licensee maintained its efforts with regard to operating rigour, particularly to provide proof of conformity of the PICs. As far as the overall waste management strategy is concerned, the Romans-sur-Isère site must make further progress, particularly in the preparation of the management of the radioactive waste produced during the large-scale works and the deployment of the management rules on all the facilities.

In 2021, ASN will be particularly attentive to the smooth running of the NZU worksite project. It will also closely monitor restarting of the TRIGA (Training, Research, Isotopes, General Atomics) facility of BNI 63 and the putting into service of Capadox, the new oxidation capability of BNI 98.

THE IMPACT OF COVID-19

ASN noted that the Covid-19 pandemic did not disrupt the normal operation of Framatome in the fabrication of nuclear fuels or the production of medical targets. The licensee managed to maintain safety and radiation protection in all its production units. One inspection was carried out on the organisation put in place during the pandemic and showed that the means deployed by the licensee were satisfactory and the level of safety maintained at the required level. The pandemic did however lead to the stoppage of the worksites of the Training, Research, Isotopes, General Atomics (TRIGA) facility, of the new oxidation capability (Capadox) and of the New Uranium Zone (NZU) from March to June 2020.

THE INDUSTRIAL AND RESEARCH FACILITIES

High flux reactor of the Laue-Langevin Institute

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

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

Through its inspection activities in 2020, ASN considers that the safety of the RHF is managed satisfactorily and that the integrated management system is correctly applied. Several inspection actions in 2020 targeted areas in which shortcomings had been detected in the preceding years. ASN has noted improvements in the management of waste and modifications, and in quality at the environmental radioactivity measurements laboratory. The ILL had established an ambitious action plan in 2018 to control fire-related risks. ASN observed that this plan was progressing but that several large-scale works were still unfinished. Attention shall continue to be focused on this area in the next few years. ASN continued its examination of the periodic safety review report in 2020 and will be attentive to the various action plans put in place by the ILL in this context.

THE IMPACT OF COVID-19

During the spring 2020 lockdown on account of the health crisis, the reactor was placed in safe condition (reactor shut down, fuel unloaded). The ILL maintained only its monitoring and servicing activities. The activities relating to the works and experiments were suspended.

Ionisos irradiator

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

The level of safety of the facility was found to be satisfactory in 2020.

ASN considers that the licensee must continue the foundation work initiated in 2019 aiming to better define the Components Important to the Protection (PIC) of the interests of the facility and more rigorous application of their requirements defined in the periodic inspection and test procedures.

In a letter dated 25 May 2020 the licensee applied for an authorisation to recover sludge from pool D1 (operated until November 1996). This file is currently being examined by ASN.

CERN accelerators and research centre

Following the signing of an international agreement between France, Switzerland and the European Organisation for Nuclear Research (CERN) on 15 November 2010, ASN and the Swiss Federal Office of Public Health (OFSP) – the Swiss radiation protection oversight body – are contributing to the verification of the safety and radiation protection requirements applied by CERN. The joint actions concern transport, waste and radiation protection.

Two joint visits by the Swiss and French Authorities took place in 2020 on the theme of following up the previous joint visits and on the security of sources. These visits revealed satisfactory practices.

FACILITIES UNDERGOING DECOMMISSIONING

Superphénix reactor and 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. In 2018, ASN authorised commencement of the second Superphénix decommissioning phase, which consists in opening the reactor pressure vessel to dismantle its internal components, in dedicated facilities constructed in the reactor building, by direct or remote manipulation. The safety and radiation protection measures implemented by EDF for these operations are on the whole satisfactory.

In 2020, a fire broke out on a decommissioning worksite, leading EDF to activate its on-site emergency plan and prompting ASN to carry out a reactive inspection. Shortcomings were found at various levels in the execution of the procedures during this incident, particularly as regards communication with the stakeholders.

Concerning the management of facility obsolescence, EDF reported difficulties in procuring certain items of equipment and significant delays in the replacement and repair of parts. ASN has asked the licensee to carry out a site-level diagnosis and to draw up an action plan on this subject.

ASN will focus particular attention on the improvement in the site's emergency organisation in 2021.

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 reactor in August 2017.

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

The technical discussions between ASN and the CEA concerning the radiological and chemical remediation of the soil of the STED continued in 2018. All the operations that can be technically achieved at a reasonably acceptable cost have been carried out. In view of the presence of residual chemical and radiological contamination, the licensee submitted a delicensing file along with a file for establishing active institutional controls in December 2019, which were deemed inadmissible by ASN in 2020 and for which the licensee must submit a new request.

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.

ASN conducted 59 inspections in small-scale nuclear activities in the Bourgogne-Franche-Comté region in 2020, comprising 23 inspections in the medical sector, 22 inspections in the industrial research and veterinary sectors, 3 inspections concerning radon exposure, 5 inspections to monitor approved organisations and laboratories, and 6 inspections specific to the transport of radioactive substances.

One significant event rated level 2 on the ASN-SFRO scale was reported to ASN in 2020.

ASN also devoted particular attention to the Framatome manufacturing plants situated in the Bourgogne-Franche-Comté region. The actions conducted by ASN in this context are described in chapter 10. ASN carried out 6 inspections in these plants in 2020.

THE INSTALLATIONS AND ACTIVITIES TO REGULATE COMPRISES:

- **small-scale nuclear activities in the medical sector:** p. 206
  - 8 external-beam radiotherapy departments,
  - 4 brachytherapy departments,
  - 14 nuclear medicine departments, of which 3 practise internal targeted radiotherapy,
  - 35 centres performing interventional fluoroscopy-guided procedures,
  - 55 computed tomography scanners for diagnostic purposes,
  - about 800 medical radiology devices,
  - about 2,000 dental radiology devices;
- **small-scale nuclear activities in the veterinary, industrial and research sectors:** p. 238
  - about 250 veterinary practices, 3 of them equipped with scanners,
  - about 400 industrial and research centres, including 31 companies with an industrial radiography activity,
  - 1 industrial irradiator per radioactive source,
  - 2 computed tomography scanners dedicated to research,
  - 2 accelerators, one for industrial irradiation, the other for research and the production of drugs for medical imaging;
- **activities associated with the transport of radioactive substances;** p. 266
- **ASN-approved laboratories and organisations:**
  - 3 organisations approved for radiation protection controls,
  - 5 organisations approved for measuring radon,
  - 1 laboratory approved for taking environmental radioactivity measurements.

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 Nuclear Power Plant (Brennilis), currently undergoing decommissioning.

In 2020, ASN carried out 44 inspections: 2 at the Monts d'Arrée Nuclear Power Plant (NPP) undergoing decommissioning, 40 in small-scale nuclear activities and 2 in the transport of radioactive substances.

In 2020, 2 significant events in the medical sector were rated level 1 on the International Nuclear and Radiological Event Scale (INES scale).

Brennilis nuclear power plant

The Brennilis NPP is situated in the Finistère *département*, on the Monts d'Arrée site 55 km north of Quimper. Baptised EL4-D, this installation (BNI 162) is an industrial electricity production prototype (70 Megawatts electric – MWe) moderated with heavy water and cooled with carbon dioxide, and it was definitively shut down in 1985.

Decree 2011-886 of 27 July 2011 authorised the NPP decommissioning operations, with the exception of the reactor block. In July 2018, EDF submitted an application file for the complete decommissioning of its installation. This file is currently being examined by ASN.

During 2020, EDF more specifically:

- continued the preparatory work for reactor block decommissioning,
- started the reactor block sample-taking operations, authorised by ASN resolution of 20 September 2019,
- continued demobilisation of the former Effluent Treatment Station (STE) decommissioning worksite and, at the request of ASN, had deep soil samples taken from ground beneath the STE for analysis,
- implemented the protocol authorised in January 2020 for the gradual and controlled raising of the water table level.

Some operations, such as taking samples from the reactor block, were delayed due to the restrictions imposed to combat the Covid-19 pandemic. The activities were nevertheless resumed at the end of 2020.

ASN considers that the licensee is conducting its work in compliance with the safety and radiation protection requirements and is demonstrating transparency in the detection, handling and analysis of the malfunctions and events occurring on its site.

THE INSTALLATIONS AND ACTIVITIES TO REGULATE COMPRISES:

- **the Basic Nuclear Installation:**
  - the Monts d'Arrée (Brennilis) NPP, undergoing decommissioning;
- **small-scale nuclear activities in the medical sector:** p. 206
  - 10 external-beam radiotherapy departments,
  - 5 brachytherapy departments,
  - 10 nuclear medicine departments,
  - 40 centres using interventional procedures,
  - 54 computed tomography scanners,
  - some 2,500 medical and dental radiology devices;
- **small-scale nuclear activities in the veterinary, industrial and research sectors:** p. 238
  - 1 cyclotron,
  - 12 industrial radiography companies, including 4 performing gamma radiography,
  - about 450 industrial equipment and research licenses;
- **activities associated with the transport of radioactive substances;** p. 266
- **ASN-approved laboratories and organisations:**
  - 5 organisations approved for radiation protection controls,
  - 14 organisations approved for measuring radon,
  - 3 head-offices of laboratories approved for taking environmental radioactivity measurements.

In 2021, ASN will continue its examination of the complete decommissioning file and of the concluding report on the Brennilis site periodic safety review submitted at the end of 2019.

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.

In 2020, ASN carried out 151 nuclear safety and radiation protection inspections: 123 inspections of the nuclear installations on the EDF sites of Belleville-sur-Loire, Chinon, Dampierre-en-Burly and Saint-Laurent-des-Eaux, and 28 inspections in small-scale nuclear activities in the Centre-Val de Loire region.

ASN also ensured 64 days of labour inspection in the Nuclear Power Plants (NPPs).

In 2020, 8 significant events rated level 1 on the International Nuclear and Radiological Event Scale (INES scale) were reported by licensees of the EDF nuclear facilities in the Centre-Val de Loire region.

ASN inspectors issued 5 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 1,300 MWe reactors commissioned in 1987 and 1988, which constitute BNI 127 and 128 respectively.

ASN considers that the performance of the Belleville-sur-Loire NPP is in line with ASN's general assessment of the EDF plants in the areas of nuclear safety and radiation protection. The environmental performance, however, is below the national average.

With regard to nuclear safety, the tightened surveillance exercised by ASN from 2017 to 2019 led the licensee to implement an action plan to improve the site's performance in facility management. ASN considers that the site's performance in this area in 2020 once again reached a generally satisfactory level and that it must keep up this level of rigour to maintain the observed improvements over the long term. The inspections revealed good management of the periodic tests and an improvement in the monitoring of parameters in the control room. Progress must nevertheless be made in the detection of deviations.

With regard to maintenance of the facilities, the NPP's performance must be improved, particularly in view of the unforeseen events induced by the performance of maintenance operations during the 10-yearly outage of reactor 1. Lastly, fire risk control is unsatisfactory: ASN effectively observed numerous deviations during inspections focusing on management of the fire risk, and two significant fire outbreaks occurred on the site in 2020.

ASN considers that the radiation protection performance of the Belleville-sur-Loire NPP is satisfactory. The licensee has maintained a high standard of rigour in radiation protection during the health crisis. It nevertheless appears that the implementation of measures to limit the exposure of certain workers to ionising radiation is insufficient.

In the area of environmental protection, ASN considers that waste management and the monitoring of discharges in normal operating conditions are satisfactory. On the other hand, the inspections carried out in 2020 revealed inadequate management of containment of the water used to extinguish fires that occurred on the site. ASN moreover observed several deviations concerning the prevention of the risk associated with Legionella. The site rapidly made commitments on this subject.

With regard to labour inspection in the context of the Covid-19 pandemic, various document and field inspections were carried out on the theme of health crisis management, particularly during the activities to seal the reactor 1 containment wall. The observations addressed to the NPP and to the subcontractor companies resulted in corrective actions. The licensee is also expected to take action in response to the finding made during the inspections conducted in the buildings of the Ultimate Backup Diesel generators (DUS), commissioned in 2020. Lastly, an inspection was carried out on the secondment of foreign employees.

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 Nuclear Rapid Intervention Force (FARN), the special emergency response force created by EDF in 2011 following the Fukushima Daiichi NPP accident. Its role is to intervene in pre-accident or accident situations, on any NPP in France, by providing additional human resources and emergency equipment.

ASN considers that the nuclear safety performance of the Dampierre-en-Burly NPP is in line with its general assessment of the EDF plants, even if the level of safety of the site has dropped compared with 2019. Environmental and radiation protection performance, for their part, remain below the national average.

As far as nuclear safety is concerned, performance in normal operational control is acceptable on the whole and progress in the configuring of systems is to be underlined. On the other hand, organisational deficiencies relating to skills, the training of operating staff and the management of the periodic tests of safety-important components led to several significant event reports during 2020. With regard to maintenance of the facilities, ASN notes that the corrective actions conducted by the site are still insufficient, particularly concerning equipment conformity and compliance with the applicable baseline requirements, since numerous deviations are detected during inspections on these subjects and in the context of reactor outage monitoring. Moreover, and for several years now, the control of the fire and explosion risks is not entirely satisfactory.

The radiation protection performance of the Dampierre-en-Burly NPP is still clearly inadequate, particularly with regard to the control of radiological cleanliness and the dispersion of contamination on worksites in controlled areas. A plan of rigour was put in place on the site in 2017, but did not produce the expected results. Given this situation, ASN will maintain targeted monitoring of the site's radiation protection in 2021.

Lastly, the environmental protection performance of the Dampierre-en-Burly NPP must be improved. Although the discharge limits for gaseous and liquid effluents are observed on the whole, the licensee must rapidly undertake corrective actions regarding management of the Legionella risk (given the exceeding of limit values observed in 2020), management of waste and management of hazardous substance containment.

With regard to labour inspection, the site must now put in place plans to remedy the nonconformities detected further to last year's actions in the electrical field. Lastly, the licensee is also expected to take action in response to the findings made during the inspections conducted in the buildings of the Ultimate Diesel Generator (DUS) commissioned in 2020. In the context of the Covid-19 pandemic, various inspections concerning management of the health crisis were carried out on documents and in the field. The observations addressed to the NPP and to the subcontractor companies resulted in corrective actions.

THE INSTALLATIONS AND ACTIVITIES TO REGULATE COMPRISES:

- **Basic Nuclear Installations:**
  - the Belleville-sur-Loire NPP (2 reactors of 1,300 MWe),
  - the Dampierre-en-Burly NPP (4 reactors of 900 MWe),
  - the Saint-Laurent-des-Eaux site: the NPP in operation (2 reactors of 900 MWe), and the 2 French Gas-Cooled Reactors (GCRs) 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) for fresh fuel;
- **small-scale nuclear activities in the medical sector:** p. 206
  - 8 external-beam radiotherapy departments,
  - 3 brachytherapy departments,
  - 11 nuclear medicine departments,
  - 32 centres using fluoroscopy-guided interventional procedures,
  - 38 computed tomography scanners,
  - some 2,700 medical and dental radiology devices;
- **small-scale nuclear activities in the veterinary, industrial and research sectors:** p. 238
  - 10 industrial radiography companies,
  - about 330 industrial, veterinary and research radiography devices;
- **activities associated with the transport of radioactive substances;** p. 266
- **ASN-approved laboratories and organisations:**
  - 2 organisations approved for radiation protection controls,
  - 4 laboratories approved for taking environmental radioactivity measurements.

CHINON SITE

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

Chinon nuclear power plant

Reactors B1, B2, B3 and B4 in operation

ASN considers that the performance of the Chinon NPP is in line with its general assessment of the EDF plants in the areas of nuclear safety, radiation protection and the environment.

ASN considers that the site is maintaining a satisfactory standard in incident and accident management and in the analysis of deviations that could affect safety. The year 2020 was nonetheless marked by an increase in significant events linked to failure of the operating teams to comply with the general operating rules, which is why ASN considers that the safety performance of the NPP is dropping.

The radiation protection performance of the Chinon NPP, which has been dropping since 2018, can be improved. The year 2020 was marked by a non-negligible number of significant radiation protection events, notably due to workers failing to wear dosimeters and to deficiencies in application of the radiation protection measures mentioned in the worksite risk analyses.

The environmental performance of the Chinon NPP must be improved. Although the discharge limits for gaseous and liquid effluents are on the whole respected, a case of exceeding of the average activity concentration was observed in 2020 in the Loire further to an error in the activity analysis of an effluent discharged by the site. Furthermore, the times taken by the NPP to reconstitute the sealing of the network that is supposed to collect the fire extinguishing water in the event of a fire are inappropriate for the risks, and the rigour of waste management is not of the required level. The licensee must take priority actions to address these deviations.

As far as labour inspection is concerned, the licensee must make improvements to ensure better control of the electrical risk and to respond to the findings made during the inspections in the buildings of the DUS sets commissioned in 2020. Lastly, an inspection was carried out on the secondment of foreign employees. In the context of the Covid-19 pandemic, various inspections concerning management of the health crisis were carried out on documents and in the field. The observations addressed to the NPP and to the subcontractor companies resulted in corrective actions.

Reactors A1, A2 and A3 undergoing decommissioning

The graphite-moderated GCRs series comprises six reactors, including Chinon A1, A2 and A3. These first-generation reactors used natural uranium as the fuel, graphite as the moderator and were cooled by gas. This plant series includes “integrated” reactors, whose heat exchangers are situated under the reactor core inside the vessel, and “non-integrated” reactors, whose heat exchangers are situated on either side of the reactor vessel. The Chinon A1, A2 and A3 reactors are “non-integrated” GCR reactors. They were shut down in 1973, 1985 and 1990 respectively.

Reactors A1 and A2 were partially decommissioned and transformed into storage facilities for their own equipment (Chinon A1 D and Chinon A2 D). These operations were authorised by the Decrees of 11 October 1982 and 7 February 1991 respectively. Chinon A1 D is partially decommissioned at present and has been set up as a museum – the Museum of the Atom – since 1986. Chinon A2 D is also partially decommissioned and houses GIE Intra (which operates robotised machines for interventions on accident-stricken nuclear installations. Complete decommissioning of the Chinon A3 reactor was authorised by the Decree if 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 (see chapter 13). ASN Chairman’s resolution CODEP-CLG-2020-021253 of 3 March 2020 requires EDF to submit a decommissioning file for the Chinon reactors A1 and A2 and to update that of Chinon A3 before the end of 2022 to take account of the changes in decommissioning scenario and time frame modifications.

The decommissioning worksites were delayed by several months in 2020 on account of the restrictions laid down to combat the Covid-19 pandemic. EDF has nevertheless put in place its activity continuity plan to maintain some of the worksites and perform the periodic inspections and tests of its equipment.

With regard to the Chinon A2 reactor, EDF has continued the decommissioning preparation operations outside the reactor pressure vessel and carried out investigations inside the pressure vessel. EDF also continued the decommissioning of the Chinon A3 heat exchangers following several interruptions in 2019 and 2020 due to the discovery of asbestos.

ASN considers that the level of safety of the Chinon nuclear installations undergoing decommissioning (Chinon A1, A2 and A3) is satisfactory. The inspections conducted in 2020 have more specifically revealed proficiency in on-site waste management and monitoring of the electrical installation inspections. Improvements are however necessary in the application of the outside contractor monitoring programme. Weaknesses were also observed in the lightning protection of Chinon A2.

THE "NUCLEAR FUEL CYCLE" FACILITIES

Inter-regional fresh fuel warehouse

Commissioned in 1978, the Chinon MIR is a facility for storing fresh fuel assemblies pending their utilisation in various EDF reactors. It constitutes BNI 99. Along with the Bugey MIR, it contributes to the management of flows of fuel assembly supplies for the reactors.

The MIR was equipped with a new handling crane in 2019. In the context of the updated baseline requirements, authorised by ASN, nominal operation of the facility resumed in 2020 with the reception and storage of fresh fuel assemblies. An inspection confirmed the smooth running of the operations in the facility.

RESEARCH FACILITIES UNDERGOING DECOMMISSIONING

Irradiated materials facility

The AMI which was declared and commissioned in 1964, is situated on the Chinon nuclear site and operated by EDF. This facility (BNI 94) has stopped operating and is waiting to be decommissioned. 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 Ceidre integrated laboratory (Lidec).

ASN completed its examination of the decommissioning file in 2020 and issued its opinion on the draft Decommissioning Decree in early 2020. The AMI Decommissioning Decree 2020-499 was published on 30 April 2020 and its entry into effect will mark the start of the facility decommissioning phase.

With a view to decommissioning the facility, the AMI activities were essentially decommissioning preparation and monitoring operations. The main activity in 2020 was the continued treatment and removal of the legacy waste and various unused items of equipment. Thus all the legacy waste from the wells (other than the magnesian waste) has been characterised and packaged. Furthermore, there is no more liquid waste to treat. The legacy magnesian waste for its part should be packaged by early 2021.

The large majority of the worksites were stopped from mid-March to the beginning of June 2020 on account of the health crisis. During this period, only the essential activities (the periodic inspections and tests in particular) were maintained. The non-essential activities were gradually resumed and returned to a normal level of activity in September 2020.

ASN considers that the management of the support functions and of the electrical power supplies in particular, is satisfactory. Particular attention must nevertheless be paid to operation of the ventilation system and determining the causes of the failures encountered. As an example, improvements are required in the monitoring of the negative pressure values recorded and the efficiency tests of the High-Efficiency Particulate Air ("HEPA") filters.

The licensee must moreover be stricter in its application of certain regulatory provisions, particular with regard to waste management or packaging.

SAINT-LAURENT-DES-EAUX SITE

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

Saint-Laurent-des-Eaux nuclear power plant

Reactors B1 and B2 in operation

ASN considers that the performance of the Saint-Laurent-des-Eaux NPP with regard to nuclear safety and radiation protection is in line with its general assessment of the EDF plants. The environmental protection performance stands out positively and is considered satisfactory on the whole.

With regard to nuclear safety, ASN observes that the site's performance has been stable since 2018 despite putting in place a safety rigour plan. The origin of the deviations has nevertheless changed. Several events reveal deficiencies in the detection of deviations, compliance with the action to take or the reference documentation used for the activities. To give an example, in 2020 the Saint-Laurent-des-Eaux NPP experienced a reactor trip with unwanted operation of a safeguard system, which revealed deficiencies in the preparation and performance of certain activities, although corrective actions have been put in place since then. ASN wishes to underline the good overall upkeep of the worksites and the apparently satisfactory condition of the inspected equipment.

As a general rule, the management of radiation protection at the Saint-Laurent-des-Eaux NPP on the whole meets the expectations of ASN. The number of deviations detected by ASN in 2020 is down compared with 2019, when a tightened radiation protection was carried out. This finding must also be correlated with the fact that only one reactor outage took place in 2020, whereas usually there are two.

The organisation of the site to meet the environmental protection regulatory requirements is considered satisfactory. The various facilities inspected are well kept. The management of waste, like the liquid and gaseous discharges, raised no particular remarks.

As far as labour inspection is concerned, further to the fire-risk inspection carried out in 2019, the NPP must continue its efforts regarding the utilisation and maintenance of the evacuation systems. Lastly, the licensee is also expected to take action in response to the findings made during the inspections conducted in the buildings of the DUS. In the context of the Covid-19 pandemic, various inspections concerning management of the health crisis were carried out on documents and in the field. The observations addressed to the NPP and to the subcontractor companies necessitated corrective actions.

Reactors A1 and A2 undergoing decommissioning

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

However, given the change in the decommissioning strategy for the GCRs indicated by EDF in 2016, ASN Chairman's resolution CODEP-CLG-2020-021253 of 3 March 2020 requires EDF to submit a new decommissioning file before the end of 2022, to modify the current decree in view of the changes in the scenario for decommissioning the reactor pressure vessel and the changes in the stated time frames (see chapter 13).

The decommissioning worksites were delayed by several months in 2020 on account of the restrictions laid down to combat the Covid-19 pandemic. EDF has nevertheless put in place its activity continuity plan to maintain some of the worksites and perform the periodic inspections and tests of its equipment.

ASN considers that the level of safety of the Saint-Laurent-des-Eaux A reactors is satisfactory. ASN's inspections found that the overall upkeep of the premises and worksites was good. In addition, the organisation put in place to control the static and dynamic containments of the facilities is satisfactory. ASN also notes that the radioactive effluents present on the nuclear waste storage areas have been repackaged in long-term containers better suited to the characteristics of the effluents. However, monitoring of ageing of the equipment used in the decommissioning operations must be improved.

Saint-Laurent-des-Eaux silos

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

Operation of this BNI is limited to surveillance and upkeep measures: radiological monitoring inspections and measurements in the silos, checking there is no water ingress, checking the relative humidity, the dose rates around the silos, the activity of the water table, monitoring the condition of the civil engineering structures. ASN's inspections found that these actions were carried out satisfactorily.

In the context of the change of decommissioning strategy for the GCRs, EDF announced in 2016 its decision to start removing the graphite sleeves from the silos without waiting for a 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.

ASN is waiting for EDF to declare the final shutdown of the facility. Submission of the decommissioning file, which will take into account the emptying, post-operational clean-out and demolition of the existing silos, is planned for 2022.

Corse (Corsica) Collectivity

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

In 2020, ASN carried out 6 inspections in Corse, of which 5 were in the medical sector and 1 in the industrial sector.

THE INSTALLATIONS AND ACTIVITIES TO REGULATE COMPRISES:

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

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- **small-scale nuclear activities in the veterinary, industrial and research sectors:**
  - some 40 veterinary surgeons using diagnostic radiology devices,
  - some 40 industrial and research centres, including 1 company with an industrial radiography activity;

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- **activities associated with the transport of radioactive substances;**

p. 266

- **ASN-approved laboratories and organisations:**
  - 2 organisations approved for measuring radon.

Overseas *départements* and regions

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

Six inspections were carried out in the small-scale nuclear activities sector on the île de la Réunion in the French Overseas *départements* and regions in 2020.

In 2020, one event concerning patients was rated level 2 on the ASN-SFRO scale.

THE INSTALLATIONS AND ACTIVITIES TO REGULATE COMPRISES:

- **small-scale nuclear activities in the medical sector:** p. 206
  - 4 external-beam radiotherapy departments,
  - 2 brachytherapy departments,
  - 3 nuclear medicine departments,
  - 24 centres performing interventional fluoroscopy-guided procedures,
  - about 30 centres in possession of at least one computed tomography scanner,
  - about 100 medical radiology practices,
  - about 1,000 dental radiology devices;
- **small-scale nuclear activities in the veterinary, industrial and research sectors:** p. 238
- **more than 70 users of veterinary radiology devices,**
  - 3 industrial radiography companies using gamma radiography devices,
  - 1 cyclotron;
- **activities associated with the transport of radioactive substances.** p. 266

Grand Est Region

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

In 2020, ASN conducted 170 inspections in the Grand Est region, of which 79 were in the NPPs in service, 4 in radioactive waste disposal facilities and on the site of the Chooz A NPP currently being decommissioned, 73 in the small-scale nuclear activities sector, 8 in the transport of radioactive substances and 6 concerning approved organisations or approved laboratories.

ASN also carried out 14.5 days of labour inspections in the NPPs.

During 2020, 19 significant events reported by nuclear installation licensees in the Grand Est region were rated level 1 on the International Nuclear and Radiological Event Scale (INES scale).

In small-scale nuclear activities, 2 significant events were rated level 1 on the INES scale (1 in the industrial sector and 1 in the medical sector).

Cattenom nuclear power plant

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

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

ASN considers that the performance of the Cattenom NPP with regard to safety is improving and, despite some persistent weaknesses, is in line with the ASN's general assessment of the EDF nuclear fleet with regard to environmental protection and radiation protection.

The year 2020 was thus marked by a degree of improvement in the site's safety performance, with results that stand out positively with respect to the rest of the EDF power plants. This trend must nevertheless be analysed in the 2020 context of a relatively low maintenance work load which is more conducive to good results. This trend therefore remains to be confirmed in the light of maintenance programmes with significantly higher workloads in the years to come and the consolidation of the results expected from the deployment of the operating rigour improvement plan initiated in 2020.

THE INSTALLATIONS AND ACTIVITIES TO REGULATE COMPRISES:

- **Basic Nuclear Installations:**
  - the Cattenom NPP (4 reactors of 1,300 MWe),
  - the Chooz A NPP (1 reactor of 305 MWe undergoing decommissioning),
  - the Chooz B NPP (2 reactors of 1,450 MWe),
  - the Fessenheim NPP (2 reactors of 900 MWe) in final shutdown status,
  - 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;**
- **small-scale nuclear activities in the medical sector:** p. 206
  - 14 external-beam radiotherapy departments,
  - 5 brachytherapy departments,
  - 20 nuclear medicine departments,
  - 93 computed tomography scanners,
  - 80 centres performing interventional fluoroscopy-guided procedures,
  - some 2,100 medical and dental radiology devices;
- **small-scale nuclear activities in the veterinary, industrial and research sectors:** p. 238
- **277 industrial and veterinary activities subject to the licensing system,**
  - 24 companies exercising an industrial radiography activity,
  - 50 research laboratories situated primarily in the universities of the region;
- **activities associated with the transport of radioactive substances;** p. 266
- **5 head offices of organisations approved in radiation protection.**

ASN has noted the strong commitment of the reactor operating teams to rigorous application of the operating rules, borne out by the absence in 2020 of reactor trips or events during several reactor shutdowns.

The efforts in maintenance have resulted in improved monitoring of the technical actions and measures that limit the deviations during maintenance operations and on worksites. This improvement, however, is offset by longer system return-to-service times, which has an impact on the end-of-outage time frames. Alongside this, the impact of the health crisis was well managed and planned for.

The number of significant events followed the improvement trend observed from the qualitative aspect, with 40 events reported compared with 51 in 2019. Nevertheless, many of these events still have to be put down to organisational or human deficiencies, in line with the preceding years; inspections carried out in 2020 highlighted numerous shortcomings in the conformity checks carried out as part of the ten-yearly outages of reactors 1 and 2 in 2016 and 2018, obliging the site to repeat a large number of conformity checks retrospectively. In addition, several recurrent outages of the Plant Radiation Monitoring System (KRT) and the Component Cooling System (RRI) are to be noted. Lastly, some minor deviations were identified in the embodiment or taking into consideration of the modifications to be made to the fire-fighting systems. The site's reporting and analysis of significant events remains satisfactory, with deadlines being observed and analyses of good quality.

The initial results of the operating rigour improvement plan put in place by EDF further to the negative trend diagnosed in 2019 are encouraging on the whole; its must be pursued in order to confirm and build on these results, particularly for the organisation, performance and monitoring of future maintenance actions.

With regard to the environment, 2020 was less constrained than 2019, which was marked by the lasting low-water period of the Moselle river. Nevertheless, the site's exposure to climatic risks, bringing increased needs for cleaning of the intermediate cooling system heat exchangers among other things, remains an issue requiring particular attention. Furthermore, a case of exceeding of the first Legionella concentration threshold was observed in the tertiary cooling system in 2020. This is an issue specific to the site that requires special management of the biocide treatment campaigns throughout the year.

A few events involving accidental spillages of chemical products (hydrazine, ferrolin) underline the need for the site to improve its product management and containment practices.

With regard to radiation protection, significant efforts have been made in worksite preparation from the radiological risks and contamination control aspects; it could benefit from being based on more direct consideration of the actual state of the facilities and its development, rather than on theoretical aspects of the optimisation approach. In addition, several deviations concerning fundamental aspects such as the control of access to prohibited areas have been noted and necessitate specific actions by the licensee.

Lastly, with regard to occupational safety, the Cattenom NPP has demonstrated its ability to put in place the necessary measures in the context of the health crisis and to adapt the site's organisation accordingly. The hydrazine spillage incident mentioned above brought to light a situation of concern within a service provider company, which received particular attention from the labour inspector.

Chooz nuclear power plant

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

Reactors B1 and B2 in operation

ASN considers that the nuclear safety performance of the Chooz B NPP is on the whole in line with the general assessment of EDF, but the radiation protection performance is below the average for the EDF plants. The environmental protection performance stands out positively and is considered satisfactory.

With regard to nuclear safety, ASN observes that the sustained progress in reactor operation witnessed over the last few years is continuing, notably with a reduction in the number of significant events despite a context of intense activity linked to the ten-yearly outage of reactor 1. Particular vigilance must be maintained regarding the management of operational documents and the traceability of validation of the inspections and the monitoring of the state of the installations.

With regard to maintenance, efforts to improve work intervention rigour must be continued. Particular attention must also be paid to the organisation of activities to guarantee the long-term durability of equipment qualification for accident conditions and the quality of the risk analyses.

In the area of radiation protection, lack of rigour in individual behaviour and shortcomings in radiological cleanliness are still observed too frequently during the ten-yearly outage of reactor 1. The licensee's in-depth reflection on the optimisation of radiation protection on worksites with high radiological risks has not yet fully borne fruit. An improvement is nevertheless noted in meeting the collective dosimetry targets during this ten-yearly outage.

ASN considers that the site's environmental protection organisation is on the whole satisfactory. Improvements are nevertheless expected in the prioritisation of curative maintenance work on the equipment involved in controlling the microbiological risks.

With regard to labour inspection, the health crisis occupied an important position in ASN's inspections and in the discussions with the licensee and the personnel representative bodies. An inspection of lifting operations was carried out with the aim of checking the conformity of the work equipment, among other things. Particular attention must be paid to the servicing and maintenance of the lifting equipment.

Reactor A undergoing decommissioning

In 2020, the decommissioning of the equipment inside the reactor vessel continued, despite a long period during which all activities were stopped on account of the health crisis. After transferring the reactor closure head to Andra's Aube repository (CSA) at the end of 2019, the year was marked by the dispatching of the first low- and intermediate-level waste packages to the activated waste packaging and storage facility (Iceda) operated by EDF on the Bugey site in the Ain *département*.

ASN's examination of the facility's safety review file submitted in 2017 continued in 2020 after it had received several complements requested of EDF.

On a more general note, ASN considers that the licensee must maintain its vigilance in the areas of radiation protection, the environment and the monitoring of service providers. The low level of activity in 2020 due to the health context, however, makes it impossible to measure the effectiveness of the action plans put in place in these areas at the request of ASN.

In the specific area of radiation protection, the commitments made in 2019 concerning the licensee's organisation were met. The risk of alpha particle contamination remains a major issue on the site and continues to be monitored with particular attention by ASN.

Lastly, with regard to occupational safety, an inspection focusing in particular on the lawfulness of the conditions of work of foreign companies on the French territory was carried out. This inspection detected irregularities concerning subcontractor companies during the provision of their services.

Fessenheim nuclear power plant

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

The year 2020 was marked by the final shutdown of the site's two reactors, one on 22 February and the other on 30 June, in accordance with the dates announced by EDF in its final shutdown declaration of 27 September 2019.

The Fessenheim site's electricity production activity ended with a highly satisfactory level of performance in terms of safety, in line with the good results obtained by the site over the last few years. The number of significant events declared during the reactor production period was below the average for the fleet and a very good standard of reactor operation was maintained. This performance reflects in particular the determination of the site's management and personnel to maintain exemplary operating rigour through to final shutdown of the reactors.

As from September 2020, in view of the ongoing personnel departures in the various departments and the end of production, the site's organisation was modified as regards the size of the operating teams, the organisation of the On-Site Emergency Plan (PUI), the fire teams' service, the site's organisation chart and the number of departments. Contrasting with the situation observed during the period of production, this period brought a transient increase in significant events with an inhabitual "organisational and human factors" component, possibly linked to the disruption of organisational and managerial practices resulting from the ongoing reorganisation of the departments.

Moreover, since production stopped, the on-site activity now concerns systems, procedures, and configurations that are less familiar to the site's teams than the previous habitual recurrent operating and maintenance operations. Consequently, in the area of the environment ASN has observed a few events stemming from system management errors that can be attributed to such inhabitual operations. The risk analysis practices must be adapted to the site's new activities and operations.

Over and beyond the activities associated with decommissioning preparation, a certain level of maintenance activity will continue, particularly for the systems remaining in operation, such as ventilation, effluent treatment of and fighting the fire risk. ASN has noted the site's proactive attitude and good management in this area of activity.

Lastly, in view of the presence of nuclear fuel on the site until 2023, ASN has prescribed, through resolution 2020-DC-0699 of 17 November 2020, the putting in place of an "adapted hardened safety core" of material and organisational measures designed to prevent uncovering of the fuel assemblies in the fuel pools in any extreme hazard situation that reaches the "hardened safety core" level. This same resolution obliges the reinforcement of some of the site's facilities, particularly the groundwater well and the associated generator set, which constitute an additional source of cooling and of electrical power that can be mobilised in the event of an accident. The necessary work was carried out in accordance with the deadline for these requirements set at 31 December 2020. Lastly, this resolution sets 31 December 2023 as the deadline for removal of the fuel from the site, which will automatically eliminate the source of the risk of any major nuclear accident.

Final shutdown of the Fessenheim site and preparation for decommissioning

Pursuant to the final shutdown declaration sent to the Minister responsible for nuclear safety and to ASN on 27 September 2019, EDF proceeded with the final shutdown of the two reactors of the Fessenheim NPP in 2020, the first on 22 February and the second on 30 June.

In June 2020, EDF published a new version of the Fessenheim NPP decommissioning plan in response to ASN's requests for complements to the initial version of the plan received with the final shutdown declaration. In this new version EDF provides the justifications requested by ASN concerning the strategy applied in choosing the decommissioning preparation operations and the details concerning primary system decontamination and the spent fuel removal schedule.

In November 2020, EDF sent the decommissioning file provided for in Article L. 593-27 of the Environment Code to the Minister responsible for nuclear safety with a view to obtaining the Decommissioning Decree. If the Minister deems this file admissible, it will refer it to ASN for examination as from 2021. Alongside this decommissioning file, ASN will also examine the concluding report of the periodic safety review of the two Fessenheim reactors submitted by EDF in September 2020. ASN will thus assess the conditions of safety of the installation during the decommissioning preparation and short-term decommissioning phases.

EDF plans a 5-year decommissioning preparation phase, which will span the period until the reactor Decommissioning Decree is obtained. Once this decree is obtained, it should take about twenty years for site decommissioning to reach the final state, with the aim of delicensing the Basic Nuclear Installation.

The main decommissioning preparation operations envisaged by EDF consist in removing all the fuel present on the site and decontaminating the primary system of each of the two reactors. The aim of this operation is to minimise the risks associated with ionising radiation during decommissioning of the installation. In addition, areas for treating and packaging the waste resulting from the future decommissioning work must be set out in the premises.

Consequently, following final shutdown the cores of the two reactors have been completely unloaded; the spent fuel has been stored in the site's cooling pools pending transfer to the La Hague treatment facilities. About ten spent fuel removal transport operations were carried out in 2020. ASN resolution 2020-DC-0699 of 17 November 2020 requires EDF to complete the fuel removal operations by the end of 2023.

EDF has also started decommissioning preparation work, notably concerning removal of the old steam generators which is planned during the decommissioning preparation phase, with the aim of freeing up and reusing the storage building for the decommissioned steam generators. EDF plans transferring the six old steam generators, currently stored on site, to its Cyclife plant in Sweden for melting down and recovery. As for the decommissioned steam generators, EDF plans recovering them in a centralised cutting and melting facility that EDF would like to set up in France. Although Article 6 of the resolution of 21 February 2020, taken jointly by the Minister responsible for nuclear safety and the ASN Chairman, opens up the prospect of a change in the regulatory framework applicable to the management of very low level waste (VLLW) (see chapter 14) in order to introduce a new possibility of targeted waivers allowing, after melting and decontamination, recovery on a case-by-case basis of very low level radioactive metal waste, the corresponding regulatory framework remains to be developed with respect to French law.

ASN carried out an in-depth inspection at the EDF's Department of Dismantling Projects and Waste (DP2D) and on the Fessenheim site in November 2019. During that inspection ASN identified shortcomings in the management of the Fessenheim decommissioning project, which at the time did not give EDF an overall picture of the project with all its interactions. In response to this, EDF set up a project dedicated to the decommissioning preparation phase, the aim of which is to guarantee that the initial decommissioning state is reached by 2025: this new organisation integrates all the EDF contributing entities in this project, starting with the site. Through this project EDF has also bolstered its organisation in order to establish and validate the structuring decisions for the decommissioning preparation phase and then for the decommissioning itself. ASN considers that the organisational changes proposed by EDF are on the whole satisfactory and will make sure that they are reflected operationally in the management of the future operations.

See chapter 13 for further information on the decommissioning of the Pressurised Water Reactors (PWRs).

Nogent-sur-Seine nuclear power plant

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

ASN considers that the performance of the Nogent-sur Seine site in nuclear safety, and to a lesser extent in radiation protection, is below the general assessment of EDF. The environmental protection performance stands out positively with respect to the average for the EDF plants and is considered satisfactory.

With regard to nuclear safety, ASN considers that the operating rigour is not of the expected standard. The significant number of system configuration errors and deviations from the reactor operating technical specifications must be addressed in priority by the licensee. ASN nevertheless notes progress in the rigour of monitoring in the control room.

As far as maintenance is concerned, given the context of sustained activity on account of the ten-yearly outage of reactor 2, ASN considers that the situation is on the whole satisfactory. The licensee must nevertheless continue its efforts in the monitoring of work interventions, primarily to better detect the nonconformities that make further interventions on the facilities necessary. This is because such nonconformities remain frequent.

As far as occupational radiation protection is concerned, the results at the end of the ten-yearly outage of reactor 2 are disappointing. The lack of control of the radiological cleanliness of certain worksites has effectively led to a large number of internal exposures of workers. Improvements in the coordination of work interventions are required. The modifications to protective measures while worksites are in progress must moreover be better formalised and tracked.

With regard to environmental protection, ASN considers that the site's results for 2020 are satisfactory. ASN notes an improvement in the control of discharges in particular, despite a context constrained by the works of the ten-yearly outage of reactor 2.

With respect to labour inspection, ASN was attentive to the adaptations of the safety instructions linked to the Covid-19 pandemic, and to compliance with them. In addition, the inspections focusing on lifting operations underlined areas lacking rigour, including in the verification of equipment conformity before use.

Aube waste disposal facility

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

At the end of 2020, the volume of waste in the facility had reached about 350,000 m^3, or 35% 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 estimate being based on better knowledge of the future waste and the waste delivery schedules.

The year 2020 was marked by a prolonged shutdown of the centre's facilities on account of the national health context. The construction of new disposal structures for the future waste continued elsewhere.

ASN considers that the CSA is operated under satisfactory conditions in the areas of safety, radiation protection and environmental protection.

The examination 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 2020, with a view to ASN making a position statement on the conditions of operation of the centre.

Deep geological disposal project

ASN considers that the scientific experiments and work conducted by Andra in the underground laboratory at Bure continued in 2020 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.

In 2020, ASN's carried out 114 inspections in the Hauts-de-France region, of which 35 were in the Gravelines Nuclear Power Plant (NPP), 75 in small-scale nuclear activities and 4 in the transport of radioactive substances.

ASN also carried out 21.5 days of labour inspection in the Gravelines NPP.

In the course of 2020, 10 significant events rated level 1 on the International Nuclear and Radiological Event Scale (INES scale) were reported by the Gravelines NPP, including one concerning radiation protection.

In small-scale nuclear activities, 4 events were rated level 1 on the INES scale. In radiotherapy, one event was rated level 3 on the ASN-SFRO scale.

Gravelines nuclear power plant

The Gravelines NPP operated by EDF is located in the Nord *département* on the shores of the North Sea, between Calais and Dunkerque. This NPP comprises six 900 Megawatts electric (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 performance of the Gravelines NPP with regard to nuclear safety, radiation protection and environmental protection is below ASN's general assessment of EDF plant performance.

Nuclear safety performance did not improve in 2020, particularly with regard to the rigour of work interventions. The licensee has initiated an action plan which aims to bring an end to a situation where deviations and inappropriate practices and behaviours have become habitual.

ASN gave the Gravelines NPP licensee formal notice to comply, before 31 October 2020, with the regulatory provisions regarding protection against the risk of explosion of external origin, imposed by the creation authorisation decrees for the Gravelines NPP reactors 1, 2, 3, 4 and 6 and by its resolution of 20 August 2015 relative to control of the risks associated with the Dunkerque methane terminal. The compliance notice deadline was met.

THE INSTALLATIONS AND ACTIVITIES TO REGULATE COMPRISES:

- **one Basic Nuclear Installation:**
  - the Gravelines NPP (6 reactors of 900 MWe) operated by EDF;
- **small-scale nuclear activities in the medical sector:** p. 206
  - 19 external-beam radiotherapy departments,
  - 3 brachytherapy departments,
  - 29 nuclear medicine departments,
  - 92 centres using fluoroscopy-guided interventional procedures,
  - 127 computed tomography scanners,
  - some 4,600 medical and dental radiology devices;
- **small-scale nuclear activities in the veterinary, industrial and research sectors:** p. 238
  - 1 accelerator intended for the inspection of freight trains,
  - 600 industrial and research organisations, including 29 companies exercising an industrial radiography activity, 3 particle accelerators including 2 cyclotrons, 38 laboratories, mainly located in the universities of the region, and 19 companies using gamma ray densitometers,
  - 340 veterinary surgeries or clinics practising diagnostic radiology;
- **activities associated with the transport of radioactive substances;** p. 266
- **ASN-approved laboratories and organisations:**
  - 3 organisations approved for radiation protection controls.

With regard to maintenance, the year 2020 was marked by significant increases in the refuelling and maintenance outage times. The licensee has undertaken a major repair program for the pipes carrying seawater. It must nevertheless continue its work on certain items of equipment protecting against external hazards and displaying levels of corrosion that could call into question their functional integrity.

As regards environmental protection, ASN considers that the Gravelines NPP must improve its management of the maintenance of equipment that uses the insulating greenhouse gas (sulphur hexafluoride – SF_6) and the facilities for treating the radioactive effluents produced by reactor operation.

With regard to radiation protection, ASN continues to find weaknesses in the control of access to certain areas presenting radiological exposure risks. Improvements are also expected in the monitoring of worksites involving internal contamination risks which were once again the cause of significant radiation protection events in 2020.

38 labour inspection operations were carried out in the Gravelines NPP in 2020. The inspections are divided between inspections conducted on the maintenance worksites, particularly during reactor outages, and thematic inspections (exposure to chemical risks, lifting risks, electrical risks). Meetings were also organised with senior management, members of the health, safety and working conditions committee, and personnel representatives. ASN has effectively been attentive to the adaptations of the safety instructions on account of the Covid-19 pandemic, and to compliance with them.

The accident rate, widened to include accidents both with and without sick leave, is the highest of all the NPPs, but there were no serious accidents in 2020.

Île-de-France Region

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

ASN carried out 198 inspections in the Île-de-France region in 2020, of which 56 were in the field of nuclear safety, 105 in small-scale nuclear activities, 12 in the transport of radioactive substances and 25 concerning approved organisations or laboratories.

In Île-de-France, 2 significant events in the transport area were rated level 1 on the International Nuclear and Radiological Event Scale (INES scale).

In the small-scale nuclear activities sector, 2 events were rated level 2 on the ASN-SFRO scale, and 12 were rated level 1 on the INES scale.

CEA SACLAY SITE

The Saclay research centre, covering an area of 223 hectares, is located about 20 km south-west of Paris, in the Essonne *département*. About 6,000 people work there. Since 2005, this centre has been primarily devoted to physical sciences, fundamental research and applied research. The applications concern physics, metallurgy, electronics, biology, climatology, simulation, chemistry and the environment. The main aim of applied nuclear research is to optimise the operation and enhance the safety of the French Nuclear Power Plants (NPPs). Eight BNIs are located in this centre. Nearby are also located an office of the French National Institute for Nuclear Science and Technology (INSTN) – a training institute – and two industrial firms: Technicatome, which designs nuclear reactors for naval propulsion, and CIS bio international, which produces radiopharmaceuticals for nuclear medicine.

THE INDUSTRIAL AND RESEARCH FACILITIES

Osiris and Isis reactors – *CEA Centre*

The Osiris pool-type reactor has an authorised power of 70 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 purposes.

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

Given the old design of this facility by comparison with the best available techniques for protection against external hazards and for containment of materials in the event of an accident, the Osiris reactor was shut down at the end of 2015. The Isis reactor was definitively shut down in March 2019. Submitted in late October 2018, the decommissioning file for the installation as a whole received information complements further to ASN's admissibility analysis. These complements give greater details of the operations planned at each stage of decommissioning and justify more precisely the initial state envisaged at the start of decommissioning and the results of the impact study.

Since the shutdown of the Osiris and Isis reactors and pending decommissioning of the facility, the removal of radioactive and hazardous materials and the decommissioning preparation operations are underway, with an organisation adapted to the new state of the facility. The spent fuel removal operations should continue until the first half of 2021.

The activities were however slowed down in 2020 by the management of the Covid-19 pandemic, which led to modification work being put on hold.

The inspections carried out by ASN in 2020 found the management of the fuel removal operations to be satisfactory. Waste management must be made more robust in order, among other things, to avoid the build-up of waste in the facility. Management of the decommissioning preparation operations remains satisfactory from the technical aspects, but delays are observed, as in the previous years. Management of baseline requirement updating deadlines needs to be improved.

Lastly, the significant events reveal in part organisational and human shortcomings in the performance of the periodic inspections and meeting their deadlines, and in the monitoring of the outside contractors who perform these inspections. ASN considers that the operator must be attentive to the maintaining of operating rigour, to the safety culture and to the management of the periodic inspections and tests, which was already found wanting in 2019.

Orphée reactor – *CEA Centre*

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

The Orphée reactor, which was definitively shut down at the end of 2019, is now in the decommissioning preparation phase. The licensee submitted the decommissioning file in March 2020. The ongoing examination of this file also focuses on the third periodic safety review of the facility, for which the report was submitted in March 2019. The last irradiated fuel from the Orphée reactor was removed in 2020, greatly reducing the risks the facility represents.

Based on the facility inspections and monitoring carried out in 2020, ASN considers that the level of safety of the Orphée reactor is on the whole satisfactory. More specifically, the measures taken by the licensee during the health crisis enabled compliance with requirements to be maintained at a good level.

The significant events nevertheless show that vigilance is required with equipment maintenance, monitoring and qualification. More specifically, the management of nuclear pressure equipment must be more robust, insofar as a number of these items contain heavy water.

Following reactor shutdown, the decommissioning preparation phase is subject to particular scrutiny by ASN, notably the adaptation of the organisation and the personnel skills to manage new activities while maintaining the level of safety of the facility and control of the schedules.

Spent fuel testing laboratory – *CEA Centre*

The Spent Fuel Testing Laboratory (LECI) was built and commissioned in November 1959. It was declared a BNI on 8 January 1968 by the French Alternative Energies and Atomic Energy Commission (CEA). An extension was authorised in 2000. The LECI (BNI 50) constitutes 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.

THE INSTALLATIONS AND ACTIVITIES TO REGULATE COMPRISES:

- **Basic Nuclear Installations regulated by the Orléans division:**
  - the CEA Saclay site, which belongs to the CEA Paris-Saclay centre,
  - the UPRA (Artificial Radionuclide Production Plant) operated by CIS bio international in Saclay,
  - the CEA Fontenay-aux-Roses site which belongs to the CEA Paris-Saclay centre;
- **small-scale nuclear activities in the medical sector:** p. 206
  - 26 external-beam radiotherapy departments,
  - 12 brachytherapy departments,
  - 39 *in vivo* nuclear medicine departments and 16 *in vitro* nuclear medicine departments (medical biology),
  - 148 centres performing fluoroscopy-guided interventional procedures,
  - more than 200 centres possessing at least one CT scanner,
  - about 850 medical radiology practices,
  - about 8,000 dental radiology devices;
- **small-scale nuclear activities in the veterinary, industrial and research sectors under the oversight of the Paris division:** p. 238
  - some 650 users of veterinary radiology devices,
  - 7 industrial radiography companies using gamma radiography devices,
  - some 130 licenses concerning research activities involving unsealed radioactive sources;
- **activities associated with the transport of radioactive substances;** p. 266
- **ASN-approved laboratories and organisations:**
  - 9 organisations approved for radiation protection controls.

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

Further to the last periodic safety review, ASN issued the resolution of 30 November 2016 (amended on 26 June 2017) regulating the continued operation of the facility through technical prescriptions relating in particular to the improvement plan that the CEA had undertaken to implement. Some of the CEA's commitments have not been fulfilled within the deadlines. In particular, the removal of the radioactive substances whose utilisation cannot be justified and the implementation where necessary of measures to place and maintain the BNI in a safe condition in the event of fire in the areas adjacent to the nuclear areas have been delayed. ASN is therefore still waiting for the CEA to submit a reliable and appropriate action plan.

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

The inspections carried out by ASN in 2020 revealed satisfactory operational management of the fire risk. Improvements are nevertheless expected in the management of the criticality risk, more specifically with the updating of the operating documents and better management of the quantities of radioactive substances present in the various areas of the facility.

Poséidon irradiator – *CEA Centre*

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

This facility is used for studies and qualification services for the equipment installed in the nuclear reactors, notably thanks to an immersible chamber, as well as for the radiosterilisation of medical products. The main risk in the facility is of personnel exposure to ionising radiation due to the presence of very high-activity sealed sources.

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

In the light of the inspections carried out in 2020, ASN considers that the facility is operated satisfactorily. By way of example, the modifications to the Poseidon source-holder elevator following a failure that occurred in early 2020 were correctly carried out with good traceability of the modifications.

However, ASN observes shortcomings in the monitoring of the lightning protection devices and the maintenance operations on the Poseidon automatic fire extinguishing system. Compliance with the regulatory periodic inspection deadlines must also be improved.

SOLID WASTE AND LIQUID EFFLUENT TREATMENT FACILITIES

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

Solid radioactive waste management zone – *CEA Centre*

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

In view of the Potential Source Term[1] (TSM) currently present in the facility, BNI 72 is one of the priorities in the CEA's decommissioning strategy which has been examined by ASN, which stated its position on these priorities among other things in May 2019 (see chapter 13).

The commitments made further to the preceding safety review in 2009 aimed to guarantee an acceptable level of safety of the facility for the next 10 years. They concerned in particular the removal of the majority of the Potential Source Term from the facility and stopping the reception of new waste from the Saclay centre in order to concentrate the facility's resources on the retrieval and packaging of the legacy waste and on the decommissioning. These commitments have not been met.

In 2017, in view of the delays in the removal from storage operations, the CEA requested that the deadlines prescribed in ASN resolution 2010-DC-0194 of 22 July 2010 for removal of the irradiated fuel from storage and removal of the waste stored in the "40 wells" area be pushed back by several years. In 2020, the CEA asked for a further extension of several years for the removal of the waste stored in the 40 wells area.

In order to be able to continue using the BNI for managing the radioactive waste from the Saclay BNIs, the CEA in 2017 asked for a change in the date of final shutdown of the facility, postponing it until the first of the following two terms was reached: either the effective date of the Decommissioning Decree or the date of 31 December 2022. It is also requesting certain arrangements for the management of certain types of waste until 2025.

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

ASN considers that the safety of the facility is acceptable, while at the same time noting numerous delays in the operations to remove the fuel and waste from storage. ASN nevertheless takes positive note of the removal of three isotopic generators from the facility in 2020, which contributes to the gradual reduction of its TSM.

1. *The Potential Source Term (*Terme Source Mobilisable *– TSM in French) corresponds to the quantity of radioactive actvity that could be involved in an incident or accident.*

In 2020, ASN inspected the organisation and methodology put in place by the CEA for the conformity check of the facility against its applicable baseline requirements, and for the development and monitoring of the action plan resulting from the periodic safety review report. ASN expects an improvement in the action plan coordination and monitoring in order to reach the level of risk control that the CEA has undertaken to achieve as quickly as possible. The CEA must moreover, when necessary, put in place compensatory measures pending the upgrading of the BNI further to its periodic safety review. ASN underlines that projects that contribute to reducing the potential source term within facilities constitute priorities for safety.

Alongside this, ASN's inspections find the facility to be in good overall condition. ASN nevertheless observes inadequate management of scheduling of the regulatory periodic inspections of the handling cranes.

Liquid effluents management zone

– *CEA Centre*

The liquid effluents management zone constitutes BNI 35. Declared by the CEA by letter of 27 May 1964, this facility is dedicated to the treatment of radioactive liquid effluents. The CEA was authorised by a Decree of 8 January 2004 to create "Stella", an extension in the BNI for the purpose of treating and packaging low-level aqueous effluents from the Saclay centre. These effluents are concentrated by evaporation then immobilised in a cementitious matrix in order to produce packages acceptable by the French radioactive waste management agency's (Andra) above-ground waste disposal centres.

The concentration process was put into service in 2010, but the appearance of cracks in the first packages led ASN to limit the packaging operations. The CEA has only packaged some effluents from one of the installation's tanks that contains 40 cubic metres (m^3) of concentrates. The CEA has since made progress in defining its packaging solution for all the facility's effluents. Thus, in June 2018, Andra authorised the packaging of these concentrates in accordance with the 12H package approval. In January 2020, the CEA obtained ASN's authorisation to put this process into service. However, the first cementation tests on 12H packages carried out with inert effluents gave unsatisfactory results and were continued until the end of 2020.

Complementary investigations concerning the stability of the structure of the low-level liquid effluents storage room (room 97) have led the CEA to suspend, since 2016, the acceptance of effluents from other BNIs. The majority of the low- and intermediate-level (LL and IL) radioactive effluents produced by the Saclay site production sources are now directed to the Marcoule Liquid Effluent Treatment Station (STEL), a Defence BNI. In November 2018, in accordance with its commitment, the CEA submitted to ASN a file presenting the management strategy for the liquid radioactive effluents from the CEA Île-de-France and the overall strategy concerning BNI 35. In this file the CEA has set out deadlines for the cementation of the legacy concentrates stored on the site, which is a priority for the facility.

Alongside this, the situation of pit 99 containing old tanks of organic effluents, with the presence of contaminated sludge in the bottom of the tanks and the bottom of the pit, remains a major clean-out challenge. Tank clean-out and dismantling studies have been carried out. An application for authorisation to perform these operations is currently being examined by ASN.

The Decree of 8 January 2004 authorising the creation of Stella also stipulated that the CEA must, within 10 years, remove the legacy effluents stored in the eight tanks called "MA500" and in tank HA4 of BNI 35. Due to the technical difficulties encountered in their retrieval and packaging, these operations lasted longer than planned. The operations to empty the last MA500 tank could not be completed, even though the licensee has good technical knowledge of the physical and chemical issues associated with the emptying of this tank. ASN is therefore waiting for the CEA to submit an action plan to complete the emptying of this tank.

The inspections carried out in 2020 evidenced good management of the facility's baseline requirements. ASN does however observe shortcomings in the monitoring and upkeep of the electrical installations of the BNI. Improvements are also expected in the recording of the requalification analyses and

Control of urban development around the Saclay site

In view of the changes in the Basic Nuclear Installations (BNIs) of the French Alternative Energies and Atomic Energy Commission (CEA) and CIS bio international, ASN had asked the CEA and CIS bio international to update their safety assessments in order to update the hazard zones defined around the BNIs.

These updates, which take into account the shutdown of the Orphée reactor and removal of the iodine-131 from the CIS bio international facility, show an effective reduction in the risks induced by the site's BNIs. The examination carried out by ASN confirms these results, making it possible to revise the provisions for controlling urban development.

Thus, applying a cautious approach to the urban development around a nuclear site where decommissioning activities present safety risks and are going to last for several years, the Prefect of the Essonne *département* has updated the Applicable Public information Notice by maintaining a land-use planning zone over a perimeter of 250 metres starting from the Saclay site fences.

The CEA – Saint Aubin station project on the route of the future line 18, which is situated at the Christ de Saclay roundabout, is now compatible with the proposed new urban development restrictions.

tests following the material modifications and compliance with the planned frequencies for the periodic inspections and tests, as witnessed by several significant events reported on this subject. Lastly, ASN considers that the replies to the follow-up letters and the information presented in the significant events reports are not detailed enough and must be improved.

FACILITIES OF THE CEA SACLAY CENTRE UNDERGOING DECOMMISSIONING

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

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

Ulysse reactor – *CEA Centre*

Ulysse was the first French university reactor. The facility, which constitutes BNI 18, has been in final shutdown status since February 2007 and has contained no fuel since 2008. The BNI Decommissioning Decree was published on 21 August 2014 and provides for a decommissioning duration of 5 years. This facility presents limited safety risks.

On 8 August 2019, the CEA announced the end of the decommissioning operations provided for in the Decommissioning Decree, with the completion of final post-operational clean-out. The facility therefore no longer has any areas regulated on account of radiation protection, or areas where nuclear waste can be produced.

At end of 2019, about a hundred blocks of concrete from the cutting-up phase of the "conventional" part of the reactor block were still present in the facility. Samples were taken from these blocks by an independent laboratory in December 2019 to check that the planned clean-out targets had been met. The results of the analyses confirmed the conventional nature of the concrete blocks, the removal of which was completed in November 2020.

After analysing the facility's safety review report, ASN communicated its conclusions to the Minister responsible for nuclear safety on 22 April 2020. On completion of this safety review, ASN has not planned to issue any particular requirements regarding the residual risks of the facility.

High-level Activity Laboratory – *CEA Centre*

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

Despite the progress of the clean-out and decommissioning operations, the accumulated delays have prevented the CEA from meeting the deadline of 21 September 2018 set by the decree authorising LHA decommissioning. The discovery of pollution in certain "intercell yards" in 2017 also led to changes being made in the operations to be carried out. Investigations into the radiological status of the soils were carried out during 2019, with results expected in the course of 2021. The licensee must submit a Decommissioning Decree modification file. It must include the justification of the time required to complete the decommissioning operations authorised by the Decree of 18 September 2008. Its submission is planned before the end of 2021. ASN will be attentive to the progress of the studies planned prior to submission of the file.

The year 2020 was marked by a change of industrial operator over the perimeter undergoing decommissioning. ASN considers that the level of safety of BNI 49 undergoing decommissioning is on the whole satisfactory. The inspections revealed good organisation between the CEA and its incoming and outgoing service providers, in order to optimise the transition between them in a restricted time frame. ASN also underlines the quality of the organisation set up between the CEA and its industrial operator for monitoring the periodic inspections and tests.

However, resumption of the service provider monitoring activities – partly postponed due to the health crisis – was slow. Compliance work on the electrical installations and the lightning protection devices must also be carried out. Lastly, ASN notes delays in the updating of the demonstration of control of fire-related risks, initially announced for the end of 2019. ASN will remain attentive to compliance with the CEA's new stated deadline of the first quarter 2021.

THE IMPACT OF COVID-19

As from the beginning of the first lockdown on account of the Covid-19 pandemic, the French Alternative Energies and Atomic Energy Commission (CEA) stopped activities of the Basic Nuclear Installations (BNIs) at the Paris-Saclay centre. The large majority of the worksites were safely shut down. Only the essential activities, primarily monitoring (including environmental monitoring) and safety oversight, were maintained. However, certain periodic inspections and tests and certain regulatory verifications and maintenance operations were not carried out by the set deadlines. These were operations for which the CEA had analysed the safety impact of not performing them and, where necessary, had defined compensatory measures.

At the end of the lockdown period, the activities of the BNIs gradually restarted on the basis of a safety analysis defining the inspections and the steps to take with a view to obtaining an activity resumption authorisation from the Director of the centre.

The CEA subsequently adapted its organisational arrangements. Thus, when the second lockdown began in November 2020, the CEA did not shut down its BNIs and it maintained the periodic inspections and tests, the regulatory verifications and the maintenance operations.

The overall experience feedback for this period still has to be compiled. Nevertheless, ASN's inspections have shown that the activity resumption measures were managed satisfactorily and the measures taken by the licensee during the crisis enabled compliance with requirements to be maintained at a good level.

Artificial Radionuclide Production Plant of CIS bio international

The Artificial Radionuclide Production Plant (UPRA) constitutes BNI 29. It was commissioned in 1964 on the Saclay site by the CEA, which in 1990 created the CIS bio international subsidiary, the current licensee. In the early 2000's, this subsidiary was bought up by several companies specialising in nuclear medicine. In 2017, the parent company of CIS bio international acquired Mallinckrodt Nuclear Medicine LCC, now forming the Curium group, which owns three production sites (in the United States, France, and the Netherlands).

The Curium group is an important player on the French and international market for the production and development of radiopharmaceutical products. The products are mainly used for the purposes of medical diagnoses, but also for therapeutic uses. Until 2019, the role of BNI 29 was also to recover disused sealed sources which were used for radiotherapy and industrial irradiation. Removal of these sources, which have been stored in the facility, is well advanced. The group moreover decided to stop its iodine-131-based productions on the Saclay site at the end of 2019, which has significantly reduced the consequences of accident situations.

More generally, ASN considers that the facility's safety improvement initiative, already observed last year, continued in 2020 despite the complications resulting from the health crisis. The measures taken by CIS bio international to ensure the continuity of its activities during the crisis enabled the safety requirements to be met. The stability of the organisation and better skills management were factors that favoured this approach.

Several projects bringing significant safety improvements are currently coming to a conclusion. Nevertheless, the time frames for carrying out the major actions undertaken by CIS bio international, some of which are difficult to deploy, must be better controlled.

The inspections found that waste management had improved, in particular with the removal of legacy waste, despite the fact that breaches of the storage rules were again noted. The implementation of a comprehensive plan to improve liquid effluent management, which had been the subject of deviations in recent years, is an appropriate response, and ASN shall check the quality of the results achieved. The organisation for managing transport operations, which are numerous and involve packages with varied contents, is also efficient, but deficiencies in quality assurance and document management must be remedied.

The number of significant events is falling significantly. Compliance with the operating rules, particularly outside working hours, with the operating range and the integration of experience feedback must be further improved. ASN also expects to see improvements in the identification of significant events. Compliance with the deadlines for the site's commitments must also be further improved.

To conclude, ASN expects CIS bio international to keep up the observed performance improvement efforts. Areas for improvement on which CIS bio international must particularly focus its efforts comprise the cross-cutting functioning of the organisation, compliance with the facility baseline requirements and management of schedules, while remaining vigilant with regard to operating rigour and improving the safety culture.

Assessment of the CEA Saclay site

ASN considers that the Basic Nuclear Installations (BNIs) of the Saclay centre are operated under suitably safe conditions on the whole and notes that certain operations contributing to the reduction of the source terms stored in the BNIs concerned were carried out in 2020. Consequently, there is no more irradiated fuel in the Orphée reactor and the removal of irradiated fuels from the centre's reactors should be completed in the first half of 2021. Moreover, several isotopic generators present in BNI 72 have been removed.

Nevertheless, the activities were slowed down by the Covid-19 pandemic, which obliged certain works and modifications to be put on standby. This is because during the first lockdown the French Alternative Energies and Atomic Energy Commission (CEA) stopped the activities of the BNIs while maintaining the essential monitoring and inspection operations (see box on previous page).

In view of the structural delays in the decommissioning operations, ASN expects the CEA to continue its efforts to make its implementation schedules for these operations more robust. ASN will maintain particular vigilance in monitoring the progress of the decommissioning and waste retrieval and packaging projects, with the aim of ensuring control of the schedules.

The decommissioning and waste recovery and packaging operations continued to fall behind schedule in 2020. ASN considers that the progress of the decommissioning projects is one of the major safety challenges for the shutdown installations and that the management of the waste from the decommissioning operations is crucial for the smooth running of the decommissioning programmes. The majority of the CEA Saclay centre BNIs are concerned, either directly or indirectly, by decommissioning or decommissioning preparation operations.

Further to the Fukushima Daiichi NPP accident, ASN had initiated stress tests on the nuclear installations. More particularly, the emergency management means of the centres were examined for the Saclay centre. In 2016, ASN prescribed the creation of new emergency management means, notably the construction or reinforcement of "hardened safety core" emergency centres capable of withstanding extreme conditions. After receiving a compliance notice from ASN in September 2019, the CEA submitted in December 2019 its file presenting and justifying the dimensioning of the future emergency management buildings, whose commissioning is planned for the end of 2021. The licensee also submitted an authorisation request to ASN in December 2020 for the commissioning of its future emergency management premises.

With regard to the emergency organisation and means, ASN requested complementary information concerning the proposed update to the 2019 On-site Emergency Plan which must be submitted by the CEA in 2021. The ASN information requests relate to the organisational or structural changes at the CEA and also concern updates of operational documents concerning each of the BNIs so that they correspond to the actual state of the facilities.

As part of its oversight actions, ASN performed an inspection further to loss of the centre's compressed air supply in order to ascertain that it has no impact on the BNIs, and observed that the overall organisation put in place to manage this situation was satisfactory. ASN also noted, during a specific inspection, the ready availability of the fire-fighting means, with tests performed on the fire network. ASN nevertheless considers that the CEA must maintain its vigilance in the performance of the periodic inspections and tests of its equipment.

CEA FONTENAY-AUX-ROSES SITE

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

The Fontenay-aux-Roses centre comprises two BNIs, namely Procédé (BNI 165) and Support (BNI 166). BNI 165 accommodated the research and development activities on nuclear fuel reprocessing, transuranium elements, radioactive waste and the examination of irradiated fuels. These activities were stopped in the 1980s-1990s. BNI 166 is a facility for the characterisation, treatment, reconditioning and storage of legacy radioactive waste from the decommissioning of BNI 165.

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

Procédé facility and Support facility
– CEA Centre

Decommissioning of the two facilities Procédé and Support, which constitute BNI 165 and BNI 166 respectively, was authorised by two Decrees of 30 June 2006. The initial planned duration of the decommissioning operations was about ten years. The CEA informed ASN that, due to strong presumptions of radioactive contamination beneath one of the buildings, to unforeseen difficulties and to a change in the overall decommissioning strategy of the CEA's civil centres, the decommissioning operations would extend beyond 2030 and that the decommissioning plan would be modified. In June 2015, the CEA submitted an application to modify the prescribed deadlines for these decommissioning operations.

ASN deemed that the first versions of these Decommissioning Decree modification application files were not admissible. In accordance with the commitments made in 2017, the CEA submitted the revised versions of these files in 2018.

The complementary studies announced in the files were submitted in the first quarter 2019.

In its examination of the periodic safety review reports received in 2017 and 2018, ASN identified that the CEA had to provide complementary information on the state of the soils, the decommissioning plan and the safety analysis report, particularly concerning the demonstration of control of the fire risks and seismic risks. Initial responses were provided in 2020 and the remainder will be submitted in 2021. ASN has also observed through inspections that a specific organisation has been in place since September 2020 for the periodic safety reviews. This seems to be appropriate, but it must prove its effectiveness.

Assessment of the CEA Fontenay-aux-Roses site

To cope with the health crisis, the CEA Paris-Saclay centre rapidly implemented its activity continuity plan. The large majority of the worksites on the Fontenay-aux-Roses site were shut down safely and only the essential activities were maintained during the lockdown. The interruption of the operating activities, the restriction of movements and the non-availability of certain service providers meant that certain regulatory inspections could not be performed. Resumption of the operating activities was subsequently authorised by the Director of the centre after carrying out a safety analysis and the appropriate checks.

The inspections carried out in 2020 showed that the licensee has good command of the management processes for noteworthy modifications and the transport of radioactive substances. The first actions decided by the CEA to remedy the deviations observed in radiation protection during the ASN inspections in 2019 are satisfactory and must be continued.

Several significant events in 2020 are linked to the presence of legacy contaminations, which were unknown to the CEA, in some pipes and ventilation ducts of the facilities. ASN will keep track of the investigation results and their follow-ups.

ASN once again underlines the lateness in conducting the studies, in the project programming and in the decommissioning schedule of the Fontenay-aux-Roses nuclear facilities. The CEA has nevertheless presented ASN with its forecasts concerning the coordination of the files and work planned on the site to reduce the source term within the facilities. ASN expects the CEA to continue to implement proactive measures to control and render reliable the time frames associated with these projects, particularly the deadlines announced for the submission of the decommissioning worksite preparatory studies, which will be examined by ASN.

Normandie Region

The Caen division regulates nuclear safety, radiation protection and the transport of radioactive substances in the 5 *départements* of the Normandie region.

In 2020, ASN carried out 188 inspections in Normandie, comprising 64 inspections in the Nuclear Power Plants (NPPs) of Flamanville, Paluel and Penly, 12 inspections on the construction site of the Flamanville 3 EPR reactor, 63 inspections on fuel cycle facilities, research facilities and facilities undergoing decommissioning, 42 inspections in small-scale nuclear activities and 7 in the transport of radioactive substances.

In addition to this, 15 days of labour inspection were carried out on the NPP sites and the Flamanville 3 construction site.

In 2020, ASN was notified of 22 significant events rated level 1 on the International Nuclear and Radiological Event Scale (INES scale), of which 19 occurred in Basic Nuclear Installations (BNIs) and 3 in small-scale nuclear activities.

ASN inspectors issued 3 violation reports in the exercise of their oversight duties.

Flamanville nuclear power plant

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

ASN considers that the performance of the Flamanville NPP in the areas of nuclear safety and radiation protection is below the general assessment of the EDF plants. The environmental protection performance is improving and is in line with the general assessment of the EDF plants.

ASN considers that the site's performance in reactor operation and management must be further improved, as recurrent deviations have been observed in the application of the operating management procedures. ASN nevertheless takes positive note of the implementation of reactive improvement actions further to these events, particularly with regard to personnel training and activity preparation. Particular attention must be paid to ensuring that these actions continue over the long term.

With regard to the maintenance operations, the licensee took advantage of the outages of the two reactors to perform compliance work on various items of equipment important for safety. The licensee also detected and corrected numerous anomalies in the application of the preventive maintenance programmes. ASN considers that the compliance work on the facilities is satisfactory but the licensee must nevertheless remain vigilant about controlling the quality of the maintenance operations.

In September 2019, ASN decided to place the Flamanville Nuclear Power Plant under tightened monitoring further to the difficulties EDF encountered during the two ten-yearly outages. During 2020, the licensee continued to implement its action plan to improve operating rigour. Improvements have been observed in the condition of the facilities and the detection of anomalies in the field. A number of deviations linked to the condition of the equipment were thus able to be remedied. The licensee has moreover carried out substantial compliance work on its facility, particularly concerning the emergency diesel generator sets. ASN nevertheless observes persistent deficiencies in the command of certain activities and will be attentive to ensuring that the new practices are properly taken on board by all the workers, especially those of outside contractors. EDF must submit a revised action plan in 2021 targeting the lines for improvement still to be deployed.

The site's performance in occupational radiation protection in 2020 remained insufficient. ASN considers firstly that skills organisation and management within the risk prevention department must be improved. Numerous deviations were also detected regarding compliance with the conditions of access to and work in certain premises. Lastly, progress is expected in implementation of the optimisation principle in the preparation of work involving greater radiation exposure risks.

The recurrence of certain events and their potential seriousness confirm that the licensee must still make substantial improvements in this area.

As regards environmental protection, ASN notes that the licensee took appropriate corrective measures as a follow-up to the various findings made during the tightened inspection of 2019. Improvements are still required in the monitoring of the service providers performing activities relating to environmental monitoring.

With regard to labour inspection, ASN considers that the frequent meetings organised in 2020 during the Covid-19 pandemic allowed the development of a management strategy adapted to the specific prevention measures within the site. Nevertheless, improvements are still required in the overall organisation of prevention, particularly concerning situations with a risk of falling from height, and the management of the prevention plans.

Paluel nuclear power plant

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

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

ASN considers that the site's nuclear safety and radiation protection performance is on the whole in line with the general assessment of the EDF plants. ASN observes progress in environmental protection, where the site's performance stands out positively with respect to the general assessment of the EDF plants.

With regard to operation and reactor operational management, ASN considers that the performance is satisfactory. The scheduling of periodic tests, however, must be carried out more rigorously, particularly during reactor outages. Activity preparation and the way the workers embrace the procedures must be improved. ASN takes positive note of the implementation of an action plan in this respect and will be attentive to its implementation.

With regard to maintenance, ASN considers that the Paluel NPP's performance is contrasted. Improvements in service provider monitoring have been noted and must be consolidated, and proficiency in the safety important equipment requalification activities has also been observed. The licensee must nevertheless remain vigilant in the preparation of maintenance activities. Several safety significant events were caused by insufficient preparation of the operations. One of these events led to the replacement of the rotary drum screen of one of the reactors.

THE INSTALLATIONS AND ACTIVITIES TO REGULATE COMPRISES:

- **Basic Nuclear Installations:**
  - the Nuclear Power Plants operated by EDF, namely Flamanville (2 reactors of 1,300 MWe), Paluel (4 reactors of 1,300 MWe) and Penly (2 reactors of 1,300 MWe),
  - the EPR Flamanville 3 reactor construction worksite,
  - the Orano spent nuclear fuel reprocessing plant at La Hague,
  - the Andra Manche repository (CSM),
  - the National large heavy ion accelerator (Ganil) in Caen;
- **small-scale nuclear activities in the medical sector:** p. 206
  - 8 external-beam radiotherapy departments (27 devices),
  - 1 proton therapy department,
  - 3 brachytherapy departments,
  - 12 nuclear medicine departments,
  - 50 centres using interventional procedures,
  - 70 computed tomography scanners,
  - some 2,100 medical and dental radiology devices;
- **small-scale nuclear activities in the veterinary, industrial and research sectors:** p. 238
  - about 450 industrial and research centres, including 20 companies with an industrial radiography activity,
  - 5 particle accelerators, including 1 cyclotron,
  - 21 laboratories situated mainly in the universities of the region,
  - 5 companies using gamma ray densitometers,
  - about 260 veterinary surgeries or clinics practising diagnostic radiology, 1 equine research centre and 1 equine hospital centre;
- **activities associated with the transport of radioactive substances;** p. 266
- **ASN-approved laboratories and organisations:**
  - 9 head-offices of laboratories approved for taking environmental radioactivity measurements,
  - 1 organisation approved for radiation protection controls.

With regard to reactor 2, the refuelling outage that should have ended in December 2019 actually ended at the beginning of 2021. The unloading inspections revealed the fact that three fuel assemblies were affected by a sealing fault caused by oxide deposits. In late 2020, ASN authorised EDF to carry out another fuel assembly reloading operation and will remain vigilant regarding compliance with the particular chemical specifications of the primary system, which are intended to prevent recurrence of this fault.

This year again ASN considers that the performance of the NPP with regard to worker radiation protection must be improved.

The licensee must ensure that the optimisation principle is properly applied, particularly on worksites representing a high dosimetric risk. Shortcomings in the preparation of activities in controlled areas and in the radiation protection culture of the operators are still observed.

ASN observes that the situation regarding environmental protection is progressing, the site having improved its organisation for preventing flows and the unplanned dispersion of liquid radioactive or hazardous substances into the environment, and the operation of the wastewater treatment station further to the tightened inspection of 2019.

ASN also notes an effective organisation for controlling discharges of ozone-depleting gases.

With regard to labour inspection, in 2020 ASN participated in various social and economic committees addressing the organization of the Paluel site in the context of the Covid-19 pandemic health crisis. ASN considers that the prevention measures implemented in this context are appropriate. ASN's inspections relating to safety revealed no significant failings. ASN does however expect to see improvements in the management of situations involving risks of falling from height.

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.

With regard to nuclear safety, ASN considers the performance of the site to be satisfactory on the whole. However, as in 2019, ASN considers that the NPP's organisation for detecting and dealing with deviations, in accordance with the applicable regulations, is not sufficiently robust and must be further improved.

With regard to reactor management and operation, ASN considers that the site's performance is improving. The number of events reported to ASN relating to operating management of the facility is down compared with the previous years, reflecting improvements which are also observed in the reactor management activities. ASN nevertheless once again observes deviations in the management of the operating procedures used in the incident or accident management phases.

With regard to maintenance of the facilities, ASN considers that monitoring of service providers and proper application of the maintenance baseline requirements must be improved in order to optimally address the coming years, which will involve a greater number of maintenance activities, particularly with the ten-yearly outage of reactor 1. Lastly, ASN's inspections have also revealed significant nonconformities in addressing the lightning hazard risk. A reactive remediation of the facility was carried out during the year.

In the area of radiation protection, ASN considers that the organisation in place must be improved. The way radiation exposure risks are taken into consideration is found to be contrasted, and ASN still detects numerous deviations during its inspections. The site 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 licensee has made progress in the prevention of the flows and unplanned dispersions of radioactive or hazardous liquid substances into the environment. ASN nevertheless considers that the site must make fundamental improvements in the management of ozone-depleting gases.

With regard to labour inspection, ASN conducted several labour inspection-related visits in 2020 concerning employees of EDF and the outside companies working in the Penly NPP. ASN did not detect any significant failings, but nevertheless made several observations with respect to the lifting risk concerning situations involving a risk of loads falling, and nonconformities in work equipment involving, among other things, situations of work at height. ASN also responded to direct requests from the employees, and checked the functioning of the employee representative bodies during the lockdown decided during the health crisis, which showed that the prevention measures were appropriately managed.

Flamanville 3 EPR reactor construction worksite

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

During the first half of 2020, EDF completed the hot test phases of the facility, which serve in particular to test operation of the nuclear steam supply system and its auxiliary systems under nominal temperature and pressure conditions. ASN considers that the organisation for performing the start-up tests is satisfactory, but that EDF must bolster its analysis of the test results, particularly regarding their representativeness and the validation of the safety criteria.

Alongside this, ASN continued the verification of the equipment quality review. This review was requested by ASN in 2018 due to serious shortcomings in EDF's monitoring of outside contractors. As in 2019, ASN considers that EDF must supplement its complementary inspections programme, particularly as regards equipment other than pressure equipment.

In 2020, EDF defined a preservation strategy for the systems, structures and components that have been mothballed until the EPR reactor is commissioned. In the last quarter 2020, ASN started the review of this strategy and conducted an inspection to check that is was properly implemented. This inspection concluded that the organisation in place is satisfactory. Further inspections will be carried out on this subject in 2021.

ASN authorised the first repairs of the reactor main secondary system welds in 2020. ASN carried out several checks on the preparation of these activities and unannounced inspections to check compliance with the requirements concerning these operations. ASN considers that the preparatory work carried out by EDF and its service providers, and the organisation gradually put in place for performing the operations, are satisfactory. ASN will continue its monitoring of these welding activities in 2021 and will be attentive to ensuring that resources and the organisation are adequate to carry out a larger volume of repairs at the same time.

Lastly, on 8 October 2020 ASN authorised the partial commissioning of the Flamanville EPR reactor for the arrival of nuclear fuel within the reactor perimeter. Several inspections were carried out to check the conformity of the facilities and the operating rigour in the transport and handling of the fuel assemblies. The verifications carried out during these inspections showed the condition of the facility and the licensee's preparedness to be satisfactory for fuel to enter the site.

As regards environmental protection, ASN notes that the licensee took appropriate corrective measures to correct the various shortcomings found during the tightened inspection of 2019. ASN considers that the licensee's consideration of environmental risks is improving.

ASN fulfils the labour inspection duties on the Flamanville 3 construction site. In 2020, ASN checked in particular that outside contractors working on the site complied with the provisions relative to labour law. Observation of the applicable safety rules formed the subject of an inspection adapted to the health crisis conditions. These inspections relating to safety revealed no significant failings. The particular context of the facility, with its partial commissioning, has also been the subject of points requiring particular attention with regard to management of the fire risk in the industrial buildings and organisation for the prevention of risks under the joint responsibility of worksite management and the licensee. ASN also responded to requests coming directly from employees and conducted investigations further to workplace accidents.

Manche waste repository

The Manche waste repository (CSM), which was commissioned in 1969, was the first radioactive waste repository operated in France. 527,225 cubic meters (m^3) of waste packages are emplaced in it. The CSM stopped accepting further waste in July 1994. From the regulatory aspect, the CSM is in the decommissioning phase (operations prior to its closure) until the installation of the long-term cover is completed. An ASN resolution shall specify the date of closure of the repository (entry into monitoring and surveillance phase) and the minimum duration of the monitoring and surveillance phase.

Examination of the periodic safety review guidance file had resulted in ASN formulating specific demands at the end of 2017, concerning the justification of the technical principles of deployment of the long-term cover, the CSM memory system and the updating of the impact study. In this context, ASN is currently examining the CSM periodic safety review report submitted by the French radioactive waste management agency (Andra) in 2019.

ASN considers that the organisational set-up implemented for operating the facilities in 2020 is satisfactory. More specifically, in the context of the Covid-19 pandemic health crisis, the licensee has put in place an activity continuity plan based on the physical protection, environmental monitoring and curative maintenance of the facilities. In the light of the regular exchanges with the licensee and the inspection carried out in December 2020, ASN considers that the measures adopted have enabled monitoring to be maintained at a satisfactory level. In addition, the analysis of the experience feedback specific to this period will enable the organisation to be further improved.

National Large Heavy Ion Accelerator

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

"Exotic nuclei" are nuclei which do not exist naturally on Earth. They are created artificially in Ganil for nuclear physics experiments on the origins and structure of matter. In order to produce these exotic nuclei, Ganil was authorised in 2012 to build phase 1 of the SPIRAL2 project, whose commissioning was authorised by ASN in 2019.

In accordance with the requirements of ASN resolution 2015-DC-0512 of 11 June 2015 relative to its first periodic safety review, Ganil continued its compliance work on the fire-detection and fire-fighting devices, the management of radioactive waste and containment of the facilities. After analysing the difficulties encountered, ASN authorised Ganil, through a resolution of 11 December 2019, to push back the deadlines for the compliance work provided for by six of the ten prescriptions of this periodic safety review.

Although the cyclotrons and the linear accelerator (SPIRAL2) continued to function during the lockdown, the Covid-19 pandemic health crisis has impacted the progress of the Ganil projects as a whole. Nevertheless, the start-up tests of the SPIRAL2 accelerator continued successfully.

In addition to the inspections it carried out, ASN participated in several technical meetings relating to the second periodic safety review of the facility, for which the licensee must submit its periodic safety review concluding report by 18 May 2021 at the latest.

ASN considers that several aspects of the organisation defined and implemented for the operation of the facilities in 2020 must be significantly improved. The licensee must in particular improve its documentation management, in relation with the updating of its safety baseline requirements, and be attentive to the transcription of the regulatory requirements into its integrated management system. Improvements are also expected in the completeness and quality of the files submitted to ASN.

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 15 km from the Channel Islands.

ORANO REPROCESSING PLANTS IN OPERATION AT LA HAGUE

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

Commissioning of the various units of the fuel reprocessing and waste packaging plants UP3-A (BNI 116) and UP2-800 (BNI 117) and the effluent treatment station STE3 (BNI 118) spanned from 1986 (reception and storage of spent fuel assemblies) until 2002 (R4 plutonium treatment unit), with the majority of the process units 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 the site's discharges and water intake are defined by ASN resolutions 2015-DC-0535 and 2015-DC-0536 of 22 December 2015.

Operations carried out in the plants

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

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

The fuel assemblies are then sheared and dissolved in nitric acid to separate the fragments of metal cladding from the spent nuclear fuel. The 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 packaging 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 will then be converted into a solid compound (U_3O_8) called "reprocessed uranium" in the TU5 facility on the Tricastin site.

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

The effluents and waste produced by the operation of the plants

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

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

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

The installations at La Hague

SHUT DOWN INSTALLATIONS UNDERGOING DECOMMISSIONING

BNI 80 – Oxide High Activity facility (HAO):

- **HAO/North**: Facility for “under water” unloading and storage of spent fuel elements,
- **HAO/South**: Facility for shearing and dissolving spent fuel elements;

BNI 33 – UP2-400 plant, first reprocessing unit:

- **HA/DE**: Facility for separating uranium and plutonium from fission products,
- **HAPF/SPF (1 to 3)**: Facility for fission product concentration and storage,
- **MAU**: Facility for separating uranium and plutonium, uranium purification and storage as uranyl nitrate,
- **MAPu**: Facility for purification, conversion to oxide and initial packaging of plutonium oxide,
- **LCC**: Central product quality control laboratory,
- **ACR**: Resin conditioning facility;

BNI 38 – STE2 facility: Effluent collection and treatment and storage of precipitation sludge, and AT1 facility, prototype facility currently being decommissioned;

BNI 47 – ELAN IIB facility, research installation currently being decommissioned.

INSTALLATIONS IN OPERATION

BNI 116 – UP3-A plant:

- **T0**: Facility for dry unloading of spent fuel elements,
- **Pools D and E**: Pools for storing spent fuel elements,
- **T1**: Facility for shearing fuel elements, dissolving and clarification of the resulting solutions,
- **T2**: Facility for separating uranium, plutonium and fission products and concentrating/storing fission product solutions,
- **T3/T5**: Facilities for purification and storage of uranyl nitrate,
- **T4**: Facility for purification, conversion to oxide and packaging of plutonium,
- **T7**: Fission products vitrification facility,
- **BSI**: Plutonium oxide storage facility,
- **BC**: Plant control room, reagent distribution facility and process control laboratories,
- **ACC**: Hull and end-piece compaction facility,
- **AD2**: Technological waste packaging facility,
- **ADT**: Waste transit area
- **EDS**: Solid waste storage area,
- **E/D EDS**: Solid waste storage/removal from storage facility
- **ECC**: Facilities for storage and retrieval of technological waste and packaged structures
- **E/EV South-East**: Vitrified residues storage facility,
- **E/EV/LH and E/EV/LH 2**: Vitrified residues storage facility extensions;

BNI 117 – UP2-800 plant:

- **NPH**: Facility for “under water” unloading and storage of spent fuel elements in pool,
- **Pool C**: Spent fuel element storage pool,
- **R1**: Facility for shearing and dissolving fuel elements and clarification of the resulting solutions (including the URP: Plutonium Redissolution Facility),
- **R2**: Facility for separating uranium, plutonium and fission products and concentrating/storing fission product solutions (including the UCD: centralised alpha waste conditioning unit),
- **SPF (4, 5, 6)**: Fission product storage facilities,
- **R4**: Facility for purification, conversion to oxide and initial packaging of plutonium oxide,
- **BST1**: Facility for secondary packaging and storage of plutonium oxide,
- **R7**: Fission products vitrification facility,
- **AML • AMEC**: Packaging reception and maintenance facilities;

BNI 118 – STE3 facility: Effluent collection and treatment and storage of bituminised waste packages:

- **E/D EB**: Alpha waste storage/removal from storage,
- **MDS/B**: Mineralisation of solvent waste.

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 originates. In order to guarantee an equitable distribution of the waste resulting from the reprocessing of the fuels of its various customers, the licensee has proposed an accounting system that tracks the entries into and exits from the La Hague plant. This system, called EXPER system, was approved by the Order of 2 October 2008 of the Minister responsible for energy.

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

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

Marking events of the year 2020

In order to replace the fission product evaporator-concentrators at La Hague, which are suffering from more advanced corrosion than imagined when they were designed, Orano is building new units, called "New Concentrations of Fission Products" (NCPF) and comprising six new evaporators. This project, which is particularly complex, has required several authorisations and was addressed by an ASN resolution in 2020, focusing on the process of three of these evaporators (NCPF T2). The authorisations to connect these new evaporators to the existing units will be the subject of further resolutions and authorisations in the coming months.

Orano made commitments concerning certain points that were insufficiently studied in the first periodic safety review of BNI 117 (UP2-800), and in particular to conduct a more detailed study of the behaviour of the civil engineering of the NPH pool in the event of an earthquake, and of the hazard risks that the Oxide High Activity (HAO) facility of the UP2-400 plant undergoing decommissioning represents for BNI 117. Orano provided complementary studies and reinforcement proposals in 2020.

In April 2017, Orano requested a modification of the UP3-A plant Creation Authorisation Decree so that CSD-C storage could be extended. This extension was authorised by the Decree of 27 November 2020 on which ASN issued a favourable opinion on 8 September 2020. It provides for significant margins with respect to the risk of reaching the French storage capacity limits for this type of waste.

FINAL SHUTDOWN AND DECOMMISSIONING OPERATIONS ON CERTAIN FACILITIES

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

Final shutdown also concerns three BNIs associated with the UP2-400 plant: BNI 38 (which comprises the effluents and solid waste treatment station No. 2 – STE2, and the oxide nuclear fuel reprocessing facility No.1 – AT1), BNI 47 (radioactive source fabrication unit – ELAN IIB) and BNI 80 (HAO facility).

In 2020, ASN continued its examination of the partial decommissioning authorisation applications for BNIs 33 and 38 submitted in April 2018. The schedule push-backs requested by the licensee lead to decommissioning completion deadlines in 2046 and 2043 instead of 2035, the current deadline prescribed for the two BNIs. ASN notes that the schedule push-backs requested are significant and largely due to the delays in legacy waste retrieval and packaging. Consequently, ASN will continue to monitor the management of these projects in 2020. Further to the additions Orano made to the file concerning firstly the elimination of the interactions between the "Intermediate-Level Plutonium" facility (MAPu) and the plutonium oxide storage facility (BST1) in the event of an earthquake, and secondly the memorandum in response to the opinion of the environmental Authority, a public inquiry was held from 20 October to 20 November 2020.

LEGACY WASTE RETRIEVAL AND PACKAGING OPERATIONS

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

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

Retrieval and packaging of the STE2 sludges

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

The scenario for the retrieval and packaging of the STE2 sludges presented in 2010 was broken down into three steps:
- retrieval of the sludges stored in the silos of STE2 (BNI 38);
- transfer and treatment, initially envisaged by drying and compaction, in STE3 (BNI 118);
- packaging of the resulting pellets in "C5" packages for subsequent disposal in a deep geological repository.

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

At the end of 2017 however, Orano Cycle informed ASN that the process chosen for treating the sludges in STE3 could lead to difficulties in equipment operation and maintenance. Orano Cycle proposed an alternative scenario using centrifugation and in August 2019 it submitted a Safety Options Dossier (DOS), which is however based on insufficiently substantiated hypotheses.

An inspection conducted at the end of 2019 confirmed that the project was not sufficiently mature for ASN to be able to give an opinion on this DOS. The DOS was to be revised, particularly in the fundamental options of the project concerning effluent treatment, discharges into the environment and control of the fire risk.

In 2020, ASN began examining the new DOS submitted by Orano in July 2020 and providing additional information, particularly on the subjects relating to reactivity of the sludge and treatment of the effluents. ASN also continued examining the application for authorisation to install recovery equipment on the roofs of the STE2 facility silos, focusing particular attention on the fire risk, the control of which is not fully demonstrated. ASN is still waiting for additional information on this latter subject.

The safety issues associated with silo 130

Silo 130 was designed and built in accordance with the safety requirements in effect in the 1960's. Today, the civil engineering structure of silo 130 is weakened by ageing and by a fire that occurred in 1981. Furthermore, part of the waste that was initially stored dry is now submerged in a large volume of water that served to extinguish the 1981 fire. The water is therefore in direct contact with the waste and can contribute to corrosion of the carbon steel liner, which at present is the only containment barrier. One of the major risks therefore concerns the dispersion of radioactive substances into the environment (infiltration of contaminated water into the water table).

Another factor that can compromise the safety of silo 130 is linked to the nature of the substances present in the waste, such as magnesium, which is pyrophoric. Hydrogen, a highly inflammable gas, can also be produced by phenomena of radiolysis or corrosion (presence of water). These elements contribute to the risks of fire and explosion.

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 water-filled silo is only ensured at present 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. In 2020, preparation of the waste retrieval operations continued and the milestone of filling the first drum of waste retrieved from silo 130 was crossed. After a prolonged shutdown of the facilities due to the lockdown imposed for management of the health crisis, and the integration of material modifications before resuming operations, including replacement of the rake cables, Orano resumed operation in October 2020 after having sent the first shipment of drums to the solid waste storage/removal from storage facility (E/D EDS) on the La Hague site.

Orano has moreover conducted an initial analysis of the feedback from the entry into service of this retrieval unit and has identified organisational improvements in the management of this type of project. These improvements concern in particular the consolidation of the methodology for transferring the facility from the project teams – including those responsible for the tests – to the future licensee's teams. ASN considers this approach to be positive.

HAO silo and Organised Storage of Hulls (SOC)

The HAO (Oxide High Activity) facility (BNI 80) ensured the first steps of the spent nuclear fuel reprocessing process: reception, storage, then shearing and dissolution. The dissolution solutions produced in BNI 80 were then transferred to the UP2-400 industrial plant in which the subsequent reprocessing operations took place.

Assessment of the La Hague site

ASN considers that the performance of the Orano La Hague site in 2020 is satisfactory in the areas of nuclear safety, radiation protection and environmental protection.

As far as the management of the Covid-19 pandemic health crisis is concerned, ASN notes that Orano managed to adapt its organisation and its modes of functioning to cope with the health risk, while maintaining the required standard of safety in its facilities in operation. Orano moreover maintained the activity of some decommissioning worksites representint significant risks.

With regard to nuclear safety, ASN considers that the site's performance remained satisfactory. Nevertheless, the detection of new delays in the performance of several periodic inspections should prompt the licensee to question the adequacy of the corrective actions already implemented to comply with the planned frequency.

With regard to operational management and the operating activities, Orano must demonstrate greater rigour in the formalisation of operator authorisations in the control room. In addition, ASN will continue to be attentive to the deployment of the facility's different operating teams.

Improvement actions have also been undertaken for the management of risks involving hazardous substances and the control of conformity of the site's Installations Classified for Protection of the Environment. ASN considers that they are satisfactory and will be watchful for the occurrence of new drifts in this respect.

ASN considers that the licensee must continue its efforts in the monitoring of outside contractors, particularly through the improvement of the monitoring means and the changes in its organisation. The licensee must also show greater rigour in the monitoring of certain services, particularly those involving fewer activities, by ensuring that the applicable regulatory requirements are integrated. Lastly, in 2021 ASN will examine Orano's request for a waiver to the principle of the licensee's direct operational responsibility, a consequence of the Orano group restructuring. In this context, ASN will check the added value introduced by this new organisation and see to the maintaining of the licensee's technical skills for the day-to-day operation of the site facilities undergoing decommissioning.

ASN considers that the licensee's organisation for controlling fire risks deteriorated in 2021. Delays have been noted in the performance of some compliance work. The licensee must also endeavour to draw full benefit from the lessons learned from the fire outbreak in February 2020 on the laundry storage platform. Lastly, ASN will be particularly attentive in 2021 to the match between the fire intervention times provided in its safety case and those observed during exercises, and the efficiency of the fire-fighting operational organization. Unannounced situational scenarios will continue to be played out on this subject.

With regard to radiation protection, ASN notes that the La Hague site's organisation and its results are on the whole satisfactory. This being said, the sampling checks carried out reveal that there are still divergences between the operational documents and the various computing aids for monitoring the regulatory checks. The licensee must thus ensure that these checks are carried out exhaustively. ASN considers that Orano must also improve the traceability of application of the recommendations or reservations expressed at the radiation protection committee meetings. Lastly, ASN will remain attentive to the experience feedback for the new radiation protection organisation implemented on the La Hague site.

The environmental protection performance of the site is on the whole satisfactory. ASN notes favourably the action plan implemented for the prevention of flows and the unplanned dispersion of radioactive or hazardous liquid substances into the environment. Nevertheless, greater rigour must be applied in the depositing of waste at the collection points provided for that purpose in the facilities.

With regard to the management of the decommissioning and legacy waste retrieval and packaging projects, ASN considers that the licensee's reflections into the fundamental improvements of project organisation and management must be continued in order to meet Orano's commitment deadlines, which are transcribed in ASN requirements or decrees. As regards project management, ASN has noted the implementation of methods of functioning that should foster greater robustness. In addition, the licensee must define the potential impact of the health crisis on the time frames of the various projects or operations and take appropriate corrective measures. In 2021, ASN will be particularly attentive to the assessment of the benefit resulting from implementation of these various improvements by Orano, particularly with regard to rigour in project management and the activity risk analyses.

BNI 80 comprises:

- HAO North, spent fuel unloading and storage site;
- HAO South, where the shearing and dissolution operations were carried out;
- the "filtration" building, which accommodates the filtration system for the HAO South pool;
- the HAO silo, in which are stored the hulls and end-pieces (fragments of cladding and fuel end-pieces) in bulk, fines coming primarily from shearing, and resins and technological waste from the operation of the HAO facility between 1976 and 1997;
- the SOC (Organised Storage of Hulls), comprising three pools in which the drums containing the hulls and end-pieces are stored.

In 2020, the licensee continued the operations prior to retrieval of the waste from the HAO silo (notably the fitting out of the future waste retrieval unit) and the tests important to safety which began in 2019.

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

For the packaging of the fission products from the reprocessing of the GCR reactor fuels and containing molybdenum in particular (PF UMo), the licensee has opted for cold crucible vitrification. The package thus produced is a standard package of vitrified UMo waste. The treatment and packaging of the fission "UMo" products contained in the SPF2 facility tanks were completed in July 2020, thereby meeting the deadline set by ASN resolution 2019-DC-0665 of 9 April 2019. ASN considers that the vitrification of these solutions constitutes a significant improvement for the safety of these old facilities due to the reduction in their potential source term in the event of an accident.

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.

In 2020, ASN carried out 111 inspections in the Nouvelle-Aquitaine region, comprising 42 inspections in the Blayais and Civaux Nuclear Power Plants (NPPs), 58 inspections in the small-scale nuclear activity sector and 11 inspections of approved organisations and laboratories.

ASN also carried out 15 days of labour inspection at the Blayais NPP and 7.5 days at the Civaux NPP.

During 2020, 8 significant events rated level 1 on the International Nuclear and Radiological Event Scale (INES scale) were reported by the NPP licensees of Nouvelle-Aquitaine. In small-scale nuclear activities, one significant radiation protection event rated level 1 on the INES scale was reported to ASN.

Within the framework of their inspection duties, the ASN inspectors drew up one violation report against a veterinary surgeon for using high-activity sealed sources.

Blayais nuclear power plant

Situated in the Gironde *département*, 50 km north of Bordeaux, the Blayais NPP is operated by EDF. This NPP comprises four 900 Megawatts electric (MWe) Pressurised Water Reactors (PWRs). Reactors 1 and 2 constitute Basic Nuclear Installation (BNI) 86 and reactors 3 and 4 BNI 110.

ASN considers that the nuclear safety performance of the Blayais NPP is in line with its general assessment of the EDF plants. ASN considers that the radiation protection and environmental protection performance fall short of its general assessment of EDF performance.

With regard to nuclear safety, although the performance of the Blayais NPP is in line with the general assessment of the EDF plants, ASN considers that it has dropped slightly compared with the preceding years. The Blayais NPP has shown its ability to satisfactorily manage a large number of maintenance and modification embodiment activities on its facilities in a difficult health crisis situation. ASN also notes that the addressing of conformity deviations is satisfactory. ASN does however observe, as in 2019, deficiencies in the quality of the operational documentation covering the preparation and performance of the activities. Lastly, the second half of the year was marked by a large number of significant events highlighting the need for the Blayais NPP licensee to implement improvement actions to maintain its performance.

ASN considers that the situation regarding worker radiation protection remains sub-standard and that the site is still not managing to restore a satisfactory level, despite putting in place preventive measures at the beginning of the year and corrective measures during the outages. This finding, made by ASN through its inspections, is corroborated by the numerous and diverse significant radiation protection events, two of which were rated level 1 on the INES scale. ASN expects a strong reaction on the part of the site to rapidly and lastingly improve its worker radiation protection performance in 2021. Radiation protection will be subject to a tightened inspection in 2021.

With regard to environmental protection, ASN has noted the actions undertaken by the licensee, but considers that their effects and results are insufficiently conclusive to lastingly remediate the legacy pollution of the site's soils and captive groundwater tables. These subjects require the implementation of determined actions on the part of the Blayais NPP licensee, with closely-spaced deadlines.

With regard to labour inspection, ASN considers that the regulatory monitoring of the electrical installations and control of the asbestos risk must be improved. ASN considers that the safety results are unsatisfactory, but takes positive note of the Blayais site's drive to identify, report and deal with risk situations. ASN has continued its monitoring of the conformity files of the heavy cranes, the locally manufactured tooling, and the ventilation of premises with specific pollution problems. Lastly, ASN has specifically monitored the health crisis, especially during the first lockdown, through its presence in the field, its participation at extraordinary meetings of the social and economic committee and by responding to individual and collective requests.

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 PWRs with a power rating of 1,450 MWe. Reactors 1 and 2 constitute BNIs 158 and 159 respectively. The site accommodates one of the regional bases of the Nuclear Rapid Intervention Force (FARN) created by EDF in 2011 further to the accident at the Fukushima Daiichi NPP in Japan. Its role is to intervene in pre-accident or accident situations, on any NPP in France, by providing additional human resources and emergency equipment.

ASN considers that the nuclear safety and radiation protection performance of the Civaux NPP stand out positively with respect to its general assessment of EDF plant performance, and that its environmental protection performance is in line with this general assessment.

ASN considers that the nuclear safety performance is improving. ASN considers that the reactor management operations are on the whole conducted with rigour and that the NPP is capable of preventing, detecting and correcting inappropriate operating actions. Nevertheless, on several occasions, the rules defining the authorised operating range of the installation and the associated operating management instructions were not followed. ASN considers that the licensee competently carried out the planned maintenance activities during the reactor 1 refuelling outage. ASN considers that these areas of progress must be consolidated in 2021 and 2022 for the second ten-yearly outages of the reactors.

With regard to radiation protection, ASN considers that the licensee has obtained satisfactory results in limiting worker exposure to ionising radiation. The licensee correctly evaluated the collective dose received by all the workers during the reactor 1 maintenance and refuelling operations.

In the area of environmental protection, ASN has observed the licensee's progress in its ability to contain an accidental spillage of hazardous products on the site. Nevertheless, the licensee must still put in place an ultimate containment basin that can ensure on-site containment of accidental spillages and fire extinguishing water should a fire break out.

With regard to labour inspection, ASN considers that the Civaux NPP's control of the asbestos risk can be improved. Specific investigations were carried out after the occurrence of workplace accidents, notably during work involving significant safety risks carried out in the space between the two containments of the reactor building. Lastly, ASN has specifically monitored the health crisis, especially during the first lockdown, through its presence in the field, its participation at extraordinary meetings of the social and economic committee and by responding to individual and collective requests.

THE INSTALLATIONS AND ACTIVITIES TO REGULATE COMPRISES:

- **Basic Nuclear Installations:**
  - the Blayais NPP (4 reactors of 900 MWe),
  - the Civaux NPP (2 reactors of 1,450 MWe);
- **small-scale nuclear activities in the medical sector:** p. 206
  - 19 external-beam radiotherapy departments,
  - 6 brachytherapy departments,
  - 24 nuclear medicine departments,
  - 88 centres performing fluoroscopy-guided interventional procedures,
  - 89 computed tomography scanners,
  - some 6,000 medical and dental radiology devices;
- **small-scale nuclear activities in the veterinary, industrial and research sectors:** p. 238
  - about 700 industrial and research centres, including 50 companies with an industrial radiography activity,
  - 1 cyclotron particle accelerator,
  - 67 laboratories situated mainly in the universities of the region,
  - about 500 veterinary surgeries or clinics practising diagnostic radiology;
- **activities associated with the transport of radioactive substances;** p. 266
- **ASN-approved laboratories and organisations:**
  - 5 organisations approved for radiation protection controls,
  - 8 organisations approved for measuring radon,
  - 4 laboratories approved for taking environmental radioactivity measurements.

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.

In 2020, ASN carried out 91 inspections in the Occitanie region, comprising 49 inspections in Basic Nuclear Installations (BNIs) 36 inspections in small-scale nuclear activities, 2 in the transport of radioactive substances and 4 concerning organisations and laboratories approved by ASN.

ASN also carried out 14.5 days of labour inspection at the Golfech Nuclear Power Plant (NPP).

During 2020, 1 significant event rated level 2 on the International Nuclear and Radiological Event Scale (INES scale) and 3 events rated level 1 were reported by nuclear installation licensees in Occitanie.

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 Megawatts electric (MWe) pressurised water reactors. Reactor 1 constitutes BNI 135 and reactor 2 BNI 142.

ASN considers that the NPP's nuclear safety and radiation protection performance, despite having improved, is below the general assessment of the EDF plants. ASN will continue its tightened inspections in these areas in 2021. ASN considers that the performance of the Golfech NPP with regard to environmental protection is on the whole in line with ASN's general assessment of the EDF plants.

In the area of nuclear safety, ASN has noted significant improvements resulting from the implementation of substantive corrective actions further to the in-depth inspection of October 2019. The inspections on the theme of operating management evidenced the significance of the work done by the Golfech NPP to increase operating rigour. ASN nevertheless considers that more rigorous application of the procedures by the workers and better preparation of the activities would have prevented the occurrence of certain significant events. Furthermore, in the area of maintenance and the management of works associated with the reactor outages, ASN considers that the site must rapidly improve its organisation in order to ensure better traceability of the activities and better management of the deviations and contingencies affecting the facilities.

With regard to worker radiation protection, ASN considers that the situation has improved with respect to 2019 but remains below the required level. The findings from inspections and the events reported by the Golfech NPP reveal inadequate application of the basic rules of radiation protection by the workers.

In the area of environmental protection, ASN considers that the Golfech NPP's monitoring and waste management results are satisfactory. The site must nevertheless finalise its strategy for containing an accidental spillage of hazardous products in certain areas of its facility.

With regard to labour inspection, ASN has noted deficiencies in the regulatory monitoring of the electrical installations and considers that the coordination of the risks linked to the interfaces between the various activities must be improved. ASN considers that the worker safety results are not satisfactory at present, but notes a drive to identify, report and deal with the risk situations to try to improve this situation. ASN has specifically monitored the health crisis, through inspections in the field, participation at extraordinary meetings of the social and economic committee and by responding to individual and collective requests.

MARCOULE PLATFORM

The Marcoule nuclear platform is situated to the west of Orange in the Gard *département*. Its six civil installations are dedicated to research activities relating to the downstream part of the fuel cycle and the irradiation of materials, and to industrial activities concerning in particular the fabrication of Mixed OXyde Fuel (MOX), the processing of radioactive waste and the irradiation of materials. The majority of the site is occupied by Defence Basic Nuclear Installations (DBNIs) which come under the responsibility of the Ministry of Defence.

CEA MARCOULE CENTRE

Created in 1955, the CEA Marcoule centre accommodates three civil installations: the Atalante laboratories (BNI 148), the Phénix NPP (BNI 71) and the Diadem storage facility (BNI 177).

Atalante facility – *CEA Centre*

The main purpose of the Alpha facility and laboratory for transuranium elements analysis and reprocessing studies, known as "Atalante" (BNI 148), created in the 1980's, is to conduct research and development concerning the recycling of nuclear fuels, 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 Laboratory for research and fabrication of advanced nuclear fuels (Lefca), transferred from the CEA Cadarache centre.

ASN plans to make a position statement in 2021 on the continued operation of the BNI on completion of examination of the facility's periodic safety review report submitted in 2016 and of the CEA's action plan, incorporating the improvement in control of the fire risk in particular.

ASN moreover carried out an in-depth analysis of an event that occurred on 19 December 2018 which led to the shattering of a vial containing a radioactive liquid while being handled in a glove box. This event injured the worker. ASN rated this event level 1 on the INES scale. In 2020, the licensee detailed the process it plans implementing to authorise the reopening of the laboratory concerned, which has been closed since the incident. The work scenario includes more specifically the operations to neutralise the reagents and retrieve the waste contained in the glove box.

ASN considers that the level of nuclear safety and radiation protection of BNI 148 Atalante in 2020 is relatively satisfactory. ASN has nevertheless observed shortcomings in radiation protection concerning the accuracy of the procedures and their adoption by the workers. The management of deviations, the monitoring of the actions implemented, the assessment of their effectiveness, and the traceability of radiological zoning histories also present shortcomings which must be remedied. ASN considers that the analysis of the causes of events displaying social, organisational and human factors is insufficiently documented and does not allow the assessment of the robustness of the measures taken to guarantee their non-recurrence.

In the area of accident management and emergency organisation and means, ASN considers that substantial efforts must be made to comply with the regulatory provisions relating to emergency situation management.

THE INSTALLATIONS AND ACTIVITIES TO REGULATE COMPRISES:

- **Basic Nuclear Installations:**
  - the Golfech NPP comprising 2 reactors of 1,300 MWe,
  - the Mélox "MOX" nuclear fuel production facility,
  - the CEA Marcoule research centre, which includes the civil BNIs Atalante and Phénix and the Diadem waste storage facility construction site,
  - the Centraco facility for processing low-activity waste,
  - the Gammatec industrial ioniser,
  - the Écrin facility for storing waste on the Malvési site;
- **small-scale nuclear activities in the medical sector:** p. 206
  - 14 external-beam radiotherapy departments,
  - 6 brachytherapy departments,
  - 21 nuclear medicine departments,
  - 98 centres performing fluoroscopy-guided interventional procedures,
  - 127 computed tomography scanners,
  - some 5,000 medical and dental radiology devices;
- **small-scale nuclear activities in the veterinary, industrial and research sectors:** p. 238
  - about 800 industrial and research centres, including 4 cyclotron particle accelerators, 27 companies exercising an industrial radiography activity and 77 laboratories situated mainly in the universities of the region,
  - about 560 veterinary surgeries or clinics practising diagnostic radiology;
- **activities associated with the transport of radioactive substances;** p. 266
- **ASN-approved laboratories and organisations:**
  - 3 laboratories approved for taking environmental radioactivity measurements,
  - 5 organisations approved for measuring radon,
  - 7 organisations approved for radiation protection controls.

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.

With regard to environmental protection, the CEA submitted two studies required by the Basic Nuclear Installation (BNI) discharges resolutions, which will be examined:

- **the health and environmental assessment of liquid and gaseous chemical discharges on the Marcoule platform;**
- **a technical-economic study of the provisions for avoiding or reducing the discharge of potentially polluted stormwaters. This study integrates the bus station project situated to the north of the Phénix BNI.**

The licensee satisfactorily continued its action plan for bringing its piezometers into compliance with the requirements of the Order of 11 September 2003 by 2024.

In the light of the inspections conducted in 2020, ASN considers that the management of on-site transport operations and environmental monitoring at the Marcoule centre are satisfactory.

With regard to emergency management, ASN authorised the implementation of the On-site Emergency Plan which will also be subject to the approval of the Defence Nuclear Safety Authority (ASND).

Complements to the examination of the stress tests carried out further to the Fukushima Daiichi NPP accident are still awaited and concern in particular the impact of the planned work to reinforce the earthquake resistance of the emergency management buildings and the proof of the habitability and accessibility of these premises in the various accident situations encountered.

Lastly, concerning the seismic hazard to consider for the Marcoule centre, the characterisation of the particular "site effects", within the meaning of Basic Safety Rule RFS 2001-01, and specific to each facility at the centre, is the subject of an ongoing technical examination.

Phénix reactor – *CEA Centre*

The Phénix NPP (BNI 71) is a demonstration fast breeder reactor cooled with liquid sodium. This reactor, with an electrical power rating of 250 MWe, was definitively shut down in 2009 and is currently being decommissioned.

The major decommissioning phases are regulated by Decree 2016-739 of 2 June 2016. ASN resolution 2016-DC-0564 of 7 July 2016 lays down various milestones and decommissioning operations for the CEA.

Removal of the spent fuel and equipment, despite unforeseen disruptions in the pace of work, continued in 2020 in accordance with the ASN requirements and the licensee's commitments made in the context of the facility's periodic safety review and transition to the decommissioning phase.

ASN considers that the level of nuclear safety and radiation protection of the Phénix NPP is on the whole satisfactory. Improvements are nevertheless expected regarding compliance with the environment resolution, optimisation of waste zoning, the times taken to implement corrective actions and preservation of the memory of the facility. Compliance with the deadlines for replying to ASN requests improved at the end of 2020, an improvement that must be maintained and continued.

Construction of the NOAH facility, which will treat the sodium from Phénix and other CEA installations, progressed in 2020 and the operating tests prior to commissioning are continuing.

The reference decommissioning scenario for the facility is currently being redefined in line with the decommissioning strategy for all the CEA facilities. These changes in the reference scenario will lead to a request to modify the Decree, which prescribes decommissioning of the NPP before the end of 2023.

Diadem facility – *CEA Centre*

The Diadem facility, currently under construction, 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).

ASN considers that worksite management is satisfactory despite the health crisis, whose impact on the project will nevertheless have to be quantified more precisely. The contractual management of the contracts is a critical point in the overall progress of the project. ASN emphasises that this facility is destined to play a key role in the CEA's overall decommissioning and waste management strategy and it is the only facility planned for the interim storage of waste packages of this type. The operations necessary for its commissioning, today planned for 2024, must therefore be a priority for the CEA. The filing of a request to modify the creation authorisation decree is planned in 2021 further to change in the package closure technology.

The CEA moreover is considering filing the first packaging approval requests, necessary for production of the intermediate-level long-lived waste (ILW-LL) packages which will be stored in the facility in 2021.

Melox plant

Created in 1990 and operated by Orano, the Melox plant (BNI 151) produces MOX fuel which consists of a mix of uranium and plutonium oxides.

ASN considers that the level of nuclear safety and radiation protection of the Melox plant is on the whole satisfactory.

The containment barriers, on which a large part of the safety case is based, are effective and robust. The licensee is continuing its efforts to deal with the breaks in containment that can occur under normal operating conditions.

The radiation exposure risks are addressed with rigour, and the licensee is continuing the work to improve dosimetry in the context of ageing facilities and the necessary optimisation of work stations. The dosimetry at the lens of the eye remains a subject of concern, particularly with regard to exposure measurement. The work to develop ergonomic radiation protection glasses adapted to the sight of each employee is completed.

On 24 June 2020, the licensee notified ASN of a significant event rated level 2 on the INES scale concerning exceeding of the annual dose limit. The licensee's analysis did not reveal any technical malfunctioning or error on the part of the operator. Nevertheless, corrective measures and complementary studies are going to be implemented, particularly with regard to the workstation ergonomics. The rating of this event might change in the light of the complementary work initiated on the committed dose evaluation.

In April 2020, ASN authorised updating of the safety baseline requirements further to the examination of the periodic safety review report submitted in 2013. In October 2018, the licensee submitted a Periodic Safety Review Guidance File (DOR) to ASN, for which the next concluding report must be submitted in 2021. ASN issued a position statement on this DOR in the second half of 2020 and sent the licensee some additional requests.

With regard to the lessons learned from the Fukushima Daiichi NPP accident, the licensee was able to resume construction of the new emergency centre following the technical, contractual and health crisis difficulties encountered in 2020. The licensee has taken temporary measures, such as the deployment of a fall-back emergency centre, to make up for the delay.

Centraco plant

The Centraco plant (BNI 160), was created in 1996 and is operated by Cyclife France, a 100% subsidiary of EDF. The purpose of the Centraco plant is to sort, decontaminate, reuse, treat and package – particularly by reducing their volume – waste and effluents with low and very 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 storage areas.**

ASN considers that the level of nuclear safety and radiation protection in the facility is on the whole satisfactory. The licensee must nevertheless improve the content of its files in order to meet the regulatory requirements. ASN considers that the safety management organisation put in place during the pandemic is on the whole satisfactory. In-service monitoring of the pressure equipment has been improved further to the inspection on this subject in 2019.

A request to modify the On-Site Emergency Plan was submitted to ASN in 2020 to bring it into compliance with the provisions of ASN resolution 2017-DC-0592 of 13 June 2017 concerning the obligations of BNI licensees regarding emergency situation preparedness and management.

In May 2020, a fire started in the waste introduction chamber of the facility's incineration furnace, the main cause of which is a recurrent equipment fault. This event was rated level 1 on the INES scale. The licensee is deploying corrective measures to prevent recurrence.

Lastly, in August 2020, ASN requested numerous complements to the DOR submitted in May 2019 for the next periodic safety review of BNI 160, for which the report was submitted in February 2021.

Gammatec ioniser

The Gammatec ioniser (BNI 170), is an industrial irradiator operated by the company Stéris since 2013. Gammatec treats products by ionisation (emission of gamma radiation) with the aim of sterilising them or improving the performance of the materials. 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 the facility in 2020 is on the whole satisfactory.

The licensee must remain attentive to ensuring compliance with the technical requirements for monitoring discharges and effluent transfers and to the formalising of all periodic inspection and test results.

Écrin facility

The Ecrin facility, BNI 175, is situated in the municipality of Narbonne in the Aude *département*, within the Malvési site operated by Orano where the first step of the fuel cycle (excluding extraction of the ores) is carried out. The transformation process produces liquid effluents containing nitrated sludge loaded with natural uranium. The entire plant is subject to the system governing Seveso high-threshold Installations Classified for Protection of the Environment (ICPEs).

Two storage basins containing the legacy sludge from the plant constitute the Ecrin BNI. These two basins have BNI classification due to the presence of traces of artificial radioisotopes. This BNI was authorised by Decree of 20 July 2015 for the storage of radioactive waste for a period of 30 years.

The Ecrin facility was commissioned by ASN resolution 2018-DC-0645 of 12 October 2018. This authorisation enabled the licensee to start in February 2019 the work defined in the authorisation decree, which continued in 2020 with the start of filling of the PERLE vault (French acronym standing for "Project for Reversible Lagoon Storage in the Ecrin BNI"). The installation of a bituminous cover on the BNI's basins has also been started.

The licensee announced in 2020 that it would be late in submitting the results, provided for by Article 7 of the creation authorisation decree, relative to the storage options feasibility study with a view to final disposal of the radioactive waste from the Orano Malvési site.

ASN considers that the level of nuclear safety and environmental protection of the Écrin facility is satisfactory.

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.

In 2020, ASN carried out 37 inspections, comprising 2 inspections in the facilities of the company Ionisos (Pouzauges and Sablé-sur-Sarthe), 31 in small-scale nuclear activities, 3 concerning approved organisations and 1 in the transport of radioactive substances.

One significant event in 2020 at the Ionisos facility in Pousauges was rated level 1 on the International Nuclear and Radiological Event Scale (INES scale), due to noncompliance with the general operating rules.

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 constitute Basic Nuclear Installation (BNI) 146 and 154 respectively.

The gamma radiation emitted is used to sterilise, destroy pathogenic germs or reinforce (by cross-linking) the technical properties of certain polymers, by exposing the products to be ionised (single-use medical equipment, packaging, raw materials and finished productions for the pharmaceutical and cosmetic industries, packing films) for a pre-determined length of time.

The installation comprises a pool for underwater storage of the radioactive sources which is surmounted by a bunker in which the ionisation operations are performed, premises for storing the products before and after treatment, offices and technical rooms.

ASN considers that operation of the irradiator at Sablé-sur-Sarthe with regard to nuclear safety and radiation protection is satisfactory. With regard to the Pouzauges irradiator, ASN considers that the licensee demonstrates transparency, but a lack of operating rigour has nevertheless been noted. ASN continued its examination of the periodic safety review reports of the two irradiators in 2020. Several modification projects concerning the Pouzauges facility are currently being examined, and ASN has authorised extension of the period of utilisation of sealed sources in the Sablé-sur-Sarthe facility.

THE INSTALLATIONS AND ACTIVITIES TO REGULATE COMPRISES:

- **Basic Nuclear Installations:**
  - the Ionisos irradiator in Sablé-sur-Sarthe,
  - the Ionisos irradiator in Pouzauges;
- **small-scale nuclear activities in the medical sector:** p. 206
  - 7 external-beam radiotherapy departments,
  - 2 brachytherapy units,
  - 11 nuclear medicine departments,
  - 40 centres performing fluoroscopy-guided interventional procedures,
  - 55 computed tomography scanners,
  - some 2,500 medical and dental radiology devices;
- **small-scale nuclear activities in the veterinary, industrial and research sectors:** p. 238
  - 1 cyclotron,
  - 26 industrial radiography companies, including 10 performing gamma radiography,
  - about 400 industrial equipment and research licenses;
- **activities associated with the transport of radioactive substances;** p. 266
- **ASN-approved laboratories and organisations:**
  - 4 agencies approved for radiation protection controls,
  - 13 organisations approved for measuring radon,
  - 1 head-office of a laboratory approved for environmental radioactivity measurements.

Provence-Alpes-Côte d'Azur Region

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

In 2020, ASN carried out 95 inspections in the Provence-Alpes-Côte d'Azur (PACA) region, comprising 52 inspections in Basic Nuclear Installations (BNIs), 38 inspections in small-scale nuclear activities, 1 in the transport of radioactive substances and 4 concerning organisations and laboratories approved by ASN.

During 2020, no significant events rated level 1 on the International Nuclear and Radiological Event Scale (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 (1 in the industrial sector and 1 in the medical sector).

CADARACHE SITE

CEA Cadarache centre

Created in 1959, the CEA Cadarache centre is situated in the municipality of Saint-Paul-lez-Durance in the Bouches-du-Rhône *département* and covers a surface area of 1,600 hectares. This site focuses its activity primarily on nuclear energy and, as concerns its civil installations in operation, on research and development to support and optimise the existing reactors and the design of new-generation systems.

The following BNIs are located on the site:
- the Pégase-Cascad installation (BNI 22);
- the Cabri research reactor (BNI 24);
- the Rapsodie research reactor (BNI 25);
- the Solid Waste Treatment Station (STD – BNI 37-A);
- the Active Effluent Treatment Station (STE – BNI 37-B);
- the Plutonium Technology Facility (ATPu – 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.

At the Cadarache centre, 10 installations are in final shutdown status, 10 are in operation and one is under construction. The CEA Cadarache centre operates numerous installations which vary in their nature and their safety implications. ASN has moreover started, is continuing or has finalised the examination of the periodic safety review guidance files or the conclusion reports for 17 of the 21 installations: Pégase-Cascad, Cabri, Rapsodie, STD, STE, ATPu, Éole, ATUe, MCMF, LPC, STAR, the waste storage area, Phébus, Minerve, Chicade, Cedra and Magenta. When examining these reports, ASN is particularly attentive to the robustness of the proposed and deployed action plans. It ensures that the installations are in conformity with the applicable regulations and that the risks and adverse effects are effectively controlled.

Pégase-Cascad facility – *CEA Centre*

The Pégase reactor (BNI 22) entered service on the Cadarache site in 1964 and was operated for about 10 years. The CEA was authorised by a Decree of 17 April 1980 to reuse the Pégase facility for the storage of radioactive substances, in particular spent fuel elements stored 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. Although a large proportion of the stored substances has been removed from the facility, the CEA is significantly behind schedule with some of the removal from storage operations initially prescribed for 2018 in the ASN Chairman's resolution CODEP-CLG-2017-006524 of 10 February 2017. This deadline was revised in ASN Chairman's resolution CODEP-CLG-2020-062379 of 21 December 2020 relative to the periodic safety review of the facility which stipulates the deadlines for the nearest stages in these removal actions before 2025. The furthest removal from storage deadlines, planned by 2035, shall fall under application of the future Decommissioning Decree of the Pegasus facility.

In 2019, the CEA submitted a decommissioning file for the Pégase part of BNI 22, which is currently being examined.

The Cascad facility, authorised by a Decree of 4 September 1989 modifying the Pégase facility and operated since 1990, remains in service, dedicated to the dry storage of irradiated fuel in wells.

The creation authorisation decree for the facility stipulates that ASN authorises the storage of fuels in Cascad for a period of 10 years. In the context of its last authorisation renewal application sent in 2014, the CEA had informed ASN of its aim to remove a portion of this fuel from storage for reprocessing in the La Hague plant before the end of 2023. These removal operations began at the end of 2020.

ASN considers that the nuclear safety and radiation protection of the Pégase and Cascad facilities for 2020 is on the whole satisfactory. It more specifically notes improvements in the monitoring of the action plans stemming from the last periodic safety review of the facilities in 2017, but remains attentive to the deadlines prescribed for the various removal from storage operations.

Cabri research reactor – *CEA Centre*

The Cabri reactor (BNI 24), created on 27 May 1964, is intended for conducting experimental programmes aiming to achieve a better understanding of the behaviour of nuclear fuel in the event of a reactivity accident. The reactor has been equipped with a pressurised water loop since 2006 in order to study the behaviour of the fuel at high combustion rates in accident situations of increasing reactivity in a Pressurised Water Reactor (PWR). Since January 2018, the CEA has been conducting a programme of tests called "CIP" (Cabri International Program), which began in the early 2000's and necessitated substantial modification and safety upgrading work on the facility.

On 25 September 2020, the licensee reported a significant event concerning a leak detected and collected in the "core water" system containment. This event and the compensatory measures proposed by the CEA are currently being examined by ASN, particularly their implications for reactor safety and protection of the environment.

The periodic safety review of the facility submitted at the end of 2017 is currently being examined by ASN.

Examination of the request to modify its authorisation decree in order to conduct irradiations on electronic equipment, which was submitted in 2019, continued in 2020. The next cycle of tests is planned for 2021.

ASN considers that the level of nuclear safety and radiation protection of the facility is on the whole satisfactory.

THE INSTALLATIONS AND ACTIVITIES TO REGULATE COMPRISES:

- **Basic Nuclear Installations:**
  - the CEA Cadarache research centre which counts 21 civil BNIs, including the Jules Horowitz reactor currently under construction,
  - the ITER installation construction site, adjacent to the CEA Cadarache centre.
  - the Gammaster industrial ioniser;
- **small-scale nuclear activities in the medical sector:** p. 206
  - 13 external-beam radiotherapy departments,
  - 3 brachytherapy departments,
  - 17 nuclear medicine departments,
  - 112 centres performing fluoroscopy-guided interventional procedures,
  - 105 computed tomography scanners,
  - some 8,200 medical and dental radiology devices;
- **small-scale nuclear activities in the veterinary, industrial and research sectors:** p. 238
  - about 400 industrial and research centres, including 3 cyclotron particle accelerators and 20 companies with an industrial radiography activity,
  - about 465 veterinary surgeries or clinics practising diagnostic radiology;
- **activities associated with the transport of radioactive substances;** p. 266
- **ASN-approved laboratories and organisations:**
  - 2 laboratories approved for taking environmental radioactivity measurements
  - 1 organisation approved for measuring radon,
  - 6 organisations approved for radiation protection controls.

Rapsodie research reactor – *CEA Centre*

The Rapsodie reactor (BNI 25) is the first sodium-cooled fast-neutron reactor built in France. It operated from 1967 to 1978. A sealing defect in the reactor pressure vessel led to its final shutdown in 1983. Decommissioning operations were subsequently undertaken, but have been partially stopped further to a fatal accident in 1994 during the washing of a sodium tank. At present the core has been unloaded, the fuel evacuated from the installation, the fluids and radioactive components have been removed and the reactor vessel is contained. The reactor pool has been emptied, partially cleaned out and decommissioned and the waste containing sodium has been removed.

The licensee is continuing the clean-out and decommissioning preparation work. ASN continued its examination of the decommissioning file in 2020 and issued an opinion on a draft decree to regulate this forthcoming phase in the life of the reactor and which also sets a new perimeter for the installation.

ASN considers that the level of nuclear safety and radiation protection of this installation in 2020 is on the whole satisfactory, particularly with regard to the organisation put in place for monitoring and dealing with deviations.

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 in a single installation. As the CEA wishes to ensure continued operation of the STD and proceed with the final shutdown of the STE, BNI 37 was divided into two BNIs: 37‑A (STD) and 37‑B (STE) by ASN resolutions CODEP‑DRC‑2015‑027232 and CODEP‑DRC‑2015‑027225 of 9 July 2015. These records were made further to the Orders of 9 June 2015 defining the perimeters of these two BNIs.

At present, the STD is the CEA's only civil BNI licensed for the packaging of intermediate-level, long-lived (ILW‑LL) radioactive waste before it is stored in the Cedra facility (BNI 164) pending transfer to a deep geological repository. This situation makes the STD an indispensable part of the CEA's decommissioning and waste management strategy.

The continued operation of the STD over the long term necessitates renovation work, which has been prescribed by ASN Chairman's resolution CODEP‑CLG‑2016‑015866 of 18 April 2016. ASN is currently examining the significant reinforcement project "Pagode", which presents particular challenges, especially regarding the civil engineering work.

In view of the state of progress of the project, the CEA has announced that it would be unable to meet the prescribed project completion date of 2021. An official request will be made to push back this deadline. In the meantime, compensatory measures concerning in particular the limiting of the quantities of radioactive substances in the facility and fire protection, are applied.

Concerning the fall of a waste package that occurred in October 2017, the analysis of the root causes, prescribed by ASN, has been carried out by the CEA head office departments. This analysis is monitored by ASN. The points concerned by the compliance notice have been satisfied, as have the majority of the requirements. An inspection carried out in 2020 on "waste management" did however show that the licensee's safety culture needed to be further improved.

The file applying for authorisation to retrieve the package from the bottom of the well was submitted in 2020 and is currently being examined. It governs the restarting of activities in the well.

The level of safety and radiation protection of the facility, integrating the action plan necessary for improvement of the safety culture and operating rigour, is relatively satisfactory.

On 23 September 2020, the CEA submitted the guidance note for the STD's next periodic safety review, for which the report will be submitted in 2022. The licensee must finalise as soon as possible the actions stemming from the last periodic safety review which were still not completed in 2020.

ASN will also remain attentive to ensuring that the analyses presented in the significant event reports and the replies to its follow-up letters are as complete as possible.

Active Effluents Treatment Station

– CEA Centre

The STE (BNI 37‑B) has been shut down since 1 January 2014. The CEA has requested the modification of a prescription in order to push back the deadline for submission of the decommissioning file for this facility, in view of the complexity of the facility and the time required to characterise the soils and equipment before starting decommissioning. ASN is currently examining this postponement request.

The periodic safety review file for the STE was submitted to ASN on 30 October 2017 and its examination continued in 2020.

Following the discovery of artificial radionuclides outside the identified area, the licensee deployed an action plan – which was the subject of discussions in 2020 – to improve stormwater management.

The level of nuclear safety and radiation protection of BNI 37‑B is on the whole satisfactory.

Plutonium Technology Facility and Chemical Purification Laboratory

– CEA Centre

The Plutonium Technology Facility (ATPu – BNI 32) produced plutonium-based fuel elements intended for fast neutron or experimental reactors as from 1967, then, from 1987 until 1997, for Pressurized Water Reactors (PWRs) using MOX fuel. The activities of the Chemical Purification Laboratory (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 decommissioning schedule has been reviewed further to the health crisis:
- for the ATPu: the removal of waste and materials from the facilities was less consequential than forecast, particularly as regards removal of the drums containing alpha-emitting radionuclides from BNI 56;
- for the LPC: further to the measurement campaigns and the subsequent obtaining of an authorisation for simplified management of criticality on the worksite at the start of the year, the cryotreatment process removal operations were resumed.

ASN considers that the level of nuclear safety and radiation protection of the facilities in 2020 is on the whole satisfactory. Despite observed improvements in the facility's waste management, further progress is expected, particularly regarding compliance with the decommissioning plan.

Masurca research reactor – *CEA Centre*

The Masurca reactor (BNI 39), whose construction was authorised by a Decree of 14 December 1966, was intended for neutron studies, chiefly on the cores of fast neutron reactors, and the development of neutron measurement techniques. The reactor has been shut down since 2007.

Final shutdown of the facility was declared by the CEA on 31 December 2018. The licensee submitted the facility decommissioning file in December 2020.

ASN considers that the level of nuclear safety and radiation protection of Masurca in 2020 is on the whole satisfactory.

Éole and Minerve research reactors – *CEA Centre*

The experimental Éole and Minerve reactors are very-low-power (less than 1 kW) critical mock-ups that were used for neutron studies, in particular to evaluate the absorption of gamma rays or neutrons by materials.

The Éole reactor (BNI 42), whose construction was authorised by a Decree of 23 June 1965, was intended primarily for neutron studies of moderated arrays, in particular those of PWRs and boiling water reactors. The Minerve reactor (BNI 95), whose transfer from the Fontenay-aux-Roses studies centre to the Cadarache studies centre was authorised by a Decree of 21 September 1977, is situated in the same hall as the Éole reactor. Teaching and research activities were carried out on these mock-ups until their final shutdown on 31 December 2017.

The CEA submitted the periodic safety review report for the Éole and Minerve facilities in February 2020. ASN continued the examination of the decommissioning files for these reactors in 2020.

Pending decommissioning, removal of the radioactive materials prescribed by ASN resolution CODEP-CLG-2016-049370 of 16 December 2016 took place before the end of 2020 deadline.

ASN considers that the level of nuclear safety and radiation protection of the Éole and Minerve reactors in 2020 is on the whole satisfactory. The facility gives ASN half-yearly reports on the progress of its decommissioning preparation operations to prove compliance with the planned schedule.

The enriched Uranium Processing Facilities – *CEA Centre*

From 1963 to 1995, the enriched Uranium and Plutonium Facilities (ATUe – BNI 52) converted uranium hexafluoride (UF_6) 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 prior assessment of the radiological condition of the facility. Consequently, the licensee has requested the modification of its decommissioning decree on several occasions to take account of the true radiological condition of the facility. At the end of 2020, ASN issued an opinion on a draft decommissioning decree amendment intended to update the regulatory oversight of the last decommissioning steps of this facility.

The level of nuclear safety and radiation protection of the ATUe facilities in 2020 is on the whole satisfactory. The only activities in the facility today are the maintenance and regulatory periodic inspection operations.

Central Fissile Material Warehouse – *CEA Centre*

Created in 1968, the Central Fissile Material Warehouse (BNI 53) was a warehouse for storing enriched uranium and plutonium until its final shutdown and the removal of all its nuclear materials on 31 December 2017. The licensee submitted its decommissioning file in November 2018, and ASN is currently examining it.

The decommissioning preparation operations initiated in 2018, notably the chemical and radiological characterisations of the facility, continued in 2020. By resolution CODEP-MRS-2020-023523 of 3 April 2020, ASN also authorised the emptying and degassing of the fuel tanks necessary for supplying the facility's fixed generator set with a view to shutting it down.

Alongside this, an inspection of the facility's periodic safety review methodology supplemented the ongoing examination of the BNI 53 safety review report, submitted in October 2017.

LECA-STAR High-Activity Laboratory – *CEA Centre*

The Active Fuel Examination Laboratory (LECA – BNI 55) and the Treatment, Clean-out and Reconditioning Station (STAR) – an extension of LECA – constitute expert assessment tools used by the CEA for the analysis of spent fuels. Commissioned in 1964, the LECA laboratory enables the CEA to carry out destructive and non-destructive examinations of spent fuel from the nuclear power, research and naval propulsion sectors. As the facility is old, it was partially reinforced in the early 2010's to increase its earthquake resistance.

On 10 July 2020, ASN issued a resolution CODEP-CLG-2020-036269 setting the requirements applicable to LECA in the light of the conclusions of its periodic safety review, which makes continued operation conditional on the limiting of the potential source term of the facility in accident situations and the performance of work to improve control of the risks relating to earthquakes, fire and flooding. The CEA had identified the reinforcements necessary to guarantee the stability of LECA in an earthquake of intensity equivalent to the maximum historically probable earthquake. These provisions are to be implemented before the end of 2023.

Commissioned in 1999, the STAR facility is an extension of the LECA laboratory, designed for the stabilisation and reconditioning of spent fuel.

The CEA submitted the STAR periodic safety review report to ASN in February 2018 and it is currently being examined.

Further to the inspections conducted in 2020, ASN remains vigilant regarding due consideration of the social, organisational and human factors in the operation of the facility and the meeting of commitments made further to the inspections and the analyses of significant events.

ASN considers that the level of nuclear safety and radiation protection of BNI 55 in 2020 is on the whole satisfactory.

Solid radioactive waste storage area – *CEA Centre*

BNI 56, declared in January 1968 for the disposal of waste, is used for storing legacy solid radioactive waste from the Cadarache centre. It comprises three pools, six pits, five trenches and hangars, which contain in particular ILW-LL from the operation or decommissioning of CEA installations. BNI 56 is one of the priorities identified by the CEA in its new decommissioning and waste management strategy.

Apart from during the first lockdown period, the operations to retrieve the waste contained in the recent pits and to empty the hangars continued.

In the preparatory phase for retrieval of the “intermediate level” waste, the CEA is continuing to characterise the composition of the waste, an operation for which an authorisation request has been submitted to ASN and is currently being examined.

With regard to environmental protection, the last periodic safety review of the facility revealed the necessity to improve the monitoring of the groundwater tables beneath the facility. The CEA started installing new piezometers for this purpose in 2020. An action plan for improving stormwater management on the facility is currently being deployed to ensure compliance with ASN resolution 2013-DC-0360 of 16 July 2013.

ASN considers that the level of nuclear safety and radiation protection of BNI 56 is satisfactory. More specifically, improvements have been observed in the tracking of the commitments made to ASN.

Phébus research reactor – *CEA Centre*

The Phébus reactor (BNI 92) is an experimental pool-type reactor with a power rating of 38 Megawatts thermal (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 periodic safety review file in October 2017 and its decommissioning file in February 2018. These two files are currently being examined.

The decommissioning preparation operations continued in 2020, notably with the removal of unused sources and operations to characterise certain items of equipment further to completion of removal of irradiated fuel from the reactor in 2019. The removal of non-irradiated materials however, initially planned for 2020, has been pushed back to 2021 due to the health crisis.

ASN considers that the nuclear safety and radiation protection of the Phébus installation in 2020 is satisfactory.

Laboratory for research and experimental fabrication of advanced nuclear fuels (Lefca) – *CEA Centre*

Commissioned in 1983, Lefca (BNI 123) was a laboratory tasked with conducting studies on plutonium, uranium, actinides and their compounds with the aim of understanding the behaviour of these materials in the reactor and in the various stages of the fuel cycle. In 2018, in preparation for the stopping of its activities, Lefca finalised the transfer of part of its research and development equipment to the Atalante laboratories (BNI 148) at Marcoule.

The CEA submitted the final shutdown declaration for the facility in April 2019. The decommissioning file should thus be submitted in 2021.

In accordance with ASN resolution 2017-DC-0597 of 11 July 2017, the CEA submitted an update of the facility’s impact study to ASN at the beginning of 2020.

ASN considers that the level of nuclear safety and radiation protection of the facility in 2020 is on the whole satisfactory. Monitoring of outside contractors and of the fire load has been improved further to the inspections conducted in these areas in 2019.

Chicade laboratory – *CEA Centre*

Since 1993, the Chicade facility (BNI 156) has been conducting research and development work on low and intermediate-level objects and waste, chiefly involving:

- **the destructive and non-destructive characterisation of radioactive objects, waste sample packages and irradiating objects;**
- **the development and qualification of nuclear measurement systems;**
- **the development and implementation of chemical and radiochemical analysis methods;**
- **the expert assessment and inspection of waste packages packaged by the waste producers.**

ASN considers that the level of nuclear safety and radiation protection of Chicade is on the whole satisfactory. With regard to environmental protection, the CEA must undertake to submit a request to modify the facility’s creation decree to take into account gaseous discharges of tritium, not provided for in its baseline requirements.

Examination of the periodic safety review concluding report submitted in 2017 continued in 2020, with the licensee submitting a series of commitments to improve the safety of the facility.

Examination of the packaging approval request for the composition of intermediate level "870 L bulkvrac sources" packages, submitted in June 2017, did not enable ASN to rule on approval. A qualification programme for this type of package must be finalised by April 2021, and proof of the number of packages that will be produced during the process development phase must be provided in order to guarantee compliance with the facility creation authorisation decree.

Cedra storage facility – *CEA Centre*

Since 2006, the Cedra facility (BNI 164) is used to store ILW-LL pending the creation of appropriate disposal routes. The CEA forecasts that this facility will be filled to capacity by 2027. The studies concerning a project to double the storage capacity began in 2020.

ASN considers that the main steps of this project need to be better defined and that CEA must look ahead to all the procedures in order to have the necessary storage capacities for overall management of the CEA's waste.

The CEA sent ASN the periodic safety review report for the facility in November 2017, and it is currently being examined. Complementary information has been requested, particularly concerning the facility's baseline requirements conformity check and the action plan.

ASN considers that the level of nuclear safety and radiation protection of Cedra is on the whole satisfactory.

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.

Commissioning of the glove boxes was refused by ASN in 2019 and no new commissioning request was made in 2020. These glove boxes are intended for work on the facility's uranium- and plutonium-bearing materials, notably for the repackaging of fissile materials and to allow better characterisation of certain materials.

ASN considers that the facility must further improve its operating rigour, and more specifically the monitoring of protection important components and their modifications.

Effluent advanced management and processing facility – *CEA Centre*

The Effluent advanced management and processing facility (Agate) BNI 171, commissioned in 2014 to replace BNI 37-B which is now shut down, uses an evaporation process to concentrate radioactive liquid effluents containing mainly beta- and gamma-emitting radionuclides.

ASN considers that the level of nuclear safety, radiation protection and environmental protection in the Agate facility is on the whole satisfactory. The CEA announced in December 2020 that the Agate evaporator would be out of service for a period of from six months to one year further to a failure on the steam production system. ASN underlines that this facility plays a central role in the management of the CEA effluents and as such constitutes a sensitive facility in the CEA's decommissioning and material and waste management strategy.

Jules Horowitz Reactor project – *CEA Centre*

The Jules Horowitz Reactor (RJH, BNI 172), under construction since 2009, is a pressurised-water research reactor designed to study the behaviour of materials under irradiation and of power reactor fuels. It will also allow the production of artificial radionuclides for nuclear medicine. Its power is limited to 100 MWth.

The installation of the reactor pool equipment continued during 2020, more particularly with the insertion of the core containment (central part of the reactor pile block) at the end of the year. Several items of equipment were also introduced into the various buildings of the facility (cooling towers, transfer conveyor, diesel fuel tanks and systems). The lining of the pools and channels of the nuclear auxiliaries building is still being installed.

The CEA made a major reorganisation of the RJH project in 2020, setting up a team integrating project ownership and project management under CEA authority, in order to enhance the efficiency of project execution and monitoring.

ASN considers that the new organisation maintains the skills of the initial teams. On the other hand, this has had consequences on the requirements with regard to conformity assessments of the assemblies containing nuclear pressure equipment. This led the CEA to submit to a request to adjust certain requirements to ASN, which responded positively for some but not all of the items of equipment.

Lastly, the CEA identified a technical problem in 2020 during the qualification tests of certain components inside the reactor pile block. Problems of wear and excessive vibration were observed at the extremities of these components. Consequently, the CEA has set up an ad hoc working group to solve this problem. The technical solutions could lead to design modifications and revising of the corresponding safety studies.

ASN considers that the RJH construction site is managed satisfactorily by the CEA and that the management and addressing of deviations is rigorous and effective.

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 Megawatts developed for 400 seconds). This international project enjoys financial support from China, South Korea, the United States, India, Japan, Russia, the European Union, who make in-kind contributions by providing equipment for the project.

The large quantities of tritium that will be brought into play in this installation, the intense neutron flow and the resulting activation of materials have serious implications regarding radiation protection and will represent true challenges for the safe management of waste during the operation and decommissioning of the installation.

The work on the site and the manufacture of equipment continued in 2020 with the objective of deploying the first hydrogen plasma by 2025. An assessment of the impact of the health crisis on the overall construction schedule is expected in 2021.

The installation of the first components of the cryostat, which help support the vacuum chamber, was specially monitored during ASN's inspections in 2020. These activities will make it possible to start the vacuum chamber assembly phase, for which the first components arrived on the site in 2020.

ITER organisation requested approval to start this assembly phase in March 2020, in accordance with the requirement (BNI 174-07) of the amended ASN resolution of 12 November 2013. ASN made numerous additional information requests in order to improve the consistency of this file and the justification of the items submitted.

Assessment of the CEA Cadarache centre

ASN considers that the level of nuclear safety of the CEA Cadarache centre in 2020 is on the whole satisfactory. The stopping of the facilities' activities for the first lockdown from March to May 2020 and their subsequent restarting were carried out satisfactorily.

ASN considers that the Basic Nuclear Installations (BNIs) are operated satisfactorily on the whole, especially the control of the condition of the equipment, compliance with the operating baseline requirements and waste management. Improvements are nevertheless expected in the in-depth analysis of significant events and the management of obsolescence of certain Protection Important Components. The CEA is moreover changing its system for managing fire loads in BNIs in order to remedy the recurrent failings in this area.

Nuclear safety management is on the whole satisfactory, but, as in 2019, ASN considers that the sharing of experience feedback and good practices between facilities must be improved, as must the management of deviations. In addition, the monitoring of service providers and subcontractors is found to be contrasted, with some BNIs remaining below standard in this area.

ASN considers that the organisation in place for the periodic safety reviews of the facilities is on the whole satisfactory. The extent to which the results of studies are taken on board or the human resources allocated to performing them seem nevertheless to vary from one BNI to another. ASN will be attentive to application of the BNI periodic safety review action plans, particularly with regard to carrying out the work identified in the reviews. The CEA must also put in place compensatory measures when actions fall behind schedule, whether due to the health crisis, to particular technical difficulties or to the priorities laid down in its general decommissioning and waste management strategy.

This strategy, on which ASN and Defence Nuclear Safety Authority (ASND) have issued a position statement, induces changes in facility renovation and new facility construction projects for the CEA Cadarache centre, in favour of certain priority decommissioning worksites. The CEA must maintain a good operating standard in the facilities in operation, while at the same time ensuring that the priority decommissioning and legacy waste retrieval and packaging projects continue to move forward.

With regard to emergency situation management, ASN considers that, despite the progress observed on certain BNIs concerning compliance with resolution 2017-DC-0592, the organisation implemented for emergency situation management requires improvements, particularly in the following of training courses and participation in emergency exercises.

ASN considers that the radiation protection situation of the CEA centre is satisfactory. Optimisation of zone transition areas and of the positioning of radiological control equipment is nevertheless necessary in certain BNIs.

ASN observes that the level of environmental protection is relatively satisfactory. With regard to monitoring of the discharges, improvements are required in the monitoring of the representativeness of measurement samples and the consideration of metrological uncertainties in the utilisation of the data. A nationwide request to this effect has been sent to all the BNIs of the CEA. Alongside this, improvements are expected in the application of ASN resolution 2013-DC-0360 of 16 July 2013 to hazardous or radiological product storage areas.

Lastly, the laboratory analysing the samples for the non-radiological parameters, which did not comply with standard 17025, has implemented compensatory measures for the continuation of measurement activities.

Gammaster ioniser

Since 2008, the company Stéris has been operating an industrial irradiator called Gammaster situated in the municipality of Marseille. Gammaster treats products by ionisation (emission of gamma radiation) with the aim of sanitising, sterilising or improving the performance of materials. The facility is made up of an industrial bunker and houses sealed sources of cobalt-60 which provide the radiation necessary for its activity.

ASN considers that the level of nuclear safety and radiation protection of the facility in 2020 is on the whole satisfactory. The licensee must remain attentive to the monitoring of the pressure equipment present in the facility.

On completion of examination of the safety review file submitted by the licensee, ASN, through resolution CODEP-MRS-2019-048140 of 5 December 2019, has set technical requirements governing the continued operation of the facility. The licensee has produced an action plan and informs ASN of its progress every six months.

CHAPTER 01

NUCLEAR ACTIVITIES: IONISING RADIATION AND HEALTH AND ENVIRONMENTAL RISKS

01 Nuclear activities: ionising radiation and health and environmental risks

Ionising radiation may be of natural origin or be produced by nuclear activities of human origin. The exposure of the population to naturally occurring ionising radiation results from the presence of radionuclides of terrestrial origin in the environment, radon emanations from the ground and exposure to cosmic radiation.

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

The various principles with which the nuclear activities must comply, particularly those of nuclear safety and radiation protection, are set out in Chapter 2.

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

1. 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 (external to the organism) or endogenous (resulting from cellular metabolism).

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

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

Cells can also repair the damage thus caused, although imperfectly or incorrectly. Of the damage that persists, that to DNA is of a particular nature because residual anomalies in the chromosomes can be transmitted by successive cellular divisions to new cells.

A single genetic mutation is far from being sufficient to cause the transformation into a cancerous cell, but this damage due to ionising radiation may be a first step towards cancerisation which appears after a variable lapse of time (5 to 20 years after exposure).

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

Subsequently, several types of cancers were observed in occupational situations, including certain types of leukemia, broncho-pulmonary cancers (owing to radon inhalation) and jawbone sarcomas. Outside the professional area, the monitoring for more than 60 years of a cohort[1] of about 85,000 people irradiated at Hiroshima and Nagasaki (Japan) has allowed the morbidity and mortality due to cancer following exposure to ionising radiation to be regularly assessed and the dose-effects relationships – which form the basis of current regulations – to be described. Other epidemiological work has revealed a statistically significant rise in cancers (secondary effects) among patients treated using radiotherapy and attributable to ionising radiation We can also mention the Chernobyl accident (Ukraine) which, as a result of the radioactive iodine released, caused in the areas near the accident an excess in the incidence of thyroid cancers in young people exposed during their childhood. The consequences of the Fukushima Daiichi accident (Japan) on the health of the neighbouring populations are not yet sufficiently known and analysed to draw epidemiological lessons from them.

The risk of radiation-induced cancer appears at different levels of exposure and is not linked to the exceeding of a threshold. It is revealed by an increase in the probability of cancer in a population of a given age and sex. Such cases are referred to as probabilistic, stochastic (produced by chance) or random effects.

1. *Cohort: group of individuals considered together and participating in a statistical study of the circumstances of occurrence of diseases.*

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.

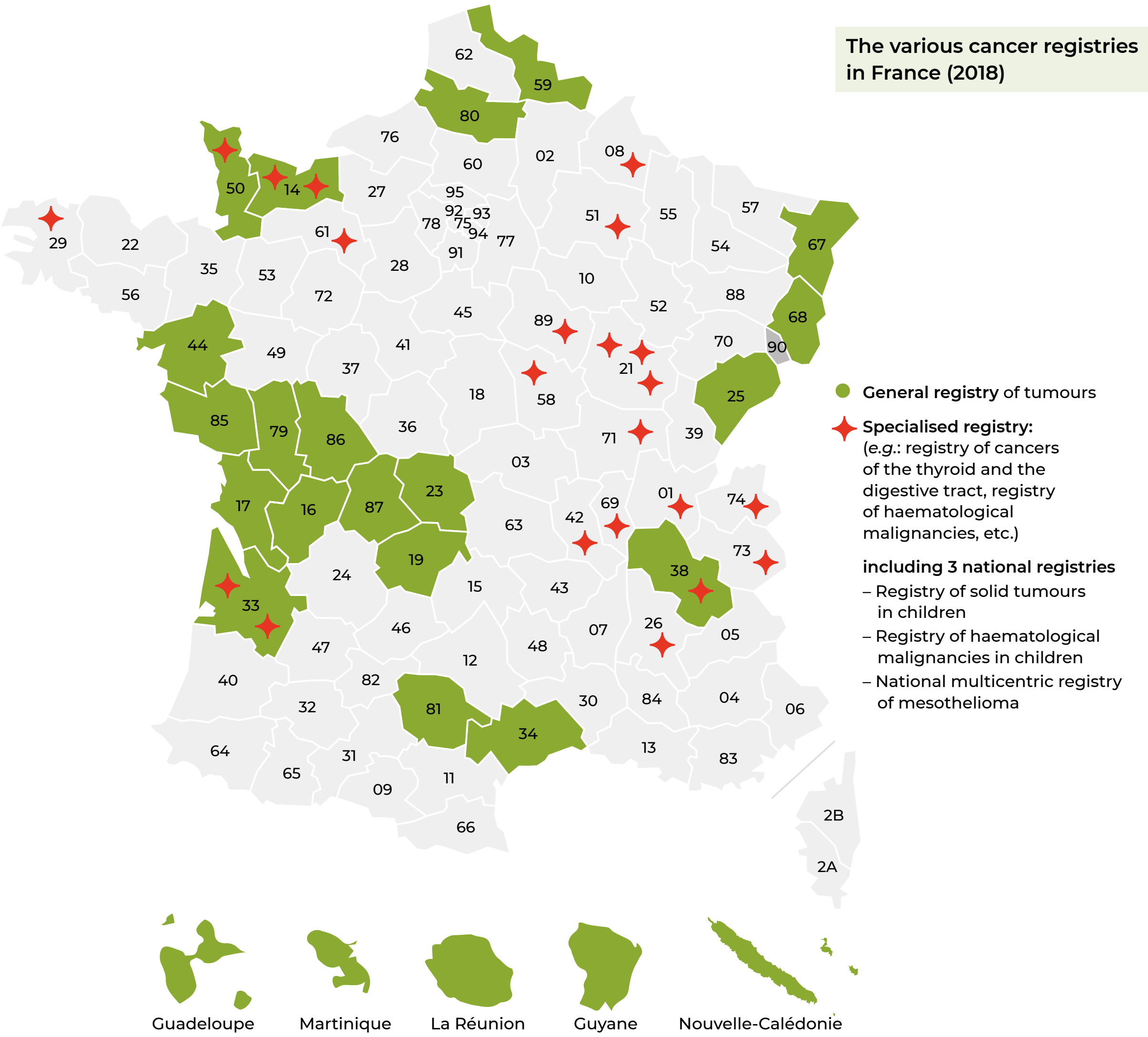
1.2 Assessment of the risks associated with ionising radiation

The monitoring of cancer epidemiology in France is based on disease registries, on the monitoring of causes of death and also, more recently, on the utilisation of data from the Medicalised Programme for Information Systems of healthcare facilities and the Long-Term Disease notifications. The registries are structures that provide "*a continuous and exhaustive collection of nominative data concerning one or more health events in a geographically defined population, for purposes of research and public health, managed by a team with the appropriate skills*". At present there are 32 cancer registries in France. Some are "general registers", concerning all types of cancer and covering one *département*[2] or more; others are "specialised registers", focusing on a particular type of cancer. Their geographical perimeter can vary (town, *département*, region, or even nationwide). Of the three national registers, one concerns pleural mesothelioma, primarily in the context of exposure to asbestos fibres, while the other two cover all the cancerous pathologies in the child and adolescent up to 18 years of age (source: iNCa).

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

Some registers, depending on the quality of their population database and their age, are used in numerous studies exploring cancer risk factors (including environmental risks). However, the registers do not necessarily cover the areas close to nuclear installations.

The various cancer registries in France (2018)



2. *Administrative region headed by a Prefect.*

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 those of Hiroshima and Nagasaki have clearly shown an excess of cancers, with the average exposure being about 200 millisieverts (mSv), studies on nuclear industry workers published in recent years suggest risks of cancer at lower doses (cumulative doses over several years).

These results support the justification of radiation protection of populations exposed to low doses of ionising radiation (nuclear industry workers, medical personnel, medical exposure for diagnostic purposes, etc.).

When there are no data on the impact of low doses on the occurrence of a cancer, estimates are provided by making linear no-threshold extrapolations of the observed effects described for high doses. These models give estimations of the risks run during exposure to low doses of ionising radiation, which nevertheless remain scientifically controversial. Studies on very large populations are currently underway to develop these models.

On the basis of the scientific syntheses of the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR), the International Commission on Radiological Protection (ICRP) has published the risk coefficients for death by cancer due to ionising radiation, i.e. 4.1% excess risk per sievert for workers and 5.5% per sievert for the general public (see ICRP Publication 103).

The evaluation of the risk of lung cancer due to radon[(3)] is based on a large number of epidemiological studies conducted directly in the home in France and on an international scale. These studies have revealed a linear relationship, even at low exposure levels (200 becquerels per cubic metre – 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 national Public Health Agency (ARS – 2018), an estimated 4,000 new cases of lung cancer are caused by radon in metropolitan France each year, far behind the number due to tobacco (the estimated number of new cases of lung cancer in Metropolitan France in 2018 was 46,363). A national plan for managing radon-related risks has been implemented since 2004 on the initiative of ASN and is updated periodically. The 4th plan (2020-2024) was published in early 2021 (see point 3.2.2).

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

The ICRP, which published new recommendations for the calculation of effective and equivalent doses (Publication 103) in 2007, is gradually updating the values of the effective dose coefficients for internal and external exposure. Its Publication 137 (2017), entitled *Occupational Intakes of Radionuclides – Part 3*, concerns 14 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 the difficulties that could arise from application of the new ICRP coefficients (Publication 137, 2017). The GPRADE submitted its opinion to ASN in 2020. ASN will issue a position statement on this opinion in early 2021 along with the publication of the report and the GPRADE opinion.

**Order of 1 September 2003 defining the methods for calculating effective doses and equivalent doses resulting from human exposure to ionising radiation.*

3. Radon is a natural radioactive gas, a progeny product of uranium and thorium, an emitter of alpha particles and has been classified as a known human pulmonary carcinogen by the International Agency for Research on Cancer (IARC) since 1987.

1.3 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.

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 The individual response to ionising radiation

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

Furthermore, the variability in individual radiosensitivity to high doses of ionising radiation has been extensively documented by radiotherapists and radiobiologists. High levels of radiosensitivity have been observed in persons suffering from genetic diseases affecting the repair of DNA and cellular signalling; in these individuals they can lead to "radiological burns". Such abnormal responses are also observed in people suffering from neuro-degenerative diseases.

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. This research work indicates that an abnormal response to ionising radiation can be expressed in three clinical forms: radiosensitivity at high doses of radiotherapy, radiosusceptibility to radiation-induced cancer, and radiation-induced degeneration (cataract or radiation-induced cardiovascular effects, for example).

Progress in research and the validation of clinical results should rapidly make it possible to define the optimum conditions for highlighting the individual response to ionising radiation in patients and to take this into account in personalised medical management.

Further to the work of the European research group on low doses (Multidisciplinary European Low Dose Initiative – MELODI) and review documents published in 2019 addressing the clinical and epidemiological aspects of the individual response to ionising radiation and the available screening tests and their robustness, the ICPR working group (TG111) dedicated to this subject is continuing its work to summarise knowledge on the individual response to ionising radiation with a view to developing international radiation protection recommendations.

Radiography room in the Léon Bourgeois clinic (Paris) in 1916

The individual response to ionising radiation is thus gradually being recognised as an important subject of research and application in radiobiology and radiation protection, while at the same raising ethical and societal questions.

1.3.2 Effects of low doses

The Linear No-Threshold relationship

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

Dose, dose rate and duration of exposure

The epidemiological studies performed on individuals exposed to the Hiroshima and Nagasaki bombings have given a clearer picture of the effects of radiation on health, concerning exposure due to external irradiation (external exposure) received in a few fractions of a second at high dose and high dose rate[4]. The studies carried out in the countries most affected by the Chernobyl accident (Belorussia, Ukraine and Russia) were also able to improve our understanding of the effects of radiation on health caused by exposure through internal contamination (internal exposure), more specifically through radioactive iodine. Studies on nuclear industry workers have given a clearer picture of the risk associated with chronic exposures at low doses established over many years, whether as a result of external exposure or internal contamination.

4. *The radioactive dose rate determines the absorbed dose (energy absorbed by the material per unit mass and time). It is measured in Gray per second (Gy/s) in the International System of Units (SI). It is used in physics and in radiation protection.*

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 through deleterious effects on the environment. 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 (process of cancer formation) a cell develops with a particular combination of DNA lesions that enables it to escape from the usual control of cellular division, and that it takes about 10 to 100 DNA lesions (mutations, breaks, etc.) at critical points to pass through these stages. All the agents capable of damaging cellular DNA (tobacco, alcohol, various chemical substances, ionising radiation, high temperature, other environmental factors, notably nutritional and free radicals of normal cellular metabolism, etc.) contribute to cellular ageing and to carcinogenesis.

Consequently, in a multi-risk approach to carcinogenesis, can we still talk about radiation-induced cancers? Yes we can, given the quantity of epidemiological data which indicate that cancer frequency increases when the dose increases, with the other main risk factors taken into account. However, the radiation-induced event can also in certain cases be the only event responsible (radiation-induced cancers in children).

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

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

2. The different sources of ionising radiation

2.1 Natural radiation

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

2.1.1 Natural terrestrial radiation (excluding radon)

Natural radionuclides of terrestrial origin are present at various levels in all the compartments of our environment, including inside the human body. They lead to external exposure of the population owing to gamma rays emitted by the uranium‑238 and thorium‑232 daughter products and by the potassium‑40 present in the soil, but also to internal exposure by inhalation of particles in suspension and by ingestion of foodstuffs or drinking water. The levels of natural radionuclides in the ground are extremely variable. The external exposure dose rate values in the open air in France, depending on the region, range from a few nanosieverts per hour (nSv/h) to 100 nSv/h.

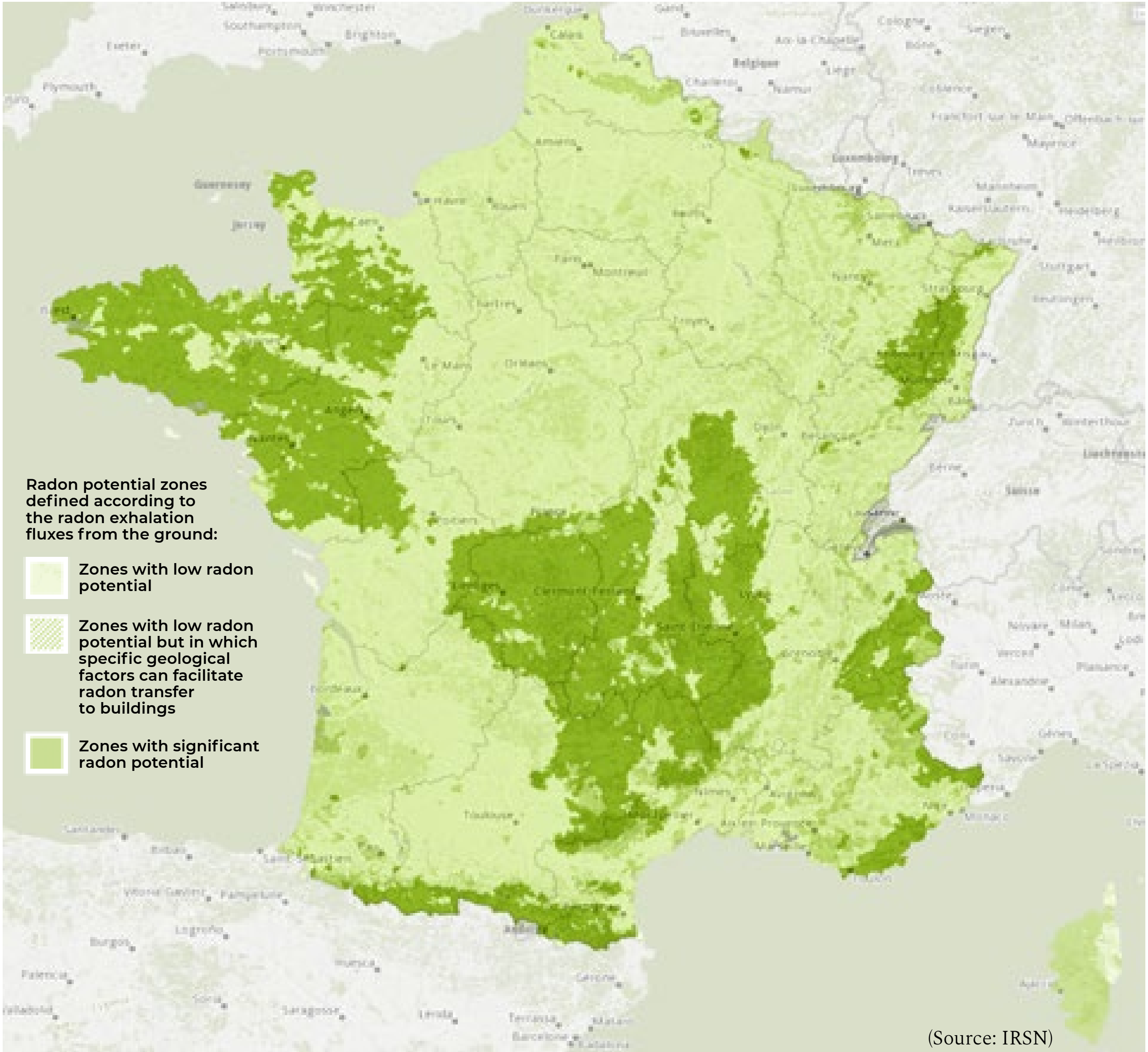
The dose rate values inside residential premises are generally higher owing to the contribution of construction materials (about 20% higher on average).

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.

According to the French Institute for Radiation Protection and Nuclear Safety (IRSN, 2015), the average internal exposure due to the incorporation of radionuclides of natural origin is estimated at 0.55 millisieverts per year (mSv/year). The two main components of this exposure are the incorporation through foodstuffs and drinking water of both potassium – 40 (0.18 mSv) and descendants of the uranium and thorium chains (0.33 mSv). This exposure can vary widely depending on individual consumption habits – particularly of fish/seafood and tobacco – from 0.4 mSv/year for people who do not consume these products to more than 3.1 mSv/year for those who consume them in large quantities.

Waters intended for human consumption, in particular groundwater and mineral waters, become charged in natural radionuclides due to the nature of the geological strata in which they lie. The concentration of uranium and thorium daughters and of potassium‑40 varies according to the resource exploited, given the geological nature of the ground. With waters displaying a high level of radioactivity, the effective annual dose resulting from daily consumption (two litres per inhabitant per day) can reach a few tens or hundreds of microsieverts (µSv).

Radon potential zones in metropolitan France defined by the Order of 27 June 2018



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), the ventilation of the rooms and the life style of the occupants.

So-called “domestic” exposure to radon (radon in dwellings) has been estimated by the IRSN through measurement campaigns which were then followed by statistical analyses (see *irsn.fr*). The average value of the radon activities measured in France has thus been estimated at 68 Bq/m^3.

These measurements have allowed the French *départements* to be classified according to the radon exhalation potential of the ground. In 2011, the IRSN published a map of France considering the radon exhalation potential of the ground, based on data from the French Geological and Mining Research Office. Based on this, a more fine-grained classification, by municipality, was published through the Ministerial Order of 27 June 2018 (see search engine by municipality and mapping accessible on *asn.fr* and *irsn.fr*).

As from 2021, the new obligation placed on radon detector analysis laboratories to communicate the dosimeter results to the IRSN will enhance knowledge of radon exposure in France (see the 3rd National Plan 2016-2019 for Radon Risk Management, 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;
- removal of radioactive waste;
- management of contaminated sites;
- activities enhancing natural ionising radiation.

2.2.1 Basic Nuclear Installations

Nuclear activities are highly diverse, covering any activity relating to the preparation or utilisation of radioactive substances or ionising radiation. These activities are subject to the general provisions of the Public Health Code and, depending on their nature and the risks that they involve, to a specific legal system. BNIs are defined in Article L. 593-2 of the Environment Code:

1. Nuclear reactors.

2. Facilities, corresponding to characteristics defined by Decree of the Council of State, for the preparation, enrichment, fabrication, treatment or storage of nuclear fuels, or for the treatment, storage or disposal of radioactive waste.

3. Installations containing radioactive or fissile substances and meeting characteristics defined by Decree of the Council of State;

4. Particle accelerators meeting characteristics defined by Decree of the Council of State.

5. Deep geological repositories for radioactive waste mentioned in Article L. 542-10-1 of the Environment Code.

The installations and facilities are subject to the BNI System, governed by Chapters III and VI of Title IX of Book V of the Environment Code and their implementing texts.

The list of BNIs as at 31 December 2020 figures in an appendix to this report.

Risk prevention and nuclear safety

The fundamental internationally adopted principle underpinning the specific organisational system and regulations applicable to nuclear safety is that of the responsibility of the licensee (see chapter 2). The public authorities ensure that this responsibility is fully assumed, in compliance with the regulatory requirements. As regards the prevention of risks for workers, BNI licensees are required to implement all necessary means to protect workers against the hazards of ionising radiation. They must more particularly ensure compliance with the general rules applicable to all workers exposed to ionising radiation (work organisation, accident prevention, medical monitoring of workers, including those of outside contractors, etc.).

As regards protection of the population and the environment, the BNI licensee must also take all necessary steps to achieve and maintain an optimum level of protection. More particularly, discharges of liquid and gaseous effluents, whether radioactive or not, are strictly limited (see chapter 3).

2.2.2 Transport of radioactive substances

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

2.2.3 Small-scale nuclear activities

Ionising radiation, whether emitted by radionuclides or generated by electrical equipment, is used in many areas, including medicine (radiology, radiotherapy, nuclear medicine and fluoroscopy-guided interventional practices), biology, research, industry, but also in veterinary applications and the conservation of foodstuffs.

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

2.2.4 Radioactive waste management

Like all industrial activities, nuclear activities can generate waste, some of which 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 the creation of any new activities or the modification of existing activities in order to:
- ensure the availability of processing routes 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 management routes.

2.2.5 Management of contaminated sites

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

Depending on the current or future uses of the site, decontamination objectives must be set. The removal of the waste produced during post-operation clean-out of the premises and removal of the contaminated 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.

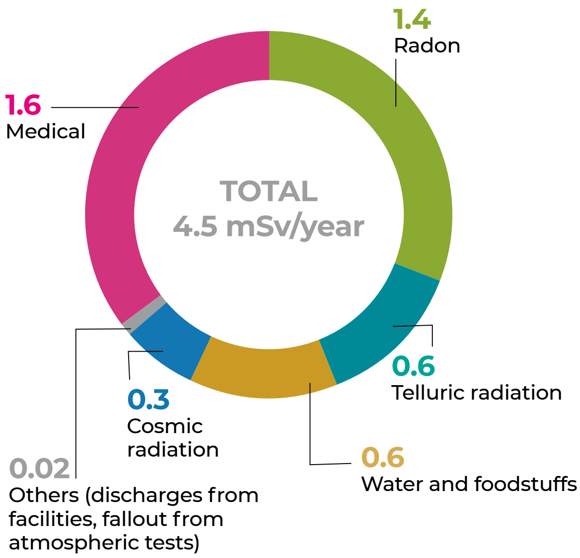
Thus, certain activities included in the definition of "nuclear activities" can use materials containing naturally occurring radioactive materials at concentration levels that could significantly increase the exposure of workers to ionising radiation and, to a lesser extent, the exposure of populations 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, which 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 (ICPEs).

DIAGRAM 1

Average exposure of the French population to ionising radiation (mSv/year)



Source: IRSN, 2015.

3. Monitoring exposure to ionising radiation

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

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

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

3.1 Doses received by workers

3.1.1 Monitoring the exposure of persons working in nuclear facilities

The system for monitoring the external exposure of persons liable to be exposed to ionising radiation, working in BNIs or in small-scale nuclear facilities for example, has been in place for several decades. This system is based primarily on the mandatory wearing of passive dosimeters for workers liable to be exposed and enables compliance with the regulatory limits applicable to workers to be checked. These limits concern the total exposure (since 2003, the annual limit expressed in terms of effective dose has been 20 mSv for 12 consecutive months), obtained by adding the dose due to external exposure to that resulting from any internal con-tamination; 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 worker, including those from outside contractors. They are grouped together in Ionizing Radiation Exposure Monitoring Information System (Siseri) managed by the IRSN and are published annually.

The results of worker exposure to ionising radiation presented below are taken from the IRSN 2019 assessment entitled *La radioprotection des travailleurs: exposition professionnelle aux rayonnements ionisants en France (Worker radiation protection: occupational exposure to ionising radiation in France)*. From the methodological aspect, as in the two preceding years, the IRSN 2019 assessment was based exclusively on data from individual monitoring of the external exposure of workers recorded in the Siseri database. The assessment of the preceding years, for its part, was produced exclusively by aggregating the annual summaries requested of the dosimetry organisations. Consequently, the 2019 results are not directly comparable with those of 2018 and 2017. Nevertheless, in order to establish trends, the results for the years 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 2019, the breakdown of the populations monitored, the collective dose (the collective dose is the sum of the individual doses received by a given group of persons), and the number of times the annual limit of 20 mSv was exceeded. They show a large 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 (58%), accounts for only 8% of the collective dose; on the other hand, the civil nuclear industry, which represents just 22% of the headcount, accounts for 40% of the collective dose and the sector concerned by exposure to natural radioactivity, which represents only 6.4% of the total headcount, accounts for 47.7% of the collective dose. The industrial sector for its part represents 4% of the headcount and accounts for 2.3% of the collective dose.

Table 3 shows that the total number of workers monitored by external passive dosimetry has increased by about 1% per year since 2015.

In 2019, the collective dose (for all areas combined) reached 112.31 man-Sv, a value that has increased by nearly 8% compared with 2018, whereas the average individual dose has increased by 7%. These increases are primarily linked to the increase in the amount of maintenance work in the nuclear sector and the increase in doses received by flight crew.

In 2019, five cases exceeding the regulatory effective dose limit of 20 mSv were registered (see Diagram 2).

Four of them concerned professionals in the medical sector while the fifth concerned a worker in the "others: private inspection and oversight organisations" sector. It should nevertheless be noted that out of these five cases of exceeding the effective dose limit, three were kept by default as there was no feedback from the occupational physician on the conclusions of the inquiry.

With regard to the dosimetry of the extremities (fingers and wrist), 28,623 workers were monitored in 2019 (i.e. 7% of the total number of persons monitored). Out of all the persons monitored, there was one case – in the medical sector – where the 500 mSv regulatory equivalent dose limit at the extremities was exceeded (552.17 mSv).

Furthermore, 4,830 workers were subject to monitoring of lens of the eye exposure. This represents an increase in monitoring of more than 38% compared with 2018. This significant increase is linked to the arrival on the market of several new dosimeters suited to this type of measurement. Eight workers (in the medical radiology sector) received an equivalent dose or more than 20 mSv. The maximum recorded dose is 34.74 mSv. This value should be compared with the future regulatory dose limit for the lens of the eye of 20 mSv/year as from 2023.

To conclude, as in the preceding years, the *Assessment of dosimetric monitoring of worker external exposure in 2019* published by the IRSN in October 2020, shows the overall effectiveness of the prevention system introduced in facilities where sources of ionising radiation are used, because for 91% of the population monitored the annual dose remained lower than 1 mSv (effective annual dose limit for the public due to nuclear activities). Exceeding the regulatory limit values remains exceptional (five cases exceeding the annual limit 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.

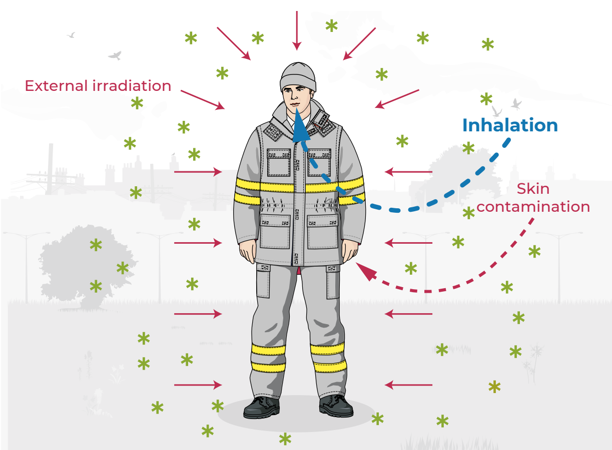
3.1.2 Worker exposure to natural radioactivity

Exposure to radioactive substances of natural origin and to radon of geological origin

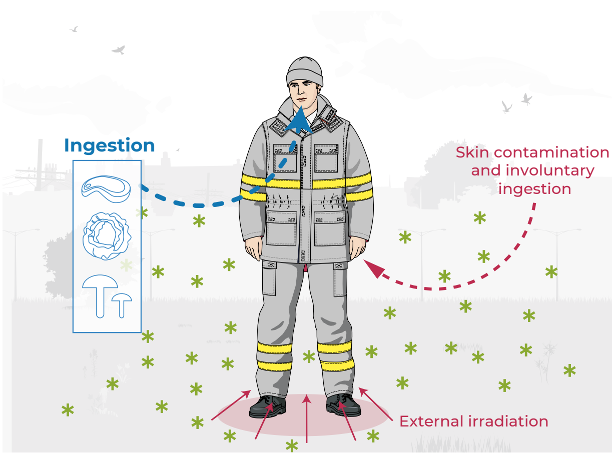
Worker exposure to radioactive substances of natural origin results either from the ingestion of dust from materials containing large amounts of radionuclides (phosphates, metal ores), or from the inhalation of radon formed by uranium decay (poorly ventilated warehouses, thermal baths) or from external exposure due to industrial process deposits (scale forming in piping for example).

The results of studies carried out in France between 2005 and 2009, published by ASN in January 2010, along with the studies published up until 2018, show that 85% of the doses received by

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

Results of dosimetry monitoring of worker external exposure to ionising radiation (exposure to natural radioactivity included) in 2019

(Source: IRSN 2019 report, October 2020 – "*Worker radiation protection: occupational exposure to ionising radiation in France*")

- Total population monitored: 395,040 workers
- Monitored population for whom the annual effective dose remained below the detection threshold: 301,493 workers, or more than 76%
- Monitored population for whom the annual effective dose remained between the detection threshold and 1 mSv: 59,468 workers, or more than 15%
- Monitored population for whom the annual effective dose remained between 1 mSv and 20 mSv: 34,074 workers, or more than 8.6%
- Monitored population for whom the annual effective dose exceeded 20 mSv: 5 workers
- Monitored population for whom the equivalent dose to the extremities exceeded 500 mSv: 1 worker
- Collective dose (sum of the individual effective annual doses): 112.3 man-Sv
- Average annual individual effective dose in the population which recorded a dose higher than the detection threshold: 1.2 mSv

Results of internal exposure monitoring in 2019 (natural radioactivity excluded)

- Number of routine examinations carried out: 228,808 (of which 0.5% were considered positive)
- Population for which a dose estimation was made: 217 workers
- Number of special monitoring examinations or verifications performed: 10,053 (of which 15% were above the detection threshold)
- Population having recorded a committed effective dose exceeding 1 mSv: 9 workers

Results of monitoring of internal exposure to natural radionuclides from the uranium and thorium decay chains in 2019

- Internal exposure:
  - collective dose for 363 workers: 126.5 man-mSv
  - Average annual individual effective dose in the population which recorded a dose higher than the detection threshold: 0.52 mSv

workers in the industries concerned remained below 1 mSv/year. The industrial sectors in which worker exposure is liable to exceed 1 mSv/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.

With regard to exposure to radon of geological origin, the results from monitoring the exposure of workers to radon have not yet been exhaustively recorded in Siseri. Consequently, not all the companies whose premises have a radon activity concentration in the air that makes individual monitoring necessary are included in the IRSN 2019 report published in October 2020.

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 IRSN calculates individual doses using 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 31st December 2019, *SievertPN* had transmitted to Siseri all the flight crew doses for 15 airlines having subscribed to the system, giving a total of 24,429 flight crew members monitored by this system. In 2019, 16.8% of the individual annual doses were below 1 mSv and 83% of the individual annual doses were between 1 mSv and 5 mSv. The maximum individual annual dose was 6.2 mSv.

3.2 Doses received by the population

3.2.1 Exposure of the population as a result of nuclear activities

The automated monitoring networks managed nationwide by the 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 normal situations, they contribute to the evaluation of the impact of BNIs (see chapter 3).

However, there is no overall monitoring system able to provide an exhaustive picture of the doses received by the population as a result of nuclear activities. Consequently, compliance with the population exposure limit (effective dose set at 1 mSv/year) cannot be controlled directly. However, for BNIs, there is detailed accounting of radioactive effluent discharges and radiological monitoring of the environment is implemented around the installations. On the basis of the data collected, the dosimetric impact of these discharges on the populations in the immediate vicinity of the installations is then calculated using models simulating transfers to the environment. The dosimetric impacts vary, according to the type of installation and the lifestyles of the chosen reference groups, from a few microsieverts to several tens of microsieverts per year. An estimation of the doses from BNIs is presented in Table 4 which shows, for each site and per year, the estimated effective doses received by the most exposed reference population groups.

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

Legacy situations, such as atmospheric nuclear tests and the Chernobyl accident (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 Report 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 below 0.01 mSv/year (IRSN Report, 2015). With regard to the fall-out in France from the Fukushima Daiichi accident, the results published for France by the 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.

TABLE 1

Monitoring of external exposure of workers in the civil nuclear field (year 2019)

	NUMBER OF PERSONS MONITORED	COLLECTIVE DOSE (man-Sv (*))	INDIVIDUAL DOSE > 20 mSv
Reactors and energy production (EDF)	24,467	6	0
Fuel cycle, decommissioning	12,552	3.41	0
Transport	686	0.08	0
Logistics and maintenance (contractors)	31,891	31.43	0
Effluents, waste	768	0.14	0
Others	7,010	1.27	0
Total civil nuclear	77,374	42.33	0

* man-Sv: unit of quantity of collective dose. For information, the collective dose is the sum of the individual doses received by a given group of persons.
(Source: IRSN report, October 2020 – "*Worker radiation protection: occupational exposure to ionising radiation in France*")

TABLE 2

Monitoring of external exposure of workers in small-scale nuclear activities (year 2019)

	NUMBER OF PERSONS MONITORED	COLLECTIVE DOSE (man-Sv (*))	INDIVIDUAL DOSE > 20 mSv
Medicine	166,059	7.38	4
Dental	42,530	1.45	0
Veterinary	20,583	0.29	0
Industry	15,827	2.67	0
Research and education	11,973	0.4	0
Natural (**)	25,328	53. 58	0
Total small-scale nuclear activities	282,300	65.77	4

* man-Sv: unit of quantity of collective dose.
** "Natural" covers flight crew and workers exposed to natural radionuclides of the uranium and thorium chains.
(Source: IRSN report, October 2020 – "*Worker radiation protection: occupational exposure to ionising radiation in France*")

TABLE 3

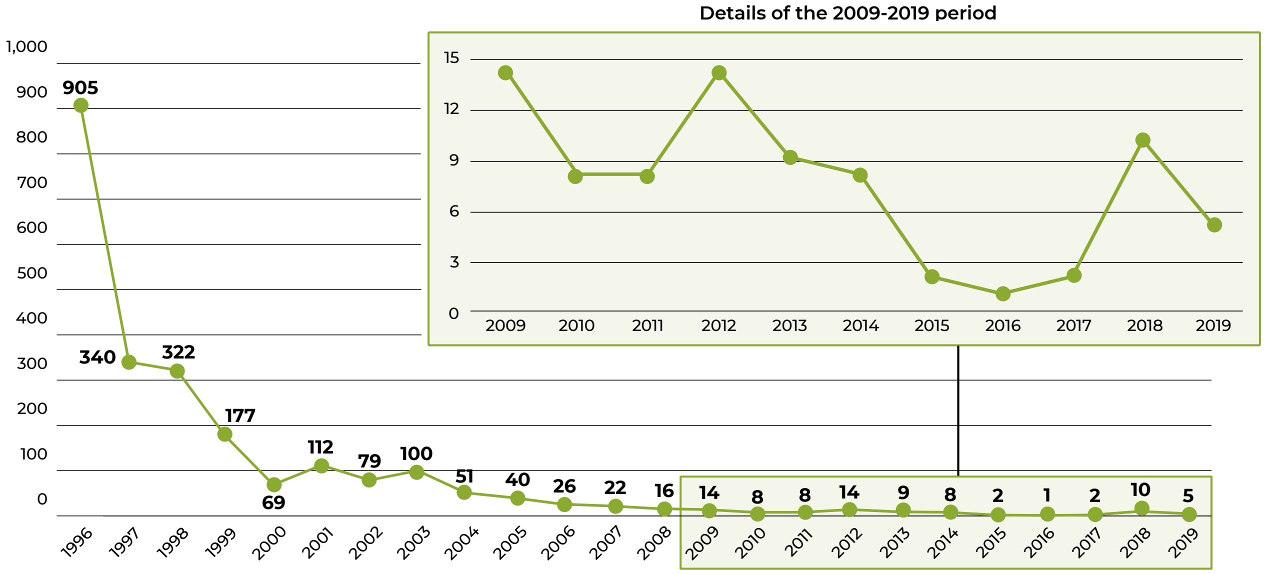
Development of number of persons monitored and average collective and individual doses in the exposed population from 2015 to 2019(*) in all areas combined (A) and in the "natural" area (B)

YEAR	NUMBER OF PERSONS MONITORED		COLLECTIVE DOSE (man-Sv)		AVERAGE INDIVIDUAL DOSE (mSv)	
	(A)	(B)	(A)	(B)	(A)	(B)
2015	372,881	352,641	104.41	65.61	0.98	0.76
2016	378,304	357,527	107.53	66.71	0.96	0.73
2017	384,198	360,694	100.58	53.52	1.03	0.72
2018	390,363	365,980	104.14	55.24	1.12	0.80
2019	395,040	369,712	112.31	58.73	1.20	0.85

* For comparison purposes, the results for 2015 and 2016 have been retroactively reassessed applying the new methodological approach.
(Source: IRSN report, October 2020 – "*Worker radiation protection: occupational exposure to ionising radiation in France*").

DIAGRAM 2

Evolution of number of workers monitored, with an annual effective dose in excess of 20 mSv from 1996 to 2019



Source: IRSN.

3.2.2 Exposure of the population to Naturally Occurring Radioactive Materials

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 generally satisfactory assessment also applies to the radiological quality of bottled water produced in France (DGS/ASN/IRSN report published in 2013).

Since 2019, measurement of the radon content of tap water and bottled water has been compulsory. To assist the introduction of this new provision, an instruction was drawn up in consultation with ASN and issued in 2018 to the Regional Health Agencies by the General Directorate for Health (ASN opinion 2018-AV-0302 of 6 March 2018 on the radon management procedures in the sanitary control of water intended for human consumption).

Exposure due to radon

In France, the regulations relative to management of the radon risk, put in place in the early 2000's for certain buildings open to the public, were extended to certain work places in 2008. In 2016, radon was introduced into the indoor air quality policy.

Transposition of Council Directive 2013/59/Euratom of 5 December 2013 laying down Basic Safety Standards for protection against the dangers arising from exposure to ionising radiation led to the amending of the provisions applicable to radon since 1 July 2018. A reference level of 300 Bq/m^3 has been introduced. It is applicable to all situations, which enables the health risk associated with radon to be managed with an all-inclusive approach. The regulations have been extended with provisions concerning the three main sectors:

- With regard to the general public, a significant improvement has been introduced: radon is now included in the information to be provided to buyers and tenants of real estate situated in areas where the radon potential could be the highest.
- In workplaces, the regulations have been extended to cover professional activities exercised on ground floor levels and in certain specific workplaces. Whatever the radon potential zone in which the workplace is situated, radon must be considered in the risk assessment. A radon measurement can be carried out in this context if necessary. If there is a risk of reaching or exceeding the reference level of 300 Bq/m^3, the employer must take action to reduce the radon activity concentration. If the action turns out to be ineffective, the employer must identify potential "radon zones" and then implement radiation protection measures, if necessary according to the level of exposure of the workers.
- In some buildings open to the public, the radon management methods have been adjusted, more specifically with the inclusion of day-care facilities for children under 6 years of age and an obligation to inform the public by displaying the radon measurement results(5). The type of action to be taken if the reference level of 300 Bq/m^3 is exceeded is graded according to the measurement results: simple corrective actions for radon concentrations between 300 and 1,000 Bq/m^3, expert assessment and remediation work if the corrective actions do not reduce the radon concentration to below the reference level or if the measurement results equal 1,000 Bq/m^3 or higher.

The results communicated by the ASN-accredited organisations for the 2018/2019 and 2019/2020 campaigns show that the majority of the screenings were carried out in educational institutions and healthcare and medical-social institutions (61% and 28% of screenings respectively). Day-care facilities children aged under 6 years, which constitute a new category of Buildings Open to the Public (ERP) subject to management of the radon risk, represent 11% of the measurements taken during the 2019/2020 campaign. The activity concentration of radon is below the reference level of 300 Bq/m^3 in 77% of the educational institutions and 87% of the healthcare and medical-social institutions screened.

5. Order of 26 February 2019 relative to the methods of managing radon in certain buildings open to the public and dissemination of information to the people frequenting these buildings.

TABLE 4

Radiological impact of BNIs since 2014 calculated by the licensees on the basis of the actual discharges from the installations and for the most exposed reference groups (data provided by the nuclear licensees)

LICENSEES/SITE	REFERENCE GROUP MOST EXPOSED IN 2019	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)					
			2014	2015	2016	2017	2018	2019
Andra / CSA	Multi-activity group Ville-aux-Bois	1.7	2.10^{-6}	2.10^{-6}	2.10^{-6}	2.10^{-6}	3.10^{-7}	3.10^{-7}
Andra's Manche repository	Hameau de La Fosse	2.5	3.10^{-4}	2.10^{-4}	2.10^{-4}	2.10^{-4}	2.10^{-4}	2.10^{-4}
Framatome Romans	Ferme Riffard	0.2	3.10^{-4}	3.10^{-4}	3.10^{-4}	2.10^{-5}	2.10^{-5}	3.10^{-5}
Orano Cycle / La Hague	Digulleville	2.8	2.10^{-2}	2.10^{-2}	2.10^{-2}	2.10^{-2}	2.10^{-2}	2.10^{-2}
Orano / Tricastin (Areva NC, Comurhex, Eurodif, Socatri, SET)	Les Girardes	1.2	3.10^{-4}	3.10^{-4}	2.10^{-4}	2.10^{-4}	9.10^{-5}	8.10^{-5}
CEA / Cadarache [b]	Saint-Paul-lez-Durance	5	2.10^{-3}	1.10^{-3}	$<2.10^{-3}$	$<2.10^{-3}$	$<3.10^{-3}$	$<2.10^{-3}$
CEA / Fontenay-aux-Roses [b]	Achères	30	1.10^{-4}	2.10^{-4}	$<2.10^{-4}$	$<2.10^{-4}$	$<2.10^{-4}$	$<2.10^{-4}$
CEA / Grenoble [c]	-	-	[c]	[c]	[c]	[c]	[c]	[c]
CEA / Marcoule [b] (Atalante, Centraco, Phénix, Melox, CIS bio)	Codolet	2	2.10^{-3}	2.10^{-5}	$<2.10^{-3}$	$<2.10^{-3}$	$<2.10^{-3}$	$<2.10^{-3}$
CEA / Saclay [b]	Le Christ de Saclay	1	2.10^{-3}	2.10^{-3}	$<2.10^{-3}$	$<2.10^{-3}$	$<2.10^{-3}$	$<4.10^{-3}$
EDF / Belleville-sur-Loire	Beaulieu-sur-Loire	1.8	4.10^{-4}	5.10^{-4}	4.10^{-4}	3.10^{-4}	4.10^{-4}	4.10^{-4}
EDF / Blayais	Braud et Saint-Louis	2.5	6.10^{-4}	5.10^{-4}	5.10^{-4}	4.10^{-4}	5.10^{-4}	4.10^{-4}
EDF / Bugey	Vernas	1.8	2.10^{-4}	2.10^{-4}	9.10^{-5}	2.10^{-4}	2.10^{-4}	2.10^{-4}
EDF / Cattenom	Koenigsmacker	4.8	8.10^{-3}	7.10^{-3}	9.10^{-3}	8.10^{-3}	9.10^{-3}	1.10^{-2}
EDF / Chinon	La Chapelle-sur-Loire	1.6	2.10^{-4}	2.10^{-4}	2.10^{-4}	2.10^{-4}	2.10^{-4}	2.10^{-4}
EDF / Chooz	Chooz	1.5	7.10^{-4}	6.10^{-4}	6.10^{-4}	4.10^{-4}	5.10^{-4}	5.10^{-4}
EDF / Civaux	Valdivienne	1.9	8.10^{-4}	9.10^{-4}	2.10^{-3}	8.10^{-4}	8.10^{-4}	2.10^{-3}
EDF / Creys-Malville	Creys-Mépieu	0.95	2.10^{-4}	2.10^{-6}	3.10^{-4}	1.10^{-4}	2.10^{-5}	2.10^{-5}
EDF / Cruas-Meysse	Savasse	2.4	2.10^{-4}	2.10^{-4}	2.10^{-4}	4.10^{-4}	3.10^{-3}	3.10^{-4}
EDF / Dampierre-en-Burly	Lion-en-Sulias	1.6	4.10^{-4}	5.10^{-4}	5.10^{-4}	5.10^{-4}	5.10^{-4}	5.10^{-4}
EDF / Fessenheim	Rheinwartenhaus	1.3	4.10^{-5}	4.10^{-5}	3.10^{-5}	2.10^{-5}	5.10^{-5}	4.10^{-5}
EDF / Flamanville	Flamanville	0.8	5.10^{-4}	2.10^{-4}	2.10^{-4}	2.10^{-4}	2.10^{-4}	7.10^{-5}
EDF / Golfech	Valence	3.4	2.10^{-4}	3.10^{-4}	3.10^{-4}	2.10^{-4}	2.10^{-4}	2.10^{-4}
EDF / Gravelines	Grand-Fort-Philippe	2.5	8.10^{-4}	4.10^{-4}	4.10^{-4}	5.10^{-4}	8.10^{-4}	1.10^{-3}
EDF / Nogent-sur-Seine	Saint-Nicolas-la-Chapelle	2.3	5.10^{-4}	4.10^{-4}	7.10^{-4}	5.10^{-4}	5.10^{-4}	4.10^{-4}
EDF / Paluel	Paluel	1.1	9.10^{-4}	4.10^{-4}	3.10^{-4}	3.10^{-4}	4.10^{-4}	3.10^{-4}
EDF / Penly	Berneval-le-Grand	3.1	4.10^{-4}	4.10^{-4}	4.10^{-4}	5.10^{-4}	5.10^{-4}	4.10^{-4}
EDF / Saint-Alban	Saint-Maurice-l'Exil	1.7	2.10^{-4}	2.10^{-4}	3.10^{-4}	2.10^{-4}	2.10^{-4}	3.10^{-4}
EDF / Saint-Laurent-des-Eaux	Lestiou	1.7	2.10^{-4}	1.10^{-4}	1.10^{-4}	1.10^{-4}	1.10^{-4}	1.10^{-4}
EDF / Tricastin	Bollène	1.3	2.10^{-4}	2.10^{-4}	2.10^{-4}	2.10^{-4}	2.10^{-4}	2.10^{-4}
Ganil / Caen	IUT	0.6	$<2.10^{-3}$	$<2.10^{-3}$	$<2.10^{-3}$	8.10^{-3}	8.10^{-3}	7.10^{-3}
ILL / Grenoble	Fontaine (gaseous discharges) and Saint-Égrève (liquids)	1 and 1.4	3.10^{-4}	2.10^{-4}	2.10^{-4}	5.10^{-5}	2.10^{-5}	3.10^{-5}

(a) For the installations operated by EDF, only the "adult" values were calculated until 2008. From 2010 to 2012, the dose of the most exposed reference group of each site for the two age classes (adult or baby) is mentioned. As from 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 the CEA. As these estimates comprise at least one term of less than 0.01 microsieverts, the values indicated are preceded by the "less than (<)" sign.

(c) As the site has no longer had radioactive discharges since 2014, the radiological impact caused by radioactive discharges has been nil since 2014.

The 4th National Plan 2020-2024 for Radon Risk Management

The 4th National Plan 2020-2024 for Radon Risk Management was published at the beginning of 2021. It fits into the framework of the 4th National Health and Environment Plan which now coordinates all the sector-based plans concerning health or the environment, which is itself driven by the National Public Health Strategy 2018-2022, of which one action aims to reduce exposure to interior pollution. This action explicitly targets the effects of radon in the home: "*over and beyond the sanitary aspects, it is question of promoting a living environment that fosters health and of reducing the effects of exposure in the home (chemical pollution, radon, etc.)*".

Following on from the preceding plans, it can be broken down into 13 actions focusing on three themes:

Theme 1: Implement an information and awareness-raising strategy

The health issue that radon represents requires continuation of the awareness-raising and information measures directed towards all the players (regional authorities, employers, building professionals, health professionals, teachers, etc.) and the general public, both nationally and locally, with the promotion and accompanying of regional measures for the integrated management of the radon risk in the home.

A specific communication campaign shall target smokers, because they constitute the population the most at risk of developing lung cancer linked to cumulative exposure to radon and tobacco.

The operational implementation of the information system incorporating all the radon monitoring results, as well as the consolidation and centralising of the existing measures, would appear to be essential for informing the public.

These actions also fall within a regulatory framework which, for the home, is supplemented by measures to inform the public, particularly buyers and tenants. Correct implementation of these new regulatory provisions by the players concerned is one of the priority goals of the 4th Radon Plan.

Theme 2: Continue to improve knowledge

The publication in 2108 of a new map on the municipal scale, based on three radon potential zones, enabled a graded approach to radon risk management to be implemented. This map must nevertheless be improved so as to better integrate certain geological factors that could facilitate radon transfer to buildings (karst zones in particular). Furthermore, the 4th Radon Plan provides for the updating of knowledge of exposure of the French population by organising the collection of measurement data, particularly during the local awareness-raising operations. The initial aim will be, if possible, to orient the measurements taken during these public awareness-raising operations organised by the Regional Health Agencies (ARS) and the regional authorities so that they cover the areas where the data are insufficient. These operations consist in proposing screening kits to the inhabitants of a given region to raise their awareness of the radon risk. Assistance is then provided if the radon concentration in the interior air of the home exceeds the reference level. Several operations of this type are conducted each year in France.

Theme 3: Better integrate management of the radon risk in buildings

The building profession organisations are becoming increasingly aware of the potential health risks from radon. In order to help their members improve their level of expertise, they recently developed training courses dealing with methods to prevent and reduce concentration levels and various media to address the needs. The various French-language aids have been listed. To supplement the offer, a guide intended for professionals and private individuals will establish prevention recommendations for new constructions and radon concentration reduction measures in existing buildings. The progress made in understanding the effectiveness of construction standards in reducing radon concentrations in indoor air needs to be consolidated.

A system of specific indicators, chosen according to their relevance and the available data allowing them to be monitored, has been put in place to evaluate the effectiveness of the national strategy implemented under the national action plan. The way the indicators evolve will be analysed each year by the steering committee that monitors the new action plan.

Implementation of the national action plan will improve the way the general public and the stakeholders concerned are informed and enhance knowledge of radon exposure in the home and how it evolves.

The data collected in 306 buildings open to the public show that the corrective actions or works to reduce the radon concentration have lowered the concentration to below 300 Bq/m^3 in only 41% of these buildings.

Results of the 3rd national radon action plan (2016-2019)

The 3rd radon action plan covered the 2016-2019 period. Although its implementation was strongly impacted by the transposition of Council Directive 2013/59/Euratom of 5 December 2013 (in 2016 for the legislative part and in 2018 and 2019 for the regulatory part), the majority of the actions concerned are either completed or in progress. The results reveal the following main points:

- A radon risk map[(6)] defined on the more precise scale of the municipality, and now including the overseas territories, was published in June 2018. It constitutes a tool common to all the management strategies, based on the division of the territory into three radon potential zones.
- The deployment of numerous communication campaigns on the radon risk and on the new regulatory provisions introduced into French law since 1 July 2018. More particularly, the local awareness raising operations for the public continued and information sessions were organised at national and local level for the various stakeholders: managers of buildings open to the public, risk prevention specialists, building trade professionals, organisations approved by ASN for measuring radon activity concentration.
- The gradual defining of good practices regarding prevention methods for new buildings and radon concentration reduction

6. Order of 27 June 2018 delimiting the radon potential zones on French territory.

TABLE 5

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

IMAGING METHOD	PROCEDURES		TOTAL COLLECTIVE EFFECTIVE DOSE: 102,198 Sv
	NUMBER	%	%
Conventional radiology (dentistry excluded)	44,175,500	54.0	17.7
Dental radiology	27,616,000	33.8	0.2
Computed tomography	8,484,000	10.4	71.2
Diagnostic interventional radiology	377,000	0.5	3.1
Nuclear medicine	1,103,000	1.3	7.8
Total	81,755,500	100.0	100.0

Source: IRSN 2014.

methods in existing buildings. This was made possible by capitalising on examples of constructions and works, experience feedback from building professionals and the publication of French and foreign studies.
- The development of training courses for building professionals, as radon is now included in broader subjects, such as indoor air quality and energy renovation.

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 30 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 the IRSN since 2002.

The average effective dose per inhabitant resulting from diagnostic radiological examinations has been evaluated at 1.53 mSv for the year 2017 (IRSN "ExPRI" study 2020) for some 85 million diagnostic procedures performed in 2017 (81.6 million in 2012), *i.e.* 1,187 procedures for 1,000 inhabitants per year. It is to be noted that as before, the individual exposure in 2017 is very varied. Consequently, although about 32.7% of the French population underwent at least one procedure (dental procedures excluded), half the patients received a dose of 0.1 mSv or less, 75% received 1.5 mSv or less, while the most exposed 5% of patients received a dose exceeding 18.1 mSv.

Conventional radiology (55.1%), computed tomography (12.8%) and dental radiology (29.6%) 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 2017 (75%) than in 2012 (71%), whereas that of dental radiology remains very low (0.3%).

In adolescents, conventional and dental radiology procedures are the more numerous (about 1,000 procedures for 1,000 individuals in 2017). Despite their frequency in this population, conventional and dental radiology procedures represent only 0.5% of the collective dose.

Lastly, it is noteworthy that:
- A national headcount estimated at more than 30,000 patients was exposed to a cumulative effective dose of more than 100 mSv in 2017 due to multiple computed tomography examinations. This figure reaches 500,000 if we consider a cumulative period of 6 years. This highly exposed population seems to be increasing in size regularly and relatively rapidly since 2012. Although most people in this population are old, a quarter of them are aged under 55 years. The question of possible radiation-induced effects is therefore raised for this specific population. It is worthwhile pointing out that these patients are in all likelihood suffering from serious pathologies and that the computed tomography examinations are probably vital for their treatment.
- Based on a sample of 120,000 children born between 2000 and 2015, the IRSN reports 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). This median value varies greatly according to the age category. For infants of less than one year, it is 0.55 mSv (highest value) and between 6-10 years it is 0.012 mSv.

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

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

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

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

Actions of ASN regional divisions in the prevention of the radon risk in the regions

In 2020, the ASN regional divisions, along with the public authorities (Regional directorate for environment, planning and housing – Dreal, Regional Health Agency – ARS, Regional directorate for enterprises, competition, consumption, labour and employment – Direccte) and the partner organisations (Cerema, trade associations, local authorities, etc.), continued the **actions to raise the awareness** of elected officials, building trade professionals, employers, managers of buildings open to the public and the general public to the regulatory changes made since 2018 (see point 3.2.2).

For example:

- In the **Pays de la Loire** and **Bretagne** region, where the *départements* (apart from Sarthe) have between 65% and 93% of their municipalities situated in zones of significant radon potential (category 3), the Nantes regional division organised jointly with the ARS, Dreal and Direccte, two "Radon mornings", one in Rennes (Ille-et-Vilaine *département*), the other as a webinar for the Vendée *département*). Between 50 and 80 representatives of local authorities, schools, healthcare and social institutions, associations and approved organisations took part in each event. Both events presented the new regulatory obligations in buildings open to the public, in the work place and in the private home (information provided to buyers and tenants) to encourage the local authorities to conduct radon measurement campaigns in the home and general public awareness-raising campaigns. In these regions, ASN also financed four actions promoted by local centres for environmental initiatives or regional authorities, notably campaigns of voluntary radon measurement in the home and assisting people faced with high radon concentrations under the Regional Health and Environment Plan in Pays de la Loire. On this account the Nantes division, in collaboration with the ARS, also participated in the launch meetings for radon measurement campaigns in the home.
- In **Bourgogne-Franche-Comté**, the concluding of the first phase of the Franco-Swiss JURADBAT project led to the launching of a website dedicated to radon and interior air quality in the Jura arc in 2019, while 2020 was devoted to measures to ensure the long-term continuity of this website. This website constitutes an online toolbox to inform the local population, the regional authorities and the building trade professionals. The website features general information, regulatory information, practical and technical sheets, interactive radon measurement maps for Switzerland and Franche-Comté, and training modules.
- In the **Centre-Val de Loire** region, the Orléans division helped inform the elected officials of the four municipalities concerned by the implementation of a screening campaign situated in zone 3 (high radon potential) of the Cher *département*.
- In **Nouvelle-Aquitaine**, the Bordeaux division put in place, jointly with the ARS, the Direccte and the Dreal, a communication plan for elected officials and managers of buildings open to the public to assist them with the implementation of the new regulatory provisions.
- In **Provence-Alpes-Côte d'Azur** and in Occitanie, the ASN regional divisions co-signed information letters for the managers of building open to the public.

In addition, the radiation protection inspections carried out in 2020 in medical or industrial facilities situated in municipalities in radon potential zone 3 were used by some regional divisions to explain the regulatory obligations of managers of building open to the public and of employers in work places.

This awareness-raising was **accompanied by targeted inspections** of buildings open to the public: state lower and upper secondary schools, managed by the departmental and regional councils respectively, and spas.

The Marseille division, jointly with the ARS, thus conducted an inspection of the Regional Council of Provence-Alpes-Côte d'Azur. The Lyon division inspected the Departmental Councils of the Isère, Haute-Loire and Rhône *départements*. It also inspected a spa in which a high concentration of radon had been measured. These inspections confirmed the need to monitor over time the measures taken by these facilities to reduce exposure to radon.

The Nantes division carried out two inspections at the Departmental Council of Sarthe (the last Departmental Council not to have been inspected in the preceding years in the Pays de la Loire and Bretagne regions) and the town of Laval to check the implementation of the radon measurement campaign in schools (primary and lower secondary schools) and the measures taken if thresholds were exceeded. These inspections revealed the exceeding of the regulatory deadlines for taking measurements and the need to update the assessments of occupational risks in this respect.

The Dijon division gave priority to the inspection of spas. Two inspections were carried out in the spas of Salin-les-bains and Luxueil-les-bains. These inspections showed that these facilities are duly aware of the radiation protection issues and take good account of the requirements of the Public Health Code and the Labour Code. Consequently, the radon screening campaigns had been carried out in the buildings open to the public and those reserved for the employees, even though the municipalities are not classified in radon potential zone 3. A few additional inspections must nevertheless be carried out to complete the worker exposure assessments.

Several other awareness-raising or oversight actions planned in 2020 were postponed due to the health crisis.

regulations and in the authorisations for nuclear activities as soon as evaluation methods are available. On the basis of the IRSN expert assessment 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 the IRSN to produce a methodological guide for assessing the impact of ionising radiation on the flora and fauna. The draft guide was submitted to ASN and presented to the GPRADE at the end of 2020.

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

In France, exposure for medical purposes represents the primary source of artificial exposure of the public to ionising radiation. This exposure is rising, mainly owing to the increasing number of computed tomography examinations. Imaging examinations have proven their benefits for both diagnosis and treatment. The issue at stake however is to avoid examinations that are not really necessary or that offer no real benefit for the patients and the results of which could be obtained by other available, non-irradiating techniques.

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

ASN's second action plan, published in July 2018, aims at continuing to promote a culture of radiation protection in medical professionals with the reinforcing of skills and the harmonising of practices in an updated regulatory framework. The actions target several areas: increasing accountability and awareness in the medical professionals, training, new practices and techniques, and the equipment. The actions continued in 2020.

With regard to the accountability and awareness of medical professionals in the justification for examinations and optimisation of the doses delivered, ASN has worked in close collaboration with the Ministry of Solidarities and Health in order to ensure the continuity of the patient radiation protection improvement measures implemented thanks to the Medical Physics Organisation Plans (POPM) put in place in the centres. Likewise, ASN has worked closely with the French National Authority for Health (HAS) in order to renew the framework agreement between the two institutions and to pursue the collaboration on the themes of quality assurance, analysis of practices, risk management and good practice recommendations.

In the area of training, ASN has approved two new professional guides prepared by learned societies and intended for practitioners qualified in interventional cardiology (in the adult or child) and installation and maintenance professionals of medical devices emitting ionising radiation.

With regard to putting in place new techniques and practices, the committee for analysing new medical techniques and practices using ionising radiation met to examine a new particle accelerator recently put into service in the United States and to gather information on staff and patient radiation protection during its use.

CHAPTER

02

THE PRINCIPLES OF NUCLEAR SAFETY AND RADIATION PROTECTION AND THE REGULATION AND OVERSIGHT STAKEHOLDERS

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, for its part, 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 and oversight of the nuclear safety and radiation protection of civil nuclear activities is the responsibility of the Nuclear Safety Authority (ASN), an independent administrative Authority, together with Parliament and the other State players, 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 expert technical analysis and assessment, more 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 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 fundamental principles contained in the legislative texts or international standards.

This primarily concerns:
- at the national level, the principles enshrined in the Environment Charter – which has constitutional value – and in the various codes (Environment Code, Labour Code, 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 the international level, ten fundamental safety principles defined by the IAEA (see box below page 124 and chapter 6, point 3.1) implemented by the Convention on Nuclear Safety (see chapter 6 point 4.1), which establishes 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 The principle of licensee responsibility

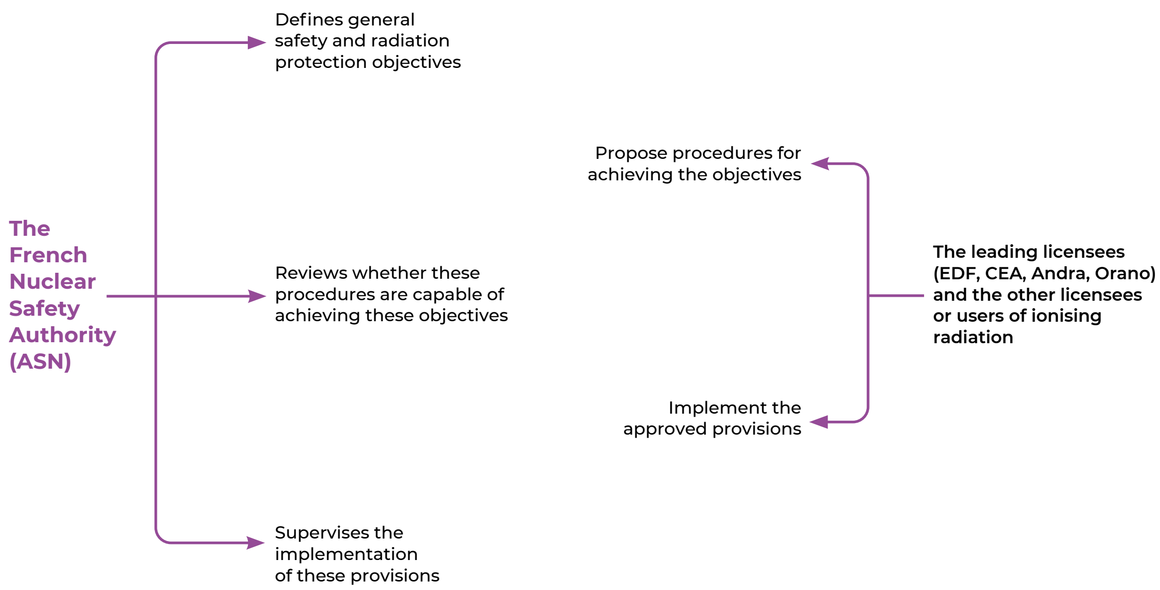
This principle, defined in Article 9 of the Convention on Nuclear Safety, is the first of IAEA's fundamental safety principles. It stipulates that responsibility for the safety of nuclear activities entailing risks lies with those who undertake or perform them.

It applies directly to all nuclear activities.

1.1.2 The "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 The 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 The public participation principle

This principle allows public participation in the decision-making process by public authorities. Following on from the Aarhus Convention, Article 7 of the Environment Charter defines it in these terms: "*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 The justification principle

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

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

1.1.6 The optimisation principle

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

This principle, referred to as the ALARA[1] 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 workplaces in order to reduce it to the strict minimum and to ensuring that medical exposure as a result of diagnostic procedures remains close to the pre-determined reference levels.

1.1.7 The 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*".

1. The ALARA (As Low As Reasonably Achievable) principle appeared for the first time in Publication 26 from the International Commission on Radiological Protection (ICRP) in 1977. It was the result of a process of reflection on the principle of optimising radiological protection. Over the past 30 years, the acceptance and implementation of the ALARA principle has developed significantly in Europe, with strong backing from the European Commission, leading in 1991 to the creation of a European ALARA network.

The fundamental safety principles

The International Atomic Energy Agency (IAEA) defines the following ten principles in its *Fundamental principles of safety* publication, IAEA Safety Standards Series – No. SF-1:

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

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

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

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

1.1.8 The 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 underpins 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. 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 consultative group for nuclear safety reporting to the Director General of the IAEA, as the 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 assume their responsibilities with respect to safety. 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 mitigating 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.

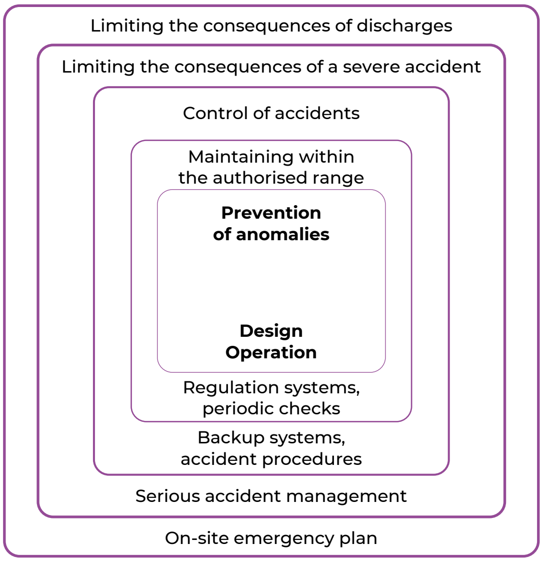
An important element for the independence of the levels of defence is the use of different technologies ("diversified" systems).

The design of nuclear installations is based on a "Defence in Depth" approach. For example, the following five levels 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 melt
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 without core melt
These accidents were studied following the Three Mile Island accident in the United States (1979) and are now taken into account in the design of new reactors such as the European PWR (Evolutionary Power Reactor – 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. These barriers must be designed to have a high degree of reliability and must be monitored to detect any weaknesses before a failure. There are three such barriers for PWR: 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 (NPPs), the level 1 Probabilistic Safety Assessments 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 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 melt.

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 nuclear safety case 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;
- break of a pipe in the primary or secondary system of a nuclear reactor;
- reactor emergency shutdown failure.

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

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

1.2.5 Operating Experience Feedback

Operating Experience Feedback (OEF), which contributes to Defence in Depth, is one of the essential safety management tools. It is based on an organised and systematic collection and analysis of the signals emitted by a system. It should enable acquired experience to be shared so that the organisation can learn (that is through the implementation of preventive measures in a structure that learns from past experience). The first goal of OEF is to understand, and thus ensure progress in technological understanding and knowledge of actual operating practices, so that whenever pertinent, a fresh look can be taken at the design (technical and documentary). As OEF is a collective process, the second goal is to share the resulting knowledge on the basis of the date of detection and recording of the anomaly, the lessons learned from it and how it was rectified. The third goal of OEF is to act on working organisations and processes, on working practices (both individual and collective) and on the performance of the technical system.

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

1.2.6 Social, Organisational and Human Factors

The importance of Social, Organisational and Human Factors (SOHF) for nuclear safety, radiation protection and environmental protection

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

ASN defines SOHF as being all the aspects of working situations and of the organisation which have an influence on the work done by the persons involved. The elements considered concern the individual (training received, tiredness or stress, etc.) and the organisation within which they work (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 facility. 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, ASN resolution 2014-DC-0420 of 13 February 2014 concerning physical modifications to BNIs requires that "*the design of the physical modification envisaged shall, when it is applied and put into operation, take account of the interactions between the modified or newly installed equipment on the one hand and the users and their needs on the other*";
- operations or activities performed by the workers during the commissioning, operation and decommissioning of nuclear facilities, as well as during the transportation of radioactive substances.

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

ASN's SOHF requirements

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

2. The stakeholders

The organisation of the 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 provisions mentioned 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 organisation concerned with the promotion or utilisation 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.

The regulation of nuclear safety and radiation protection in France depends essentially on three players: Parliament, the Government and ASN.

2.1 Parliament

Parliament's principal role in the field of nuclear safety and radiation protection is to make laws. Two major acts were therefore passed in 2006: Act 2006-686 of 13 June 2006, on Transparency and Security in the Nuclear field (TSN Act) and Programme Act 2006-739 of 28 June 2006, on the sustainable management of radioactive materials and waste.

In 2015, Parliament adopted Act 2015-992 of 17 August 2015 concerning Energy Transition for Green Growth (TECV Act), an entire section of which is devoted to nuclear matters (Title VI – "Reinforcing nuclear safety and information of the citizens"). This Act reinforces the framework which was created in 2006.

Pursuant to the provisions of the Environment Code, ASN regularly reports on its activity to Parliament, notably to the Parliamentary Office for the Evaluation of Scientific and Technological Choices (OPECST) and to the parliamentary commissions concerned.

The role of the OPECST is to inform Parliament of the consequences of scientific or technological choices so that it can make informed decisions; to this end, the OPECST gathers information, implements study programmes and conducts evaluations. ASN reports regularly to OPECST on its activities, notably by presenting its annual *Report on the state of nuclear safety and radiation protection* to it.

ASN also reports on its activities to the Parliamentary Commissions 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 the 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 Safety (HCTISN).

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

2.2.1 The 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 individual resolutions 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, Employment and Integration. That concerning the radiation protection of patients is the responsibility of the Minister for Solidarity and Health.

The Ministers responsible for nuclear safety and for radiation protection approve the ASN internal rules of procedures by means of an Interministerial Order. They also approve ASN technical regulations and certain individual resolutions affecting their own particular field (for example: setting BNI discharge limits during operation, BNI delicensing, etc.).

The Nuclear Safety and Radiation Protection Mission

The Nuclear Safety and Radiation Protection Mission (MSNR), within the General Directorate for Risk Prevention at the Ministry for Ecological 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.

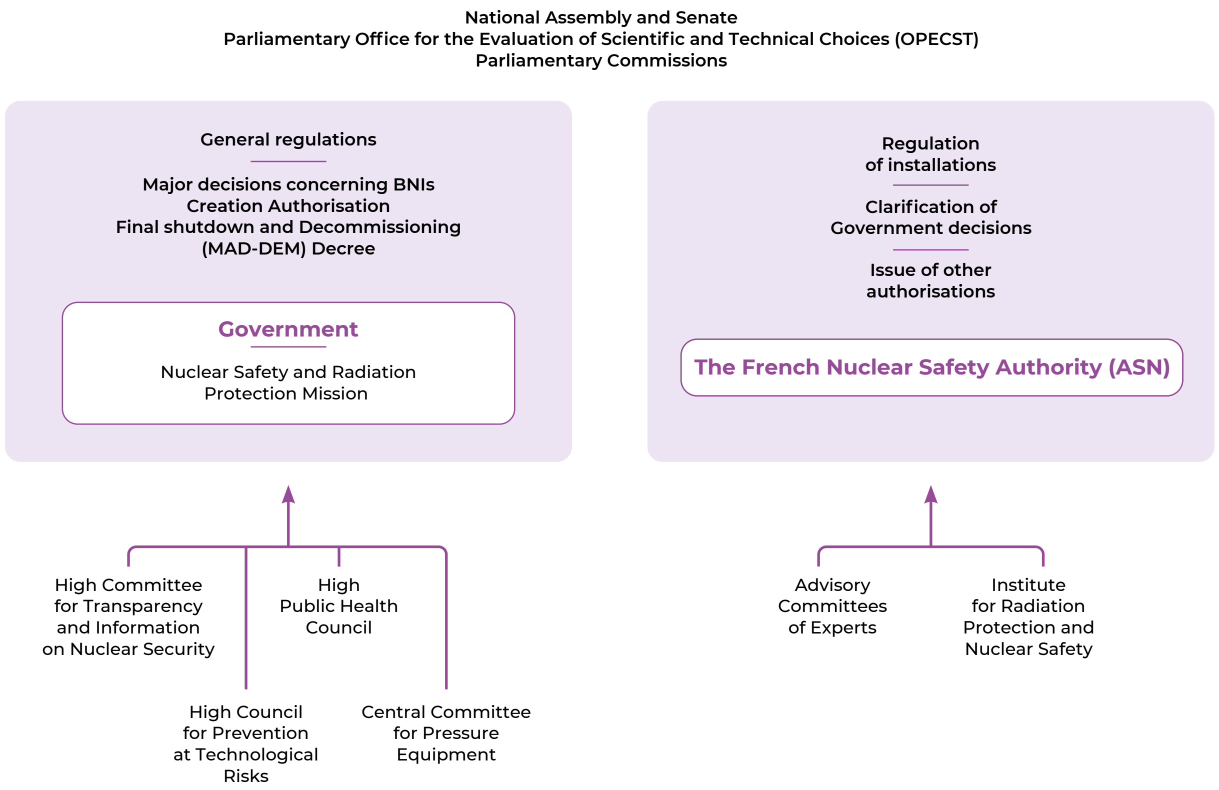
Defence and Security High Official

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 population 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 Transition, with the support of its Defence and Security High Official (HFDS) administration 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 the IRSN.

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

Regulation of nuclear safety and radiation protection in France



2.2.2 The decentralised State services

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

ASN maintains close relations with the Regional Directorates for the Environment, Planning and Housing (Dreal), the Regional and Interdepartmental Directorate for Public Works and Development of Île-de-France (Driea), 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 the conclusions from 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 The French Nuclear Safety Authority

The French Nuclear Safety Authority (*Autorité de sûreté nucléaire* – 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 6-year term. Three are appointed by the President of the Republic and one by the President of each Parliamentary assembly. ASN comprises departments placed under the authority of its Chairman.

For the purposes of technical analysis and assessment, it more particularly draws on the services of the IRSN and the Advisory Committees of Experts (GPE).

2.3.1 Role and duties

Regulation

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

It can issue technical regulations to complete the implementing procedures for decrees and orders adopted in the nuclear safety or radiation protection field, except for those relating to occupational medicine. These regulations must be approved by the Minister responsible for nuclear safety or the Minister responsible for radiation protection. Approval orders and approved resolutions are published in the *Journal Officiel*.

Authorisation

ASN reviews BNI creation 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 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 issued by its Commission are published in its *Bulletin Officiel* on its website (*asn.fr*).

Oversight

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 these 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 administrative enforcement committee 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 the management of radiological emergency situations. It provides technical assistance to the competent Authorities for the drafting of emergency response plans, taking account of the risks resulting from nuclear activities.

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

Chapter 4 of this report describes ASN actions in this field.

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

Information

ASN participates in informing the public in its areas of competence. Chapter 5 of this report describes ASN actions in this field.

Definition of orientations and oversight of research

The quality of ASN's resolutions and decisions relies primarily on robust technical expertise which, in turn, requires the best and most up-to-date knowledge. In this field, Article L. 592-31-1 of the Environment Code comprises provisions giving ASN competence to ensure that public research is tailored to the needs of nuclear safety and radiation protection.

On the basis of the work of its Scientific Committee (see point 2.5.3), ASN issued three opinions on research needs in 2012, 2015 and 2018. Since the publication of its third opinion, ASN has devoted efforts to establishing and strengthening its relations with research organisations and institutions in charge of programming and financing research nationally and at a European level. The 2020 health context however limited the scheduled meetings, notably at an international level.

Finally, in 2020, ASN revised its research strategy. The envisaged changes aim to ensure more regular updating of its research recommendations and facilitate their dissemination and their adoption by the stakeholders.

The Fukushima Daiichi NPP accident in Japan highlighted the need for more research in the field of nuclear safety and radiation protection. A Call for Projects (AAP) in these fields was therefore issued by the French National Research Agency (ANR) under the Investing in the Future programme. ASN is a member of the steering committee for this AAP, which led to 23 projects being carried out between 2013 and 2018.

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 from either the Government or any other person or institution. The President of the Republic may terminate the duties of any member of the Commission in the event of serious breach of his or her obligations.

The Commission defines ASN's 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 2020, the ASN Commission met 85 times. It issued 27 opinions and 19 decisions.

ASN actions in the field of research

In the field of research, ASN set itself the objectives of identifying its needs, publishing them and making them known among the institutions, licensees and research laboratories, so that they are incorporated into the research programmes.

In order to reinforce its approach, ASN is also involved in steering committees, such as that of the National Research Agency (ANR), on research in the fields of nuclear safety and radiation protection. ASN also takes part in selecting research projects financed by Euratom. These calls for projects supported by structures such as the General Secretariat for Investment and the European Commission helped numerous projects emerge in response to the research needs identified by ASN over the past ten years, on subjects such as non-destructive examinations, severe accidents, organisational and human factors, the biological and health effects of low doses of ionising radiation, or the conditioning of waste and its geological disposal.

The scientific watching brief conducted by ASN has also identified a number of subjects which have been studied little if at all since they were identified by ASN in 2012. In order to remedy this situation, ASN will for the first time in 2021 have a budget envelope specifically devoted to financing these orphan subjects.

In addition, ASN will continue its meetings with the authorities, institutions, research laboratories and licensees in France and abroad, for discussions on research needs.

ASN head office departments

The ASN head office departments comprise an Executive Committee, an Office of Administration, a Management and Expertise Office, an Oversight Support Office and nine departments covering specific themes.

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

The role of the departments is to manage national affairs concerning the activities under their responsibility. They take part in defining the general regulations and coordinate and oversee the actions of the ASN regional divisions:

- The Nuclear Power Plant Department (DCN) is responsible for regulating and monitoring 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/oversight 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 offices: "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 offices: "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 drafting 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, certification of packaging and of relevant organisations). It took charge of oversight of the security of radioactive sources. The DTS comprises two offices: "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 Laboratory for Particle Physics (CERN) or the International Thermonuclear Experimental Reactor (ITER) project. The DRC comprises five Offices: "Radioactive Waste Management", "Monitoring of Laboratories-plants-waste-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 the IRSN and the various health authorities – organising the scientific, health and medical watch with regard to the effects of ionising radiation on health. It contributes to the drafting of the regulations in the field of radiation protection, including with respect to natural ionising radiation, and the updating of health protection measures should a nuclear or radiological event take place. The DIS comprises two offices: "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

THE IMPACT OF COVID-19

ASN ORGANISATION DURING THE LOCKDOWN PERIODS

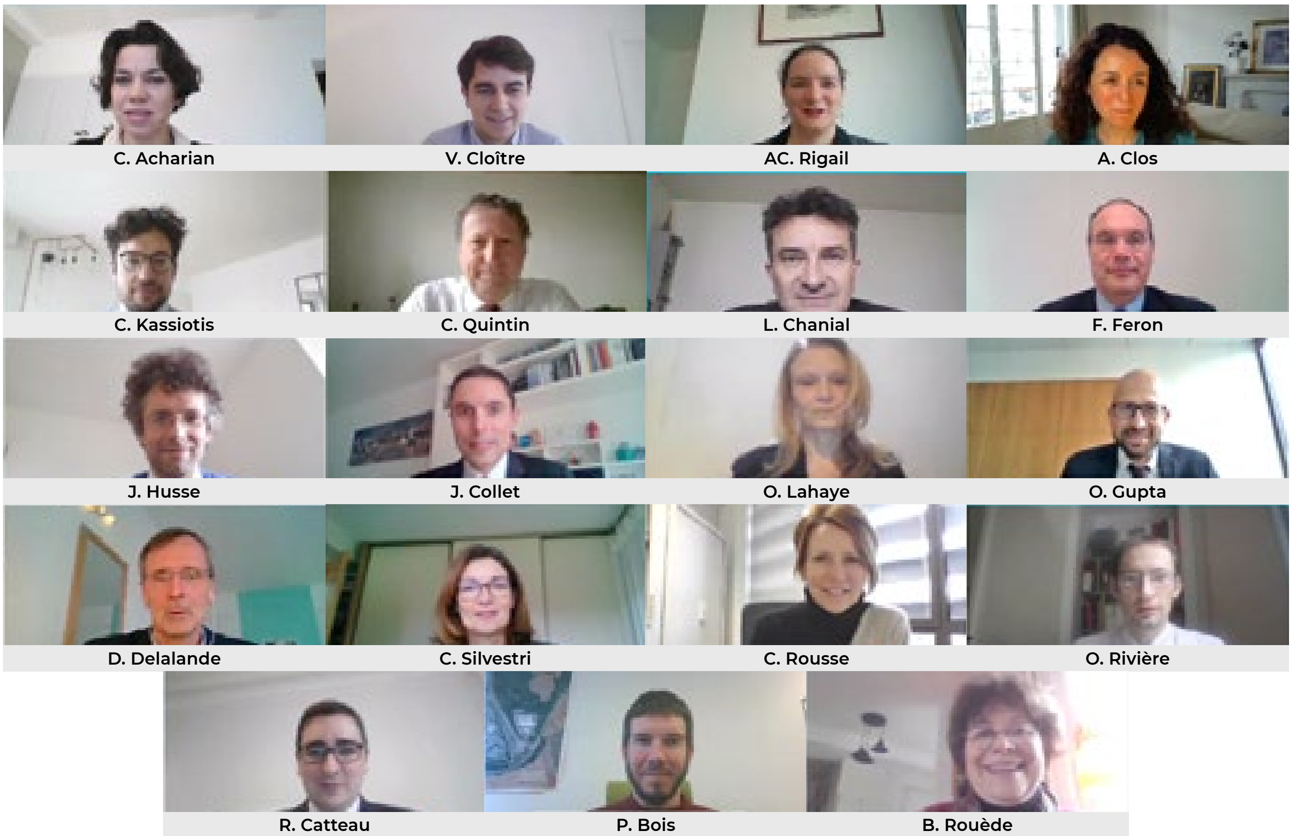
The March 2020 health crisis led ASN to adapt its organisation.

During the first lockdown, the technical resources made available by ASN enabled all its staff to work from home. This enabled examination of the technical files to continue and ASN major position statements to be prepared, on time. The on-call and emergency system was also maintained. Pending implementation of appropriate health protocols, on-site inspections were initially suspended, except when absolutely necessary (incidents) and were replaced by remote inspections. Subsequently, and before the end of the first lockdown period, ASN resumed a number of on-site inspections. Work was done to define the scope of the inspections to be performed, at the same time as identifying the measures to protect the personnel required to conduct these inspections. The operations and organisation as a whole were regularly discussed with the Health, Safety and Working Conditions Committee (CHSCT). This latter was asked to issue opinions on a certain number of texts (organisation, inspection guide mementos during a health crisis).

During the period after the lockdown was lifted, from mid-May until the end of August, ASN continued to prefer home-working for a large share of its personnel. It also reinforced its on-site inspection actions, in addition to its remote-inspections.

In September and October, ASN continued with its on-site inspection activities and, for the staff who so wished, experimented with a home-working quota of up to three days per week (instead of the one day hitherto authorised). The deterioration in the health situation and the Government's decision to institute another lockdown at the end of October, led ASN to suspend this experiment, with all staff again working from home five days a week. It did however attempt to maintain its on-site inspections and adapted them to the situation, notably in the medical field (see chapters 3 and 7).

The members of the management committee



in the legal training of staff and in coordinating regulations steering committees.

- The Information, Communication and Digital Usages Department (DIN) implements ASN information and communication policy in the fields of nuclear safety and radiation protection. It coordinates ASN communication and information actions targeting different audiences, with a focus on handling requests for information and 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 two offices: "Communication and Information" and "IT and Digital Usages".

The regional division heads

Absent: A. Neveu

- 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 (European Nuclear Safety Regulators Group – ENSREG), the IAEA or the NEA. It ensures similar coordination in the more informal structures taking the form of associations (*e.g.* Western European Nuclear Regulators Association – WENRA – which it chairs, International Nuclear Regulators Association – INRA, Heads of European Radiation Control Authorities – HERCA) or cooperative groups under multilateral State-based initiatives (*e.g.* Nuclear Safety and Security Working Group – NSSG, under the G7).
- The Office of Administration (SG) helps to provide ASN with the adequate, appropriate and long-term resources necessary for it to function. It is responsible for managing human resources, including with regard to skills, and for developing social dialogue. It is also responsible for ASN real estate policy and its logistical and material resources. It is in charge of implementing the ASN budget policy and ensures optimised use of its financial resources. The SG comprises three offices: "Human Resources", "Budget and Finance", "Logistics and Real Estate".
- The Management and Expertise Office (MEA) provides ASN with a high-level of expertise. It ensures that ASN's actions are coherent, by means of a quality approach and by overseeing coordination of the workforce. The MEA consists of six staff in charge of expert appraisals, research, quality and relations with the IRSN. The MEA is in charge of overseeing the research network and the quality network at ASN.
- The Oversight Support Office (MSC) ensures that the inspections carried out by ASN are pertinent, harmonised, effective and in-line with ASN's values. For this purpose, it more particularly coordinates the processes involved in drawing up and monitoring the ASN inspection programme to check the approved organisations of the departments.

ASN regional divisions

For many years, ASN has benefited from a regional organisation built around its eleven regional divisions. These regional divisions operate under the authority of the regional representatives. The Director of the Regional Directorate for the Environment, Planning and Housing (Dreal) or of the Regional and Inter-departmental Directorate for the Environment and Energy (Driee) in which the division in question is located takes on this responsibility as regional representative. He/she is placed at the disposal of ASN to fulfil this role. This person is delegated with power of signature by the ASN Chairman for decisions at the local level.

The regional divisions carry out most of the direct inspections on the BNIs, on radioactive substance transport operations and on small-scale nuclear activities, and review most of the authorisation applications filed with ASN by the nuclear activity managers 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

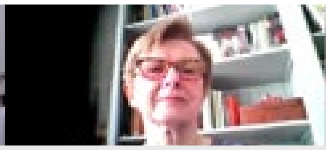
Human resources

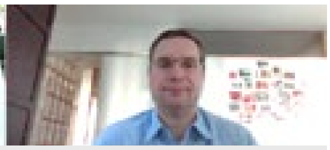
As at 31 December 2020, the total ASN workforce stood at 529, divided between the head office departments (295 staff members), the regional divisions (231 staff members) and various organisations abroad (3 staff members).

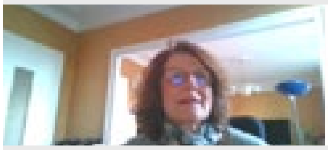
This workforce can be further broken down as follows:
- 448 tenured or contract staff members
- 81 staff members seconded by public establishments (National Radioactive Waste Management Agency – Andra, *Assistance publique – Hôpitaux de Paris* (AP-HP), CEA, IRSN, Departmental Fire and Emergency Response Service).

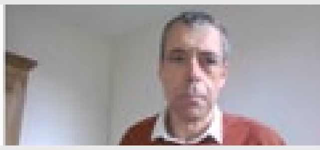
The regional representatives

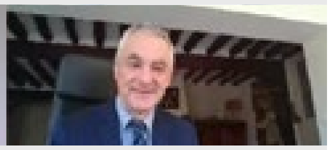

AA. Médard


C. Tourasse

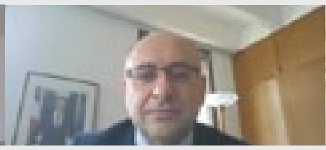

H. Brûlé


A. Bonneville


JP. Lestoille


O. Morzelle


H. Vanlaer


L. Tapadinhas


JP. Deneuvy

ASN utilises a diversified hiring policy with the aim of ensuring that there are sufficient numbers of the qualified and complementary human resources needed to perform its duties.

Skills management

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

The ASN Administrative Enforcement Committee

Nuclear Ordinance 2016-128 of 10 February 2016 created the ASN Administrative Enforcement Committee (Articles L. 592-41 to L. 592-44 of the Environment Code).

Its implementation required on the one hand the publication of regulatory provisions for application of the Ordinance, Decree 2019-190 of 14 March 2019 codifying the provisions applicable to basic nuclear installations, the transport of radioactive substances and transparency in the nuclear field and, on the other, appointment of its members.

The Committee comprises four regular members, two State advisers appointed by the Vice-President of the Council of State and two advisers from the *Cour de cassation* (Court of Appeal) appointed by the first President of the *Cour de cassation*. It also includes four alternate members, designated under the same rules as the regular members.

When referred to by the ASN Commission, the Administrative Enforcement Committee may hand down an administrative sanction, the administrative fine set out in 4° of II of Article L. 171-8 of the Environment Code, when a formal notice decision, issued beforehand by ASN against a licensee or nuclear activity manager to require compliance of the activity with the regulations in force, has not been met by the latter (Article L. 171-8 of the Environment Code).

The provisions of Article L. 596-7 of the Environment Code specify that "*if the ASN Commission decides to open proceedings leading to the imposing of a fine, it notifies the persons concerned of the grievances and brings the matter before the Administrative Enforcement Committee mentioned in Article L. 592-41, which appoints a rapporteur among its members. Events that date back more than three years cannot be brought before the committee if nothing has been done during this period to try to look for, record or sanction the events.*"

The amount of the administrative fine is up to 10 million euros in the event of a breach of the provisions applicable to Basic Nuclear Installations, 1 million concerning pressure equipment, 30,000 euros for the transport of radioactive substances and a maximum of 15,000 euros concerning small-scale nuclear activities (Articles L. 596-4 of the Environment Code and L. 1333-31 of the Public Health Code).

The procedure for pronouncing the administrative fine makes provision for compliance with the adversarial principle and no penalty can be imposed without the person/entity concerned or their representative having been heard or summoned.

The Committee's decision may be made public.

The decisions pronounced by the Administrative Enforcement Committee may be referred to the administrative jurisdiction (Council of State) by the person concerned, by the ASN Chairman or by the third parties.

A first meeting between ASN and the appointed members of the Committee was held on 12 October 2020.

The ASN Administrative Enforcement Committee will be effectively established with the appointment of its Chair by the regular members and the adoption of its internal rules of procedure, which will be published in the *Official Journal of the French Republic (Journal Officiel de la République française)*.

"Nuclear safety" inspector training programme, Pressurised Water Reactor (PWR), Laboratories, Plants, Decommissioning and Waste (LUDD) and cross-disciplinary qualification

Mandatory qualification

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

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

Specific PWR training
- Pressurised Water Reactor
- Fire
- External hazards
- Ventilation
- Nuclear Pressure Equipment (PE)
- Monitoring of PWR safety

Specific LUDD training
- Introduction to atomic engineering
- Fire
- External hazards
- Ventilation

Specific cross-disciplinary training
- Pressurised Water Reactor
- Fire
- External hazards
- Ventilation

Qualifying professional experience

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

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

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

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

Pursuant to the provisions of Article L. 592-22 and L. 592-23 of the Environment Code, which notably state that "*[ASN] appoints the nuclear safety […] and radiation protection inspectors from among its staff*" and Decree 2007-831 of 11 May 2007 setting out the procedures for appointing and qualifying nuclear safety inspectors, which states that "*the nuclear safety inspectors and staff responsible for inspecting nuclear pressure equipment […] are chosen according to their professional experience and their legal and technical knowledge*", ASN has set up a formalised process leading to the qualification of a large number of its staff to perform its inspections and, as applicable, judicial policing duties. ASN also carries out labour inspectorate duties in the NPPs, pursuant to Article R. 8111-11 of the Labour Code. For each of the inspectors concerned, 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.

Training activities were adapted to the context of the health crisis, by minimising the delays in the accreditation decision-making process. On 31 December 2020, ASN employed 320 nuclear safety or radiation protection inspectors holding at least one accreditation, or nearly 60% of the 529 ASN staff.

Nearly 2,300 training days were given to ASN staff during the course of 130 sessions as part of 80 different in-person or video courses. A large volume of self-training hours should be added to these figures.

The Training Committee, set up in 2019, oversees the constant improvement of the training system and ensures that it matches the needs and strategic goals set out in the Multi-year Strategic Plan.

Social dialogue

As a State administration, ASN has three social dialogue bodies:
- the Social Dialogue Committee (SDC), with competence for all questions concerning the organisation and working of the departments, workforce and budget aspects;
- the Joint Consultative Commission (CCP) with competence for all individual or collective questions concerning ASN's tenured contract staff;

- the Health, Safety and Working Conditions Committee (CHSCT) with competence for all questions concerning the occupational health and safety of ASN staff.

These three bodies allow wide-ranging and regular internal discussions on all subjects affecting its organisation, its operations and the working environment of its personnel.

During the course of 2020, the ASN SDC met on two occasions to tackle various subjects and, for some of them, issued an opinion on texts presented by the administration: Covid-19 and organisation of the continuity of activity; inspection procedures in a pandemic context; management guidelines regarding mobility and enhancement of career paths at ASN; working of the training committee; training results, social balance, information concerning senior positions.

The SDC meetings were also an opportunity to review the results of arrangements such as home-working during the lockdown period, or the new organisation of the departments and the home-working and flexible home-working experiments.

For its part, the CHSCT focused on ensuring that occupational health and safety aspects were taken into account in ASN's organisational and operational changes and in the performance of its duties. It met twice in 2020 in ordinary session and four times in extraordinary session. Regular remote meetings between the personnel representatives and the administration were held during the lockdown and post-lockdown periods, to share information and discuss adaptations to the organisational and operational instructions needed given the developing health context.

The debates and exchanges with the personnel representatives mainly concerned Covid-19 and the prevention of occupational risks, during the course of inspections, but also with regard to the staff's return to the sites. All of the measures taken were formalised in "mementos" submitted to the CHSCT for its opinion.

A reporting system for acts of violence, discrimination, moral or sexual harassment, or sexist actions within ASN, drawn up jointly with the personnel representatives, was approved by the CHSCT.

As every year, the CHSCT also examined the annual general health and safety situation, the radiation protection balance, or the SST (occupational health services) results at the CEA.

Coordination of the prevention assistants network continued remotely and the network actively participated in drafting the return to site memento. The members of the CHSCT received SST training.

Finally, at the beginning of 2020, the CHSCT sent a delegation to visit the headquarters (DCN). The scheduled visits to Marseille and Paris had to be postponed.

Finally, in consultation with the members 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 updated the consolidated Occupational Risks Assessment Document (DUERP).

For its part, the Joint Consultative Commission (CCP), with competence for contractual staff, met twice in 2020. The debates primarily concerned the processes for increasing the salaries of ASN contractual staff and their career development and mobility projects.

It should be noted that regarding the actions decided on by the CCP, and for the third consecutive year, the administration organised a meeting in September 2020, bringing together all the ASN contract staff members.

Professional ethics

The ethical rules concerning the ASN commissioners, staff and experts, as set out in several legislative and regulatory texts since 2011, are compiled in the two appendices to the ASN internal rules of procedure adopted in 2018: the first contains provisions regarding the professional ethics of the commissioners and staff, while the second contains provisions concerning external analysis and assessment performed at the request of ASN, for example by the Advisory Committees (see below).

The rules in force at ASN, with the aim of preventing conflicts of interest, more specifically include the following 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 CODEP-CLF-2012-033820 by the ASN Chairman applies the DPI requirements to the members of the Commission, the management committee and the Advisory Committee for Radiation Protection for Medical and Forensic Applications of Ionising Radiation (GPMED). Until mid-July 2017, the DPI were posted on the ASN website. The DPI are henceforth declared on the single remote-declaration site. About sixty people are subject to the DPI;
- Declarations of interests and assets to the High Authority for Transparency in Public Life (HATVP) derived from Act 2013-907 of 11 October 2013 on Transparency in Public Life: the members of the Commission submit their declarations on the HATVP website. The same applies to the Director General, the Deputy Director Generals, and the Office of Administration since 15 February 2017 following modification of the Act of 13 October 2013;
- "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: the professional ethics coordinator and the ASN staff carrying out labour inspectorate duties in the NPPs are subject to this obligation;
- Management by the ASN Director General of his or her financial instruments in conditions which preclude all right of review on his or her part, pursuant to article 25 quater of the 13 July 1983 Act and Decree 2017-547 of 13 April 2017: the ASN Director General submitted justification data to the HATVP before 2 November 2017.

In a decision dated 28 January 2020, the ASN Chairman appointed Alain Dorison as 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. The alert concerns an ethical problem, but also the case of a staff member witnessing a misdemeanour or serious prejudice during the exercise of their duties.

In addition to the obligations recalled above, ASN defined a new internal monitoring procedure for staff wishing to work in the private sector or requesting permission to add a professional activity in order to create or take over a company, in accordance with Act 2019-828 of 6 August 2019 on the transformation of the civil service and Decree 2020-69 of 30 January 2020. Actions to raise personnel awareness in order to enhance the in-house ethics culture and prevent conflicts of interest were also carried out, such as placing practical documents on-line on the intranet (for example, on the prevention of conflicts of interest and the role of ethical supervision in the event of departures to the private sector), the inclusion of a module on professional ethics rules applicable to ASN staff during training sessions held for new arrivals and a video interview in which the professional ethics coordinator uses a few examples to explain professional ethics and which professional activities require particular vigilance.

Financial resources
ASN's financial resources are presented in point 3.

In its opinion of 23 April 2019, ASN considers that the creation of a single budget programme specifically for the regulation and oversight of safety and radiation protection is the current priority in order to:
- on the one hand, make all the efforts made by the State on behalf of the regulation and oversight of nuclear safety and radiation protection more legible and more visible both to Parliament and to the public, at a time when the importance of the nuclear sector in energy policy is being reaffirmed;
- on the other, enable ASN to improve how it controls and optimises the resource devoted to the technical expert assessments it orders, as is done abroad in the nuclear field and in France with regard to industrial risks.

ASN management tools
ASN's management tools are more specifically evaluated during peer review missions (Integrated Regulatory Review Service – IRRS), devoted to analysis of the French system of regulation and oversight of nuclear safety and radiation protection (see box below).

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.

Available on *asn.fr*, the PSP for the period 2018-2020 comprises the following five strategic points:
- reinforce implementation of a graded and efficient approach to our regulation and oversight;
- improve the running of technical investigations;
- 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.

In the current context, this plan remains particularly valid and requires further action on each of the points recalled above. For example, the Covid-19 pandemic requires acceleration of the ASN's digital transformation actions, which naturally fall under point 4 of the PSP. This is why the PSP was extended for a further two years. At the end of 2021, ASN will initiate a strategic review for the drafting of a new PSP for a five-year period (2023-2027).

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 sharing of experience and the definition of coherent common positions.

Quality management system
To guarantee and improve the quality and effectiveness of its actions, ASN defines and implements a quality management system inspired by the international standards of the IAEA and the International Standard Organisation (ISO). 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 stakeholders;

ASN international audits (IRRS missions)

The International Atomic Energy Agency's (IAEA) Integrated Regulatory Review Service (IRRS) missions are designed to improve and reinforce the efficiency of national nuclear regulatory frameworks, while recognising the ultimate responsibility of each State to ensure safety in this field. These missions take account of regulatory, technical and strategic aspects, make comparisons with IAEA Safety Standards and, as applicable, take account of best practices observed in other countries.

These audits are 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 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 15 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 Nuclear Power Plant (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 an active player, as was the case in 2019 in Germany, the United Kingdom, Canada and Norway.

- 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 Safety

The TSN Act created a High Committee for Transparency and Information on Nuclear Safety (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 HCTISN can issue an opinion on any question in these fields, as well as on controls and the relevant information. It may also examine all questions concerning the accessibility of information on nuclear safety and propose all 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 2020 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.

It 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 Ordinance 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 relating to 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

The CLIs 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 Articles R. 125-50 and following of the Environment Code. It was reinforced by the 2015 TECV Act.

The duties and activities of the CLIs are described in chapter 5.

The roles of the Anccli are to represent the CLIs in dealings with the national and European authorities and to provide assistance to the commissions with regard to questions of common interest.

2.5 ASN's technical support organisations

ASN benefits from the expertise of technical support organisations to prepare its decisions. The IRSN is the main one. For several years now, ASN has been devoting efforts to ensuring greater diversification of its experts.

2.5.1 The Institute for Radiation Protection and Nuclear Safety (IRSN)

The 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. Since then, these texts have been modified, notably by Article 186 of the TECV Act and Decree 2016-283 of 10 March 2016 relating to the IRSN.

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

Article L. 592-45 of the Environment Code specifies that the 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. The 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 the IRSN. As the ASN Chairman is now a member of the IRSN Board, ASN contributes to setting the direction of the IRSN's strategic planning.

The 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.

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

The 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.

The IRSN workforce
As at 31 December 2020, the IRSN's overall workforce stood at 1,800 employees, of whom 430 are devoted to ASN technical support.

The 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 the IRSN to support ASN.

TECV Act
This 17 August 2015 Act clarifies the organisation of the system built around ASN and the IRSN:
- It enshrines the existence and duties of the 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.

THE IMPACT OF COVID-19

ADVISORY COMMITTEE MEETINGS IN 2020

Given the context of the pandemic, the way in which Advisory Committee (GPE) meetings were held had to be adapted, so that their activities could continue.

The plenary in-person meetings were replaced by discussions organised according to the following interaction and contribution procedures:
- virtual meetings in the form of written after-the-fact exchanges. Two consultations of this type were set up;
- plenary video-conference meetings allowing the direct interactions that are vital for building expertise. Six days of this type were organised.

- It recalls that ASN benefits from the IRSN technical support, indicating that this support comprises expert analysis and assessment activities "*supported by research*".
- It clarifies the relations between ASN and the 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 the IRSN opinions.

2.5.2 Advisory Committees of Experts

In preparing its decisions, ASN relies on the opinions and recommendations of eight Advisory Committees of Experts (GPEs). A distinction is made between the expert assessment requested from the IRSN (see point 2.5.1) and that requested from the GPEs.

At ASN's request, the GPEs issue an opinion on certain technical dossiers with particularly high potential consequences prior to decisions being taken. 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.

ASN renews the composition of the Advisory Committees every four years. They are broken down according to their areas of expertise:
- the Advisory Committee for decommissioning (GPDEM) created in October 2018,
- the Advisory Committee for Nuclear Reactors (GPR) renewed in October 2018,
- the Advisory Committee for Laboratories and Plants (GPU) renewed in October 2018,
- the Advisory Committee for Waste (GPD) renewed in October 2018,
- the Advisory Committee for Transport (GPT) renewed in October 2018,
- the Advisory Committee for Nuclear Pressure Equipment (GPESPN) renewed in October 2018,
- the Advisory Committee for the Radiation Protection of Workers and the Public for Industrial and Research Applications, as well as for ionising radiation of natural origin and in the environment (GPRADE) extended for one year in December 2020,
- the Advisory Committee for the Radiation Protection of Health Professionals, the Public and Patients for Medical and Forensic Applications of Ionising Radiation (GPMED) extended for one year in December 2020.

For most of the subjects covered, the GPEs examine the reports produced by the IRSN, by an expert working group or by one of the ASN departments. The representatives of the ASN departments or external structures which carried out the expert assessment prior to a GPE meeting, present their conclusions to the group. Following each consultation, the GPE consulted can send the ASN Director General a written opinion, plus recommendations where necessary. The contents of the dossier are made available to the members of the GPEs so that they can reach an informed and independent conclusion. This independent perspective is of use for the decision-making process.

In addition to being consulted on the dossiers submitted by a licensee, the Advisory Committees act as guarantor of nuclear safety and radiation protection doctrine and contribute to its development. They can be invited to take part in the debate on

TABLE 1

Advisory Committee meetings in 2020

GPE	DATE	MAIN TOPIC
GPR	12 and 13 November 2020	• Results of the generic phase of the 4th periodic safety review of the 900 MWe reactors
GPR	17 and 23 November 2020	• Periodic safety review of the High Flux Reactor (RHF – BNI 67) operated by the Laue-Langevin Institute (ILL)
GPESPN	8 September 2020	• In-service resistance of 900 MWe reactor pressure vessels during the 10 year period following their 4th ten-yearly outage
GPESPN	26 November 2020	• Updating of "inconel zones of main primary system of reactors of the 900, 1,300 and 1,450 MWe plant series" file (except Fessenheim)
GPU	Online consultation from 20 May to 15 June 2020	• Draft Guide No. 26 *Management of criticality risk in BNIs* (ASN/IRSN guide)
GPU	12 October 2020	• Periodic safety review of BNI 118 (STE3) of the La Hague facility: health and environment impact assessment
GPDEM	Online consultation from 5 June to 6 July 2020	• Decommissioning and safety review file for Phébus (BNI 92)
GPD	Online consultation from 3 July to 30 September 2020	• ASN presentations: bituminous waste; results of PNGMDR public debate; GPE internal regulations • The IRSN presentations: physico-chemical behaviour of drums of bituminous waste; *Cigéo* disposal of bituminous waste; harmfulness of radioactive materials and waste • Andra technical document: disposal of drums of bituminous waste; gradual development of the *Cigéo* disposal centre and corresponding decision milestones
GPRADE	3 March 2020	• GPRADE recommendations concerning occupational exposure to radon
GPMED and GPRADE	6 October 2020	• Operating results and review of changes to the Advisory Committees • Presentation of work by the working group on updating of the national Guide *Medical intervention in the case of a nuclear or radiological event* • Presentation of the Guide for assessment of the radiological impact on fauna and flora (GPRADE)
GPMED	1 December 2020	• Working methodology and prospects for the revision of the diagnostic reference levels (NRD)

changes to regulations, or on a general nuclear safety or radiation protection topic.

As an expert assessment body, the members of the Advisory Committees are required to abide by the provisions of the external expert assessment charter in Appendix 2 to the ASN internal rules of procedure. Each member of an Advisory Committee draws up a declaration of interest (which is made public in the particular case of the GPMED which deals with health products questions, in accordance with the health expert assessment charter of 21 May 2013 as set out in Article L. 1452-2 of the Public Health Code).

The provisions concerning the prevention of conflicts of interest were reinforced at the end of 2019, with the adoption of the new internal regulations common to the eight GPEs. 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. The IRSN for its part publishes the summaries of the technical investigation reports it presents to the GPEs.

Advisory Committee for Decommissioning (GPDEM)
Chaired by Michèle Viala, the GPDEM comprises 33 experts appointed for their competence in the field of BNI decommissioning. The GPDEM was consulted once with regard to the decommissioning project for the Phébus facility. This consultation will continue in 2021.

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. An on-line information meeting was held in 2020, jointly with Andra and the IRSN. The GPD was thus consulted on several topics, including bituminous waste.

Advisory Committee for Nuclear Pressure Equipment (GPESPN)
Since 2009, the GPESPN has replaced the Standing Nuclear Section 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. In 2020, it held two plenary meetings, including the final meeting which closed the file on the in-service resistance of the 900 Megawatts electric (MWe) reactor pressure vessels. It was asked to take part in the meeting of the GPR on the results of the 4th periodic safety review of the 900 MWe reactors.

Advisory Committee for Radiation Protection in Medical and Forensic Applications of Ionising Radiation (GPMED)
Chaired by Bernard Aubert, the GPMED comprises 36 experts appointed for their competence in the field of radiation protection of health professionals, the general public and patients and for medical and forensic applications of ionising radiation. In 2020, it held two plenary meetings, one of which was organised jointly with the GPRADE. A call for candidates will be issued during the course of 2021, in preparation for the renewal of the Committee scheduled for December 2021.

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 30 experts appointed for their competence in the fields of radiation protection of workers (other than health professionals) and the public, for industrial and research applications using ionising radiation and for exposure to ionising radiation of natural origin, and protection of the environment. In 2020, it held two plenary meetings, one of which was organised jointly with the GPMED. A call for candidates will be issued during the course of 2021, in preparation for the renewal of the Committee scheduled for December 2021.

Advisory Committee for Nuclear Reactors (GPR)
The GPR is chaired by Thierry Charles and comprises 35 experts appointed for their competence in the field of nuclear reactors. In 2020, it held two plenary meetings, including the meeting to examine the results of the 4th periodic safety review of the 900 MWe reactors. This meeting was open to the members of the GPESPN, the Anccli, the CLIs concerned and to associations.

Advisory Committee for Transport (GPT)
The GPT currently has no Chair and comprises 25 experts appointed for their competence in the field of transport. It did not meet in 2020.

Advisory Committee for Laboratories and Plants (GPU)
The GPU is chaired by Alain Dorison and comprises 32 experts appointed for their competence in the field of laboratories and plants concerned by radioactive substances. In 2020, it was consulted once during an on-line meeting on the ASN draft guide on criticality control. It held a plenary meeting dedicated to the periodic safety review of BNI 118, which it had visited beforehand.

2.5.3 Scientific Committee

ASN calls on the expertise of a Scientific Committee reporting to the Commission, in order to assist it with identifying research subjects to be conducted or taken further in the fields of nuclear safety and radiation protection. In a decision dated 6 November 2018, the ASN Commission appointed the nine members of the Scientific Committee for four years, on the basis of their expertise notably in the fields of research. Under the Chairmanship of Michel Schwarz, the Committee comprises Benoît De Boeck, Jean-Marc Cavedon, Edward Lazo, Catherine Luccioni, Antoine Masson, Jean-Claude Micaelli, Christelle Roy and Marc Vannerem. The Scientific Committee maintained its two annual plenary meetings in 2020. It also continued its meetings with the research laboratories, notably with respect to the ageing of non-metallic materials. In the field of radiation protection, it drafted an opinion on the research to be carried out in relation to internal exposure to uranium and the various chemical forms of tritium. This opinion will be published at the beginning of 2021.

2.5.4 The ASN's other technical support organisations

To diversify its expertise and benefit from other particular skills, ASN committed credits of €45,000 in 2020.

In 2020, ASN notably received support for the continued development of the inspection of complex licensee projects.

2.6 The pluralistic working groups

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

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

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

The Working Group tasked with drafting the PNGMDR comprises environmental protection associations, experts, representatives from industry and regulatory authorities, alongside the radioactive waste producers and managers. It is co-chaired by the General Directorate for Energy and the Climate at the Ministry for Ecological Transition and by ASN.

The work of the PNGMDR working group is presented in greater detail in chapter 14.

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

Pursuant to an Interministerial Directive of 7 April 2005 on the action of the public authorities in the case of an event leading to a radiological emergency situation, ASN, together with the ministerial departments concerned, is tasked with defining, preparing for and implementing the necessary measures to manage a post-accident situation.

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

The work of the Codirpa is presented in greater detail in chapter 4.

2.6.3 The Committee for the Analysis of New Techniques and Practices using Ionising Radiation

The Committee for the Analysis of New Techniques and Practices using Ionising Radiation (Canpri) was created on 8 July 2019.

It is chaired by ASN, comprises 16 experts appointed by ASN, representing their learned societies, and representatives of the French health institutions. This committee met on 22 September 2020.

2.6.4 The other pluralistic working groups

Considering that it was necessary to move forward with regard to the reflections and work being done on the contribution of humans and organisations to the safety of nuclear facilities, ASN decided in 2012 to set up the Steering Committee for Social, Organisational and Human Factors (Cofsoh). The end-purposes of the Cofsoh are firstly to allow exchanges between the stakeholders on the difficult subject of social, organisational and human factors, and secondly to draw up documents proposing joint positions by the various members on given subjects and to propose directions for studies to be undertaken in order to clarify subjects that lack data or clarity.

ASN also heads the national committee in charge of monitoring the National Plan for the management of radon risks. In 2019 and 2020, the Committee more specifically worked on preparing the results of the 3rd plan (2016-2019) and preparing the 4th radon plan for the period 2020-2024. The Committee met six times for this purpose (see chapter 1). Within the framework of this plan, ASN has since 2018 been in charge of a working group tasked with coordinating communications about management of the radon risk.

2.7 The other stakeholders

As part of its mission to protect the general public from the health risks of ionising radiation, ASN cooperates closely with other institutional stakeholders with competence for 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 institution reporting to the Ministry in charge of health, has taken up the functions of the French Health Products Safety Agency (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 27 June 2017.

2.7.2 French National Authority for Health

The essential role of the French National Authority for Health (HAS), an independent administrative Authority created in 2004, is to maintain an equitable health system and improve the quality of patient care. The Authority and its activities are presented on its website *has-sante.fr*. An ASN-HAS agreement, signed on 4 December 2008, was renewed on 15 December 2015. An ASN-HAS action plan is appended to this agreement and is regularly updated.

2.7.3 French National Cancer Institute

Created in 2004, the French National Cancer Institute (INCa) is primarily responsible for coordinating activities in the fight against cancer. The Institute and its activities are presented on its website *e-cancer.fr*. Regular discussions take place between the INCa and ASN.

TABLE 2

Status and activities of the main civil nuclear safety regulators(*)

COUNTRY/ REGULATORY AUTHORITY	STATUS			ACTIVITIES						
					RADIATION PROTECTION			SECURITY (PROTECTION AGAINST MALICIOUS ACTS)		
	ADMINIS-TRATION	GOVERNMENT AGENCY	INDEPEN-DENT AGENCY	SAFETY OF CIVIL INSTAL-LATIONS	LARGE NUCLEAR FACILITIES	EXCLUDING BNIs	PATIENTS	SOURCES	NUCLEAR MATERIALS	TRANSPORT SAFETY
Europe										
Germany/BMUB + *Länder*	▪			▪	▪	▪	▪	▪	▪	▪
Belgium/AFCN		▪		▪	▪	▪	▪	▪	▪	▪
Spain/CSN			▪	▪	▪	▪	▪	▪	▪	▪
Finland/STÜK		▪		▪	▪	▪	▪	▪	▪	▪
France/ASN			▪	▪	▪	▪	▪	▪(**)		▪
United Kingdom/ ONR		▪		▪	▪			▪	▪	▪
Sweden/SSM		▪		▪	▪	▪	▪	▪	▪	▪
Switzerland/ENSI			▪	▪	▪				▪	▪
Other countries										
Canada/CCSN			▪	▪	▪	▪	▪	▪	▪	▪
China/NNSA	▪			▪	▪	▪		▪	▪	▪
Korea/NSSC		▪		▪	▪	▪		▪	▪	▪
United States/ NRC			▪	▪	▪	▪	▪	▪	▪	▪(***)
India/AERB		▪		▪	▪	▪	▪	▪	▪	▪
Japan/NRA		▪	▪	▪	▪	▪	▪	▪	▪	
Russia/ *Rostekhnadzor*	▪	▪		▪	▪			▪	▪	▪
Ukraine/SNRIU	▪	▪		▪	▪	▪		▪	▪	▪

* Schematic, simplified representation of the main areas of competence of the entities (administration, independent agencies within Government or independent agencies outside government) responsible for regulating nuclear activities in the world's nuclear countries.
** Responsibility for source security was given to ASN by the Ordinance of 10 February 2016. This provision came into force on 1 July 2017.
*** National transports only.

2.8 The safety regulators: an international comparison

Table 2 describes the status and activities of the safety regulators. In terms of status, most of these regulatory authorities are Government or independent agencies. With regard to their activities, most of them regulate and oversee the complete spectrum of nuclear activities, including in terms of protection against malicious acts (except for France with regard to malicious acts).

3. Financing the regulation of nuclear safety and radiation protection

Since 2000, all the personnel and operating resources involved in the performance of the responsibilities entrusted to ASN have been covered by the State's general budget.

In the 2020 Budget Act, the ASN budget (action 9 of programme 181 "Risk prevention") amounted to €65.77 million in payment credits (CP). It included €48.12 million for personnel expenses and €17.65 million in CP for operating credits for ASN head office and its 11 regional division, and intervention credits. The ASN's budget is divided among five different public policy programmes:

- action 9 "Regulation and oversight of nuclear safety and radiation protection" of programme 181 "Risk prevention" covers the ASN workforce and personnel credits, as well as the operating, investment and intervention spending incurred for the performance of its duties;
- in addition, a certain number of operating costs (for head office and the regional divisions) are incorporated into the support programmes of the Ministry for the Economy, Finance and Recovery (programme 218), the Ministry for Ecological Transition (programme 217) and the General Secretariat of the Government (programme 354). ASN's assets for these various programmes, in terms of both actions carried out for ASN and credits, cannot be identified with any accuracy owing to the overall, shared nature of these programmes;
- finally, pursuant to the provisions of Article L. 592-14 of the Environment Code, "*ASN is consulted by the Government regarding the share of the State subsidy to the IRSN corresponding to the technical support mission performed by this Institute on behalf of ASN*". These ASN support credits are part of action 11 "Research in the field of risks" of programme 190 "Research in the fields of sustainable energy, development and mobility".

The total IRSN budget for 2020 amounted for its part to €269.5 million, of which €83 million were devoted to the provision of technical support for ASN. The IRSN credits for providing ASN with technical support come in part (€40.3 million) from programme 190 (see below). The rest (€42.7 million) comes from a contribution from the nuclear licensees. This contribution was put into place by the budget amendment Act of 29 December 2010.

In total, in 2020, the State's budget for transparency and the regulation of nuclear safety and radiation protection in France amounted to €335.42 million.

By way of comparison, the amount of taxes collected by ASN in 2020 amounted to €849.57 million:

- €574.73 million from BNI taxes (paid into the State's general budget);
- €126.18 million from additional "support", "disposal" and "research" taxes (allocated to various establishments, including Andra, municipalities and Public Interest Groupings (GIP);
- €148.66 million from the special contribution for the management of radioactive waste (allocated to Andra).

This complex funding structure is detrimental to the overall clarity of the cost of regulation. It moreover leads to difficulties in terms of budgetary preparation, arbitration and implementation.

BNI Tax, additional "research", "support" and "disposal" taxes, special Andra contribution and contribution to the IRSN

Pursuant to the Environment Code, the ASN Chairman is responsible for assessing and ordering payment of the Basic Nuclear Installation (BNI) tax, introduced under Article 43 of the 2000 Budget Act (Act 99-1172 of 30 December 1999). The revenue generated by this tax, the amount of which is set yearly by Parliament, came to €574.73 million in 2020. The proceeds go to the central State budget.

In addition, for certain BNIs, said Act 99-1172 of 30 December 1999 also creates three additional taxes, known as "research", "support" and "disposal", respectively. The revenue from these taxes is allocated to funding economic development measures and research into underground disposal and storage by the National Agency for Radioactive Waste Management (Andra). The revenue from these taxes represented €126.18 million in 2020, of which €3.30 million were paid in 2020 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 2020.

Finally, Article 96 of Act 2010-1658 of 29 December 2010 creates an annual contribution to the Institute of Radiation Protection and Nuclear Safety (IRSN) to be paid by BNI licensees. This contribution is in particular set aside to finance the review of the safety cases submitted by the BNI licensees. The revenue from this contribution amounted to €62.7 million in 2020.

TABLE 3

Breakdown of licensee contributions

LICENSEE	AMOUNT FOR 2020 (millions of euros)			
	BNI TAX	ADDITIONAL WASTE AND DISPOSAL TAXES	SPECIAL ANDRA CONTRIBUTION	CONTRIBUTION ON BEHALF OF THE IRSN
EDF	544.78	96.67	115.92	48.42
Orano-Framatome	16.66	6.20	7.44	5.71
CEA	4.78	18.34	25.30	6.92
Andra	5.41	3.30	-	0.40
Others	3.10	1.67	-	0.71
Total	574.73	126.18	148.66	62.16(*)

* The amount allocated to the IRSN is capped at €62.5 million.

4. Outlook

Drawing on the lessons learned from the two lockdown periods, ASN will devote efforts to consolidating its working methods. The first will aim to reinforce and update its activity continuity plan, taking in aspects beyond simply the pandemic (electrical power outage, etc.). The year 2021 will also be put to good use to reinforce the IT resources, notably with regard to video-conferencing. At the same time, ASN will begin its transition to a new information system.

If the health situation so allows, ASN will also resume the fixed home-working and flexible home-working experiment in order to redefine the breakdown between remote and in-person activities, while ensuring the quality of the tasks to be performed and preserving the collective approach. It will also use 2021 as an opportunity to consolidate the new inspection methods (*in situ* and remotely).

In accordance with its Multi-Year Strategic Plan, but also based on the lessons learned from the lockdown periods, ASN will consolidate its skills, on the one hand by modifying its training methods, giving greater importance to evaluation and self-training and, on the other, by continuing with its policy of developing senior positions, which will be occupied by staff with solid professional experience in the fields of nuclear safety and radiation protection, or those which contribute to this (support or transverse functions).

Following its suspension owing to the health context, ASN will be renewing its request for the creation of a single budget programme devoted to the regulation of nuclear safety and radiation protection.

With regard to research, ASN will use the budget resources allocated to it in order to carry out actions consistently with the opinions produced so far.

In terms of expert analysis and appraisal, work will be done to renew the agreement between ASN and its technical support organisation, the IRSN. The Advisory Committees will continue their programme of work in 2021. Meetings will be maintained and, depending on the health conditions, the methods of interaction and contribution will be adapted. The mandates of the GPMED and GPRADE will be extended to 31 December 2021, and will be renewed in 2022.

ASN will initiate a strategic review for the drafting of its new Multi-Year Strategic Plan, during the course of 2022, and it will from now on cover a five-year period.

TABLE 4

Budget structure of the credits allocated to transparency and the regulation of nuclear safety and radiation protection in France

MISSION	PROGRAMME	ACTION	NATURE	BUDGET RESOURCES				REVENUE
				INITIAL BUDGET ACT 2020 AE (€M)	INITIAL BUDGET ACT 2020 CP (€M)	INITIAL BUDGET ACT 2021 AE (€M)	INITIAL BUDGET ACT 2021 CP (€M)	BNI TAX 2020 (€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)	48.12	48.12	49.41	49.41	
			Operating and intervention costs	12.65	17.65	59.73	17.73	
			Total	60.77	65.77	109.14	67.14	
		Action 1: Prevention of technological risks and pollution	Operation (evaluation) of the High Committee for Transparency and Information on Nuclear Safety (HCTISN)	0.15	0.15	0.15	0.15	
			Sub-total	60.92	65.92	109.29	67.29	
Ministerial mission **Oversight of Government actions**	**Programme 217:** Management and coordination of policies for ecology, sustainable development and mobility **Programme 354:** State's regional administration	-	Operation of ASN's 11 regional divisions (real estate, etc.)	The credits allocated to ASN for these various programmes cannot be identified owing to the overall, shared nature of these programmes				
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					574.73
Interministerial mission **Research and higher education**	**Programme 190:** Research in the fields of energy and sustainable development and planning	**Sub-action 11-2 (area 3):** French Institute for Radiation Protection and Nuclear Safety (IRSN)	The IRSN technical support activities for ASN	41.15	41.15	41.8	41.8	
		Sub-action 11-2 (3 other areas): French Institute for Radiation Protection and Nuclear Safety (IRSN)	-	129.62	129.62	125.40	125.40	
Annual contribution on behalf of the IRSN instituted by Article 96 of budget amendment Act 2010-1658 of 29 December 2010 dedicated to the IRSN's activities (apart from technical support for ASN)			-	19.5	19.5	19.4	19.4	
Annual contribution on behalf of the IRSN instituted by Article 96 of budget amendment Act 2010-1658 of 29 December 2010 dedicated to the IRSN's activities in support of ASN			-	42.7	42.7	41.9	41.9	
			Sub-total	**232.97**	**232.97**	**228.5**	**228.5**	**574.73**
Grand Total (excluding the IRSN and programmes 217, 218 and 354)				**144.77**	**149.77**	**192.99**	**150.99**	**574.73**
Grand Total ASN (excluding programmes 217, 218 and 354) and the IRSN				**293.89**	**298.89**	**337.79**	**295.79**	

CHAPTER 03

REGULATION OF NUCLEAR ACTIVITIES AND EXPOSURE TO IONISING RADIATION

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 monitoring 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 the French Nuclear Safety Authority (ASN). With the aim of ensuring greater administrative efficiency, ASN has also been entrusted with the oversight of regulations concerning the environment and Pressure Equipment (PE) in Basic Nuclear Installations (BNIs).

Control and regulation of nuclear activities is a fundamental responsibility of ASN. Its primary goal is to ensure that a party responsible for a nuclear activity effectively assumes its obligations. ASN has a vision of control and regulation encompassing material, organisational and human aspects. Following safety and radiation protection assessments in each activity sector, the ASN implements its oversight action by issuing resolutions, binding requirements, inspection follow-up letters, plus penalties as applicable.

The oversight priorities are defined with regard to the risks inherent in the activities, the behaviour of those responsible for the activities and the means they deploy to control them. In the priority areas, ASN must reinforce its oversight. Conversely, for lower-risk areas, ASN must be able to explicitly scale-back its regulation and oversight.

1. Verifying that the licensee assumes its responsibilities

1.1 The principles of ASN's oversight duties

ASN's oversight aims primarily to ensure that those responsible for an activity effectively assume their obligations and comply with the requirements of the regulations concerning nuclear safety and radiation protection, in order to protect persons and the environment from radioactivity-related risks.

It applies to all the phases in the performance of the activity, including the decommissioning phase for nuclear facilities:
- before the licensee exercises an activity subject to authorisation, by reviewing and analysing the files, documents and information provided by the licensee to justify its project with regard to safety and radiation protection. This verification aims to ensure that the information and demonstration supplied are both relevant and sufficient;
- during exercise of the activity, by visits, inspections, verification of licensee operations entailing significant potential consequences, review of reports supplied by the licensee and analysis of significant events. This oversight includes an analysis of any justifications provided by the licensee.

ASN applies the principle of proportionality when determining its actions, so that the scope, conditions and extent of its regulatory action are commensurate with the human and environmental protection implications involved.

When applicable, this oversight can call on the support of the French Institute for Radiation Protection and Nuclear Safety (IRSN).

1.2 The scope of regulation of nuclear activities

Article L. 592-22 of the Environment Code states that ASN must regulate compliance with the general rules and particular requirements of safety and radiation protection, applicable to:
- licensees of Basic Nuclear Installations (BNIs);
- the manufacturers and users of Nuclear Pressure Equipment (NPE) used in the BNIs;
- those in charge of Radioactive Substances Transport (TSR);
- those in charge of activities entailing a risk of exposure of individuals and workers to ionising radiation;
- those in charge of implementing ionising radiation exposure monitoring measures;
- the nuclear licensees, their suppliers, contractors or subcontractors when they carry out activities important for the protection of persons and the environment outside the perimeter of the BNIs.

In this chapter, these persons or entities are called the "licensees".

ASN also oversees the entities and laboratories that it approves in order to take part in the inspections and oversight of nuclear safety and radiation protection. ASN carries out labour inspectorate duties in the Nuclear Power Plants (NPPs) (see chapter 10).

2. Ensuring that regulation is proportionate to the implications

ASN aims to organise its regulatory work using a graded approach appropriate to the implications of the activities. It follows a continuous improvement approach to its regulation and oversight practices in order to consolidate the effectiveness and quality of its actions. ASN uses Operating Experience Feedback (OEF) from more than 40 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 the 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 (OEF), 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 pressure equipment monitoring organisations;
- presence in the field, also frequently outside actual inspections;
- dialogue 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 important events marking the operation of a nuclear activity.

Regulation and monitoring of Basic Nuclear Installations

Nuclear safety is "the set of technical provisions and organisational measures related to the design, construction, operation, shutdown and decommissioning of BNIs, as well as the transport of radioactive substances, which are adopted with a view to preventing accidents or limiting their effects". This notion includes the measures taken to optimise waste and effluent management.

The safety of nuclear installations is based on the implementation of the following principles, defined by the International Atomic Energy Agency (IAEA) in its fundamental safety principles for nuclear installations (Safety series No. 110) and then to a large extent incorporated into the European Directive on Nuclear Safety of 8 July 2014, which modifies that of 2009:
- responsibility for nuclear safety lies primarily with the licensee;
- the organisation responsible for regulation and oversight is independent of the organisation responsible for promoting or using nuclear power. It must have responsibility for licensing, inspection and formal notice, and must have the authority, expertise and resources necessary for performance of the responsibilities entrusted to it. No other responsibility shall compromise or conflict with its responsibility for safety.

In France, the Environment Code defines ASN as the organisation meeting these criteria, except for Defence-related nuclear facilities and activities, which are regulated by the provisions of the Defence Code.

Ordinance 2016-128 of 10 February 2016 implementing the Energy Transition for Green Growth Act 2015-992 of 17 August 2015 (TECV Act) expanded the scope of ASN regulation to the suppliers, contractors and subcontractors of licensees, including for activities performed outside BNIs.

In its regulatory duties, ASN is required to look at the equipment and hardware in the installations, the individuals in charge of operating it, the working methods and the organisation, from the start of the design process up to decommissioning. It reviews the steps taken concerning nuclear safety and the monitoring and limitation of the doses received by the individuals working in the facilities, and the waste management, effluents discharge monitoring and environmental protection procedures.

Regulation of pressure equipment

Numerous systems in nuclear facilities contain or convey 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 individual resolutions and checking the in-service monitoring of the pressure equipment installed within the perimeter of a BNI.

Pressure equipment operation is regulated. This regulation in particular applies to the in-service monitoring 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 NPE.

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 is in charge of drafting and monitoring technical regulations concerning radiation protection.

The scope of ASN's regulatory role in radiation protection covers all the activities that use ionising radiation. ASN exercises this duty, where applicable, jointly with other State services such as the Labour Inspectorate, the Inspectorate for Installations Classified for Protection of the Environment, the departments of the Ministry of Health and the French National Agency for Medicines and Health Products Safety (ANSM).

This action directly concerns either the users of ionising radiation sources, or organisations approved to carry out technical checks and inspections on these users.

The methods of regulating the radiation protection stakeholders 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 56 reactors in operation, the two Fessenheim reactors shutdown in 2020 (distributed among the 19 NPPs), the Flamanville EPR (Evolutionary Power Reactor) and the eight reactors being decommissioned. The regulation of safety, radiation protection and labour inspection very often covers common topics, such as worksite organisation or the conditions of use of outside contractors.

The ASN labour inspectors have four essential duties:
- checking application of all aspects of labour legislation (health, occupational safety and working conditions, occupational accident inquiries, quality of employment, collective labour relations);
- advising and informing the employers, employees and personnel representatives about their rights, duties and labour legislation;
- informing the administration of changes in the working environment and any shortcomings in the legislation;
- facilitating conciliation between the parties.

The ASN labour inspectors have the same powers and the same prerogatives as common law labour inspectors. They belong to the labour inspectorate system for which the central authority is the General Directorate for Labour.

The duties of the labour inspectors are based on international standards (International Labour Organisation – ILO, Convention No. 81) and national regulations. ASN carries them out in liaison with the other Government departments concerned, mainly the departments of the Ministry responsible for labour.

ASN has set up an organisation designed to deal with these issues. The action of the ASN labour inspectors (17 staff, representing 6.4 Full-Time Equivalent and 2 for the labour inspectorate mission) has been reinforced in the field 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 Committees on Safety and Working Conditions (CIESCT), as well as regular discussions with the social partners.

2.2 Internal checks performed by the licensees

2.2.1 Internal oversight of the licensees of Basic Nuclear Installations

In 2017, ASN issued a resolution (2017-DC-0616 of 30 November 2017) which specifies the criteria for distinguishing the noteworthy modifications requiring ASN authorisation from those simply requiring notification. It also defines the requirements applicable to the management of noteworthy modifications, more particularly the internal check procedures to be implemented by the licensees.

ASN checks correct application of the provisions stipulated by this resolution.

2.2.2 Internal monitoring of radiation protection by the users of ionising radiation sources

The provisions of Articles R. 4451-40 to R. 4451-51 of the Labour Code effect an in-depth reorganisation of the procedures for the performance of technical inspections, now referred to as "verifications". They harmonise the relevant requirements with those applicable to other risks, notably the electrical risk (Article R. 4226-14), or more generally for work equipment (Article R. 4323-22), making the measures to be taken proportionate to the nature and scale of the risk. During the lifetime of the work equipment or the facilities, these verifications take the form of initial verifications (by an accredited organisation), which may be repeated, and periodic verifications (by the Radiation Protection Advisor – RPA). The Order of 23 October 2020, set out in Article R. 4451-51, notably determines the work equipment or work equipment categories and the type of radioactive sources for which the employer is required to conduct an initial verification and, as applicable, to repeat it and the procedures and conditions for the performance of these verifications.

2.3 ASN approval of organisations and laboratories

ASN can draw on the results of inspections performed by the independent organisations and laboratories that it approves and whose actions it monitors.

Article L. 592-21 of the Environment Code states that ASN issues the required approvals to the organisations participating in the verifications and monitoring concerning nuclear safety or radiation protection.

TABLE 1

Methods of ASN regulation of the various radiation protection players

	EXAMINATION/AUTHORISATION	INSPECTION	OPENNESS AND COOPERATION
Users of ionising radiation sources	• Users of ionising radiation sources Examination of the dossiers 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
Organisations approved for radiation protection checks	• Examination of approval application files for performance of inspections required by Article R. 1333-172 of the Public Health Code • Organisation audit • Delivery of approval	• Second level inspection: – in-depth inspections at head office and in the branches of the organisations – unannounced field inspections	• Jointly with the professional organisations, drafting of rules of good practices for performance of radiation protection checks

TABLE 2

Radiation protection checks performed in 2019 by organisations approved for radiation protection checks

	MEDICAL	VETERINARY	RESEARCH/ TEACHING	INDUSTRY EXCLUDING BNIs	BNIs	TOTAL
Sealed sources	1,625	28	2,786	11,454	14,998	30,891
Unsealed sources	577	8	975	1,111	5,690	8,361
Mobile electrical generators of ionising radiation	2,648	277	173	838	56	3,992
Fixed electrical generators of ionising radiation	10,787	858	589	5,496	206	17,936
Particle accelerators	430	154	527	104	39	1,254
Dental	2,019					2,019
Total	18,086	1,325	5,050	19,003	20,989	64,453

The list of approved 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 2019, the Organisations Approved for Radiation Protection (OARP) verifications carried out 64,453 verifications, with the breakdown per type of source and per field being given in Table 2.

The reports of the verifications performed in each facility by the OARP are at the disposal of and examined by ASN personnel on the occasion of:
- licence renewals or modifications requiring ASN authorisation;
- inspections.

Examination of these reports on the one hand makes it possible to check that the mandatory verifications have actually been carried out and, on the other, enables the licensees to be questioned about the steps taken to remedy any nonconformities.

ASN also approves laboratories to conduct analyses requiring a high level of measurement quality if the results are to be usable. ASN thus approves laboratories to monitor radioactivity in the environment (see point 4.3).

The updated list of approvals issued by ASN is available on *asn.fr*.

On the advice of the standing sub-committee in charge of the Carriage of Dangerous Goods within the High Council for the Prevention of Technological Risks, ASN approved:
- the training organisations for drivers of vehicles carrying radioactive materials; two organisations have been approved;
- the organisations responsible for certifying the conformity of packaging designed to contain 0.1 kilogramme (kg) or more of uranium hexafluoride (UF_6);
- 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 UF_6 packaging.

As at 31 December 2020, the following are approved or accredited by ASN:
- 37 organisations tasked with radiation protection verifications; three approvals or approval renewals were delivered in 2020;
- 102 organisations tasked with measuring radon activity concentration in buildings. Fourteen of these organisations can also carry out measurements in cavities and underground structures, while twelve are approved to identify sources and means of radon ingress into buildings. In 2020, ASN issued 70 new approvals or approval renewals;
- 4 organisations qualified for NPE inspections;

Regulatory changes expected in 2021 regarding radiation protection checks

The Order of 23 October 2020 determined the working equipment and type of radioactive sources for which the employer has the initial check conducted, along with the procedures.

The current regulations defining the procedures for approval of organisations for radiation protection checks (ASN resolution 191) and the inspections that they perform (ASN resolution 175) will change in 2021:
- The rules that the nuclear activity managers will need to have checked by an Organisation Approved for Radiation Protection checks (OARP) will concern the management of effluent and waste, defined in ASN resolution 95, as well as the design, operation and maintenance of *in vivo* nuclear medicine facilities, defined in ASN resolution 463. The draft Order and draft ASN resolution, repealing resolution 175, were opened up to public participation in January 2021.
- Resolution 191 will be revised in 2021.

- 3 organisations qualified for NPE and Simple Pressure Vessels (RPS) within the perimeter of BNIs (in-service monitoring);
- 19 inspection departments qualified for in-service monitoring of NPE and RPS within the perimeter of NPPs;
- 67 laboratories for environmental radioactivity measurements covering 906 approvals, of which 259 are approvals or approval renewals delivered during 2020.

3. Efficient regulation and oversight

3.1 Inspection

3.1.1 Inspection objectives and principles

The inspection carried out by ASN is based on the following principles:
- The inspection aims to verify compliance with the provisions that are mandatory under the regulations. It also aims to assess the situation with regard to the nuclear safety and radiation protection implications; it seeks to identify best practices, practices that could be improved and assess possible developments of the situation.
- The scope and depth of the inspection is adjusted to the risks inherent in the activity and the way they are effectively taken into account by those responsible for the activity.
- The inspection is neither systematic nor exhaustive; it is based on sampling and focuses on the subjects with the highest potential consequences.

3.1.2 Inspection resources implemented

To ensure greater efficiency, ASN action is organised on the following basis:
- inspections, at a predetermined frequency, of the nuclear activities and topics of particular health and environmental significance;
- inspections on a representative sample of other nuclear activities;
- inspections of approved organisations.

The inspections may be unannounced or notified to the licensee a few weeks before the visit. They take place mainly on the site or during the course of the activities (work, transport operation, etc.). They may also concern the head office departments or design and engineering departments at the major nuclear 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:
- routine inspections;
- reinforced inspections, which consist in conducting an in-depth examination of a targeted topic by a larger team of inspectors than for a routine inspection;
- in-depth inspections, which take place over several days, concern a number of topics and involve about ten or so inspectors. Their purpose is to carry out detailed examinations and they are overseen by senior inspectors;
- inspections with sampling and measurements. With regard to both discharges and the environment of the facilities, these are designed to check samples that are independent of those taken by the licensee;
- event-based inspections carried out further to a particularly significant event;
- worksite inspections, ensuring a significant ASN presence on the sites on the occasion of reactor outages or particular work, especially in the construction or decommissioning phases;
- inspection campaigns, grouping inspections performed on a large number of similar installations, following a predetermined template.

Labour inspectorate work in the NPPs entails various types of interventions[1], which more particularly involve:
- checking application of the Labour Code by EDF and outside contractors in the NPPs (verification operations that include inspections);
- participation in meetings of the Health, Safety and Working Conditions Commissions, created as of 2020 for EDF, of Social and Economics Committees and the Inter-company Committees on safety and working conditions (EPR construction site);
- conducting inquiries on request, following complaints or based on information, following which the inspectors may take decisions as specified by the labour regulations, such as cessation of the works or the obligation to have the work equipment verified by an accredited organisation.

The implementation of remote-inspection methods during the health crisis led ASN to modify the inspection indicators. For this type of inspection, the critical examination of documents transmitted by a nuclear activity manager, performed during the on-site inspection preparation phases, becomes the primary method. It is then no longer possible to differentiate between the preparation of the inspection, involving this documentary examination, and the inspection itself.

The following paragraphs will therefore present the number of inspector-days corresponding to the on-site inspections and the number of remote inspections. The number of inspector-days in these paragraphs cannot therefore be directly compared with that of previous years, because it only reflects the time spent on the site and does not take account of the remote inspections.

In addition, Table 6 presents the total number of inspector-days devoted to inspections, whether performed on-site, remotely, or using a combination of the two methods.

ASN sends the licensee an inspection follow-up letter, published on *asn.fr*, which officially documents:
- 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 an inspection can lead to administrative or criminal penalties (see point 6.2).

Some inspections are carried out with the support of an IRSN representative specialised in the facility checked or the topic of the inspection.

1. *The intervention is the unit representative of activity traditionally used by the labour inspectorate.*

THE IMPACT OF COVID-19

ADAPTATION OF INSPECTION DURING THE HEALTH CRISIS

ASN carried out the scheduled inspections in its 2020 programme up until the first lockdown on 16 March 2020.

On that date, the inspectors, as well as the licensees and nuclear activity managers, were subject to working restrictions, designed to halt the spread of Covid-19. Unless absolutely necessary, for example if a significant event occurred, the on-site inspections were suspended. ASN immediately began to look at ways of continuing with its inspections.

ASN rapidly defined methods for remote-inspection by the inspectors. These notably involved examining documents relating to routine operations (periodic test records, operating documents, etc.) along with audio and video conferences with the activity manager. ASN used digital tools, hitherto little employed, such as real-time and off-line remote-examination of the physical operating parameters of the reactors.

In order to take account of the significant reduction in maintenance work on the facilities, this type of inspection first of all targeted operational activities (operation of reactors, periodic tests, etc.).

The follow-up letters for the inspections performed remotely are placed online on the *asn.fr* website, in the same way as the on-site inspections.

In the medical facilities, and as detailed in chapter 7, ASN first of all suspended its inspections during the first lockdown, to avoid creating an additional workload on hospital structures already under considerable pressure. The inspections were subsequently carried out after first of all checking that the facilities were in a position to make their teams available to answer the inspectors' questions.

At the beginning of April, ASN reassessed the inspections that it was essential to perform on-site, targeting field observations that could not be carried out remotely, as well as topics of particular importance during the crisis, such as waste management, or the organisation of the teams in a pandemic context. The on-site inspections thus resumed in early May, with strict rules in place to ensure the safety of the inspectors and those with whom they were in contact.

Therefore, between 15 March and 15 May 2020, 18 on-site inspections were carried out: 12 on safety and the possible consequences of the epidemic on the working of the facilities and 6 on labour inspectorate subjects. 26 inspections were conducted remotely during this period.

At the beginning of June, ASN decided to plan ahead, given the uncertainties surrounding the health situation and set priorities for its entire inspection programme for 2020, defining:

- those inspections to be performed in 2020;
- those which may be cancelled or postponed to 2021.

The objectives of the initial inspection programme were also revised: the prioritisation made it possible to estimate the volume of inspections that might not be maintained owing to lockdown, targeting those with lesser safety implications. Following this step, ASN planned to perform about 1,500 inspections in 2020.

The pace of inspections, both on-site and remotely, returned to normal as of mid-June, reaching the same level as in previous years up until the end of the year, despite the changing health situation. More particularly, during the second lockdown, on-site inspections were considered to be activities for which home-working was not applicable and the rate of inspection remained at a satisfactory level.

For 2020, a total of 1,573 inspections was carried out. Fewer than 400 inspections were cancelled for various reasons, as a result of prioritisation and constraints external to ASN, for example the workload on hospitals treating Covid-19 patients, or the postponement of reactor outages.

The true benefit of remote-inspections for suitable topics, combining them with a field part ("mixed" inspections) if necessary, and categorisation of the inspections according to the priorities established, giving greater flexibility to the inspection programme in the case of particular events, are the two main lessons learned and will be continue to be used by ASN.

ASN inspectors

ASN has inspectors designated and accredited by its Chairman, pursuant to 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 expertise 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 tools (inspection guides, decision aids) to assist them in their inspections.

As part of its continuous improvement policy, ASN encourages the exchange and integration of best practices used by other inspection organisations:

- by organising international exchanges of inspectors between Safety Authorities, either for the duration of one inspection or for longer periods that could extend to a secondment of up to several years. Thus, after having observed its advantages, ASN adopted the concept of in-depth inspections described earlier. However, ASN 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 inspections on different licensees and facilities in order to acquire a broader view of this field of activity. This choice also allows greater transparency in the exercise of the respective responsibilities of the licensee and the inspector;
- by welcoming 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), French National Agency for Drug and Health Product Safety (ANSM), Regional Health Agencies (ARS), etc. ASN also proposes organising joint inspections with these authorities on activities falling within their common areas of competence;

TABLE 3

Breakdown of inspectors per inspection field as at 31 December 2020

INSPECTOR CATEGORIES	DEPARTMENTS	DIVISIONS	TOTAL
Nuclear Safety Inspector	108	118	226
including nuclear safety inspectors for transport	*15*	*31*	*46*
Radiation protection inspector	37	102	139
Labour inspector	2	17	19
Number of inspectors all fields	145	175	320

TABLE 4

Number of inspections per field

BNIs (EXCLUDING PRESSURE EQUIPMENTS)	PRESSURE EQUIPMENTS	TRANSPORT OF RADIOACTIVE SUBSTANCES	SMALL-SCALE NUCLEAR ACTIVITIES	APPROVED ORGANISATIONS AND LABORATORIES	TOTAL
669	82	62	668	92	1,573

- by encouraging its staff to take part in inspections on subjects in different regions and fields, notably to ensure the uniformity of its practices. Each ASN inspector in a particular region takes part in at least one inspection performed in a different region. This rule was considerably relaxed in 2020 owing to the Covid-19 context and the need, at certain times, to avoid the spread of the virus between regions.

Table 3 presents the headcount of inspectors, which stood at 320 on 31 December 2020. Some inspectors operate in several inspection areas, and all the operational entity heads and their deputies fulfil both managerial and inspection functions.

Most of the inspections are carried out by inspectors assigned to the regional divisions, who represent 55% of the ASN inspectors. The 145 inspectors assigned to the departments take part in ASN inspections within their field of competence; they represent 45% of the inspector headcount and carried out 13% of inspections in 2020, with most of their work being the examination of files.

As previously mentioned, ASN continuously improves the efficiency of its oversight by targeting and modulating its inspections (graded approach) according to the scale of the implications for the protection of persons and the environment.

In 2020, the ASN inspectors carried out a total of 1,573 inspections, representing 2,607 inspection man-days in the field and including 320 remote inspections, broken down into areas as shown in Table 4.

ASN inspections programme

To guarantee a distribution of the inspection resources that is proportionate to the safety and radiation protection implications of the various facilities and activities, ASN drafts a planned inspections schedule every year, taking account of the inspection implications in terms of risk (see point 3.1). This programme is not communicated to either the licensees or to those responsible for nuclear activities.

ASN monitors the performance of the programme and the follow-up given to the inspections, through periodic reviews. This follow-up enables the inspected activities to be assessed and contributes to the continuous improvement of the inspection process.

Information relative to the inspections

ASN informs the public of the steps taken following the inspections by posting the inspection follow-up letters online, on *asn.fr*.

Moreover, for each in-depth inspection, ASN published an information notice on *asn.fr*.

3.1.3 Inspection of Basic Nuclear Installations and Pressure Equipment

In 2020, 1,579 inspector-days were devoted to the on-site field inspection of BNIs and NPE, corresponding to 632 inspections. 17% of the inspections were unannounced. 119 remote inspections were also carried out.

In the NPPs, inspection work in the field can be broken down into 850 inspector-days (343 on-site inspections), 565 inspector-days in the other BNIs (226 on-site inspections), that is mainly the "fuel cycle" facilities, research facilities and installations undergoing decommissioning, and 165 for NPE (63 on-site inspections).

The remote inspection work entailed 59 inspections for the NPPs, 41 inspections for the other BNIs and 19 inspections for NPE.

In the light of the increased risk of spreading the virus as a result of in-depth inspections, none were performed in 2020.

The ASN labour inspectors also carried out 1,045 interventions during the 187 inspection-days in the NPPs.

3.1.4 Inspection of radioactive substances transport

89 inspector-days were devoted by ASN to on-site inspection of transport activities, corresponding to 48 on-site inspections. 18% of these inspections were unannounced. In addition, 14 remote inspections were carried out.

3.1.5 Inspection of small-scale nuclear activities

ASN organises its inspection activity so that it is proportionate to the radiological issues involved in the use of ionising radiation and consistent with the actions of the other inspection services.

In 2020, 824 inspector-days were devoted to on-site inspections of small-scale nuclear activities, corresponding to 500 on-site inspections, 11% of which were unannounced, plus 168 remote inspections. This inspection work was more particularly divided among the medical, industrial and research and veterinary sectors.

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 2020, 115 inspector-days were devoted to checking approved organisations and laboratories, corresponding to 73 inspections, 34% of which were unannounced, plus 19 remote inspections.

3.1.7 Checks on exposure to Radon and Naturally Occurring Radioactive Materials

ASN also checks radiation protection in premises where the exposure of persons to naturally occurring radiation may be reinforced owing to the underlying geological context (radon in buildings open to the public and in the workplace).

Monitoring exposure to radon

Article R. 1333-33 of the Public Health Code states that the activity concentration of radon in buildings open to the public is measured either by the IRSN, or by organisations approved by ASN. These measurements are to be taken between 15 September of a given year and 30 April of the following year.

Article R. 4451-44 of the Labour Code stipulates that, whenever required, the initial checks on the radon activity concentration in areas identified owing to the radon risk must be carried out by accredited organisations or by organisations approved by ASN.

The number of approved organisations, depending on the type of measurement, is given in Table 5.

Monitoring natural radioactivity in water intended for human consumption

Natural radioactivity in water intended for human consumption is monitored by the Regional Health Agencies (ARS). The procedures used for these checks take account of the recommendations issued by ASN and taken up in the 13 June 2007 Circular from the General Directorate for Health.

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.

TABLE 5

Number of organisations approved for measuring radon levels(*)

	NUMBER OF APPROVED ORGANISATIONS (AS AT 12/31/2020)
Level 1 option A(**)	102
Level 1 option B(***)	14
Level 2(****)	12

* The IRSN is also competent for the measurement of radon (R. 1333-36 of the Public Health Code).
** Workplaces and premises open to the public for all building types.
*** Workplaces, cavities and underground structures (except buildings).
**** Represents complementary investigations.

TABLE 6

Breakdown of inspection days by topic in 2020 (including remote inspection days)

PER FIELD	NUMBER OF DAYS (COORDINATION + CO-COORDINATION)	INSPECTIONS PERFORMED	% ON SITE	% ON DOCUMENT	% MIXED
Basic Nuclear Installation/Pressurised Water Reactor	2,097	402	8%	15%	77%
Basic Nuclear Installation/Laboratories Plants Waste and Decommissioning	1,359	267	16%	15%	69%
Basic Nuclear Installation/Pressure Equipment	435	82	16%	23%	61%
Small-scale nuclear activities/Industry	807	248	7%	20%	73%
Small-scale nuclear activities/Medical	1,509	328	1%	30%	70%
Small-scale nuclear activities/Natural radioactivity	35	9	0%	67%	33%
Small-scale nuclear activities/Polluted sites and ground	3	2	0%	0%	100%
Small-scale nuclear activities/Research	190	50	0%	18%	82%
Small-scale nuclear activities/Veterinary	96	31	0%	16%	84%
Transport of radioactive substances	235	62	15%	23%	63%
Approved Organisations/Approved laboratories	374	92	4%	21%	75%
Total	7,137	1,573	8%	20%	72%

3.2.1 Analysing the files transmitted by Basic Nuclear Installation 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 considers it necessary, ASN requests an opinion from its technical support organisations, the most important of which is the 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.

The 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 installations. For certain dossiers, ASN asks the competent Advisory Committee of Experts (GPE) for its opinion. For other matters, the 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 (PWRs). 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 reported to ASN or submitted to it for authorisation. Moreover, the licensee must perform periodic safety reviews to update the assessment of the facility, taking into account any changes in techniques and regulations, and experience feedback. The conclusions of these reviews are submitted by the licensee to ASN, which can issue new binding requirements for continued operation.

The other files submitted by BNI licensees

A large number of dossiers concern specific topics such as fire protection, fuel management in PWRs, relations with the outside contractors, etc.

The licensee therefore also periodically provides activity reports as well as summaries of water intake, liquid and gaseous discharges and 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

Background

The international Conventions ratified by France (Article 19vi of the Convention on Nuclear Safety of 20 September 1994; Article 9v of the Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management of 5 September 1997) require that BNI licensees, on account of the defence in depth principle, implement a reliable system for early detection of any anomalies that may occur, such as equipment failures or errors in the application of operating rules. Ten years previously, the "Quality Order" of 10 August 1984 already required the adoption of such a system.

Based on 30 years of experience, ASN felt that it would be useful to transpose this approach, initially limited to nuclear safety, to radiation protection and protection of the environment. ASN thus drafted three guides defining the principles and reiterating the obligations binding on the licensees with regard to notification of incidents and accidents:

- Guide of 21 October 2005 contains the provisions 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 the procedures for notification of radioactive substances transport events (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 on 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 are events which are sufficiently important in terms of safety, the environment or radiation protection to justify that ASN be rapidly informed of their occurrence and subsequently receive a fuller analysis. Significant events must be reported to it, as specified in the Order of 7 February 2012 (Article 2.6.4), the Public Health Code (Articles L. 1333-13, R. 1333-21 and R. 1333-22), the Labour Code (Article R. 4451-74) and the regulatory texts applicable to the transport of radioactive substances (for instance, the European Agreement concerning the International 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 and radiation protection improvement approach. It requires the active participation of all players (users of ionising radiation, carriers, etc.) in the detection and analysis of deviations.

It enables the authorities:
- to ensure that the licensee has suitably analysed the event and taken appropriate measures to remedy the situation and prevent it from happening again;
- to ensure that other parties responsible for similar activities benefit from experience feedback about the event.

The purpose of this system is not to identify or penalise any individual person or party.

Moreover, the number and rating on the International Nuclear and Radiological Event Scale (INES scale) of the significant events which have occurred in a nuclear facility are not on their own indicators of the facility's level of safety. On the one hand, a given rating level is an over-simplification and is unable to reflect the complexity of an event and, on the other, the number of events listed depends on the level of notification compliance. The trend in the number of events does not therefore reflect any real trend in safety levels.

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 company 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 the provisions of 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 needed to avoid an aggravation of the situation or to mitigate the consequences of the event. The notification time of two working days, mentioned in the ASN notification guides, does not apply when the consequences of the event require intervention by the public authorities.

When a given event potentially concerns several facilities, it is referred to as a "generic" event. The most common example is a fault in an equipment item installed on several nuclear reactors (see chapter 10). In this case, ASN analyses the event as a single event, with the response being essentially common to all the facilities affected. This process follows the IAEA recommendations, which specify that a single notification may be appropriate in the case of an event affecting defence in depth and concerning several similar facilities.

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 event 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, the 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 the 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 the IRSN, constitute the basis of operating experience feedback. The examination of operating experience feedback may lead to ASN requests for improvements to the condition of the facilities and the organisation adopted by the licensee, but also to changes to the regulations.

OEF comprises the events which occur in France and abroad in nuclear facilities or in those presenting non-radiological hazards, if it is pertinent to take them into account in order to reinforce nuclear safety or radiation protection.

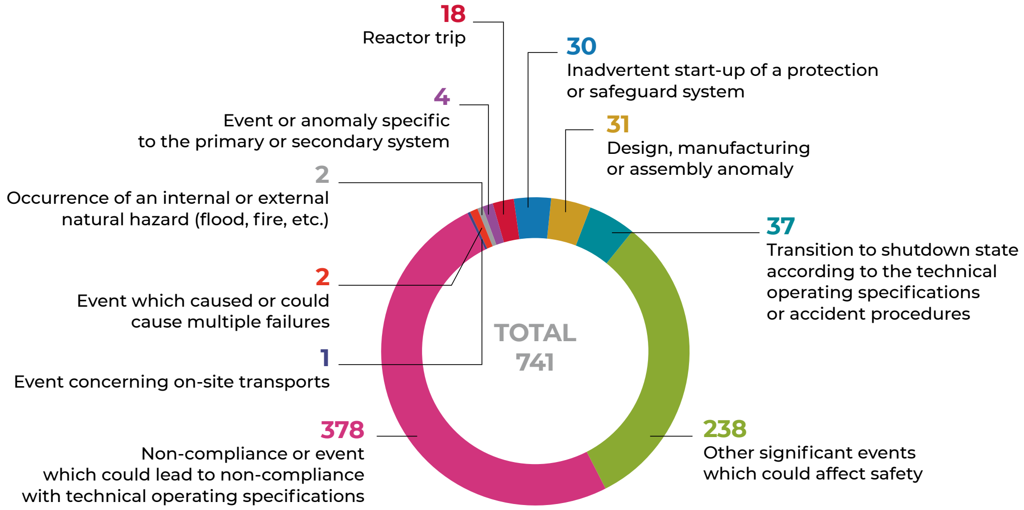
3.3.3 Technical inquiries held in the event of an incident or accident concerning a nuclear activity

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 board of inquiry, determine its composition (ASN staff and people from outside ASN), define the subject and scope of the investigations and gain access to all necessary elements in the event of a judicial inquiry.

Decree 2007-1572 of 6 November 2007 on technical inquiries into accidents or incidents concerning a nuclear activity specifies the procedure to be followed. It is based on practices defined for the other boards of inquiry and takes account of aspects specific to ASN, notably its independence, its own roles, its ability to impose binding requirements or sanctions.

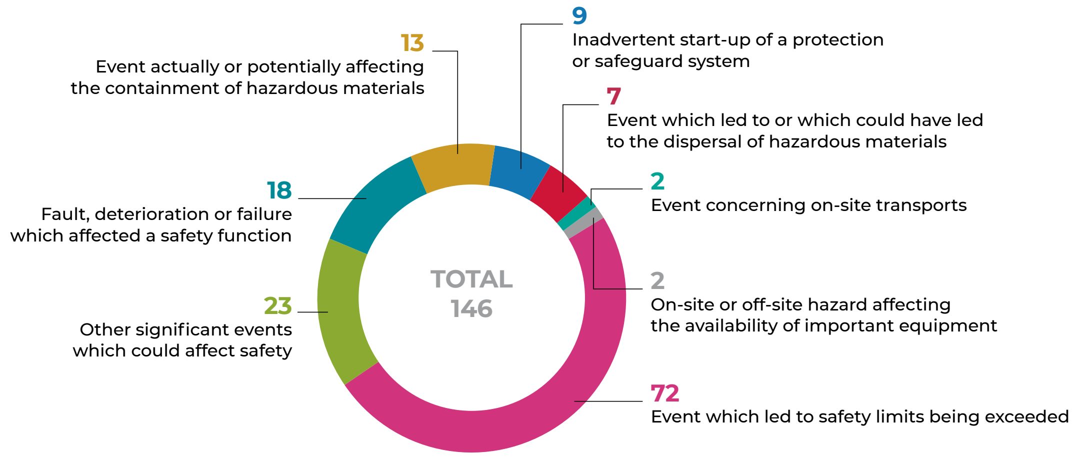
GRAPH 1

Events involving safety in NPPs notified in 2020



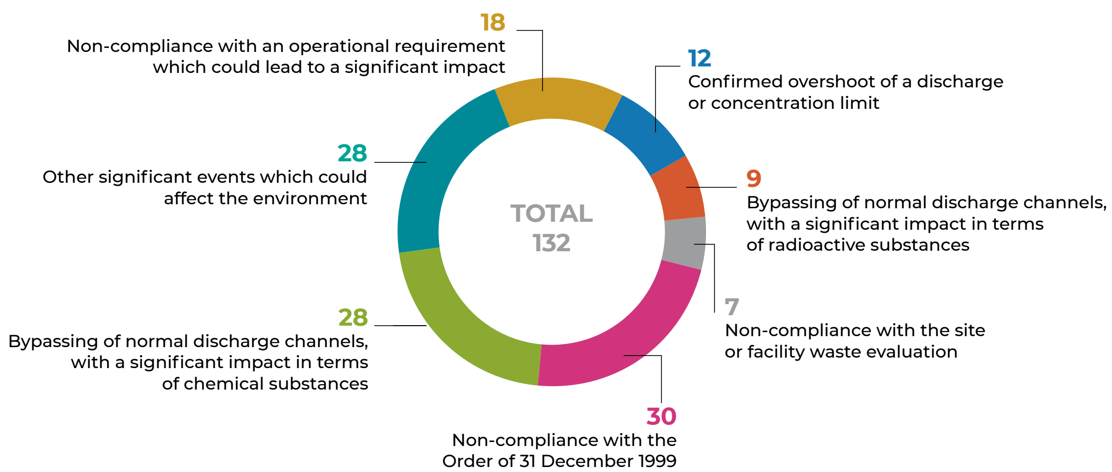
GRAPH 2

Events involving safety in BNIs other than NPPs notified in 2020



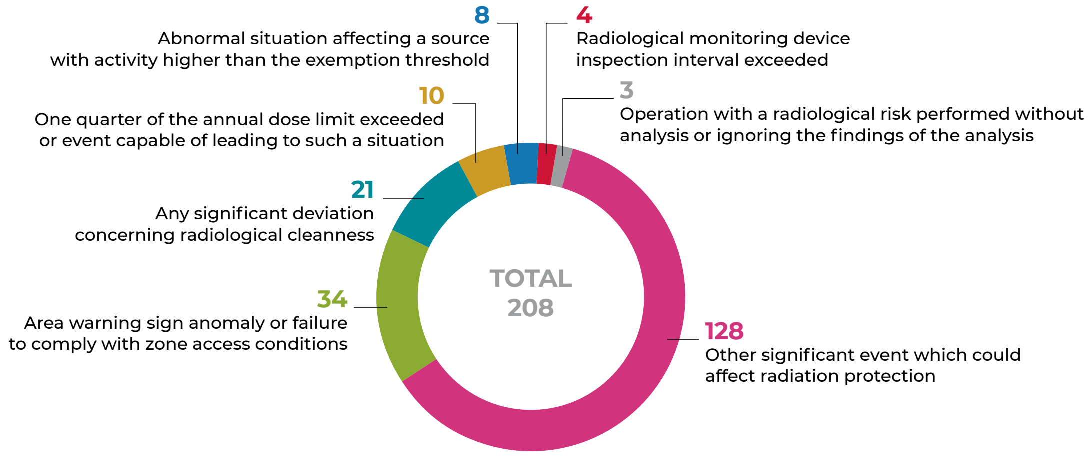
GRAPH 3

Significant environment-related events in BNIs notified in 2020



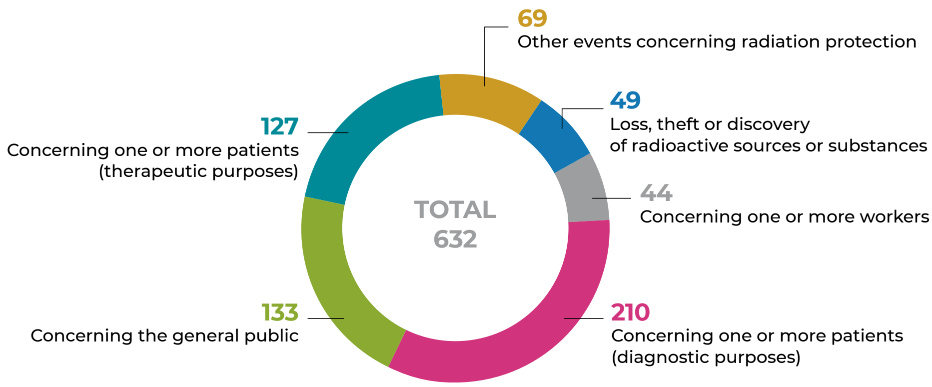
GRAPH 4

Events involving radiation protection in BNIs notified 2020



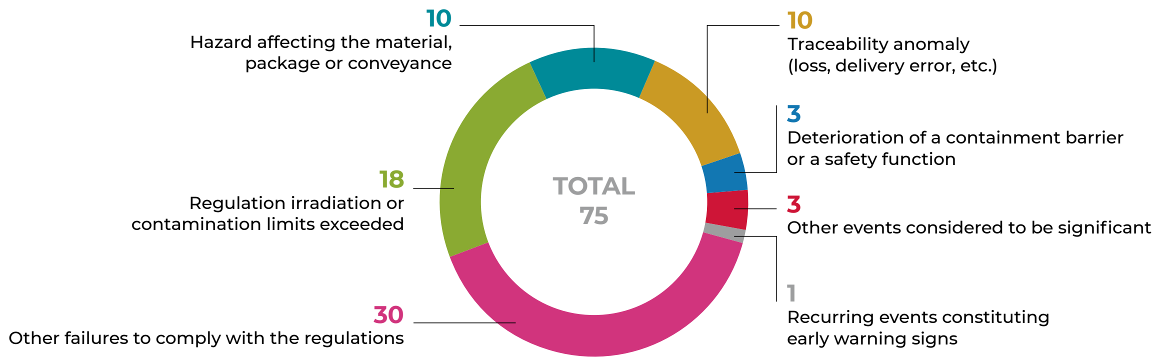
GRAPH 5

Events involving radiation protection (other than BNIs and transport of radioactive substances) notified in 2020



GRAPH 6

Events involving the transport of radioactive substances notified in 2020



3.3.4 Statistical summary of events

In 2020, 1,933 significant events were reported to ASN:
- 1,227 significant events concerning nuclear safety, radiation protection, the environment and the on-site transport of hazardous materials in the BNIs, of which 1,142 were rated on the INES scale (1,035 "level 0" events, 105 "level 1" events and 2 "level 2" events). Of these events, 26 significant events were classified as "generic events" – they concern several reactors, 6 of which were rated "level 1" on the INES scale and 1 "level 2" on the INES scale;
- 75 significant events concerning the transport of radioactive substances on the public highway, including 4 "level 1" events on the INES scale;
- 631 significant events concerning radiation protection in small-scale nuclear activities, including 160 rated on the INES scale (25 "level 1" events).

In 2020, two events were rated "level 2" on the INES scale, both in the field of BNIs:
- the first concerns the internal contamination of a worker in a fuel pellets fabrication workshop in the Melox plant operated by Orano Cycle on the Marcoule site;
- the second concerns seismic resistance faults on the diesel emergency generator sets of 10 of EDF's nuclear reactors.

As indicated earlier, these data must be used with caution: they do not in themselves constitute a safety indicator. ASN encourages the licensees to report incidents, which contributes to transparency and the sharing of experience.

The breakdown of significant events rated on the INES scale is given in Table 7. As the INES scale does not apply to significant events concerning patients, the rating of significant events affecting one or more patients in radiotherapy on the ASN-SFRO scale[2] is specified 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 reported to ASN in 2020, differentiating between them according to the various notification criteria for each field of activity.

3.4 Raising the awareness of professionnals and cooperating with the other administrations

Regulation is supplemented by awareness-raising programmes designed to ensure familiarity with the regulations and their application in practical terms appropriate to the various professions. ASN aims to encourage and support initiatives by the professional organisations that implement this approach by issuing best practices and professional information guides.

ASN publishes "avoiding accidents" sheets with the aim of sharing its OEF analyses.

Awareness-raising also involves joint actions with other administrations and organisations which oversee the same facilities, but with different prerogatives. One could here mention the labour inspectorate, the medical devices inspectorate work by the ANSM, the medical activities inspectorate work entrusted to the technical services of the Ministry of Health, or the oversight of small-scale nuclear activities at the Ministry of Defence entrusted to the Armed Forces General Inspectorate.

TABLE 7

Number of significant events rated on the INES scale between 2015 and 2020

		2015	2016	2017	2018	2019	2020
Basic Nuclear Installations	Level 0	848	847	949	989	1,057	1,035
	Level 1	89	101	87	103	112	105
	Level 2	1	0	4	0	3	2
	Level 3 and +	0	0	0	0	0	0
	Total	**938**	**948**	**1,040**	**1,092**	**1,172**	**1,142**
Small-scale nuclear activities (medical and industry)	Level 0	126	111	144	143	142	135
	Level 1	25	30	36	22	35	25
	Level 2	2	0	3	0	2	0
	Level 3 and +	0	0	0	0	0	0
	Total	**153**	**141**	**183**	**165**	**179**	**160**
Transport of radioactive substances	Level 0	56	59	64	88	85	71
	Level 1	9	5	2	3	4	4
	Level 2	1	0	0	0	0	0
	Level 3 and +	0	0	0	0	0	0
	Total	**66**	**64**	**66**	**91**	**89**	**75**
	Grand Total	**1,157**	**1,153**	**1,289**	**1,348**	**1,439**	**1,377**

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 a radiotherapy medical procedure.

Operating Experience Feedback

Following the fire that occurred on 26 September 2019 in the Lubrizol facility in Rouen, ASN initiated a number of actions with the Basic Nuclear Installations (BNIs) in order to learn lessons from this accident and, if necessary, initiate reinforcement of the measures to prevent and control non-radiological risks in BNIs.

More specifically, ASN sent a letter to all licensees on 28 October 2019, asking them to make a review of the adequacy and effectiveness of the various barriers in place inside their facilities to control risks related to the storage of hazardous substances, as well as their good knowledge of the nature and quantities of the hazardous substances present.

In addition to examining the answers submitted by the licensees, ASN carried out inspections on this topic, notably involving simulation exercises for the intervention teams. All the inspections scheduled on this topic could not be performed in 2020 owing to the health crisis and this inspection campaign will continue in 2021.

At the same time, ASN is examining the need to reinforce the regulatory requirements during the work to revise the BNI Order of 7 February 2012 and the transposition to BNIs of the European Parliament and Council Directive 2012/18/EU of 4 July 2012 on the control of major-accident hazards involving dangerous substances, known as the "Seveso 3" Directive. The reinforced provisions will notably concern the implementation of risk control measures and the data to be provided by the licensees in the safety case with regard to the control of non-radiological hazards.

Finally, together with the Ministries that were involved in managing the fire at the Lubrizol facility, the Steering Committee for management of the post-accident phase (Codirpa) is examining what lessons can be learned.

3.5 Information about ASN's regulatory activity

ASN attaches importance to coordinating Government departments and informs the other administration 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;
- reactor outage summaries;
- thematic publications.

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 amended ASN resolution 2013-DC-0360 of 16 July 2013, 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 specifically to PWRs. This resolution was approved by the Minister for Ecological and Solidarity-based Transition in an Order of 14 June 2017.

Apart from the above-mentioned general provisions, ASN resolutions set specific requirements for each facility, more particularly the water intake and discharge limits.

Monitoring discharges from BNIs

The monitoring of discharges from an installation is essentially the responsibility of the licensee. The ASN requirements regulating discharges stipulate the minimum checks that the licensee is required to carry out. This 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 cross-analysis. The results of these "cross-checks" are sent to ASN. This programme of cross-checks defined by ASN is a way of ensuring that the accuracy of the measurements taken by the licensee laboratories is maintained over time.

The inspections carried out by ASN

Through dedicated inspections, ASN ensures that the licensees actually comply with the regulations binding on them with regard to the management of discharges and the environmental and health impact of their facilities. Every year, it carries out about 90 inspections of this type, split into three topics:
- prevention of pollution and management of detrimental effects;
- water intake and effluent discharge, monitoring of discharges and the environment;
- waste management.

Each of these topics covers both radiological and non-radiological aspects.

Every year, ASN carries out 10 to 20 inspections with sampling and measurement. They are generally unannounced and are run with the support of specialist, independent laboratories appointed by ASN. Effluent and environmental samples are taken for radiological and chemical analyses. Finally, every year, ASN carries out several reinforced inspections which aim to check the organisation put into place by the licensee to protect the environment; the scope of the inspection is then broadened to cover all of the above-mentioned topics. Within this context,

Sealing of the samples taken during an unannounced ASN inspection – January 2021

simulations such as exercises to test the organisation implemented for pollution management can be carried out.

2016-2021 Micro-pollutants Plan

The 2016-2021 Micro-pollutants Plan[(3)] to preserve the quality of water and biodiversity, presented by the Minister for Ecology in September 2016, aims to protect surface waters, groundwater, 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. This plan meets the good water quality objectives set by the framework directive on water and contributes to those of the framework strategy directive for the marine environment, by limiting the input of pollutants into the marine environment from water courses.

For the NPPs, the campaigns to search for hazardous substances in water concluded that close monitoring of copper and zinc discharges was required. Under the Micro-pollutants Plan, the ASN action initiated in 2017 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 substances.

To allow a revision of the emission limits for copper and zinc, among other things, ASN is examining EDF's requests for modification of the requirements concerning water discharge and intake for the NPPs of Dampierre-en-Burly and Belleville-sur-Loire. The modification application file submitted by the licensee of the Dampierre-en-Burly NPP was the subject of an online public consultation from 15 December 2020 to 15 January 2021.

Accounting of BNI discharges

The rules for accounting of discharges, both radioactive and chemical, are set in the general regulations by amended ASN resolution 2013-DC-0360 of 16 July 2013 relative to control of the detrimental effects and the impact of BNIs on health and the environment. These rules were set so as to guarantee that the discharge values accounted by the licensees, notably those taken considered in the impact calculations, will in no case be underestimated.

For discharges of radioactive substances, accounting is not based on overall measurements, but on an analysis per radionuclide, introducing the notion of a "reference spectrum", listing the radionuclides specific to the type of discharge in question.

The principles underlying the accounting rules are as follows:
- radionuclides for which the measured activity exceeds the decision threshold for the measurement technique are all counted;
- the radionuclides of the "reference spectrum" for which the measured activity is below the decision threshold (see box page 164) are considered to be at the decision threshold level.

For discharges of chemical substances with an emission limit value set by an ASN binding requirement, when the concentration values measured are below the quantification limit, the licensee is required by convention to declare a value equal to half the quantification limit concerned.

Monitoring discharges in the medical sector

Pursuant to ASN resolution 2008-DC-0095 of 29 January 2008, radioactivity measurements are taken on the effluents coming from the places that produce them. In hospitals that have a nuclear medicine department, these measurements chiefly concern iodine-131 and technetium-99m. In view of the difficulties encountered in putting in place the permits to discharge radionuclides into the public sewage networks, as provided for by the Public Health Code, ASN has created a working group involving administrations, "producers" (nuclear physicians, researchers) and sanitation professionals. The report from this working group formulating recommendations to improve the efficiency of the regulations was presented in October 2016 to the Advisory Committee for Radiation Protection (GPRADE), for industrial and research applications of ionising radiation and the environment. ASN consulted the stakeholders in 2017 on this subject. The report from the working group and a circular letter intended for the professionals concerned were published in the ASN website on 14 June 2019.

In the small-scale industrial nuclear sector, few plants discharge effluents apart from the cyclotrons (see chapter 8). The discharge permits stipulate requirements for the discharges and their monitoring, which are subject to particular scrutiny during inspections.

3. A micro-pollutant can be defined as an undesirable substance detectable in the environment at very low concentrations. Its presence is due, at least in part, to human activity (industrial processes, agricultural practices or day to day activities) and it may, at these very small concentrations, create negative effects on living organisms owing to its toxicity, its persistence and its bioaccumulation.

4.1.2 Evaluating the radiological impact of nuclear activities

The radiological impact of effluents produced by medical activities

The radiological impact of the effluents or waste produced by the nuclear medicine departments underwent a recent assessment, which concluded that these discharges represent a low dose impact for persons outside the health facility (see point 1.2.3).

The radiological impact of BNIs

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, amended, concerning control of detrimental effects and the impact of BNIs on health and the environment). The result is to be assessed considering the allowable annual dose limit for the public (1 millisievert per year – mSv/year) defined in article R. 1333-11 of the Public Health Code, which corresponds to the sum of 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 and are detailed in the facility's impact assessment. During its assessment, ASN devotes efforts to verifying that these models are conservative, in order to ensure that the impact assessments are not underestimated.

In addition to the impact assessments produced on the basis of discharges from the facilities, the licensees are required to carry out environmental radioactivity monitoring programmes (aquatic environments, air, earth, milk, grass, agricultural produce, etc.), more specifically to verify compliance with the hypotheses used in the impact assessment and to monitor changes in the radioactivity level in the various compartments of the environment around the facilities (see point 4.1.1).

The doses from BNIs for a given year are estimated on the basis of the actual discharges from each installation accounted for the year in question. This assessment takes account of discharges from the identified outlets (stack, river or sea discharge pipe), the diffuse emissions not channelled to the outlets (for example tank vent) and the sources of radiological exposure to ionising radiation present in the installation.

The estimate is made in relation to one or more identified reference groups. These are uniform groups of people (adults, children, infants) receiving the highest average dose out of the entire population exposed to a given installation, following realistic scenarios (taking into account the distance to the site, meteorological data, etc.). All of these parameters, specific to each site, explain most of the differences observed between sites and from one year to another.

The Table entitled "Radiological impact of BNIs since 2014" in chapter 1 presents an assessment of the doses due to BNIs calculated by the licensees for the most exposed reference groups.

For each of the nuclear sites presented, the radiological impact remains far below, or at most represents about 1% of the limit for the public, this limit being 1 mSv/year. Therefore in France, the discharges produced by the nuclear industry have an extremely small radiological impact.

4.1.3 Monitoring within the European framework

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, it 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 notably gives its assessment of the monitoring equipment and methodologies used and of the organisational setup.

Since 1994, the European Commission has carried out the following verification inspections:
- the La Hague reprocessing plant and the Manche disposal facility of the French National Radioactive Waste Management Agency (Andra), in 1996;
- the Chooz NPP in 1999;
- the 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 Cadarache site in 2011;
- the environmental radioactivity monitoring facilities in the Paris area in 2016;
- the La Hague reprocessing plant in 2018.

4.2 Environmental monitoring

4.2.1 The French National Network for Environmental Radioactivity Monitoring

In France, many parties are involved in environmental radioactivity monitoring:
- the nuclear facility licensees, who perform monitoring around their sites;
- ASN, the IRSN (whose duties as defined by Decree 2016-283 of 10 March 2016 include participation in radiological monitoring of the environment), the Ministries (General Directorate for Health, General Directorate for Food, General Directorate for Competition Policy, Consumer Affairs and Fraud Control, etc.), the services of the State and other public players carrying out monitoring duties across the national territory or in particular sectors (for example, foodstuffs controlled by the Ministry for Agriculture);
- the approved air quality monitoring associations (local authorities), environmental protection associations and Local Information Committees (CLIs).

With regard to 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).

The French National Network of Environmental Radioactivity Measurements (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 a laboratories approval procedure (see point 4.3).

The guidelines of the RNM are decided by a network steering committee made up of representatives from all the stakeholders in the network: ministerial departments, regional health agencies, representatives of nuclear licensee or association laboratories, members of the CLIs, the IRSN, ASN, etc.

4.2.2 The purpose of environmental monitoring

The licensees are responsible for monitoring the environment around their facilities. The content of the monitoring programmes to be implemented in this respect (measurements to be taken and frequency) is defined in amended ASN resolution 2013-DC-0360 of 16 July 2013, and in the individual requirements applicable to each installation (Creation Authorisation Decree, discharge licensing orders or ASN resolutions), independently of the additional measures that can be taken by the licensees for the purposes of their own monitoring.

This environmental monitoring:
- contributes to understanding the radiological and radio-ecological state of the facility's environment through measurements of parameters and substances regulated in the requirements, in the various environmental compartments (air, water, soil) as well as in the biotopes and food-chain (milk, plants, etc.): a datum is determined before the facility is created and monitoring the environment throughout the lifetime of the facility enables any changes in this datum to be followed;
- helps verify that the impact of the facility on health and the environment is in conformity with the impact assessment;
- detects any abnormal increase in radioactivity as early as possible;
- ensures there are no facility malfunctions, notably by analysing the groundwater and checking licensees' compliance with the regulations;
- contributes to transparency and information of the public through the transmission of 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 detrimental effects 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 centre, and so on. The minimum contents 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 RNM.

4.2.4 Environmental monitoring nationwide by the IRSN

The IRSN's nationwide environmental monitoring is carried out by means of measurement and sampling networks dedicated to:
- air monitoring (aerosols, rainwater, ambient gamma activity);
- monitoring of surface water (watercourses) and groundwater (aquifers);
- monitoring of the human food chain (milk, cereals, fish, etc.);
- terrestrial continental monitoring (reference stations located far from all industrial facilities).

This monitoring is based on:

- continuous on-site monitoring using independent systems (remote-monitoring networks) providing real-time transmission of results. This includes:
  - the *Téléray* network (ambient gamma radioactivity in the air) which uses a system of continuous measurement monitors around the whole country. The density of this network is being increased around nuclear sites within a radius of 10 to 30 kilometres around BNIs;
  - the *Hydrotéléray* network (monitoring of the main water-courses 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.

THE IMPACT OF COVID-19

ENVIRONMENTAL MONITORING DURING THE LOCKDOWN

The Basic Nuclear Installation (BNI) licensees perform the regulation monitoring of the environment around their sites, in accordance with the requirements of the ASN resolutions governing water intake and consumption, the discharge of gaseous and/or liquid effluents and environmental monitoring around the facilities.

As a result of the Covid-19 health crisis, during the lockdown in Spring 2020, some licensees had to temporarily adapt their regulation environmental monitoring programme to the activity continuity plans implemented. These modifications or compensatory measures were monitored by ASN throughout the lockdown period by means of regular meetings with the various licensees. They for example concerned bringing back in-house certain tasks that were usually subcontracted, relaxing the frequency or prioritisation of certain samples and/or analyses. Similarly, ASN granted a few days grace for the transmission of regulation documents, such as the monthly registers, to ensure that the information they contained was exhaustive.

This lockdown period also accelerated the process to implement the dematerialisation of certain procedures, such as approval prior to certain effluent management operations provided for in the resolutions issued by ASN.

During the second lockdown in the Autumn of 2020, the licensees mentioned no particular difficulties and maintained their environmental monitoring programme in accordance with the above-mentioned resolutions.

Summary of knowledge acquired 10 years after the publication of the *Tritium White Paper*

In 2020, ASN published the *Tritium White Paper*, presenting the state of scientific knowledge on the presence and sources of tritium in the environment, as well as the environmental and health impact of this radionuclide. It also included recommendations from two pluralistic think tanks, along with the resulting action plan.

Ten years after this *White Paper* was published, in 2020, ASN published the summary of the knowledge acquired in the fields studied.

Knowledge concerning metrology, control of discharges, environmental monitoring and assessment of the impact of tritium on human health has progressed, providing answers to the questions raised by ASN, even if some actions still have to be finalised. The metrological advances include the drafting of several standards for measuring tritium in the matrices of the environment and effluent discharges, as well as the adoption of inter-laboratory comparison tests. Research into tritium transfer and its activity level in the environment has been carried out. Understanding of the toxicity of tritium has also progressed, notably by showing that the effects of tritium at concentration levels close to those found in the environment remain extremely limited. At higher concentration levels that can be encountered in the effluents produced by the facilities, biological effects that differ according to the physical-chemical forms of tritium are observed, which underlines the importance of differentiating between them in the discharges from facilities so that the corresponding risks can be characterised. The studies performed revealed the prevalence of the “free” form of tritium in discharges from the facilities, confirming the low corresponding impact. The inventory of tritium discharges from the Basic Nuclear Installations (BNIs) and Defence Basic Nuclear Installations (DBNI) as well as the balance of the corresponding dosimetric impacts are published yearly by ASN on the *Tritium White Paper* website.

Given the tangible improvements in knowledge, in particular concerning metrology and characterisation of the physical-chemical forms of tritium in discharges, ASN closed the work of the tritium action plan oversight committee in 2020. Oversight of the research work still in progress, notably on the subject of the biological effects of tritium and the corresponding health hazards, will now take place in a different format, for example during special research seminars or days. ASN thus asked the French Institute for Radiation Protection and Nuclear Safety (IRSN) to organise a “research” day in the first half of 2021 devoted to this subject and to invite the parties concerned, notably the members of the tritium action plan oversight committee.

At the same time, in conjunction with the IRSN, ASN is closely monitoring a tritium measurement campaign in the Loire which was started in November 2020, with the aim of improving knowledge of the dispersal conditions for the tritium discharged into the environment by the Nuclear Power Plants (NPPs) on the Loire and Vienne rivers. The results of this study will be published during the course of 2021.

Every year, the 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 (Ukraine) accident. Traces of artificial radioactivity associated with discharges can sometimes be detected near installations. To this can be added very local contaminations resulting from incidents or past industrial activities, and which do not represent a health risk.

Based on the results of nationwide radioactivity monitoring published in the RNM and in accordance with the provisions of amended ASN resolution 2008-DC-0099 of 29 April 2008, the IRSN regularly publishes a *Detailed summary of the radiological state of the French environment*. The third edition of these results was published at the end of 2018 and corresponds to the period 2015-2017. The IRSN also produces regional radiological reports providing more precise information about a given region.

4.3 Laboratories approved by ASN to guarantee measurement quality

Articles R.1333-25 and R.1333-26 of the Public Health Code require the creation of a RNM and a procedure to have the radioactivity measurement laboratories approved by ASN. The RNM working methods are defined by the above-mentioned amended ASN resolution of 29 April 2008.

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 the 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. The list of the types of measurements covered by an approval is set by the above-mentioned amended ASN resolution of 29 April 2008.

In total, an approval covers about 50 measurements, for which there are as many Inter-laboratory Comparison Tests (ILT). These tests are organised by the IRSN in a five-year cycle, which corresponds to the maximum approval validity period.

In order to produce operating experience feedback from the inter-laboratory comparison tests organised by the IRSN, since they were set up in 2003, ASN and the IRSN decided to organise a joint seminar in 2021 bringing together all the environmental monitoring stakeholders (laboratories of nuclear facility licensees, public institutions, universities, private, association or foreign players, etc.).

4.3.1 Laboratory approval procedure

The above-mentioned amended ASN resolution 2008-DC-0099 of 29 April 2008 specifies the organisation of the national network and sets the approval arrangements for the environmental radioactivity measurement laboratories.

The approval procedure notably includes:
- presentation of an application file by the laboratory concerned, after participation in an ILT;
- review of it by ASN;
- examination of the application files – which are made anonymous – by a pluralistic approval commission which delivers an opinion on them.

The laboratories are approved by ASN resolution published in its *Official Bulletin*. The list of approved laboratories is updated every six months.

4.3.2 The approval commission

The approval commission is tasked with ensuring that the measurement laboratories have the organisational and technical competence to provide the RNM with high-quality measurement results.

The commission is authorised to propose approval, rejection, revocation or suspension of approval to ASN. It issues a decision on the basis of an application file submitted by the candidate laboratory and its results in the inter-laboratory comparison tests organised by the IRSN. It meets every six months.

The commission, chaired by ASN, comprises qualified persons and representatives of the State services, laboratories, standardising authorities and the IRSN.

4.3.3 Approval conditions

Laboratories seeking approval must set up an organisation meeting the requirements of standard NF EN ISO/IEC 17025 concerning the general requirements for the competence of calibration and test laboratories.

In order to demonstrate their technical competence, they must take part in ILTs) organised by the IRSN. The ILT programme, which now operates on a five-yearly basis, is updated annually. It is reviewed by the approval commission and published on the RNM's website (*mesure-radioactivite.fr*). Up to 70 laboratories sign up for a type of test, including a number of laboratories from other countries.

The approval commission defines the evaluation criteria used for analysis of the ILTs. When the result obtained in an ILT by a laboratory is not conclusive enough, ASN may, on the advice of the approval commission, issue an approval for a trial period of one to two years for example, or make issue of the approval dependent on the provision of additional data, or even the participation in a further corroborating test.

In 2020, the IRSN organised six ILTs. Since 2003, 88 ILTs have been carried out, covering 59 types of approval. The most numerous approved laboratories (54 of them) are in the field of monitoring of radioactivity in water. About 30 to 40 laboratories are approved for measurement of biological matrices (fauna, flora, milk), atmospheric dust, air, or ambient gamma dosimetry. There are 30 laboratories for 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, milk, aquatic fauna and flora, etc.).

In 2020, ASN issued 259 approvals or approval renewals. As at 1 January 2021, the total number of approved laboratories stood at 67, which represents 906 approvals of all types currently valid.

The detailed list of approved laboratories and their scope of technical competence is available on *asn.fr*.

TABLE 8

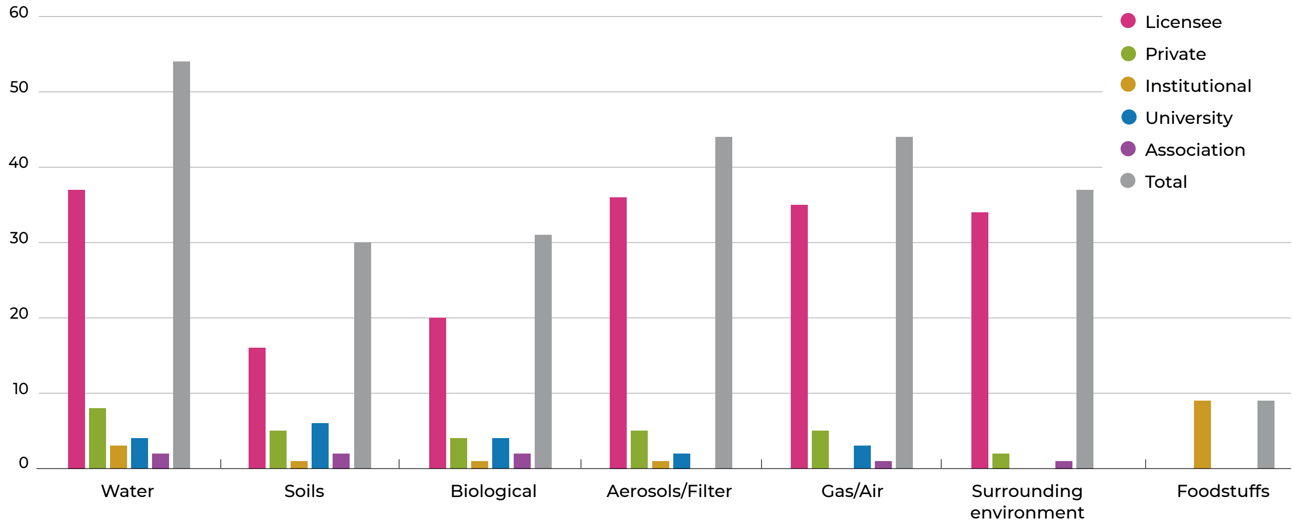
Example of radiological monitoring of the environment around BNIs

ENVIRONMENT MONITORED OR TYPE OF INSPECTION	CATTENOM NPP (ASN RESOLUTION 2014-DC-0415 OF 16 JANUARY 2014)	ORANO PLANT AT LA HAGUE (ASN RESOLUTION 2015-DC-0535 OF 22 DECEMBER 2015)
Air at ground level	• 4 stations continuously sampling atmospheric dust on a fixed filter with daily measurements of total β activity (βG) – γ spectrometry if βG > 2 mBq/m³ – Monthly γ spectrometry on groups of filters per station • 1 continuous sampling station downwind of the prevailing winds, with weekly measurement of atmospheric ³H	• 5 stations continuously sampling atmospheric dust on a fixed filter, with daily measurements of the total α activity (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 ³H • 5 continuous sampling stations with bi-monthly measurement of atmospheric ¹⁴C • 5 continuous measurement stations for ⁸⁵Kr 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 ³H	• 2 continuous sampling stations including one under the prevailing winds with weekly measurement of αG, βG and ³H – 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 ³H • Continuous sampling in the river at the good mixing point – ³H measurement (average daily mixture) • Annual sampling in aquatic sediments, fauna and flora upstream and downstream of the discharge point with γ spectrometry, free ³H measurement and, on fish, organically bound ¹⁴C and ³H • Periodic sampling from a stream and in the dam adjoining the site with measurements of βG, K, ³H	• Daily seawater samples from 2 points on the coast, with daily measurements (γ spectrometry, ³H) at one of these points and for each of the 2 points, α and γ spectrometry and βG, K, ³H and ⁹⁰Sr measurements • Quarterly seawater samples at 3 points offshore with γ spectrometry and βG, K, ³H measurements • Quarterly samples of beach sand, seaweed and limpets at 13 points with γ spectrometry + ¹⁴C 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 ¹⁴C measurement • Quarterly sampling of offshore marine sediments at 8 points with α and γ spectrometry and ⁹⁰Sr measurement • Weekly to six-monthly samples of water from 19 streams around the site, with αG, βG, K and ³H measurements • Quarterly sampling of sediments from the 4 main streams adjacent to the site, with γ and α spectrometry • Quarterly samples of aquatic plants in 3 streams in the vicinity of the site with γ spectrometry and ³H measurement
Groundwater	• Monthly sampling at 4 points, bi-monthly at 1 point and quarterly at 4 points with βg, K and ³H measurement	• 5 sampling points (monthly check) with αG, βG, K and ³H measurement
Water for consumption	• Annual sampling of water intended for human consumption, with βG, K and ³H measurements	• Periodic sampling of water intended for human consumption at 15 points, with αG, βG, K and ³H measurements
Soil	• 1 annual sample of the topsoil with γ spectrometry	• Quarterly samples at 7 points with γ spectrometry and ¹⁴C measurement
Vegetation	• 2 grass sampling points, including one under the prevailing winds, monthly γ spectrometry and quarterly ¹⁴C and C measurements • Annual campaign for the main agricultural crops, with γ spectrometry, ³H and ¹⁴C measurements	• Monthly grass sampling at 5 points and quarterly at 5 other points with γ spectrometry and ³H and ¹⁴C measurements, – Annual α spectrometry at each point • Annual campaign for the main agricultural crops, with α and γ spectrometry, ³H, ¹⁴C and ⁹⁰Sr measurements
Milk	• 2 points sampling points situated at 0 to 10 km from the installation, including one under the prevailing winds, with monthly γ spectrometry, quarterly ¹⁴C measurement and annual ⁹⁰Sr and ³H measurement	• 5 sampling points (monthly check) with γ spectrometry, K, ³H, ¹⁴C and ⁹⁰Sr measurement

αG = α global; βG = β global
* Measurements of total concentration of potassium and by spectrometry for 40K.

GRAPH 7

Breakdown of the number of approved laboratories for a given environmental matrix as at 1 January 2021



5. Inspections concerning fraud and processing of reported cases

5.1 Managing, monitoring and control of fraud

Since 2015, several cases of irregularities that could be considered to be falsifications have been brought to light at known manufacturers, suppliers or organisations who have been working for many years on behalf of the French nuclear industry. Confirmed cases of counterfeit or falsification have also been encountered in a number of other countries in recent years. The term of irregularity is employed by ASN to cover any intentional modification, alteration or omission of certain information or data. An irregularity detected by ASN can be dealt with by a judge in a case of criminal fraud.

The number of confirmed or suspected cases only represents a very small proportion of the nuclear activities, but these cases show that neither the robustness of the monitoring and inspection chain, for which the manufacturers, suppliers and licensees have prime responsibility, nor the high level of quality required in the nuclear industry, have been able to totally rule out the risk of counterfeit, fraud and falsification. Not all of these cases were detected by the licensee's monitoring process, which must now be more adequately tailored to the prevention, detection, analysis and processing of cases of fraud.

In 2016, ASN began to look at adapting BNI inspection methods in an irregularity context. In so doing, it questioned other oversight administrations, its foreign counterparts and the licensees with regard to their practices, in order to learn the pertinent lessons. This particular risk led to changes in the ASN oversight methods, but it continues to be dealt with using the existing procedures. In addition to its inspectors, ASN recruited an officer from the *Gendarmerie nationale* in 2019, who brings his experience to bear and enhances inspection practices in the fight against fraud type irregularities.

In 2018, ASN also reminded the BNI licensees and the main manufacturers of nuclear equipment that an irregularity is a deviation as defined by the BNI Order. The requirements of the BNI Order therefore apply to the prevention, detection and processing of cases that can be considered to be fraud. More generally, the regulatory requirements concerning the safety and protection of persons against the risks related to ionising radiation also apply. For example, applying a signature to certify that an activity has been correctly carried out, whereas in reality it has not could, depending on the circumstances, be a breach of the rules of organisation, technical inspection of activities, skills management, etc.

In 2020, ASN carried out 25 inspections devoted in part or in full to the search for irregularities. They mainly took place on the nuclear sites: the inspectors were able to identify suspicious cases compromising the performance of important activities: inspection sheets pre-filled out before these inspections were actually carried out, failure to carry out these inspections, signature by a checker on a date when they were apparently absent, and so on. These cases are first of all dealt with as deviations from the regulatory requirements. They are also the subject of discussions with the site management and the head office departments of the licensees, so that they can be addressed as a priority. Depending on the potential implications of the deviation, a report or notification is sent to the Public Prosecutor's Office. One report was sent in 2020.

In order to improve practices, ASN shares its experience feedback:
- with the licensees. For example, it participated in a day of debates organised by EDF;
- with its foreign counterparts. ASN notably takes part in the working groups of the Nuclear Energy Agency and the Multinational Design Evaluation Programme for new reactors, which held discussions on this subject. ASN is coordinating action to produce a model for rapid information between safety regulators when irregularities occurring abroad are discovered in a country.

Particular cases of irregularity are mentioned in point 2.2.2 of chapter 10.

5.2 Processing of reported cases

At the end of November 2018, ASN set up an online portal to enable anyone wishing to notify it of irregularities potentially affecting the protection of persons and the environment (whistle-blower) to do so.

By means of a system of pseudonyms for the notifications received, ASN guarantees the confidentiality of anyone sending it a notification. Only a request from a judicial authority could override this confidentiality, something which has not yet happened. It is however preferable for the person sending in the notification to leave their contact details so that ASN can:
- acknowledge receipt of the notification;
- contact them if clarification is required (this is frequently the case);
- inform them if action has been taken following their notification.

In 2020, 33 notifications were sent to ASN: slightly less than half *via* the notification portal, the others by other means of transmission (5 notifications by mail, 7 by direct contact with the geographically competent ASN division, etc.). The notifications received vary in terms of the field concerned, whether a BNI or small-scale nuclear facility, and in their content. Some are also forwarded by ASN to other administrations when it is not competent to deal with them. This could for example be the case of information concerning the security of a BNI, which is the responsibility of the Defence and Security High Official at the Ministry for Energy.

Eleven notifications have been verified during the course of inspections. The follow-up measures are managed within the same framework as the routine inspections.

For nine notifications, ASN contacted the authors of the notification again in order to obtain clarification.

Six of the notifications received in 2020 were anonymous: two of them, even if their content was taken into account in the overall monitoring actions, did not lead to targeted actions, as they were too vague and their anonymous authors could not be contacted. In addition, ASN was unable to inform the authors of the anonymous notifications of the action taken.

6. Identifying and penalising deviations

ASN implements enforcement measures, making it possible to oblige a licensee or party responsible for a nuclear activity to restore compliance with the regulations, along with penalties.

6.1 Fairness and consistency in the decisions regarding enforcement and sanction measures

In certain situations in which the actions of the licensee or party responsible for a nuclear activity fail to comply with the regulations or legislation, or when it is important that appropriate action be taken by it to remedy the most serious risks without delay, ASN may resort to enforcement measures and impose the penalties provided for by law. The principles of ASN actions in this respect are:
- actions that are impartial, justified and appropriate to the level of risk presented by the situation concerned. Their scale is proportionate to the health and environmental risks associated with the deviation identified and also take account of factors relating to the licensee (past history, behaviour, repeated nature), the context of the deviation and the nature of the requirements contravened (regulations, standards, "rules of good practice", etc.);
- administrative actions initiated on proposals from the inspectors and decided on by ASN in order to remedy risk situations and non-compliance with the legislative and regulatory requirements as observed during its inspections.

ASN has a range of tools at its disposal regarding the party responsible for a nuclear activity or a licensee, more particularly:
- the inspector's observations;
- the official letter from the ASN departments (inspection follow-up letter);
- formal notice from ASN to regularise the administrative situation or meet certain conditions, within a given time-frame;
- administrative penalties applied after formal notice.

In addition to ASN's administrative actions, reports can be drafted by the inspector and sent to the Public Prosecutor's Office.

6.2 An appropriate policy of enforcement and sanctions

When ASN observes non-compliance with the legislative and regulatory provisions applicable to nuclear safety or radiation protection (provisions of the Public Health Code and the Labour Code), enforcement measures or sanctions may be taken against the licensees or parties responsible for a nuclear activity, after an exchange of views – in accordance with the right of defence – and prior formal notice.

In the event of failure to comply with the applicable provisions and requirements, the law (Environment Code and Public Health Code) makes provision for graduated enforcement measures and administrative sanctions:
- deposit in the hands of a public accountant of a sum covering the total cost of the work to be performed;
- have the work carried out without consulting the licensee or the party responsible for the nuclear activity and at its expense (any sums deposited beforehand can be used to pay for this work);
- suspension of the operation of the facility or of the transport operation until conformity is restored, or suspension of the activity until complete performance of the conditions imposed and the adoption of interim measures at the expense of the person served formal notice, in particular in the event of urgent measures to protect human safety;
- a daily fine (an amount set per day, to be paid by the licensee or the party responsible until full compliance with the requirements of the formal notice has been achieved);
- administrative fine.

It should be noted that these last two measures are proportionate to the gravity of the infringements observed. The administrative fine falls within the competence of the ASN Administrative Enforcement Committee (see chapter 2).

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 above-mentioned interests;

TABLE 9

Number of reports transmitted by the ASN inspectors between 2015 and 2020

	2015	2016	2017	2018	2019	2020
Report excluding labour inspection in the NPPs	14	7	13	14	8	4
Labour inspection report in the NPPs	3	1	5	2	4	8

- 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, misdemeanours or breaches. This will for example be non-compliance with the provisions concerning the protection of workers exposed to ionising radiation, non-compliance with formal notice served by ASN, performance of a nuclear activity without the required administrative title, 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 makes provision for criminal penalties, 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 also makes provision for criminal penalties, consisting of a fine of from €3,750 to €15,000 and a term of imprisonment of six months to one year, depending on the gravity of the infringement, with additional penalties being possible for legal persons.

Class 5 penalties (fines) are stipulated in the field of nuclear safety for infringements mentioned in Article R. 596-16 of the Environment Code, as well as in the field of radiation protection for infringements mentioned in Articles R. 1337-14-2 to 5 of the Public Health Code, for example with regard to non-compliance with the requirements for notification of a significant event, to the administrative system (transmission of the title application file, compliance with general requirements, information concerning changes to the Radiation Protection Advisor).

With regard to pressure equipment, the provisions of Chapter VII of Title V of Book V of the Environment Code, which apply to products and equipment representing a risk, which covers pressure equipment, including that installed in BNIs, notably provide for the payment of a fine, plus a daily penalty payment as applicable, until compliance with the formal notice served on the licensees. This chapter also includes provisions applicable to the manufacturers, importers and distributors of such equipment, aiming to ban the marketing, commissioning or continued operation of an equipment item and to serve the licensee with formal notice to take all steps necessary to ensure conformity with the legislative and regulatory provisions applicable to its activity.

In the performance of their duties in NPPs, the ASN labour inspectors have at their disposal all the inspection, decision-making and enforcement resources of ordinary law inspectors (pursuant to Article R. 8111-11 of the Labour Code). Observation, formal notice, administrative sanction, report, injunction (to obtain immediate cessation of the risks) or even stoppage of the works, offer the ASN labour inspectors a broad range of incentive and constraining measures.

6.3 2020 results concerning enforcement and sanctions

As a result of infringements observed, the ASN inspectors (nuclear safety, BNI, transport of radioactive substances or nuclear pressure equipment inspectors, labour inspectors and radiation protection inspectors) transmitted 12 infringement reports to the Public Prosecutor's Offices, eight of which concerned labour inspections in the NPPs.

ASN served formal notice to BNI licensees and nuclear activity managers on three occasions. Table 9 shows the number of reports issued by the ASN inspectors since 2015.

CHAPTER 04

RADIOLOGICAL EMERGENCY AND POST-ACCIDENT SITUATIONS


Scanner
le QR code
Rentrer le code sur l'interface sécurisée pour vo... des comprimés
interface-iode.fr
Recherche par code
Code retirant
Indiquer un code retirant
Rechercher
IODURE DE POTASSIUM 65
Pharmacie Centrale des Armées,
comprimé sécable
A NE PRENDRE QUE SUR INSTRUCTIONS DES AUTORITES COMPE
PHARMACIE CENTRALE DES ARMEES
Plan particulier

04

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 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 liable to compromise public health, include:
- emergency situations arising on Basic Nuclear Installations (BNIs);
- 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 or party responsible for the activity and the public authorities.

The French Nuclear Safety Authority (ASN) is involved in managing these situations, with regard to questions concerning the regulation of nuclear safety and radiation protection and, backed more particularly by the expertise of its technical support organisation, the Institute for Radiation Protection and Nuclear Safety (IRSN), it has the following four key duties:
- check the steps taken by the licensee and ensure that they are pertinent;
- advise the authorities on population protection measures;
- take part in the dissemination of information to the population and media;
- act as Competent Authority within the framework of the international Conventions on Early Notification and Assistance.

In 2005, at the request of the Prime Minister, ASN also set up a Steering Committee for the Management of the Post-Accident Phase (Codirpa) so that, following on from the management of a radiological emergency, preparations can be made for the post-accident phase. This Committee proposed aspects of doctrine to the Government for the emergency phase exit, transitional and long-term periods, published in November 2012.

Since then, the Codirpa has been giving thought to new aspects of doctrine based notably on the lessons learned from the accident which struck the Fukushima Daiichi Nuclear Power Plant (NPP) in Japan in March 2011 and the national exercises carried out on this subject. This work has led to new proposals for the population protection zoning strategy, in order to set up a system that is simpler and more operational.

1. Anticipating

Four main principles underpin the protection of the general public against Basic Nuclear Installation (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 The Basic Nuclear Installation emergency and contingency plans

The emergency and contingency plans relative to accidents occurring at a BNI define the measures necessary to protect the site personnel, the general public and the environment, and to control the accident.

a) Major Nuclear or Radiological Accident National Response Plan
ASN took part in drafting the Major Nuclear or Radiological Accident National Response Plan (PNRANRM), which was published by the Government in February 2014. The Plan incorporates the lessons learned from the Fukushima Daiichi Nuclear Power Plant (NPP) accident and the post-accident doctrine drawn up by Codirpa in 2012. It specifies the national response to 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.

National emergency exercises and barrier measures at the ASN Emergency Centre

" 'Exercise – exercise – exercise' ". This morning, at 08h01, we were informed by the general alert system that a fire had broken out on "unit 12" of the Chinon Nuclear Power Plant (NPP). EDF triggered its On-site Fire Emergency Plan (PUI) outside the controlled area at 08h01, and then its radiological safety PUI at 9h52."

On 1 December 2020, ASN activated its Montrouge Emergency Centre for a national emergency exercise on the EDF NPP at Chinon (Indre-et-Loire – 37). This exercise was an opportunity to test the adaptation of ASN's emergency response organisation to the constraints arising from the health context.

In order to comply with the health instructions and protect the staff, a large number of measures had been implemented. The activation of the Emergency Centre was limited, to allow physical distancing between the emergency team members and movements around the emergency centre were kept to the strict minimum, with audio-conferences held outside the Emergency Centre. The unit in charge of international relations was also activated "remotely". Finally, no observers were allowed to attend the exercise in order to limit the number of people on the site.

Masks and sanitiser were available to the teams throughout the day, the workstations were repeatedly disinfected, with frequent ventilation operations, throughout the course of the day.

Locally, the Orleans division was also mobilised on a reduced scale, notably with the dispatch of a staff member who joined the *département* level operations centre of the office of the Indre-et-Loire Prefect, which was also activated on a much reduced scale. In order to limit the risks of contamination, no staff member went to the Chinon NPP site.

b) Off-site Emergency Plans

In the vicinity of the facility, the Off-site Emergency Plan (PPI) is established by the Prefect of the *département* concerned pursuant to Articles L. 741-6, R. 741-18 et seq. of the Domestic Security Code, "*to protect the populations, property and the environment, and to cope with the specific risks associated with the existence of structures and facilities whose perimeter is localised and fixed. The PPI implements the orientations of civil protection policy in terms of mobilisation of resources, information, alert, exercises and training*". These Articles also stipulate the characteristics of the facilities or structures for which the Prefect is required to define a PPI.

The PPI specifies the initial actions to be taken to protect the general public, the roles of the various services concerned, the systems for giving the alert, and the human and material resources likely to be engaged in order to protect the general public.

The PPI falls within the framework of the Disaster and Emergency Response Organisation (Orsec) which describes the protective measures implemented by the public authorities in large-scale emergencies. Therefore, beyond the application perimeter of the PPI, the *département* or *zone Orsec* plan is activated. ASN assists the Prefect, who is responsible for the drafting and approval of the PPI, by analysing the various aspects with its technical support organisation, the Institute for Radiation Protection and Nuclear Safety (IRSN), including those concerning the nature and scale of the radiological consequences of an accident.

The PPIs currently make it possible to plan the public authorities' response in the first hours of the accident in order to protect the population living within a 20 kilometres (km) radius around the affected reactor. This distance was increased from 10 to 20 km following the Ministry of the Interior's publication on 3 October 2016 of an Instruction concerning the response to a major nuclear or radiological accident – "*Changes in national doctrine for drafting or modifying PPIs around NPPs operated by EDF*". In 2017, it published a guide intended for the offices of the Prefects in order to implement this instruction by updating the PPIs for the NPPs to take account of the changes, in particular the preparation for "immediate" evacuation within a 5 km radius, the inclusion of consumption restrictions as of the emergency phase and the expansion of the PPI radius for NPPs to 20 km.

The PPIs comprise a "reflex" phase which includes an immediate licensee alert of the populations within a 2 km radius of the facility, requiring them to take shelter and await instructions. The additional measures to be taken beyond the zone covered by the PPI are specified, as applicable, through a joint approach which can be based on the Orsec arrangements, taking account of the characteristics of the accident and the weather conditions.

c) On-site Emergency Plan

As part of the BNI commissioning authorisation procedures, ASN examines and approves the PUIs and their updates (Article R. 593-31 of the Environment Code).

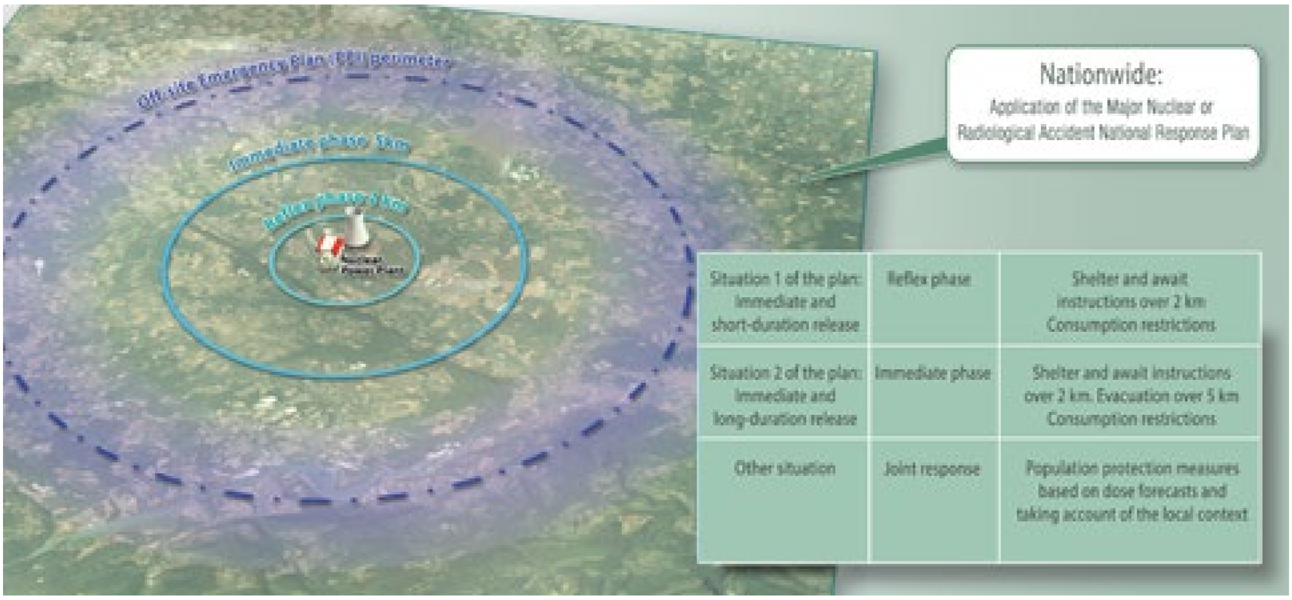
The PUI, prepared by the licensee, is designed to restore the plant to a controlled and stable condition and mitigate the consequences of an event. It defines the organisational actions and the resources to be implemented on the site. It also includes the provisions for rapidly informing the public authorities. 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 Response plans for radioactive substances transport accidents

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.

DIAGRAM 1

Major Nuclear or Radiological Accident National Response Plan



ASN examines and approves the management plans for events linked to the transport of radioactive substances drawn up by the stakeholders in the transport of such substances pursuant to the international regulations for the carriage of dangerous goods. These plans describe the steps to be taken, depending on the nature and scale of the foreseeable hazards, in order to avoid damage or, as necessary, mitigate the effects. The content of these plans is defined in ASN Guide No. 17.

To deal with the possibility of a radioactive substances transport accident, each *département* Prefect must include in their implementation of the PNRANRM a part devoted to this type of accident, the Orsec Transport of Radioactive Materials (TMR) 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 the incidents or accidents which could affect nuclear installations or radioactive substances transport operations, 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 therefore drafted Circular DGSNR/DHOS/DDSC 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 situations.

Given the large number of potential originators of an alert and the corresponding alert circuits, 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 *Département* Operational Fire and Emergency Centre – Alert Processing Centre (CODIS-CTA), 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 Nuclear, Radiological, Biological and Chemical (NRBC) Plan.

1.1.4 Controlling urban development around nuclear sites

The aim of controlling urban development is to limit the consequences of an accident for the population and property. An approach of this type has been in place since 1987 around non-nuclear industrial facilities and was reinforced following the AZF plant accident 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 (ICPEs) and lead to more stringent measures.

The actions to control urban development entail a division of responsibilities between the licensee, the mayors and the State:
- The licensee is responsible for its activities and the related risks.
- The mayor is responsible for producing the town planning documents and issuing building permits.
- The Prefect informs the mayors of the existing risks, verifies the legality of the steps taken by the local authorities and may impose institutional controls as necessary.

ASN supplies technical data in order to characterise the risk, and offers the Prefect its assistance in the urban development control process.

The current approach to controlling activities around nuclear facilities exclusively concerns those subject to a PPI and primarily aims to preserve the operational nature of the contingency plans, in particular for sheltering and evacuation, limiting the population numbers concerned whenever possible. It focuses on the PPI "reflex" zone, determined by the Circular of 10 March 2000 revising the PPIs for BNIs, the pertinence of which was confirmed by the instruction of 3 October 2016. In this "reflex" zone, immediate steps to protect the population are taken in the event of a rapidly developing accident.

A Circular from the Ministry responsible for the Environment of 17 February 2010 concerning the control of activities in the vicinity of BNIs liable to present dangers off the site asked the Prefects to exercise increased vigilance with regard to urban development in the vicinity of nuclear facilities. This Circular states that the greatest possible attention must be paid to projects that are sensitive owing to their size, their purpose, or the difficulties they could entail in terms of protection of the general public in the "reflex" zone.

ASN is consulted on construction or urban development projects situated within this zone. The opinions issued are based on the principles explained in ASN Guide No.15 on the control of activities around BNIs published in 2016. This Guide, drawn up by a pluralistic working group jointly overseen by ASN and the General Directorate for Risk Prevention (DGPR), comprising elected officials and the National Association of Local Information Commissions and Committees (Anccli), has the following basic objectives:
- preserve the operational nature of the contingency plans;
- give priority to regional development outside the "reflex" zone;
- allow controlled development that meets the needs of the resident population.

1.2 The emergency situation stakeholders

The response by the public authorities to a major nuclear or radiological accident is determined by a number of texts concerning nuclear safety, radiation protection, public order and civil protection, as well as by the emergency plans.

Act 2004-811 of 13 August 2004 on the Modernisation of Civil Protection, makes provision for an updated inventory of risks, an overhaul of operational planning, performance of exercises involving the general public, information and training of the general public, an operational watching brief and alert procedures. Several Decrees implementing this Act, codified in Articles L. 741-1 to L. 741-32 of the Domestic Security Code, more specifically concerning the Orsec plans and PPIs, clarified it in 2005.

How radiological emergency situations are dealt with is specified in the Interministerial Directive of 7 April 2005 on the action of the public authorities in the case of an event leading to a radiological emergency situation (see Diagram 1).

Thus, at the national level, ASN is an active participant in interministerial work on nuclear emergency management.

The Fukushima Daiichi NPP accident showed that it was necessary to improve preparation for the occurrence of a multifaceted 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.

1.2.1 Local response organisation

In an emergency situation, several parties have the authority to take decisions:
- The licensee of the affected nuclear facilities deploys the response organisation and the resources defined in its PUI (see point 1.1.1).
- ASN has a duty to monitor the licensee's actions in terms of nuclear safety and radiation protection. In an emergency situation, it calls on assessments by the 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 PPI. He/she keeps the population and the mayors informed of events. ASN assists the Prefect with managing the situation.
- The Prefect of the defence and security zone is responsible for coordinating reinforcements and the support needed by the Prefect of the *département*, for ensuring that the steps taken between *départements* are consistent and for coordinating regional communication with national communication.
- Owing to his or her role in the local community, the Mayor has an important part to play in anticipating and supporting the measures to protect the population. To this end, the mayor of a municipality included within the scope of application of a PPI must draw up and implement a local safeguard plan to provide for, organise and structure the measures to accompany the Prefect's decisions. The mayor also plays a role in relaying the information and heightening population awareness, more particularly during iodine tablet distribution campaigns.

1.2.2 National response organisation

In a radiological emergency situation, each Ministry – together with the decentralised State services – is responsible for preparing and executing national level measures within their field of competence.

In the event of a major crisis requiring the coordination of numerous players, a governmental crisis organisation is set up, under the supervision of the Prime Minister, with the activation of the Interministerial Crisis Committee (CIC). The purpose of this Committee is to centralise and analyse information in order to prepare the strategic decisions and coordinate their implementation at interministerial level. It comprises:
- all the Ministries concerned;
- the competent safety Authority and its technical support organisation, the IRSN;
- representatives of the licensee;
- administrations or public institutions providing assistance, such as *Météo-France* (national weather service).

1.3 Protecting the population

The steps to protect the populations during the emergency phase, as well as the initial actions as part of the post-accident phase, aim to protect the population from exposure to ionising radiation and to any chemical and toxic substances that may be present in the releases. These measures are mentioned in the PPIs.

1.3.1 General protection measures

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.

Taking stable iodine tablets is a means of saturating the thyroid gland and protecting it from the carcinogenic effects of radioactive iodines.

The Circular of 27 May 2009 defines the principles governing the respective responsibilities of a BNI licensee and of the State with regard to the distribution of iodine tablets.

This Circular requires that, as the party responsible for the safety of its facilities, the licensee finances the public information campaigns within the perimeter of the PPI and carries out permanent preventive distribution of the stable iodine tablets, free of charge, through the network of pharmacies.

The national campaign of iodine tablets distribution to the populations within the zone covered by the PPIs between 10 and 20 km around the NPPs, was launched in September 2019.

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 taking over the roles previously held by the Health Emergency Preparedness and Response Organisation – Eprus). Each Prefect defines the procedures for distribution to the population in their *département*, relying in particular on the mayors for this.

This arrangement is described in a Circular of 11 July 2011 concerning the storage and distribution of potassium iodide tablets outside the zones covered by a PPI. Pursuant to this Circular, the Prefects have drawn up plans to distribute stable iodine tablets in a radiological emergency situation, which can be included in exercises being held for the local implementation of the PNRANRM.

The Prefect may also take measures to ban the consumption of foodstuffs liable to have been contaminated by radioactive substances as of the emergency phase (until the facility has been restored to a controlled and stable state).

The purpose of these measures, taken before the releases cease, is to facilitate management of the post-accident phase. Once the releases are over and the facility has returned to a stable state, further population protection steps are decided on, according to the deposition of radioactive materials in the environment. Depending on the ambient radioactivity level, this could involve:
- evacuating the population for a variable length of time;
- restrictions on the self-consumption of foodstuffs produced locally;
- checks on foodstuffs prior to marketing, in accordance with the maximum allowable levels of radioactive contamination defined at European level for the sale of foodstuffs.

1.3.2 Care and treatment of exposed persons

In the event of a radiological emergency situation, a significant number of people could be contaminated by radionuclides. These persons shall be cared for by the emergency response teams duly trained and equipped for this type of operation.

The Circular of 18 February 2011 defines national doctrine concerning the use of emergency and care resources in the event of a terrorist act involving radioactive substances. These provisions, which also apply to a nuclear or radiological accident, aim to implement a unified nationwide methodology for the use of resources, in order to optimise efficiency.

The Medical intervention following a nuclear or radiological event Guide, the drafting of which was coordinated by ASN and which was published in 2008, accompanies Circular DHOS/HFD/DGSNR No. 2002/277 of 2 May 2002 concerning the organisation of medical care in the event of a nuclear or radiological accident, giving all the information of use for the medical response teams in charge of collecting and transporting the injured, as well as for the hospital staff. Under the aegis of the General Secretariat for Defence and National Security (SGDSN), a new version of this Guide taking account of changes to certain practices, is currently under preparation.

1.4 Understanding the long-term consequences

The post-accident phase concerns the handling over a period of time of the consequences of long-term contamination of the environment by radioactive substances following a nuclear accident. It covers the handling of consequences that are varied (economic, health, environmental and social), by their nature complex and that need to be dealt with in the short, medium or even long term, with a view to returning to a situation considered to be acceptable.

The conditions for reimbursement for the damage resulting from a nuclear accident are currently covered by Act 68-943 of 30 October 1968, amended, concerning Civil Liability in the field of nuclear energy. France has also ratified the protocols signed on 12 February 2004, reinforcing the Paris Convention of 29 July 1960 and the Brussels Convention of 31 January 1963 concerning Civil Liability in the field of nuclear energy. These protocols and the measures necessary for their implementation are codified in the Environment Code (Section I of Chapter VII of Title IX of Book V). These provisions and the new liability thresholds set by the two protocols entered into force in February 2016, pursuant to the 17 August 2015 Act on Energy Transition for Green Growth (TECV Act). An Order of 19 August 2016 sets the list of sites with more limited risks which benefit from a reduced liability amount.

As part of its ongoing analysis of the management of the post-accident phase, the Codirpa, set up by ASN in 2005 at the request of the Prime Minister, worked to learn the lessons from the post-accident management employed in Japan after the Fukushima Daiichi disaster, but also the experience feedback from emergency exercises.

Following this work, the Codirpa recommended a number of changes to post-accident doctrine, which ASN transmitted to the Prime Minister, who accepted them in June 2020. The main one is simplification of the post-accident zoning, constituting the basis for the population protection measures:
- To protect the population from the risk of external exposure, the population evacuation perimeter (uninhabitable zone) would be maintained, on the basis of an annual effective dose value of 20 millisieverts per year (mSv/year) for the first year, due to external exposure alone. The consumption and sale of foodstuffs produced locally would be prohibited within this zone.

- To limit exposure of the population to the risk of contamination through consumption, a non-consumption perimeter for fresh local produce is proposed. First of all, this perimeter would be defined from the largest of the population protection perimeters (sheltering, ingestion of iodine, etc.) determined during the emergency phase. It would then be refined using environmental contamination measurements and the available models.
- With regard to the sale of local produce, the Codirpa proposes adopting a regional approach per agricultural production and livestock sector, based on the maximum allowable radioactive contamination levels defined by the European authorities for the sale of foodstuffs.

In addition, to meet the request for support for initiatives to transfer aspects of the doctrine to the regional level, the Codirpa set up a working group involving numerous associations (including the Anccli), the IRSN but also representatives national and decentralised administrations. The work done led to:

- the creation of an Anccli/ASN/IRSN website raising post-accident awareness (*post-accident-nucleaire.fr*). This site enables elected officials, health professionals, associations, education personnel and economic players to access documents and information of use for preparing or managing life in a region contaminated by a nuclear accident;
- the publication of a practical guide intended for the inhabitants of a region contaminated by a nuclear accident;
- frequently asked questions/answers drawn up with and for health professionals on subjects concerning health and everyday life.

This initial information work will be continued over the long term, and the post-accident awareness-raising website will be enhanced in the future with Codirpa producing information to support and assist the post-accident stakeholders.

2. ASN's role in an emergency and post-accident situation

2.1 The four key duties of ASN

In an emergency situation, the responsibilities of ASN, with the support of IRSN, are as follows:

- check the steps taken by the licensee and ensure that they are pertinent;
- advise the authorities on population protection measures;
- take part in the dissemination of information to the population and media;
- act as Competent Authority within the framework of the international Conventions on Early Notification and Assistance.

Checking the steps taken by the licensee

As in a normal situation, ASN exercises its roles as the regulatory authority in an accident situation. In this particular context, ASN ensures that the licensee exercises in full its responsibility for keeping the accident under control, mitigating the consequences, and rapidly and regularly informing the public authorities. It draws on the 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 the IRSN. This analysis covers both a diagnosis of the situation (understanding of the situation of the installation affected, analysis of the consequences for humans and the environment) and a prognosis (assessment of possible developments, notably radioactive releases). These recommendations more specifically concern the steps to be taken to protect the population in the emergency and post-accident phases.

Circulation of information

ASN is involved in informing:

- the media and the public: publication of press releases and organisation of press conferences; it is important that this action be coordinated with the other entities required to communicate (Prefects, licensees at both local and national levels, etc.);
- institutional and associative stakeholders: local authorities, ministries, offices of the Prefect, political authorities, general directorates of administrations, Anccli, Local Information Committees, etc.;
- foreign nuclear safety Regulators.

Function of Competent Authority as defined by International Conventions

The Environment Code provides for ASN to fulfil the role of Competent Authority under the 1986 International Conventions on early notification and assistance. As such, it collates and summarises information for the purpose of sending or receiving notifications and for transmitting the information required by these Conventions to the international organisations (International Atomic Energy Agency – IAEA – and European Union) and to the countries affected by the possible consequences on their own territory, jointly with the Ministry for Foreign Affairs.

2.2 Organisation in the event of a major accident

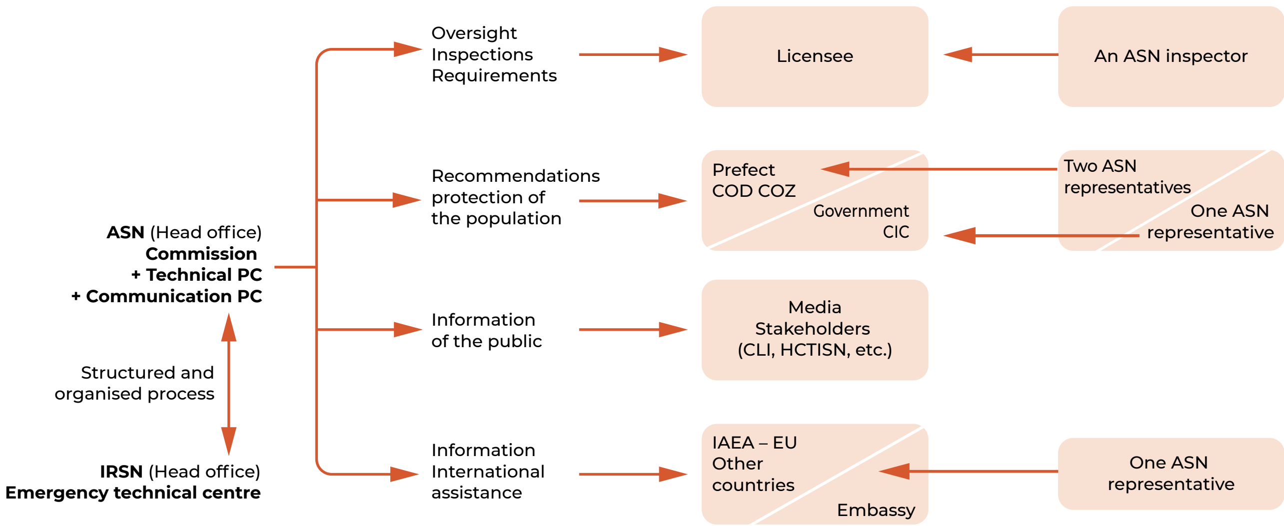
The ASN emergency response organisation set up to deal with a major accident more specifically comprises:

- the participation of ASN staff in the various units of the Interministerial Crisis Committee (CIC);
- the creation of a national Emergency Centre in Montrouge (Île-de-France region) organised around an emergency director and various specialised units:
  - an "information management and coordination" unit, in charge of supporting the emergency director;
  - a logistics unit;
  - a "safety" unit in charge of understanding and assessing the ongoing event;
  - a "protection of persons, the environment and property" unit, notably in charge of proposing population protection actions;
  - an "internal and external communication" unit;
  - an "international relations" unit;
  - a "forward planning" unit.

The working of the 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.

DIAGRAM 2

The role of ASN in a nuclear emergency situation



COD: Departmental Operations Centre – **COZ:** Zone Operations Centre – **CIC:** Interministerial Crisis Committee – **CICNR:** Interministerial Committee for Nuclear or Radiological Emergencies – **CLI:** Local Information Committee – **HCTISN:** High Committee for Transparency and Information on Nuclear Safety – **PC:** Command Post

Experience feedback from the Fukushima Daiichi NPP accident also leads ASN to envisage sending one of its representatives, if necessary, to the French embassy of a country in which a nuclear accident occurred.

In 2020, the national Emergency Centre was activated on three occasions, once for a national exercise and twice for real situations. Owing to the health crisis, the exercises scheduled for 2020 could not be held, except for the exercise in the Chinon NPP in December, for which the emergency centres of the various stakeholders were activated on a minimum scale, with some work being carried out remotely and in compliance with the barrier measures (mandatory mask-wearing, sanitiser, shift changeovers outside the emergency centre, etc.). The schedule of exercises for 2021 and 2022 was revised so that some which had been cancelled in 2020 could be carried out.

On 21 February 2020 at 8h30, as a result of several intruders penetrating the protected area of the Tricastin NPP in the Drôme *département* (26), the on-call team was activated in the Montrouge Emergency Centre, to check with the licensee there were no safety consequences for the installations.

On 30 June 2020, ASN was informed of an outbreak of fire in the reactor building undergoing decommissioning at the Creys-Malville NPP in the Isère *département* (38). ASN activated its Emergency Centre in order to monitor the development of the situation and the steps taken by the licensee.

The ASN emergency response organisation was also partially activated on several occasions in 2020.

In the night of Thursday 4 to Friday 5 June 2020, the Belleville-sur-Loire NPP in the Cher *département* (18) triggered the ASN general alert system owing to a fire in reactor 2 (outside the controlled area) which led to the site's PUI being activated. On 10 December 2020, ASN was alerted by the European Community Urgent Radiological Information Exchange (ECURIE) following detection of a high level of radioactivity in the Finnish Olkiluoto 2 reactor.

For these events, and even without actually activating the Emergency Centre, the ASN on-call team was mobilised remotely in order to collect the information needed to monitor the situation and be ready to intervene if necessary.

During exercises, or in the event of a real emergency, ASN is supported by a team of analysts working in the IRSN's Technical Emergency Centre.

ASN's alert system allows mobilisation of its Emergency Centre staff and those of the IRSN. This automatic system sends an alert signal to the staff equipped with appropriate reception devices, as soon as it is remotely triggered by the BNI licensee originating the alert. It also sends the alert to the staff of the SGDSN, the General Directorate for Civil Security and Emergency Management, the Interministerial Emergency Management Operations Centre, *Météo-France* and the ministerial operational monitoring and alert centre of the Ministry for Ecological Transition.

A radiological emergency toll-free 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 24/7. The information provided during the call is transmitted to the on-call team. Depending on the severity of the event, ASN may activate its Montrouge Emergency Centre by triggering the alert system. If not, only the ASN local level (regional division concerned) intervenes to perform its Prefect support and communication duties, if necessary calling on the expertise of the national departments. In order to enhance the graduated nature of the ASN response and organisation in the event of an emergency, for situations not warranting activation of the Emergency Centre, the system has been adapted for the creation of a national level support unit to assist the regional division concerned. The format and duties of this unit are tailored to each situation.

Since 2018, an on-call duty system reinforces the robustness and the mobilisation and intervention reactivity of the ASN staff. This system remained operational throughout 2020, including during the lockdown periods.

Diagram 2 summarises the role of ASN in a nuclear 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.

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 instruction, involve the licensee, the Ministries, the offices of the Prefects and services of the *départements*, ASN, the Defence Nuclear Safety Authority[1] (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, ASN together with the SGDSN, the General Directorate for Civil Security and Emergency Management and the ASND, prepared the 2020 programme of national nuclear and radiological emergency exercises concerning BNIs and radioactive substance transport operations. This programme was announced to the Prefects by the interministerial instruction of 16 January 2020. However, this programme was significantly affected by the Covid-19 health crisis.

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 2020.

In addition to the national exercises, the Prefects are asked to conduct local exercises for 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.

TABLE 1
Positions of the various players in a radiological emergency situation

	DECISION	EXPERT APPRAISAL	INTERVENTION	COMMUNICATION
Public authorities	Government (CIC) Prefect (COD, COZ)	–	Prefect (PCO) Civil protection	Government (CIC) Prefect (COD)
	ASN (PCT)	IRSN (CTC) *Météo-France*	IRSN (mobile units)	ASN IRSN
Licensees	National and local levels	National and local levels	Local level	National and local levels

CIC: Interministerial Crisis Committee – **COD:** Departmental Operations Centre – **COZ:** Zone Operations Centre – **CTC:** Emergency Technical Centre – **PCO:** Operational Command Post – **PCT:** Technical Command Post

TABLE 2
National civil nuclear and radiological emergency exercises conducted in 2020

NUCLEAR SITE	DATE OF EXERCISE	MAIN CHARACTERISTICS
Tricastin NPP (Drôme – 26)	21 February	Mobilisation of the on-call team in the Emergency Centre, ensuring compliance with barrier measures
EDF Creys-Malville site undergoing decommissioning (Isère – 38)	30 June	Outbreak of fire on the site Reduced scale activation and compliance with barrier measures
EDF's Chinon NPP (Indre-et-Loire – 37)	1 December	Reduced scale activation and compliance with barrier measures Simulated remote media pressure (interviews by telephone)

1. *Defence Nuclear Safety Authority (ASND), in charge of regulation and oversight of nuclear safety and radiation protection for defence-related activities and facilities, more particularly those operated by the CEA.*

ASN Emergency Centre during the emergency exercise of 2 February 2021 on the Orano La Hague site

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 2020, 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 2019.

ASN is also heavily involved in the preparation and performance of other emergency exercises that have a nuclear safety component and are organised by other players such as:
- its counterparts for nuclear security (Defence and Security High Official reporting to the Minister in charge of energy – HFDS) or for Defence-related facilities (ASND);
- international bodies (IAEA, European Commission, Nuclear Energy Agency);
- the Ministries for Health, the Interior, etc.

In August 2020, ASN thus took part in an IAEA RANET exercise. This exercise was held over several days and considered a nuclear reactor accident in France. It was performed entirely remotely and notably enabled ASN to test the tools for notification and the exchange of information internationally in the event of a nuclear accident in France. A French request for assistance was also sent to the IAEA, with simulation of the transmission of information about the measures taken in the field by the various international players who responded to the assistance request.

The experience acquired during these exercises should enable the ASN personnel to respond more effectively in real emergency situations.

3.2 Assessing with a view to improvement

Assessment meetings are organised immediately after each exercise in each emergency centre and at ASN a few weeks after the exercise. ASN, along with the other players, endeavours to identify best practices and the areas for improvement brought to light during these exercises.

These assessment meetings enable the players to share their experience through a participative approach. They more specifically revealed:
- the importance of having scenarios that were as realistic as possible, in real meteorological conditions and that were technically complex enough to be able to provide useful experience feedback;
- the importance of communication in an emergency situation, in particular to inform the public and foreign authorities as rapidly as possible and avoid the spread of rumours liable to hamper good emergency management, in France and in other countries;
- the importance of providing the decision-makers with a clear view of the radiological impacts in the form of maps: the tool called Criter developed by the IRSN gives a representation of the results of environmental radioactivity measurements.

4. Outlook

The year 2020 was marked by the health crisis.

ASN nonetheless made sure that its emergency alert system was available at all times, notably thanks to its on-call team which remains available and reachable 24/7 and to the adaptation of its Montrouge Emergency Centre to take account of the health instructions (distance between workstations, mandatory mask-wearing, remote-working, etc.).

Most of the national nuclear emergency exercises in 2020 were cancelled, so ASN carried out simulations with its on-call team in order to ensure their readiness, notably with regard to the initial response when a radiological emergency situation is triggered. ASN will also exercise greater vigilance in preparedness for the management of emergency situations in 2021 by taking part in all the national exercises and reinforcing its internal and external training efforts.

ASN also made sure that the crisis organisation at the licensees remained fully operational, by continuing with regular discussion meetings and, during the course of inspections, by verifying the effectiveness of the Covid-19 related measures taken (see page 12 – 'Covid-19' in the introduction to this report).

With regard to management of the post-accident phase, the Codirpa continued its work following its new mandate received from the Prime Minister for the period 2020-2024. This new mandate is the opportunity to develop the Codirpa's working methods in order to reinforce the contribution of local stakeholders to the preparation of the recommendations made by the committee to the Government (see page 28 – Notable Events – Codirpa in the introduction to this report).

Finally, ASN will continue with its information and support actions regarding changes to post-accident doctrine for all the stakeholders (local information committees, licensees, State departments, etc.).

CHAPTER 05

INFORMING THE PUBLIC AND OTHER AUDIENCES

05 Informing the public and other audiences

At ASN, the French Nuclear Safety Authority, informing the public and other audiences is the centre of its activities. The Acts of 2006 on Transparency and Security in the Nuclear Field and 2015 on Energy Transition for Green Growth entrusted ASN with the mission of making a statement on the state of nuclear safety and radiation protection in France. Consequently, throughout the year ASN informs the citizens, the media, the institutional and professional audiences of the situation of the Basic Nuclear Installations (BNIs) and small-scale nuclear activities with respect to the safety and radiation protection requirements. It presents its regulatory and oversight activity and the actions it takes in this respect, and widely disseminates its resolutions and position statements, explaining them where necessary. After each inspection, ASN publishes an "inspection follow-up letter" which sets out its findings and the recommendations for the licensee: nearly 25,000 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 stakeholders and the public on its draft resolutions. To this end, it ensures that the principles of nuclear safety and radiation protection are understood by the widest possible audience, it produces explanatory documents and it endeavours to render even the most technical issues understandable.

In 2020, in order to continue its activity of informing the public and other audiences despite the constraints linked to the health crisis, ASN developed new ways of sharing information and having interchanges: remote press conferences, online presentation of the annual report, video conferencing for the Local Information Committee (CLI) meetings, online hearings, etc. All these means, combined with putting new resources on line (films, ASN-IRSN exhibition) and increased presence on the networks, have enabled the dialogue with the various audiences to be maintained throughout the year.

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 62,000 visits per month on average, the *asn.fr* website is at the heart of the system for informing the various audiences. It posts the majority of draft opinions and resolutions for consultation. The website is also a reference source of information for the more informed audiences: expert citizens, members of environmental associations and professionals. In all, more than 2.5 million pages of the website were viewed in 2020.

To satisfy the needs for explanations inherent to a wide audience, the publication formats are varied and meet new expectations, particularly on the social networks. New educational content is also regularly put online.

ASN takes care to translate into English the majority of the information notices, press releases, publications and content concerning major issues. These English translations support ASN's work in large international organisations and foster a concerted global vision of nuclear safety and radiation protection.

Lastly, ASN sends its two-monthly *Lettre de l'Autorité de sûreté nucléaire* (Nuclear Safety Authority Newsletter) to more than 5,000 subscribers. This publication provides a summary of the most noteworthy topical issues and information relative to ASN resolutions and actions, including on the international front. To subscribe to the ASN newsletter, simply register on *asn.fr*.

On another note, further to the irregularities discovered at the Creusot Forge plant in 2016, ASN has stepped up the fraud prevention and detection measures in the nuclear sector. These measures include a readily accessible reporting system: the website *asn.fr* provides a secured form for submitting reports, guaranteeing the protection of whistle-blowers and the confidential treatment of the information received.

1.1.2 The social networks

The website content, which can be consulted on smartphones or tablets, is also shared on the main social media (primarily Twitter, Facebook and LinkedIn). The news feeds of the ASN social media accounts convey the main position statements. The major events in which ASN participates (parliamentary hearings, public meetings) are announced and can be followed in real time on the social networks.

Since 2011, social media have been integrated in the communication organisation set up for the emergency exercises and participate in the "media pressure simulations". The issue at stake is to take into account factors such as the immediacy of the reactions, the urgency of the need for information and the speed of dissemination of incorrect or incomplete information, etc. In such emergency situations, whether simulated or real, ASN takes care to ensure the consistency, speed and clarity of the information delivered to the audiences, including when several players are involved.

ASN news is followed and passed on by more than 13,000 subscribers on Twitter, nearly 25,000 on LinkedIn and nearly 4,000 on Facebook.

1.1.3 The ASN/IRSN exhibition

As part of their duty to inform the public, ASN and the Institute for Radiation Protection and Nuclear Safety (IRSN) have created educational content to develop knowledge of nuclear activities and radiation protection among high school pupils, students, employees, hospital personnel, patients, etc. and more generally the public at large.

This content exists in several forms at present: an exhibition of some 80 display boards plus educational leaflets. These vectors are designed to provide information on radioactivity – whether natural or artificial – its uses, its implications and its effects on humans and the environment. Requests for information concerning this popularised content, the booklets and the exhibition are to be made to *info@asn.fr*.

At the end of 2020, a website bringing together all the resources of the ASN-IRSN exhibition was put on line.

ASN-IRSN exhibition accessible at the address: www.irsn.fr/expo-asn-irsn/Documents/index.html

1.1.4 The ASN Information Centre

Any citizen can address requests for information to ASN, either online (at the address *info@asn.fr*), by letter or by telephone. In 2020, the Centre responded to more than 600 requests in diverse areas (technical questions, requests for transmission of administrative documents, information relative to the environment, publications, documentary searches, etc.).

Information and iodine tablet distribution campaigns

Every 7 years or so, an information and stable iodine tablet distribution campaign targets the populations living in the vicinity of Nuclear Power Plants (NPPs) over the entire zone covered by the Off-Site Emergency Plans (PPI*) (see Chapter 4 point 1.1.1 b). Over and beyond the distribution of stable iodine tablets, the aim is to develop citizens' awareness of the nuclear risk and knowledge of the means to protect themselves against it.

An information and iodine tablet distribution campaign began in 2019 in a radius of 10 to 20 kilometres (km) around the NPPs further to the extension of the PPIs. It is complementary to the 2016-2017 campaign which concerned residents in the 0-10 km zone. Led by the Ministry of the Interior, this campaign involves the Ministries of Health and Solidarities and of National Education, ASN, the Institute for Radiation Protection and Nuclear Safety (IRSN), pharmacists, general practitioners, mayors, Local Information Committees (CLIs) and EDF.

In January 2021, the collection rate of iodine tablets from pharmacies had reached 85% for schools and about 25% for private individuals. These results are lower than for the preceding campaign (2016) even though the population was informed in the same manner (personally addressed postal mail, press relations, social networks, toll-free number, website); this can be explained by the fact that this type of operation is completely new in these regions. In effect, stable iodine tablets have been distributed in the 0-10 km zone since 1997, but only since September 2019 in

the 10-20 km zone. Tablets shall be sent by post to the people who have not collected them from a pharmacy at the beginning of 2021, as was done in the previous campaigns in the 0-10 km zone.

ASN considers that development of the radiation protection culture of the population living in the 10-20 km zone is a major area for progress for all the actors, and that additional measures must be taken without waiting for the next distribution campaign planned for 2022.

** PPI: French acronym meaning "Off-site Emergency Plan: a local plan put in place by the Prefect to manage the consequences on the neighbouring population of an accident occurring on a site presenting risks.*

1.2 ASN and the professionals

ASN produces specific publications, organises and takes part in numerous symposia and seminars to make known the regulations, to raise professionals' awareness of the responsibilities and the implications of nuclear safety and radiation protection, and lastly to encourage the reporting of significant events.

1.2.1 Making known the regulations and enhancing the radiation protection culture

ASN considers that having clear regulations based on the best safety standards is an important factor for improving the safety of Basic Nuclear Installations (BNIs). Over the last few years it has thus undertaken a major overhaul of the technical and general regulations applicable to BNIs, while always being attentive to the clarity and completeness of the information delivered to the professionals concerning these regulations. The same goes for radiation protection of workers and patients in the medical and industry sectors: ASN makes guides, practical sheets and reference manuals available to everyone.

The *Contrôle* magazine and the *Les Cahiers de l'ASN* booklets

Considered a reference by informed audiences, *Contrôle* magazine was published quarterly for more than 20 years until the end of 2016 (more than 200 issues). The last 100 issues of *Contrôle* magazine can still be consulted on *asn.fr*. A *Cahier de l'ASN* booklet provides popularised information on the implications and processes of the 4th periodic safety review of the 900 Megawatts electric (MWe) nuclear reactors.

The subjects at the core of media attention

A number of subjects received particular attention from the media and the public opinion in 2020: the Flamanville Evolutionary Power Reactor (EPR reactor) construction site, the 4th periodic safety review of the 900 Megawatts electric (MWe) reactors – particularly that of reactor 1 of the Tricastin Nuclear Power Plant (NPP) – the final shutdown and decommissioning of the Fessenheim NPP, the detection of an abnormal tritium value in the River Loire.

The year was marked by the Covid-19 pandemic. Numerous questions were asked on the safety of the nuclear installations and the organisation put in place by ASN for their oversight. The journalists moreover remained extremely attentive to the question of the anomalies in the nuclear equipment welds announced by EDF in 2018-2019. The anomalies in the Flamanville EPR reactor penetration welds were the subject of numerous interactions with the press. The incidents that occurred on certain nuclear sites (Flamanville, Golfech, Bugey, Dampierre-en-Burly and Gravelines) also interested the local media.

With regard to current news in the medical sector, the press focused in particular on dose optimisation, exposure to radon, and the distribution of iodine tablets around the NPPs.

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 2020, it published an update of Guide No. 32 "In vivo *nuclear medicine facilities: minimum technical design, operating and maintenance rules*" and of Guide No. 30 "*Policy with regard to risks and drawbacks of the BNIs and the licensees' integrated management system*".

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. In this section ASN has published the series of medical sector inspection results in 2019 (nuclear medicine, radiotherapy, brachytherapy and fluoroscopy-guided interventional practices). The professionals are directed to the online services platform for their online formalities where necessary.

1.2.2 A platform to facilitate online procedures

Declaration of possession of devices and sources, declaration of radioactive substance transport activities or declaration of modifications concerning on-site transport: month by month, the regulatory procedures are gradually being transformed into online services accessible *via* the *teleservices.asn.fr* portal. ASN is thus working to facilitate administrative procedures for professionals, which helps to promote the culture of safety and radiation protection. The reporting of significant events in the transport of hazardous materials is now done online, as is the case for significant events concerning radiation protection, guaranteeing that all the stakeholders are informed immediately.

1.2.3 A newsletter and regular meetings to share good practices

The newsletter *Patient safety – Paving the way for progress* was created in March 2011 to keep radiotherapy professionals informed of the lessons learned from significant radiation protection events. Since July 2019 it alternates between subjects devoted to radiotherapy, diagnostic medical imaging (conventional, computed tomography scanning and nuclear medicine) and fluoroscopy-guided interventional practices. Produced by multidisciplinary working groups coordinated by ASN, the newsletter offers a thematic presentation of the good practices of medical departments and the recommendations developed by the learned societies of the discipline concerned and the health and radiation protection institutions.

Two issues were published in 2020: "Safeguarding the medication circuit in nuclear medicine" (March) and "Prior radiotherapy treatments" (July).

In medical imaging, an "Experience feedback" sheet was also published on the "Choice of activimeter calibration channel" (March).

These publications are available on *asn.fr*.

ASN regularly participates in the congresses of the medical and radiation protection sector. Due to the health crisis, the meetings that ASN habitually attends, such as the "Days of the French Association of Radiographers" (AFPPE), the French Radiology Days and the Congresses of Radiation Protection Expert-Officers, were postponed or held as virtual events.

The production of a resolution

In 2020, in response to numerous questions it had received concerning the way it established its resolutions, ASN proposed to describe this complex process in a very short animated film. It is quite a challenge to explain several years of work involving examinations, inspections, expert assessments and work by Advisory Committees of Experts and involvement of the public and other audiences in just 3 minutes! The film *La fabrique de la décision* (*The development of a resolution*), an educational aid complementing those that already exist, was made public prior to the consultation on the conditions of continued operation of the 900 Megawatts electric (MWe) reactors beyond 40 years.

ASN is also the initiator of national and regional thematic professional seminars. An information campaign on the security for radioactive sources was organised in 2020 and deployed in Lille, Caen, Marseille and Nantes. The seminars intended for medical institutions were postponed till 2021 on account of the health crisis. These events provide the opportunity to interchange with specialised audiences, to enhance knowledge of the regulations and the 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 make themselves available to answer more than 500 requests from the press, including 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.

Each year at the time of the publication of its annual *Report on the state of nuclear safety and radiation protection in France*, ASN meets regional press journalists. In 2020, on account of the health crisis, ASN informed the media of its oversight activity news by adopting a new format of regional video conferences. These conferences were held from the end of May to mid-September. They brought together a large number of journalists.

At these meetings, the ASN regional divisions report on ASN's assessment of the safety of the facilities in the regions. The current regional news in the area of radiation protection is addressed, whether it concerns the medical and industrial sectors, sites contaminated by radioactive substances, population exposure to radon, or former mining sites, etc.

1.4 ASN's relations with elected officials and institutional bodies

Each year, ASN presents its annual *Report on the state of nuclear safety and radiation protection in France* to the Parliamentary Office for the Evaluation of Scientific and Technological Choices (OPECST). This report, which constitutes the reference document on the state of the activities regulated by ASN, is also submitted to the President of the Republic, to the Government and to Parliament. It is sent out to more than 2,000 addressees: heads of administrative authorities, elected officials, licensees and persons/entities in charge of regulated activities or installations, associations, professional unions and learned societies, etc.

Each year ASN is given about ten hearings before Parliament on its activity, on subjects relating to nuclear safety and radiation protection and in the context of the budget bill. ASN also maintains regular contact with the national and local elected officials, advising and assisting them at their request.

During the lockdown period in 2020, ASN made itself available on several occasions to present its assessment of the state of nuclear safety and to explain its various organisational arrangements. The ASN regional divisions responded to the requests of the Departmental Councils or the CESER[1] on subjects relating to nuclear safety and radiation protection (ageing of the nuclear fleet, management of radioactive waste, etc.).

1.5 International cooperation in the field of communication

ASN invests itself on the international scene to promote experience feedback and the sharing of best practices in informing the public. ASN thus regularly participates in working groups on communication and informing the various audiences, coordinated by the International Atomic Energy Agency (IAEA), and in cooperation missions funded by the European Commission (see chapter 6). Each year ASN receives foreign delegations to share its practices. ASN is currently chairing the *Working group on public communication* of the Nuclear Energy Agency. In this context it is participating in two projects, one relative to a course in communication on the nuclear risk, the other relative to ways of enhancing the credibility of the nuclear regulators.

In early 2020, ASN was able to interchange with its Belgian and Spanish counterparts on its practices for informing and involving the various audiences. Relations between information departments of the nuclear regulators were maintained by virtual means and enabled the crisis communication practices deployed in the context of the pandemic to be shared.

1. *Regional Economic Social and Environmental Council.*

1.6 The ASN staff and information

In order to issue high-quality, clear and understandable information, ASN offers its staff training in spoken and written communication and emergency management, tailored to their various responsibilities.

ASN has a duty to inform the public in the event of an emergency situation[(2)]. In order to prepare for this, ASN staff receive specific training and take part in emergency exercises. About ten emergency exercises are held each year, 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).

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 nuclear activity licensees 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 Basic Nuclear Installation licensees
All BNI licensees must establish an annual report concerning more specifically their situation and the steps they take with regard to the prevention of risks for public health and the environment[(3)]. ASN has published recommendations for the drafting of these reports in a guide published in 2010 (ASN Guide No. 3). The reports are often presented at CLI meetings (see point 2.3.4).

Access to information in the possession of the licensees
Since the Act on Transparency and Security in the Nuclear Field (called the "TSN Act") came into force, the nuclear sector has a system governing public access to information.

In application of the Environment Code, licensees must communicate to any person who so requests, the information they hold on the risks their activity presents for public health and the environment and on the measures taken to prevent or reduce these risks.

This right to information on the risks also concerns those responsible for the transport of radioactive substances when the quantities involved exceed the thresholds set by law.

The Commission for Access to Administrative Documents
If a licensee refuses to communicate a document, the requesting party can refer the issue to the Commission for Access to Administrative Documents (CADA), an independent administrative Authority. If the opinion of the CADA is not followed, the dispute may be taken before the administrative jurisdiction which will rule on whether or not the information in question can be communicated.

ASN is particularly attentive to the application of this right to information, in compliance with the protection of interests provided for in law (security, business confidentiality, etc.).

2.2 Information given to populations living in the vicinity of Basic Nuclear Installations

The Energy Transition for Green Growth Act (known as 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.

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 2020, 90 draft guides, opinions and resolutions were thus submitted for public consultation, including the draft concerning the conditions for continued operation of the 900 MWe reactors beyond 40 years.

2.3.1 Consultation of the public on draft ASN resolutions

Article L. 123-19-1 of the Environment Code provides for a procedure of consultation of the public *via* the Internet on draft resolutions other than individual resolutions having an impact on the environment.

ASN has decided to apply this widely. Consequently, all draft ASN regulations concerning BNIs, including those relating to nuclear pressure equipment, are considered as having an impact on the environment and are therefore subject to public participation. The same approach is applied for the ASN regulations relative to the transport of radioactive substances.

ASN's regulations relating to radiation protection are also submitted to public participation if they concern activities involving significant discharges into the environment, producing a significant quantity of waste, causing significant nuisance for the neighbourhood or representing a risk for the people living nearby and the surrounding environments in the event of an accident.

Lastly, although they are not of a statutory nature, ASN applies this same procedure to certain draft guides and draft opinions.

Three consultations in 2020 concerned draft ASN regulations.

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2. Pursuant to Article L. 592-32 of the Environment Code.
3. See Article L. 121-15 of the Environment Code.

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.

2.3.2 Consultation of the public on draft individual resolutions

The individual resolutions[4] on nuclear safety and radiation protection can form the subject of several public consultation procedures which are presented below.

The public inquiry

In application of the Environment Code, the BNI creation authorisation and decommissioning applications form the subject of a Public inquiry[5]. The file that undergoes the public inquiry contains the impact analysis and the risk control analysis, among other things. The latter provides a clearly understandable inventory of the risks that the projected installation represents and an analysis of the measures taken to prevent these risks. This analysis also includes a non-technical summary intended to facilitate the general public's understanding of the information it contains.

Since 2017, the public inquiry files can be consulted[6] online throughout the duration of the inquiry, and are provided in printed format in one or more predetermined places as soon as the public inquiry opens. The preliminary safety report (a more technical document) is not included in the public inquiry file but can be consulted throughout the inquiry period under the conditions set by the order governing the inquiry.

Disclosure of drafts on *asn.fr*

The individual resolutions that are not subject to public inquiry and are likely to have a significant effect on the environment (such as BNI modification projects or operating conditions that could cause a significant increase in water intakes or discharges) are subject to an Internet consultation. In this context, the licensee's file is made available to the public on *asn.fr*.

During 2020, 43 consultations concerned draft individual resolutions relating to BNIs and the transport of radioactive substances and 48 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 these files.

Digital technologies and citizen participation practices are bringing ASN to change the public consultation framework to ensure effective participation of the public in the decision-making process.

2.4 The actors in the area of information

2.4.1 High Committee for Transparency and Information on Nuclear Security

The High Committee for Transparency and Information on Nuclear Security (HCTISN), created by the TSN Act, is a body that informs, discusses and debates on nuclear activities, their safety and their impact on human health and the environment. It can also deal with any issue concerning the accessibility of nuclear security information and propose any measures such as to guarantee or improve transparency.

The HCTISN develops opinions and makes them public. It organises four plenary meetings per year, at which major topical subjects are presented and discussed: all the presentations can be consulted online at *hctisn.fr*. The ASN Chairman is a member of the High Committee; ASN sits on the board of the HCTISN in an advisory capacity, takes part in its various working groups and regularly provides information on the subjects on plenary session agendas.

In 2019, with the assistance of ASN, the IRSN, EDF and the National Association of Local Information Committees and Commissions (Anccli), the HCTISN set up the consultation on the continued operation of the 900 MWe reactors. At the end of 2020, all the consultation actors presented the way in which they had taken account of the public and other audiences contributions and expectations collected in 2019. All the documents relating to this consultation can be consulted on the website *concertation.suretenucleaire.fr*.

4. Individual resolution: resolution that applies to a licensee for a given installation.
5. In application of the provisions of Article L. 123-12 of the Environment Code.
6. See: 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.

The functional framework of the Local Information Committees and the Site Monitoring Committees

The Local Information Committees (CLIs), whose creation is incumbent upon the President of the Departmental Council, comprise various categories of members: representatives of *département* General Councils, of the municipal councils or of the deliberative assemblies of the groups of communities and the Regional Councils concerned, members of Parliament elected in the *département*, representatives of environmental protection associations or of economic interests and representatives of employee trade union and medical profession union organisations, and qualified personalities. The representatives of State services, including ASN, and of the licensee have an automatic right to participate in the work of a CLI in an advisory capacity. The TECV Act provides for the participation of foreign members in the CLIs of border *départements*. The CLIs are chaired by the President of the Departmental Council or by an elected official from the *département* designated by the President for this purpose. They receive the information they need to fulfil their functions from the licensee, from ASN and from other State services. They may request expert assessments or have measurements taken on the installation's discharges into the environment. All Basic Nuclear Installation (BNI) sites have a CLI, except for the Ionisos facility in Dagneux in the Ain *département*.

The CLIs are funded by the regional authorities, and by ASN which devotes about 1.25 million 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 CLIs in application of the Decree of 7 February 2012[*].Providing frameworks for discussion and information concerning the actions of the licensees of the targeted installations, they promote the informing of the public. They are, for example, kept informed of the incidents and accidents affecting the installations – and even of installation creation, extension or modification projects.

ASN is invited to the meetings of the monitoring committees for defence sites and former mining sites.

** In application of Article L. 125-2-1 of the Environment Code.*

2.4.2 The Institute of Radiation Protection and Nuclear Safety

The IRSN implements a policy of information and communication that is consistent with the objectives agreement signed with the Government.

The TECV Act obliged the IRSN to render public the opinions it issues to the authorities who referred matters to it. Thus since March 2016, the 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 the IRSN in response to ASN's request. On subjects of concern that prompt questions on the part of the public or the public actors, ASN and the IRSN ensure that their statements are properly coordinated in order to guarantee coherent, clear and consistent information.

Alongside this, each year the 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, the IRSN can request the participation of informed audiences, neighbourhood residents, or even the public at large. The IRSN in this case provides them with information that is complete and understandable, and in return notes their subjects of concern and their questions in order to integrate them in the expert assessment work carried out for ASN.

2.4.3 The Local Information or Monitoring Committees

The CLIs often have a general mandate of monitoring, informing and consultation with regard to nuclear safety and radiation protection. They analyse the impacts on people and the environment of the nuclear activities of the installations of the nuclear sites around which they have been set up[7].

ASN considers that the smooth functioning of the CLIs contributes to safety and it maintains a meaningful dialogue with them. It is attentive to ensuring that the CLIs are as fully informed as possible, including by attending their public meetings. In partnership with Anccli, ASN fosters the networking of the CLI special advisors and gives the CLIs the necessary tools and assistance for them to provide reliable information to "layman" audiences. ASN assisted the CLIs at their request: on technical issues through its inspectors, and on questions of dissemination of information through its communication supervisors. The ASN-IRSN exhibition was made available to the CLIs whenever requested.

The ASN inspectors can also give the CLI representatives the opportunity to take part in inspections[8]. They motivate the BNI licensees to facilitate CLI access to files of the procedures in which their opinion will be required, and encourage involving the CLIs in the preparation of emergency exercises.

7. The operating framework for the CLIs is defined by Articles L. 125-17 to L. 125-33 of the Environment Code and by Decree 2008-251 of 12 March 2008 relative to the CLIs for the BNIs, and by Decree 2019-190 of 14 March 2019 codifying the provisions applicable to BNIs, to the transport of radioactive substances and to transparency in the nuclear field.

8. In the current situation, only the ASN inspectors and the experts accompanying them have an enforceable right of access to the licensee's facilities. This means that the consent of the licensee is necessary for observers from CLIs to participate in inspections.

In the same spirit, ASN considers that the development of a diversified range of expertise in the nuclear field is essential to enable the CLIs to base their opinions on expert assessments other than those carried out for the licensee or ASN itself.

The CLIs and informing the various audiences

The CLIs organise plenary meetings and set up specialist commissions. The TECV Act obliges each CLI to hold at least one public meeting per year. ASN promotes exchanges of good practices in order to make these public meetings moments of worthwhile discussion and opportunities to contribute to having a well-informed population.

The majority of the CLIs have a website or have pages on the website of the local authority that supports them; some twenty CLIs publish a newsletter (sometimes as inserts in the news bulletin of a local authority).

In 2020, the CLI conference was entirely restructured so that it could be held as a virtual event extending over one week. It brought together 340 participants *via* a digital platform.

The programme focused on two key topics among the concerns of the CLIs: crisis management, based on the lessons learned from Covid-19 and from the Lubrizol accident, and post-accident management.

The participants were also invited to a special session of the HCTISN plenary meeting devoted to taking account of the public's contributions in the consultation concerning the 4th periodic safety review of the 900 MWe reactors.

2.4.4 National Association of Local Information Committees and Commissions

Article L. 125-32 of the Environment Code provides for the setting up of an association of CLIs (see point 2.4.3), and the Decree of 12 March 2008 details the mandate of this federation. Anccli brings together the 34 French CLIs and the 34 committees put in place for the defence-related installations. The Anccli has a scientific committee and has set up five thematic advisory groups ("Radioactive materials and waste", "Post-accident – territories", "Safety", "Decommissioning" and "Health"). It is also heavily involved in the discussion and interchange bodies set up by its partners (HCTISN, ASN, IRSN, etc.).

Partnership with ASN

Anccli interchanges with ASN very regularly and participates in several of its permanent or occasional working groups. Anccli fosters the enhancing of the technical competence of CLI members by organising thematic seminars with the IRSN in the context of its expert assessment work carried out for ASN. Anccli, with ASN and the IRSN, maintains a technical dialogue on the high-stake issues and takes part in the public consultations on nuclear questions. Each year, in collaboration with Anccli, ASN organises the national CLI Conference which is attended by more than 250 people and represents a day of experience-sharing and collective reflection on the issues common to the CLIs.

The activity of Anccli

Anccli runs the network of CLIs that it represents. By ensuring a regular watch and issuing clarifications and information that can be readily understood by the general public, Anccli helps give the CLIs the means to fulfil their duties of informing the various audiences. Attentive to the concerns of the CLIs and in relation with diverse sources of expertise, Anccli conducts national reflections on nuclear safety issues and widely passes on the results of this work (Anccli positions) to the national and European bodies and to local elected officials and CLI audiences.

CHAPTER 06

INTERNATIONAL RELATIONS

06 International relations

Through its participation in a range of bilateral, European and multilateral cooperation frameworks, the French Nuclear Safety Authority (ASN) aims to promote the adoption of ambitious international baseline requirements. Within these frameworks, ASN also ensures that the French positions and doctrines are made known and advantage is taken of the best practices internationally to achieve progress in nuclear safety and radiation protection in France.

As part of its actions, and within its area of competence, ASN proposes France's positions on international negotiations to the Government and represents France in international and community entities in this field.

1. ASN's objectives regarding international relations

The international arena is a strategic challenge to which ASN devotes particular attention and resources. ASN's actions in this field aim for continuous improvement in safety, based on changing knowledge and sharing of practices, in particular in terms of regulation and oversight. This action also aims to ensure ambitious harmonisation of international requirements regarding nuclear safety and radiation protection.

ASN's objectives internationally are thus organised around four main points:

- to promote the creation of ambitious international baseline requirements;
- to make the French and European positions and regulations known to its counterparts;
- to encourage international work on the priority technical issues identified by ASN;
- to benefit from the best international practices to achieve progress in nuclear safety and radiation protection in France.

To achieve these goals, ASN maintains close bilateral relations with numerous countries. It also takes part in numerous multilateral exchanges within bodies and organisations with a variety of statuses, whether at European level, notably with the European Nuclear Safety Regulators Group (ENSREG) and the Western European Nuclear Regulators Association (WENRA) or, more broadly, at an international level, notably with the International Atomic Energy Agency (IAEA) or the Nuclear Energy Agency (NEA) of the Organisation for Economic Cooperation and Development (OECD).

Through its bilateral relations, ASN's goal is direct exchanges with its counterparts on current issues or on particular points regarding regulation or oversight. These exchanges are an opportunity for ASN to share its experience and compare its positions and practices in order to progress. They also shed an outside light on position statements, technical questions or societal acceptability, thereby enriching the national debates and consolidating decisions and resolutions. They also enable ASN to be directly informed of the nuclear safety and radiation protection situation at its counterparts. In this respect, ASN's relations with its counterparts in neighbouring countries are of particular interest. They are also essential in the management of emergency situations.

Europe is one of the priority areas for ASN's international actions. ASN's goal is to contribute to the sharing, harmonisation and improvement of nuclear safety and radiation protection. Within European associative or community circles, ASN's aim is to share its vision of the priority safety issues, to compare its analyses and to conduct discussions on practices in use at its counterparts, in order to help establish and maintain a high level of stringency in nuclear safety and radiation protection at the European level, which can be based on harmonised baseline requirements and doctrines established together.

The final ASN goal is for nuclear safety and radiation protection best practices and regulations to be shared outside Europe. On this point, it aims to ensure that European doctrine, which promotes the highest levels of stringency, constitutes a benchmark worldwide, notably for countries adopting new reactor models and countries gaining access to nuclear energy for the first time. These international exchanges, which take place in a variety of circles, also enable ASN to benefit from international best practices and experience, thus helping to advance nuclear safety and radiation protection in France.

ASN therefore works within three main cooperative frameworks. It aims to ensure that a constant and balanced presence is maintained within each one, considering that each one is specific and that the complementarity between them contributes to the target of harmonisation and continuous improvement of nuclear safety.

2. The European framework for ASN's international relations

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 and its working groups

The Treaty instituting the European Atomic Energy Community (EURATOM) was signed on 25 March 1957 and constitutes primary law in the field, allowing the harmonised development of provisions allowing a strict regime of oversight for nuclear safety and security and radiation protection. The European Union (EU) Court of Justice, considering that the fields of radiation protection and nuclear safety form an inseparable whole, 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.

ASN experts participate in the work of the EURATOM Treaty committees and working groups:
- group of experts specified in Article 31 (Basic Radiation Protection Standards);
- group of experts specified in Article 35 (verification and monitoring of radioactivity in the environment);
- group of experts specified in Article 36 (information concerning the monitoring of radioactivity in the environment);
- group of experts specified in Article 37 (notifications relative to radioactive effluent discharges).

Two video-conference meetings were held in 2020, along with a seminar on the radiosensitivity of children.

2.2 The European Euratom Directive on the Safety of Nuclear Facilities

The Council 2009/71/Euratom Directive of 25 June 2009, revised in 2014 following the accident at the Fukushima Daiichi NPP, establishes 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*).

It notably makes provision for greater powers and independence for the national safety regulators, reinforces requirements regarding transparency, sets an ambitious safety objective for the entire European Union (derived from the baseline safety requirements produced by the WENRA), establishes a European peer review system for safety topics and requires periodic safety reviews after 10 years. It also reinforces provisions concerning education and training.

This Directive and its amendment are transposed into French law.

It should however be noted that European legislation does not yet enshrine in law the institutional independence of the safety regulators. In 2020, ASN coordinated the drafting of France's second national report on the implementation of the provisions of the Directive, which was transmitted to the European Commission in July 2020.

2.3 The European Euratom Directive on the Management of Spent Fuel and Radioactive Waste

On 19 July 2011, the Council of the EU adopted a Directive establishing a community framework for the responsible and safe management of spent fuel and radioactive waste (Directive 2011/70/Euratom). The adoption of this Directive contributes to reinforcing safety within the EU, by making the Member States more accountable for the management of their spent fuels and their radioactive waste.

This Directive is legally binding and covers all the aspects of spent fuel and radioactive waste management, from production through to long-term disposal.

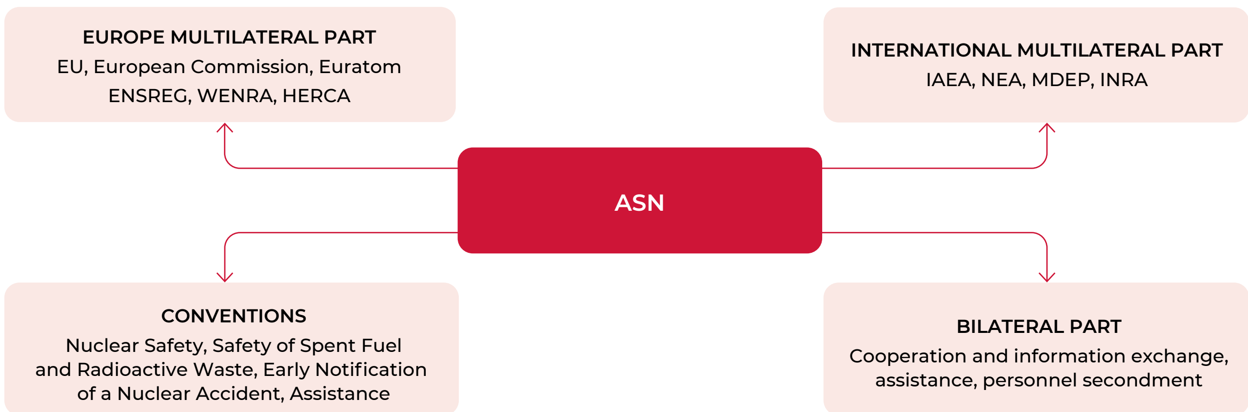
It reiterates the prime responsibility of the producers and the ultimate responsibility of each Member State to ensure the management of the waste produced on its territory, making sure that the necessary measures are taken to guarantee a high level of safety and to protect workers and the general public against the dangers of ionising radiation.

It clearly defines the obligations regarding the safe management of spent fuel and radioactive waste and requires that each Member State adopt a legal framework for safety issues, making provision for the creation of:
- a competent regulatory authority with a status that guarantees its independence from the waste producers;
- authorisation procedures involving authorisation applications examined on the basis of the safety cases required from the licensees.

The Directive regulates the drafting of the national spent fuel and radioactive waste management policies to be implemented by each Member State. More specifically, it requires each Member State to establish a legislative and regulatory framework designed to set up national programmes for the management of spent fuel and radioactive waste.

The Directive also contains provisions concerning transparency and participation of the public, the financial resources for management of spent fuel and radioactive waste, training, as well as obligations for self-assessment and regular peer reviews. These aspects constitute major advances in reinforcing the safety and accountability of spent fuel and radioactive waste management in the EU. The Energy Transition for Green Growth Act (TECV Act) and the Ordinance of 10 February 2016 ensured that the provisions of the Directive were transposed into French law.

ASN action on the international stage



WENRA publishes a set of reference levels for research reactors

During its plenary meeting of November 2020, the Western European Nuclear Regulators' Association (WENRA) approved a set of safety reference levels applicable to research reactors.

Implementing those already approved by WENRA for power reactors and applicable to the field of research reactors, the WENRA working group in charge of these facilities supplemented its approach by drafting particular safety reference levels to address the specificity and diversity of these reactors.

331 safety reference levels are thus now available for the 18 member countries of WENRA, as well as for Russia as an associate member, and for the 12 observer countries.

The authorities of the WENRA member countries will be able to begin incorporating these levels into their national regulations, thus contributing to harmonisation of the regulations in this area.

Publication of these safety reference levels is a milestone for WENRA, more particularly at the European level, as one of its main objectives is to reinforce harmonisation of regulations between countries, by establishing ambitious safety objectives.

This work reiterates the central position of the reference levels defined by WENRA in the hierarchy of documents and reports produced by the association during the course of its activities.

2.4 The Euratom European Directive on Radiation Protection Basic Standards

Directive 2013/59/Euratom of 5 December 2013 on Radiation Protection Basic Standards applies to the justification, optimisation and limitation of doses, regulatory control, preparedness for emergency situations, training and other related fields (for example the radon risk, Naturally Occurring Radioactive Materials and Construction Materials – NORM). Three Decrees, published in June 2018, which in particular modify the regulatory parts of the Defence, Environment, Public Health and Labour Codes, transposed it into French law.

2.5 The European Nuclear Safety Regulators Group (ENSREG)

The ENSREG was created in 2008 and brings together experts delegated by the Member States of the EU, with the aim of supporting the European Commission in its legislative initiatives in the field of nuclear safety and radiation protection.

The ENSREG helped bring about a political consensus in the drafting of European Directives on nuclear safety and the management of spent fuel and waste. The ENSREG also took part in the process to revise the Nuclear Safety Directive, following on from the assessment and analysis of the Fukushima Daiichi NPP accident.

The activities of the ENSREG are underpinned by three working groups, devoted to installations safety and international cooperation (WG1), the safe management of radioactive wastes and spent fuels (WG2) and transparency in the nuclear field (WG3) respectively. ASN contributes to the work done by each of them.

In accordance with the Safety Directive of 2014, the ENSREG organises European topical peer reviews. The first of these exercises concerned the management of the ageing of electricity generating nuclear reactors and research reactors with a power of 1 Megawatt (MW) or greater. Each of the participating countries first of all drafted a national report, which was then examined in 2018 by experts appointed by the Member States. This examination led to the drafting of a report on the generic results and a report on the specific results per country. All of these reports were adopted by a plenary session of the ENSREG and published on the ENSREG site at the end of 2018. On this basis, the national action plans from the countries were submitted in September 2019. They are available on the ENSREG website. The national report and the national action plan for France are also available on the ASN website, in both French and English.

In 2020, the Member States began their work on the second topical peer review. They first of all drew conclusions from the experience gained during the first exercise and then set up a steering committee headed by a member of the ASN Commission. On the basis of a proposal from the WENRA, they also chose the topic of fire hazard management for this second topical peer review.

At the end of 2020, ASN also published the closing report for the French national action plan on the implementation of additional safety measures following the peer review of the European stress tests.

2.6 The European Community Urgent Radiological Information Exchange system (ECURIE)

ECURIE is one of the rapid action systems set up by the European Commission, which has an information exchange network for receiving and triggering an alert and thus for rapidly circulating information within the EU in the event of a radioactive emergency or major nuclear accident.

This system was put into place in 1987 by a Decision of the Council of the EU of 14 December 1987, notably in the wake of the Chernobyl (Ukraine) accident in 1986. This Decision came into force on 21 March 1988 and was ratified by all the Member States of the EU and a certain number of third-party countries, such as Switzerland and Turkey.

2.7 The Western European Nuclear Regulators' Association (WENRA)

The WENRA was created in 1999 at the initiative of ASN and is an association whose members are the heads of the safety regulators of the European countries with electricity generating reactors. Other European countries, or major non-European countries with power generating reactors, take part in WENRA's activities as either observers or associate members.

The WENRA's actions are based on experience sharing by safety regulators with a view to developing a common approach and harmonised safety rules for reactors, waste management facilities and research reactors.

The WENRA draws on three working groups, each with competence in a field of nuclear safety:
- the Reactor Harmonisation Working Group (RHWG);
- the Working Group on Radioactive Waste and Decommissioning (WGWD);
- the Working Group on Research Reactors (WGRR).

Each of these the groups has defined "reference levels" for each technical topic, based on the most recent standards from the IAEA and on the strictest approaches adopted in the EU.

The WENRA strategic committee met in July and examined the concrete implementation of the strategy defined by the WENRA for the period 2019-2023. In November 2020, the WENRA held its plenary meeting remotely, under the Chairmanship of Olivier Gupta, ASN Director General. This main results of this meeting were:
- the adoption of reference levels for research reactors (see box);
- the approval of the updated reference safety levels for nuclear power reactors;
- the creation of cross-cutting areas for work between the three working groups, to reinforce harmonisation when the reference levels for common topics are established.

In addition, following the work carried out under the aegis of the RHWG, the WENRA sent the ENSREG a proposal in 2020 for "management of fire hazard" to be the subject of the next topical peer review, a periodic exercise stipulated in the 2014 Safety Directive (see above). The ENSREG approved this proposal in November 2020 and the WENRA will thus carry out work to draft the technical specifications in 2021.

2.8 The association of the Heads of European Radiological Protection Competent Authorities (HERCA)

In the field of radiation protection, HERCA, founded in 2007, also at the instigation of ASN, is an informal association of the Heads of the European Radiological protection Competent Authorities. Its aim is to reinforce European cooperation in radiation protection and to harmonise national practices.

HERCA now comprises 56 authorities from 32 European countries, including the 27 members of the EU, Iceland, Norway, the United Kingdom, Serbia and Switzerland. ASN is responsible for the technical secretariat.

Six expert groups are currently working on the following themes:
- practices and sources in the industrial and research fields;
- medical applications of ionising radiation;
- preparedness for and management of emergency situations;
- veterinary applications;
- natural radiation sources;
- education and training.

HERCA is preparing a strategy with its main focus being reinforced cooperation between the radiation protection Competent Authorities. This first of all requires shared knowledge of the various national approaches, in order to be in a position to harmonise the regulatory approaches. In 2020, HERCA thus analysed the documents produced by the International Commission on Radiological Protection (ICRP) concerning changes to radiation protection standards in order to identify areas warranting specific attention for changes to the regulations. In 2021, it will be organising exchanges with the ICRP on the subject. It also plans to organise several seminars, notably concerning the implementation of national radon risk management plans or the deployment of radiation protection experts and officers as required by the European Directive on Radiation Protection Basic Standards.

2.9 The European Commission's assistance programmes

Between 2007 and 2020, the actions of the EU with regard to assistance and cooperation for third-party countries in the field of nuclear safety continued under the Instrument for Nuclear Safety Cooperation (INSC). In 2020, *via* the INSC, ASN took part in a project.

As of 1 January 2021, a new European Instrument for Assistance and Cooperation in Nuclear Safety (EINS), currently being approved by the European Parliament, will take the place of the previous instrument. For the period from 1st January 2021 to 31st December 2027, the budget envelope stands at €300 million.

The goals of the new EINS instrument concern:
- the promotion and implementation of the strictest nuclear safety and radiation protection standards in nuclear facilities and for radiological practices in third-party countries;
- the implementation of frameworks and methods for application of effective checks on nuclear materials in third-party countries;
- the drafting and implementation of responsible strategies for the ultimate disposal of spent fuel, for waste management, for delicensing of facilities and for clean-out of former nuclear sites.

These instruments are supplemented by other international technical assistance programmes that respond to resolutions taken by the G8 or by IAEA to improve nuclear safety in third-party countries and which are financed by contributions from donor States and from the EU.

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3. The multilateral framework for ASN's international relations

At the multilateral level, cooperation takes place notably within the framework of the IAEA, a United Nations entity founded in 1957, and the NEA, created in 1958. These two agencies are the two most important intergovernmental organisations in the field of nuclear safety and radiation protection.

3.1 The International Atomic Energy Agency (IAEA)

The IAEA, a United Nations organisation based in Vienna, comprises 172 Member States. The IAEA's activities are focused on two main areas: one of them concerns the control of nuclear materials and non-proliferation and the other concerns all activities related to the peaceful uses of nuclear energy. In this latter field, two IAEA departments are tasked with developing and promoting nuclear energy on the one hand, and the safety and security of nuclear facilities and activities on the other.

In continuation of 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 NPP accident, the IAEA is in particular focusing its work on the following fields: Safety Standards and peer review missions.

Safety standards

The IAEA Safety Standards describe 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 comprises 24 highest level representatives from the safety regulators, appointed for a term of 4 years. It coordinates the work of five committees tasked with drafting documents in their respective fields: NUSSC (Nuclear Safety Standards Committee) for the safety of reactors, RASSC (Radiation Safety Standards Committee) for radiation protection, TRANSSC (Transport Safety

Standards Committee) for the safety of radioactive substances transport, WASSC (Waste Safety Standards Committee) for the safe management of radioactive waste and EPReSC (Emergency Preparedness and Response Standards Committee) for preparedness and coordination in a radiological emergency situation. Represented by ASN, France is present on each of these committees, which meet twice every year. Representatives of the various French organisations concerned also take part in the technical groups which draft these documents. Owing to the health situation, the 47th and 48th meetings of the CSS and the meetings of the five committees were held remotely. This working method, which was somewhat degraded owing to the restrictions on direct exchanges between delegates, enabled the most important work to be continued on drafting of the standards and was also the opportunity to share experience about safety management in an epidemic context.

Peer review missions

The IAEA proposes peer review missions in the field of safety to the Member States. These services consist of expert missions organised by the IAEA in countries which ask for them. Each team of auditors consists of experts from other Member States and from the IAEA. These audits are produced on the basis of the IAEA's baseline safety standards. Several types of audit are proposed, notably the IRRS (Integrated Regulatory Review Service) missions devoted to the national regulatory framework for nuclear safety and the working of the safety regulator, the Operational Safety Review Team (Osart) missions, in which experts from NPP licensees take part, devoted to the safety of NPPs in operation and, finally, the ARTEMIS missions, devoted to national radioactive waste and spent fuel management programmes. The audit results are written up in a report transmitted to the requesting country and may comprise various levels of recommendations and also recognise good practices. It is up to the requesting country to take account of the recommendations issued by the experts. A follow-up mission, the purpose of which is to verify the progress made in taking account of the recommendations, is held between 18 months and 3 years after the initial mission, depending on the type of audit. The latest ASN information concerning these missions is presented below.

IRRS Missions

The IRRS missions are devoted to analysing all aspects of the framework governing nuclear safety and the activity of a safety regulator. ASN is in favour of holding these peer reviews on a regular basis, with widespread dissemination of their results. It should be noted that, pursuant to the provisions of the 2009/71/Euratom Directive amended in 2014, the Member States of the EU are already subject to periodic and mandatory peer reviews of their general nuclear safety and radiation protection oversight organisation.

Owing to the global health situation, very few IRRS missions could be held in 2020 and those in which ASN should have taken part were postponed.

ASN also informed the IAEA of its desire to host an IRRS mission in France concerning the full range of its activities in the first half of 2024.

Osart Missions

In France, the performance of Osart missions, devoted to the safety of NPP operation, is requested from the IAEA by ASN, in coordination with the licensee of the NPPs, EDF.

Owing to the health crisis, the Osart mission initially scheduled for November and December 2020 in the Paluel NPP (Normandy) was postponed to the end of 2021.

The regional training and assistance missions

ASN responds to requests from the IAEA secretariat, in particular to take part in regional radiation protection training and in assistance missions. The beneficiaries are often countries of the French-speaking community.

In addition and still under the supervision of the IAEA, ASN is also involved in the Regulatory Cooperation Forum (RCF). This forum, created in 2010, aims to establish contacts between the safety regulators of countries adopting nuclear energy for the first time and the safety regulators of the leading nuclear countries, in order to identify their needs and coordinate the support to be provided, while ensuring that the fundamental principles of nuclear safety are met (independence of the regulator, appropriate legal and regulatory framework, and so on).

In 2020, in addition to a detailed review of the situation of the safety Authorities in Bangladesh, Belarus, Ghana, Morocco and Poland, the RCF reinforced its cooperation with the EU (INSC) and with "regional" safety regulator forums.

Harmonisation of communication tools

ASN takes part in the INES consultative committee, a body comprising experts in the evaluation of the significance of radiation protection and nuclear safety events, tasked with advising the IAEA and the INES national representatives of the member countries on the use of the International Nuclear and Radiological Event Scale (INES scale), and its updates. In this respect it was closely involved in the work to revise the INES scale manual recently published by the IAEA, the previous version of which was about ten years old. In addition to the updates to take account of advances in scientific knowledge, this revision also includes guidelines for communication in how to use the scale as well on how to apply it in a crisis.

Generally speaking, ASN is closely involved in the various actions carried out by the IAEA, providing significant support for certain initiatives, notably those which were developed following the Fukushima Daiichi NPP accident.

Management of nuclear and radiological emergency situations

ASN takes part in the IAEA's work to improve notification and information exchanges in radiological emergency situations.

On this subject, ASN takes part in the exercises 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 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 as well as provisions and tools for the assessment and prognosis in 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 2020, ASN took part in two ConvEx-1 and ConvEx-2 type exercises.

ASN also takes part in defining international assistance strategy, requirements and means and in developing the Response Assistance Network (RANET).

3.2 The Nuclear Energy Agency (NEA) of the OECD

Created in 1958, the NEA today comprises 36 member countries from among the most industrially developed states. Its main goal is to help the member countries to maintain and expand the scientific, technological and legal bases essential to the safe, environmentally-friendly and economical use of nuclear energy.

Within the NEA, ASN is more particularly involved in the work of the Committee on Nuclear Regulatory Activities (CNRA). It also takes part in the Committee on Radiological Protection and Public Health, the Radioactive Waste Management Committee, the Committee on Decommissioning of Nuclear installations and Legacy Management, as well as several working groups of the Committee on the Safety of Nuclear Installations.

The various NEA committees coordinate working groups of experts from the member countries. Within the CNRA, ASN contributes to the working groups on inspection practices, acquired operating experience, regulation of new reactors, safety culture, codes and standards, as well as public communication by safety regulators.

3.3 The Multinational Design Evaluation Programme (MDEP) for new reactor models

The MDEP is an association of safety regulators created in 2006 by ASN and the American Nuclear Regulatory Commission (NRC). The MDEP aims to share experience and approaches in the regulatory evaluation of new reactor models, to contribute to harmonisation of safety standards and their implementation.

Programme members

With the inclusion of Argentina in 2017, the MDEP now comprises 16 national safety regulators: AERB (India), ARN (Argentina), ASN (France), CCSN (Canada), FANR (United Arab Emirates), HAEA (Hungary), NNR (South Africa), NNSA (China), NRA (Japan), NRC (United States), NSSC (South Korea), ONR (United Kingdom), *Rostechnadzor* (Russian Federation), SSM (Sweden), STUK (Finland), TAEK (Turkey).

Organisation

The broad outlines of the work done within the MDEP are defined by a strategy committee and implemented by a technical steering committee, which has been chaired by an ASN deputy Director General since 2014. The work is carried out by working groups for the main nuclear reactor designs currently under construction around the world: the European PWR (Evolutionary Power Reactor – EPR) from Framatome, the AP-1000 from the American Westinghouse, the Korean APR-1400, the Russian VVER and the Chinese HPR-1000 (Hualong). A transverse working group concerns the inspection of nuclear component suppliers, the Vendor Inspection Cooperation Working Group (VICWG).

Each of the groups dedicated to a particular reactor model 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 2020

In 2020, having noted the end of the work being done on several reactor models, the programme members and its technical secretariat, NEA, initiated a review of the future framework for the MDEP as of 2022, the year of closure of the programme. Eight of its 16 members, including ASN, will be withdrawing at the end of 2021 and only the activities relating to the VVER and HPR-1000 reactors will be continuing. The new framework for international cooperation between the safety regulators concerned in the field of EPR reactor operations has yet to be defined.

Finally, this change makes provision for the transfer of Nuclear Component Supplier Inspection Activities (VICWG) to the NEA's CNRA committee (see above).

3.4 The International Nuclear Regulators' Association (INRA)

The International Nuclear Regulators Association (INRA) comprises the heads of the regulators of Canada, France, Germany, Japan, South Korea, Spain, Sweden, the United Kingdom and the United States. This association is a forum for regular and informal discussions concerning topical matters in these various countries 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.

In 2020, four remote meetings were held. They enabled the members primarily to discuss the management of the Covid-19 health crisis and its consequences for safety.

4. International Conventions

ASN is the national point of contact and the competent authority for the two nuclear safety conventions which deal with NPPs (Convention on Nuclear Safety) and spent fuel and radioactive waste (Joint Convention on the Safety of Spent Fuel Management and the Safety of Radioactive Waste Management). ASN is also the Competent Authority for the two Conventions dedicated to the operational management of the possible consequences of accidents (the Convention on the Early Notification of a Nuclear Accident and the Convention on Assistance in the case of a Nuclear Accident or Radiological Emergency).

4.1 The Convention on Nuclear Safety

The Convention on Nuclear Safety is one of the results of international discussions initiated in 1992 in order to contribute to maintaining a high level of nuclear safety worldwide.

The Convention sets a certain number of nuclear safety objectives and defines the measures which aim to achieve them. The Convention on Nuclear Safety was signed by France in 1994 and entered into force on 24 October 1996. At the end of 2020, it had 90 contracting parties.

The objectives of the Convention are to attain and maintain a high level of nuclear safety worldwide, to establish and maintain effective defences in nuclear facilities against potential radiological risks and to prevent accidents which could have radiological consequences and mitigate their consequences should they occur. The areas covered by the Convention have long been part of the French approach to nuclear safety.

In 2015, the contracting parties to the Convention, taking account of the lessons learned from the Fukushima Daiichi NPP accident, adopted the Vienna Declaration on nuclear safety. This

Declaration, which extensively incorporates the principles of the European Directive on the Safety of Nuclear Facilities, sets precise and ambitious safety objectives aiming to prevent other nuclear accidents worldwide and to mitigate the radiological consequences if one were to occur.

The Convention makes provision for review meetings by the contracting parties every three years, to develop cooperation and the exchange of experience.

As Competent Authority, ASN coordinates French participation in this three-yearly peer review exercise, in close collaboration with the institutional and industrial partners concerned. This coordination work concerns the drafting of the national report, analysis of the reports from the other contracting parties and participation in the review meetings.

The French report for the 8th review meeting of the contracting parties to the Convention was submitted in August 2019 and published on that date on the ASN website. Owing to the health crisis, it was not possible to hold this review meeting in March 2020 and it was postponed to 2023.

4.2 The Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management

The Joint Convention is the counterpart to the Convention on Nuclear Safety for the management of spent fuel and radioactive waste from civil nuclear activities. France signed it on 29 September 1997, and it entered into force on 18 June 2001. There were 83 contracting parties to this Convention at the end of 2020. In the same way as the Convention on Nuclear Safety, it is based on a peer review mechanism comprising the presentation of a national report by each contracting party every three years, which undergoes review by the other contracting parties, as well as a contracting parties peer review meeting.

The French report, the production of which is coordinated by ASN, was presented to the IAEA in October 2020 and is available on the ASN website. At the end of 2020, with the support of the French Institute for Radiological Protection and Reactor Safety (IRSN), ASN also began the review of the national reports from the other contracting parties.

Owing to the health crisis, the Joint Convention's 7th review meeting scheduled for May 2021, was postponed to the summer of 2022.

4.3 The Convention on Early Notification of a Nuclear Accident

The Convention on Early Notification of a Nuclear Accident entered into force on 27 October 1986, six months after the Chernobyl accident and had 127 contracting parties at the end of 2020.

The contracting parties undertake to inform the international community as rapidly as possible of any accident leading to the uncontrolled release of radioactive substances into the environment and liable to affect a neighbouring State. For this purpose, 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, the Unified System for Information Exchange in Incidents and Emergencies (USIE), which is present in ASN's emergency centre and is tested on the occasion of each exercise.

The Interministerial Directive of 30 May 2005 specifies the conditions of application of this text in France and mandates ASN as the Competent National Authority. It is therefore up to ASN to notify the events without delay to the international institutions, to rapidly provide pertinent information about the situation, in particular to border countries, so that they can take the necessary population protection measures and, finally, to provide the ministers concerned with a copy of the notifications and the information transmitted or received.

4.4 The Convention on Assistance in the Event of a Nuclear Accident or Radiological Emergency

The Convention on Assistance in the event of a Nuclear Accident or Radiological Emergency entered into force on 26 February 1987 and had 122 contracting parties at the end of 2020.

Its aim is to facilitate cooperation between countries should one of them be affected by an accident having radiological consequences. This Convention has already been activated on several occasions as a result of irradiation accidents caused by abandoned radioactive sources. More specifically, France's specialised medical services have already provided treatment for the victims of such accidents.

It is in this respect that following the explosion in the Port of Beirut on 4 August 2020, the Lebanese government called on the IAEA for help, through its RANET assistance network, notably to examine the potential loss of integrity of medical and industrial radioactive sources. The IAEA then in turn called on ASN, which submitted an assistance proposal, together with the French Institute for Radiation Protection and Nuclear Safety, the Ministry for Europe and Foreign Affairs and the international relations department at the Alternative Energies and Atomic Energy Commission (CEA). The delegation, which went to Beirut from 11 to 18 September, found no evidence of any radiological anomaly.

5. The bilateral framework for ASN's international relations

ASN collaborates with about 20 foreign safety regulators under bilateral agreements. Most of these agreements are bilateral administrative arrangements between ASN and its counterparts, but they are sometimes part of broader Governmental agreements (as is the case with Germany, Switzerland, Belgium and Luxembourg).

The countries with which ASN maintains particularly close relations are, on the one hand, neighbouring countries, especially those whose border is situated close to a French nuclear facility and, on the other, the major nuclear countries and the countries using French nuclear technologies.

Bilateral relations allow the exchange of information at several levels. First of all, at the strategic level, notably through high-level bilateral meetings, the exchanges concern points of doctrine and regulations and topical subjects concerning each authority (organisational and regulatory changes, events, experience feedback, etc.). Exchanges are also held at the technical and operational levels, in particular during thematic workshops or cross-observations of inspections, enabling practices to be compared in greater detail and, as applicable, identify those from which ASN could draw inspiration.

ASN organises a Franco-German workshop on the subject of the 4th periodic safety reviews of the Nuclear Power Plants

A workshop on the subject of the fourth periodic safety reviews of the French Nuclear Power Plants (NPPs) was held over two half-days on 7 and 11 December 2020, by the Franco-German Commission's working group on reactor safety. This workshop was opened up to a wide range of participants, notably from among the German expert commissions. 35 participants from the BMU (Federal Ministry for the Environment and Nuclear Safety), the RSK (German expert commission for reactors), the GRS (BMU technical support organisation), the authorities of the Land Bade-Württemberg, the French Institute for Radiological Protection and Reactor Safety (IRSN) and ASN took part in this workshop, which was held online owing to the health crisis.

ASN's objective was to share information and good practices associated with the periodic safety review procedure, notably with regard to public involvement, as well as the approaches to certain technical aspects of the reviews, such as management of ageing or reinforced protection against natural hazards. For the German participants, the workshop was an opportunity to find out about the situation in France, the progress and technical content of the periodic safety reviews of the 900 Megawatts electric reactors, learn the relevant lessons and anticipate questions from the German public.

The workshop's first half-day was devoted to the ASN and the IRSN presentation of the various topics associated with the periodic safety reviews: process, legal and transboundary aspects, public involvement, technical aspects. The questions collected on the German side were then addressed in detail during the second half-day.

The workshop was particularly well received by the German participants, who underlined the interest, transparency and quality of the exchanges.

The health crisis which affected all countries meant that ASN was unable to maintain the same pace of bilateral meetings with its counterparts as in previous years, in particular during the first half of 2020. A number of bilateral meetings were subsequently held by means of appropriate remote formats. This type of meeting, as well as intensified exchanges of information by email, enabled ASN to maintain a relatively satisfactory level of contact with its counterparts, drawing to a large extent on the dynamics that existed beforehand.

Experience feedback from safety management owing to the health situation was a systematic topic of exchanges with the ASN counterparts throughout the year. The other principal topics of the exchanges were the fourth periodic safety reviews of the reactors and subjects concerning decommissioning and radioactive waste management.

5.1 Bilateral cooperation between ASN and its foreign counterparts

GERMANY

The Franco-German Commission (DFK) was created as an inter-governmental body and involves several competent authorities at both national and Prefect levels. With regard to ASN, it involves both the head office departments and the Strasbourg regional division. In addition to the Commission's plenary meetings, two working groups meet regularly, one to address the safety of Nuclear Power Plants (NPPs) in border areas, the other the management of emergency situations.

In 2020, the Commission and its working groups held remote a meeting on **15 and 16 December**. The scaled-down plenary meeting of the Commission was an opportunity to present the changes to the situation in each of the two countries and to schedule the meetings for 2021. A Franco-German workshop on the subject of the fourth periodic safety review of the French NPPs was also held (see box).

BELGIUM

ASN cooperates on all subjects within its field of competence with its counterpart the Belgian *Agence Fédérale de Contrôle Nucléaire* (AFCN). This leads to cooperation both nationally and locally, with certain of the ASN regional divisions. The Franco-Belgian steering committee was unable to meet in 2020.

The AFCN and the Lille regional division held two inspections in France on the organisation of occupational radiation protection in industrial radiography, in Outreau, and on interventional radiology in an emergency cardiology ward of a clinic in Amiens.

CANADA

A video-conference between the Chairs of the Canadian (CCSN) and French (ASN) nuclear safety authorities was held on **6 November 2020**. During the call, the subjects of small modular reactor projects, gender equality and the project for personnel secondments between the two Authorities were discussed.

CHINA

In 2020, exchanges with the Chinese nuclear safety regulator (NNSA) mainly concerned preparations for the renewal of the cooperation agreement and for the exchanges planned for 2021, notably the bilateral meeting and cross-inspections concerning the regulation and oversight of NPPs in operation.

SPAIN

On 26 November 2020, a remote bilateral meeting was organised between ASN and the Spanish nuclear safety regulator (CSN). The main topics discussed were the conditions for improving the preparedness and precautionary culture among the population, the public's perception of the role of the authorities in an emergency situation, the role of expert appraisal and analysis in the decision-making process and societal acceptance of protection measures. Organisational changes at the safety regulators and oversight methods were also discussed.

UNITED STATES

In February 2020, ASN welcomed the Commissioner of the American nuclear safety regulator (NRC), David A. Wright, to Montrouge for an interview with a member of the Commission and a visit to the CEA Saclay site facilities on the subject of decommissioning, the retrieval of legacy waste and research into accident-tolerant nuclear fuel.

The 11th bilateral meeting between ASN and the NRC was held **on 2 December 2020**, *via* video-conference. During this meeting, the discussions notably concerned the respective national and regulatory current issues, decommissioning projects and issues, new nuclear reactor projects (EPR-2), NRC's experience of Small Modular Reactor (SMR) authorisation and personnel secondments between the two Authorities. Olivier Gupta, President of WENRA, also gave an update on the activities of WENRA.

FINLAND

A technical meeting between ASN and the Finnish safety regulator (STUK) was held **on 17 and 18 November 2020**, *via* video-conference. The discussions primarily concerned topical technical subjects regarding the EPRs in each of the two countries.

JAPAN

The annual meeting with the Japanese nuclear safety regulator (NRA), scheduled for September, could not take place. Similarly, technical visits involving ASN's Lyon regional division had to be postponed. Remote information exchanges on current issues concerning the two regulators were however fruitful (safety management during the health crisis, operating license for the fuel reprocessing plant at Rokkasho, extension of the La Hague off-site emergency plan, management of tritiated water from Fukushima Daiichi, etc.). Moreover, at the invitation of the NRA, an ASN Commissioner took part in a meeting in Tokyo and Fukushima to prepare for the event to mark 10 years since the accident at the Fukushima Daiichi NPP.

LUXEMBOURG

The Franco-Luxembourg joint Commission on nuclear safety held its 18th meeting **on 4 February 2020** at the ASN headquarters in Montrouge. The Commission comprises the national and Prefect level competent authorities and the Ministries of Foreign Affairs. It discussed recent developments in the two countries regarding nuclear safety and radiation protection, including the 2019 report on the Cattenom NPP, current issues in the medical field (graduated approach, radiotherapy inspections, justification files for new practices), periodic safety reviews on the French NPP fleet, and the preparation for and management of emergency situations, notably the experience feedback from the emergency exercise carried out in the Chooz NPP.

POLAND

In parallel with the official visit by the President of the Republic to Poland, the ASN Chairman, Bernard Doroszczuk, met his counterpart, Dr Młynarkiewicz, **on 3 February 2020**. The meeting covered the continued cooperation between ASN and the Polish Nuclear Power Programme (PAA), notably for the future construction of nuclear power reactors in Poland. It was impossible to hold the bilateral meeting scheduled for 2020.

RUSSIA

The bilateral meeting scheduled to take place in Moscow in April with the Russian nuclear safety regulator (*Rostechnadzor*) was cancelled, as were the technical meetings and site visits planned for the Leningrad NPP. To the extent possible, these meetings and technical exchanges will be rescheduled for 2021.

SWEDEN

The annual meeting between ASN and its Swedish counterpart, the SSM, initially planned for 2020, had to be postponed to 2021. The two regulators however held a virtual meeting in October 2020, during the course of technical discussions with the Orléans regional division. These discussions mainly concerned the management of routine activities during the health crisis, and more particularly inspection practices.

SWITZERLAND

The Franco-Swiss commission was created as an inter-governmental body and involves several competent authorities at both national and Prefect levels. This commission did not meet in 2020 owing to the health crisis. With regard to ASN, this Commission involves both the head office departments and the ASN Lyon and Strasbourg regional divisions.

5.2 ASN assistance actions in a bilateral framework

ASN may be required to respond to assistance requests *via* bilateral actions with the safety regulator of the country concerned, in addition to the European (INSC) and international (RCF) instruments. The purpose of this cooperation is to enable the beneficiary countries to acquire the safety culture and transparency that are essential for a national system of nuclear safety and radiation protection oversight. Nuclear safety oversight must be based on national competence and ASN consequently only provides support for the establishment of an adequate national framework, ensuring that the national safety regulator

Bilateral meeting between the Spanish nuclear safety regulator and ASN – 26 November 2020

it advises retains full responsibility for its oversight of the nuclear facilities. It pays particular attention to countries acquiring technologies of which it has experience in France.

ASN considers that developing an appropriate safety infrastructure requires a minimum of 15 years before a nuclear power reactor can begin to operate in good conditions. For these countries, the goal is to set up a legislative framework and an independent and competent safety regulator with the financial and human resources it needs to perform its duties and to develop skills in terms of safety, safety culture and oversight as well as in radiological emergency management. In 2020, ASN became involved in an INSC project on behalf of Turkey.

5.3 Personnel secondments between ASN and its foreign counterparts

Understanding the working and practices of foreign nuclear safety and radiation protection regulators enables pertinent lessons to be learned for the working of ASN and the training of its personnel. One of the means used to achieve this is the secondment of personnel, generally for periods of 1 to 3 years. This immersion in the activities and working of the counterpart safety regulator is a unique means of assimilating subjects of common interest. Since 8 January 2018, an ASN staff member has been seconded to the United States Nuclear Regulatory Commission (NRC) for a period of three years while an NRC staff member who had been working at the ASN Waste, Research Facilities and Fuel Cycle Facilities completed their secondment period in March 2020. Since 1st January 2019, an experienced ASN inspector has been on secondment to the British safety regulator (ONR). A secondment of this type is currently being considered with the Canadian safety regulator as of the end of 2021.

6. Outlook

Owing to the global health crisis, 2020 was a disrupted year for ASN at the international level. It led to significant changes in the conditions for the preparation and performance of international exchanges. In a difficult context, ASN nonetheless succeeded in maintaining exchanges with its counterparts, even if remotely.

In 2021, and subject to developments in the health situation, ASN will aim to maintain dynamic exchanges with countries in both Europe and Asia (Japan, China, South Korea) as well as with the North-American continent (United States and Canada). It will focus on identifying subjects it considers to be priorities for such exchanges, in order to share experience and good practices. Experience feedback from the health crisis will no doubt be the subject of in-depth exchanges.

At the European level, ASN will continue to help finalise HERCA's strategic review in order to optimise the way in which current radiation protection issues are addressed. Within WENRA and ENSREG, ASN will also contribute to the work to prepare for the second topical peer review, required by the Nuclear Safety Directive, which will deal with the management of fire hazards. For ASN, this action will be one of its international priorities.

CHAPTER 07

MEDICAL USES OF IONISING RADIATION

07 Medical uses of ionising radiation

For more than a century now, medicine has made use of ionising radiation produced either by electric generators or by radionuclides in sealed or unsealed sources for both diagnostic and therapeutic purposes. The benefits and usefulness of these techniques have long been proven, but they nevertheless contribute significantly to the exposure of the population to ionising radiation. They effectively represent the second source of exposure for the population (behind exposure to natural ionising radiation) and the leading source of artificial exposure (see chapter 1).

1. Nuclear-based medical activities

1.1 The different activity categories

Nuclear-based therapeutic medical activities, particularly those dedicated to the treatment of cancer, include external-beam radiotherapy, brachytherapy and internal targeted radiotherapy (ITR)[1].

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 different techniques used primarily for invasive medical or surgical procedures for diagnostic, preventive or therapeutic purposes.

These different activities and the techniques used are presented in sections 2 to 7.

1.2 Exposure situations in the medical sector

1.2.1 Exposure of health professionals

The risks for health professionals arising from the use of ionising radiation are firstly the risks of external exposure generated by the medical devices (devices containing radioactive sources, X-ray generators or particle accelerators) or by sealed and unsealed sources (particularly after administering RadioPharmaceutical Drugs – RPDs[2]). When using unsealed sources, the risk of contamination must also be taken into consideration in the risk assessment (in nuclear medicine and in the biology laboratory).

According to the data collected in 2019 by the Institute for Radiation Protection and Nuclear Safety (IRSN), 229,172 people working in the areas of medical and veterinary activities were subject to dosimetric monitoring of their exposure. The average annual individual dose is 0.3 millisievert (mSv). This dose is stable with respect to 2017 and 2018.

Radiology activities (radiodiagnosis and interventional radiology) represent the largest proportion (45%) of exposed medical personnel, with a relatively low average annual dose of 0.2 mSv. Nuclear medicine represents 3% of the headcount but the average annual whole-body dose in nuclear medicine personnel is 0.8 mSv. 16,922 medical personnel members (7.4%) were monitored by extremity dosimeters. The average dose at the extremities is 13.94 mSv; it has doubled compared with 2018 (6.22 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 cell while at the same time preserving the healthy neighbouring tissues to the greatest possible extent.

Whatever the case however, control of the doses delivered during imaging examinations and treatments is a vital requirement that depends not only on the skills of the patient radiation protection professionals but also on the procedures for optimising and maintaining equipment performance.

Controlling doses in medical imaging remains a priority for ASN which, following on from the first plan initiated in 2011, published a new opinion on 24 July 2018, along with a second plan, in order to continue promoting a culture of radiation protection with the professionals (see chapter 1).

1.2.3 Exposure of the public

With the exception of incident situations, the potential impact of medical applications of ionising radiation is likely to concern:
- members of the public who are close to facilities that emit ionising radiation;
- 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;
- sewage network and wastewater treatment plant personnel who could be exposed to effluents or wastes produced by nuclear medicine departments.

The available data on the impact of these discharges on the public (persons outside the health care institution) lead to estimated doses of a few tens of microsieverts per year for the most exposed persons, notably persons working in sewage networks and wastewater treatment plants (IRSN studies, 2005 and 2014).

1.2.4 The environmental impact

The available information concerning radiological monitoring of the environment carried out by the IRSN, in particular the measurement of ambient gamma radiation, on the whole reveals no significant exposure level above the variations in the background

1. Internal Targeted Radiotherapy (ITR) aims to administer a RadioPharmaceutical Drug (RPD) emitting ionising radiation which will deliver a high dose to a target organ for curative or palliative purposes.

2. An RPD is a drug containing one or more radionuclides. RPDs can be used for diagnostic (scintigraphy) or therapeutic (internal targeted radiotherapy) purposes.

radiation. On the other hand, radioactivity measurements in major rivers or wastewater treatment plants of large towns occasionally reveal the presence of artificial radionuclides used in nuclear medicine (*e.g.* iodine-131) exceeding the measurement thresholds.

However, no trace of these radionuclides has been measured in water intended for human consumption (see chapter 1).

1.2.5 Significant radiation protection events

Significant Radiation Protection Events (ESRs) are required to be notified to ASN since 2007. These notifications provide the professionals with increasingly valuable experience feedback, helping to improve radiation protection in the medical field. In 2020, ASN published two *Patient Safety* newsletters entitled "Safeguarding the medication circuit in nuclear medicine" and "Prior radiotherapy treatments", and three experience feedback sheets, one in nuclear medicine "Choice of activimeter calibration channel", the other two in radiotherapy, "Overdosing during a stereotactic radiotherapy treatment of multiple intracranial locations" and "Accidental irradiation at a distance from the target volume further to a malfunction during target volume delineation". These documents have been widely distributed in France. In addition to this, the incident notices are published on *asn.fr*.

Since July 2015, radiotherapy departments can report ESRs online. *Teleservices.asn.fr* was extended to cover the entire medical sector in April 2017. This portal is integrated in the one-stop vigilance portal created by the Ministry of Health.

In 2020, 532 ESRs (Graph 1) were reported to ASN in the medical field, fewer than in 2019 (617 ESRs). This drop in the total number of reported events with respect to 2019 concerns all the activities. The Covid-19 pandemic is very probably one of the factors explaining this, insofar as medical activity was reduced during this period. However, we cannot confirm this hypothesis until the health care activity data have been published. ASN emphasizes the importance of reporting significant radiation protection events in order to share experience feedback and improve radiation protection.

Graphs 2, 3 and 4 illustrate the distribution of the number of ESRs in 2020 by activity category, how they have evolved since 2010, and the distribution of events by area of exposure (impact on the environment, exposure of the public, exposure of patients, exposure of medical workers), and by activity category concerned.

The reported events originate mainly from Computed Tomography (31%), radiotherapy (23%) and nuclear medicine (25%) departments.

Furthermore, the events chiefly concern exposure of patients (65%) and foetuses in pregnant women unaware of their pregnancy (24%).

In the light of the events reported to ASN in 2020, the most significant findings from the radiation protection aspect are:
- for medical professionals: Fluoroscopy-Guided Interventional (FGI) practices (external exposure of operators, and their hands in particular) with cases where dose limits are exceeded, and nuclear medicine (contamination of workers, external exposure);
- for patients:
  - radiotherapy, with overdoses linked in particular to target errors, wrong-side errors and fractionation errors;
  - nuclear medicine, with radiopharmaceutical drug administration errors;
- for the public and the environment: nuclear medicine, with losses of sources, leaks from radioactive effluent pipes and containment structures.

Detailed information per category is provided in sections 2 to 6.

1.2.6 The risks and the oversight priorities

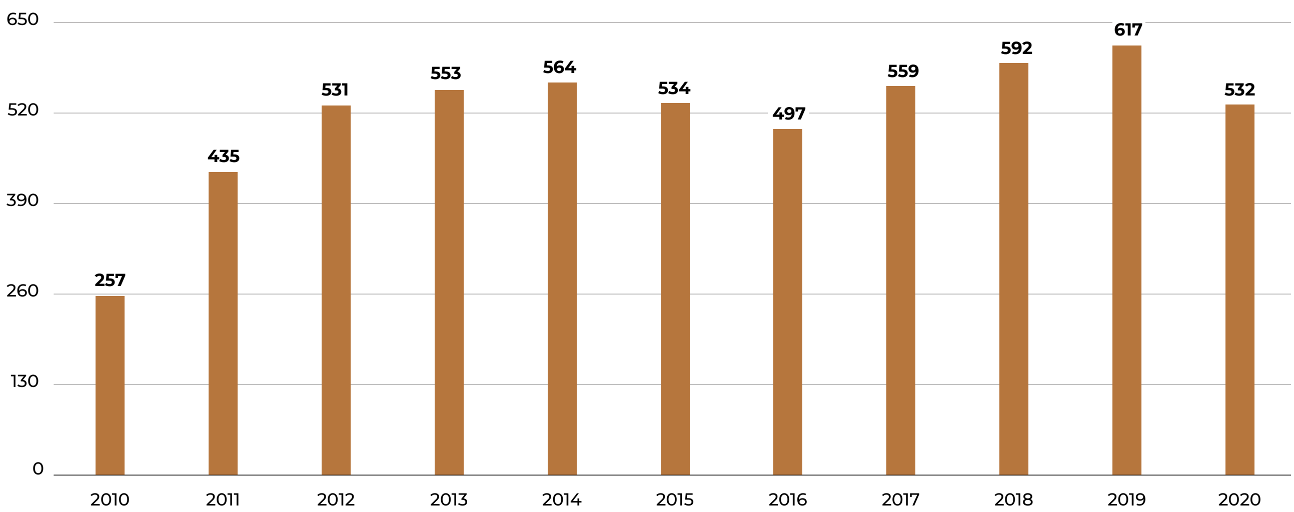
In order to establish its oversight priorities, ASN has classified the nuclear-based medical activities according to the risks for the patients, the personnel, the public and the environment. This classification takes particular account of the doses delivered or administered to the patients, the conditions of use of ionising radiation sources by the medical professionals, the possible impact on the environment, the significant events reported to ASN and the radiation protection situation in the institutions exercising these activities.

On the basis of this classification (Table 1), ASN considers that its oversight must focus in priority on external-beam radiotherapy, brachytherapy, nuclear medicine and FGI 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

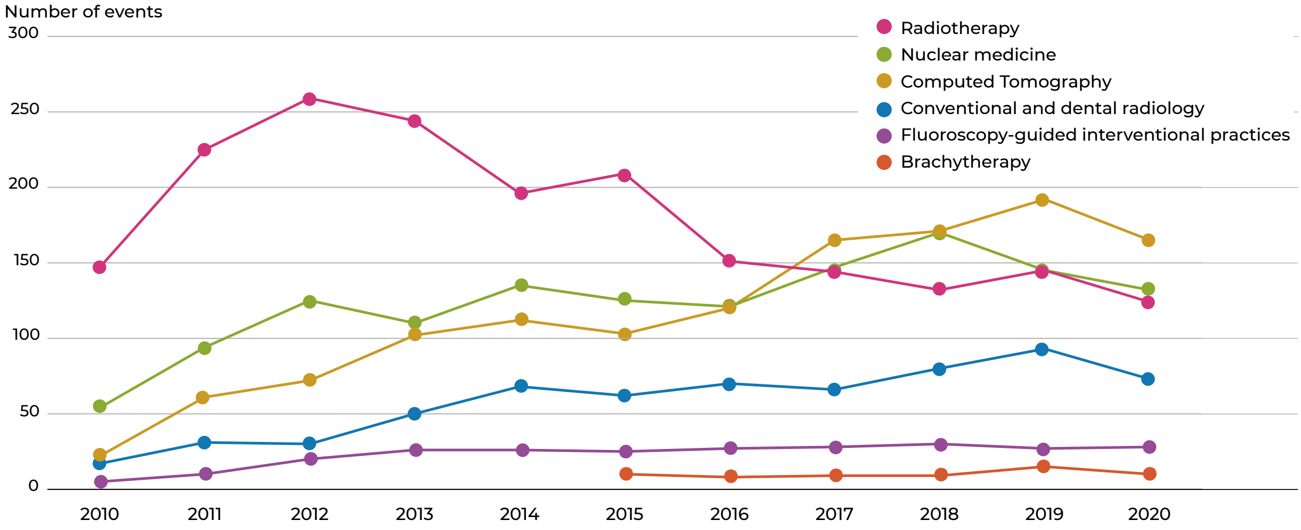
GRAPH 1

Trends in the number of annual ESR notifications from 2010 to 2020



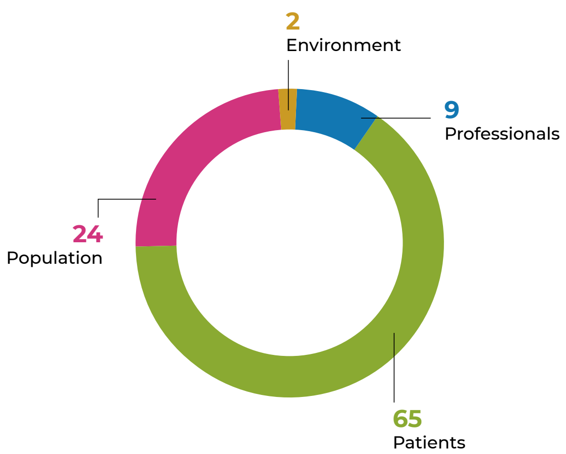
GRAPH 2

Number of ESRs per activity category during the period 2010-2020



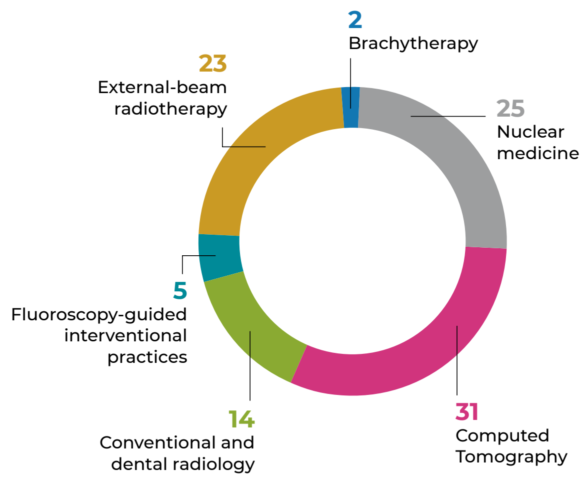
GRAPH 3

Breakdown of ESRs per area of exposure in 2020 (%)



GRAPH 4

Breakdown of ESRs per activity category concerned in 2020 (%)



indicators for conducting regional and national assessments. This procedure is supplemented by more detailed investigations addressing specific themes defined in an annual or multi-year framework.

The radiation protection situation in the medical environment has been assessed essentially on the basis of the indicators associated with the control points.

1.2.7 Oversight actions conducted in the context of the health crisis

The health crisis associated with the Covid-19 pandemic and the lockdowns have led ASN to adapt its oversight actions as described in chapter 3. In the medical sector, particularly affected by the workloads involved in the care and treatment of Covid-19 patients, ASN suspended all inspections save exceptions during the first lockdown. Specific inspection methods were subsequently defined. Prior to any inspection, whether conducted on site or remotely, the person/entity in charge of the nuclear activity was contacted to verify that the healthcare centres had the staff necessary for the inspection to be carried out.

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 resolutions (see points 4 to 7).

THE IMPACT OF COVID-19

DIFFICULTIES ENCOUNTERED BY PERSONS/ENTITIES RESPONSIBLE FOR NUCLEAR ACTIVITIES IN APPLYING THE REGULATORY OBLIGATIONS

Faced with a large number of difficulties, the persons/entities responsible for nuclear activities were unable to meet all their regulatory obligations. ASN anticipated these difficulties as of March 2020. It worked with the learned societies (representing the radiotherapists, medical physicists and nuclear medicine physicians), the medical device manufacturers and maintenance companies, and the institutions (Ministry of Health, Ministry of Labour, the French Health Products Safety Agency – ANSM, the French High Council for Public Health – HCSP, and the French National Cancer Institute – INCa) to define the measures to take in the area of radiation protection.

The various learned societies issued recommendations for adapting the organization of patient management that are compatible with the dual constraints of radiation protection and health aspects (grouping Covid-19 patient appointments at the end of the day, management of the nuclear medicine department waiting room) and allowing for possible tensions due to a lack of medical staff (absence). For example, for the simplest radiotherapy treatments, the presence of three radiographers for two accelerators was tolerated, whereas the regulations require two radiographers per accelerator. Similarly, a collegial reflection was also conducted on medical device quality controls, defining the absolutely vital controls to perform in the interim period until it is possible to carry out all the required controls.

Alongside this, in addition to the regulatory measures taken by the Government (Ordinance 2020-306 of 25 March 2020) which eased certain requirements concerning, for example, the deadlines imposed on those responsible for nuclear activities for performing certain checks or training in application of the Public Health Code or the Labour Code (radiation protection controls, radiation protection refresher training validity period), the ANSM issued information mentioning the possibility of adapting the frequency of the third-party quality controls, of internal and external audits and of internal controls.

THE IMPACT OF COVID-19

ADAPTATION OF METHODS OF INSPECTION IN HEALTH CARE CENTRES

Nuclear activity licenses issued by ASN in the medical sector

The Covid-19 pandemic has obliged health care centres to adapt the organisation of patient management to be compatible with the twofold radiation protection and health constraints. The departments thus had to use equipment or premises under conditions not covered by the licenses to possess and use radioactive sources. For example, the Computed Tomography (CT) scanners of the nuclear medicine or radiotherapy departments were used for diagnostic purposes (chest scan in particular), in the management of patients suspected of being infected by Covid-19. Similarly, the radiation-protected Internal Targeted Radiotherapy (ITR) rooms in nuclear medicine or even formerly Pulsed Dose-Rate (PDR) rooms in brachytherapy were used to accommodate Covid-19 patients because they have the advantage of being single rooms and having air filtering systems suited to the viral risk insofar as they are under negative pressure. We can mention, for example, the validation by a radiologist and a medical physicist of the new use of a nuclear medicine or radiotherapy CT scanner for diagnostic purposes, or the reinforcement of room contamination verifications.

Furthermore, the license application examination and issuing methods were adapted: reduction in the number of documents required when filing the application, in the license validity period and in the application examination time. It was thus possible to issue licenses to hold and use a CT scanner within 24 hours when circumstances so required.

Inspections

In order to continue its oversight while ensuring the safety of the ASN staff and the personnel met during the inspection, ASN defined new inspection methods as of April 2020. Depending on the situations of the centres, the inspections were conducted either on site in the conventional manner, or entirely remotely or through a combination of the two methods. The documents to be provided and the document verification points prior to the inspection were defined by adapting them to the nuclear activities (radiotherapy, Fluoroscopy-Guided Interventional (FGI) practices, nuclear medicine, Computed Tomography). The interchanges that are usually held on a face-to-face basis, such as the synthesis meetings, were organised by video conference.

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 R. 5211-12 to R. 5211-24). The CE marking, which certifies conformity with these essential requirements, is mandatory. Further to technological developments, the Order of 15 March 2010 laying down the essential requirements applicable to medical devices has been modified to reinforce the provisions concerning the display of the dose during imaging procedures. The new European Regulation 2017/745 will enter into effect on 26 May 2021 and its implementation will extend until May 2027. It will concern implantable medical devices (such as the microspheres used in nuclear medicine).

The RPDs used in nuclear medicine are covered by a Marketing Authorisation (MA) delivered by the French Health Products

TABLE 1

Classification of nuclear-based medical activities according to the radiation exposure risks

ACTIVITIES	PATIENTS	MEDICAL PROFESSIONALS	PUBLIC AND ENVIRONMENT
External-beam radiotherapy	3	1	1
Brachytherapy	2	2	2
Internal targeted radiotherapy	3	2	3
Fluoroscopy-guided interventional practices	2 to 3 depending on the procedures	2 to 3 depending on the procedures	1
Diagnostic nuclear medicine	1 to 2 depending on the procedures	2 to 3 depending on the procedures	2
Computed Tomography	2	1	1
Fluoroscopy-guided procedures on remotely-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

TABLE 2

Regulatory work in progress in the area of patient radiation protection

	EXISTING TEXT	WORK IN PROGRESS
Quality assurance in radiotherapy	Resolution 2008-DC-0103 of 1 July 2008	Undergoing updating revision
Qualifications of physicians or dental surgeons who perform procedures using ionising radiation for medical or research purposes involving humans, to the qualifications required to be designated coordinating physician of a nuclear activity for medical purposes or to request a license or registration as a physical entity	Resolution 2020-DC-0694 of 8 October 2020	Undergoing approval
List of medical activities using medical devices emitting ionising radiation subject to the registration system and the requirements relative to these activities	Resolution 2021-DC-0704 of 4 February 2021	Undergoing approval

Safety Agency (ANSM) or by the European Medicines Agency (EMA). Pending delivery of an MA, they can be granted a Temporary Authorisation for Use (ATU) – the French version of compassionate use – which can be for named patients or cohorts.

The monitoring of sources (radioactive sources including RPDs, devices emitting ionising radiation, particle accelerators) is subject to specific rules figuring in the Public Health Code (Articles R. 1333-152 to R. 1333-164).

1.3.3 Radiation protection of patients

Justification and optimisation – The protection of patients undergoing medical imaging examinations or therapeutic procedures using ionising radiation is regulated by specific provisions of the Public Health Code (Articles R. 1333-45 to R. 1333-80). The principles of justification of the procedures and optimisation of the delivered doses constitute the cornerstone of this regulation. However, contrary to the other applications of ionising radiation, the principle of dose limitation does not apply to patients, because of the need to adapt the delivered dose for 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*.

ASN continues to update, and if necessary supplement, the regulatory framework with specific provisions regarding optimisation, quality assurance, training and qualification.

1.3.4 Administrative procedures

Decree 2018-434 of 4 June 2018 provided the details necessary for implementation of the new system of procedures applicable to small-scale nuclear activities: in application of Article L. 1333-7 of the Public Health Code, a third and "simplified" authorisation system called "registration" will be put in place as of 2021, in addition to the existing notification and licensing systems.

The list of medical activities subject to registration has been defined on the basis of the radiation exposure risks (Table 1) by ASN resolution 2008-DC-0103 of 1 July 2008. This system will thus be applied to computed tomography and FGI practices, activities involving radiation exposure risks. Conventional radiology and dental radiology will continue to come under the notification system. 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

Radiotherapy, along with surgery and chemotherapy, is one of the key techniques employed to treat cancerous tumours. More than 200,000 patients[3] are treated each year, which represents nearly 4.2 million radiation sessions. Radiotherapy uses ionising radiation to destroy malignant cells (and non-malignant cells in a small number of cases). The ionising radiation necessary for the treatments is produced by an electric generator or emitted by radionuclides in sealed sources. We distinguish external-beam radiotherapy, where the source of radiation (particle accelerator or a radioactive source such as Gamma Knife®) is external to the patient, from brachytherapy, where the source is placed as close as possible to the cancerous lesion.

The installed base of external-beam radiotherapy facilities in 2020 comprises 536 particle accelerators installed in 174 radiotherapy centres subject to ASN licensing. The French Radiotherapy Observatory (source: National Cancer INstitute – INCa, 2019), lists 819 radiotherapists in 2019.

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 mega-electronvolts (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).

ASN issued 95 licenses in 2020. The majority of these cases concerned the updating of an existing license.

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 (Positon Emission Tomography – PET, Magnetic Resonance Imaging – MRI, 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 multileaf collimator.

In its guide giving recommendations for the practice of external-beam radiotherapy and brachytherapy (Recorad) published in September 2016, the French Society for Radiation Oncology (SFRO) considers that this irradiation technique is used as the basic technique by all the French centres for all patients receiving curative treatment. It has nevertheless been observed in the last few years that the proportion of treatments using this technique is giving way to intensity-modulated conformal radiotherapy.

2.1.2 Intensity-Modulated (conformal) Radiotherapy

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 modulated 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 (Volumetric Modulated Arc Therapy – VMAT®, RapidArc®) depending on the manufacturer, is achieved using conventional isocentric linear accelerators equipped with this technological option.

Helical radiotherapy

Helical radiotherapy, or tomotherapy, enables radiation treatment to be delivered by combining the continuous rotation of an accelerator with the longitudinal movement of the patient during the treatment. The technique employed is similar to the principle of helical image acquisitions obtained with computed tomography. A photon beam, emitted at a voltage of 6 MV and a dose-rate of 8 Gy/min, shaped by a multileaf collimator enabling the intensity of the radiation to be modulated, allows the irradiation of large volumes of complex shape as well as extremely localised lesions, which may be in anatomically independent regions. The system requires the acquisition of images under the treatment conditions of each session for comparison with reference computed tomography images in order to reposition the patient.

In 2019, there were 42 devices of this type installed in France (source: Radiotherapy observatory, INCa 2019).

2.1.3 Stereotactic radiotherapy

Stereotactic radiotherapy is a treatment method that aims at delivering high-dose radiation to intra- or extracranial lesions with millimetric accuracy through multiple mini-beams which converge at the centre of the target. In stereotactic radiotherapy treatments, the total dose is delivered either in a single session or in a hypofractionated manner, depending on the disease being treated. The term radiosurgery is used to designate treatments carried out in a single session.

This technique firstly requires great precision in defining the target volume to irradiate, and secondly that the treatment be as conformal as possible, that is to say that the irradiation beams follow the shape of the tumour as closely as possible.

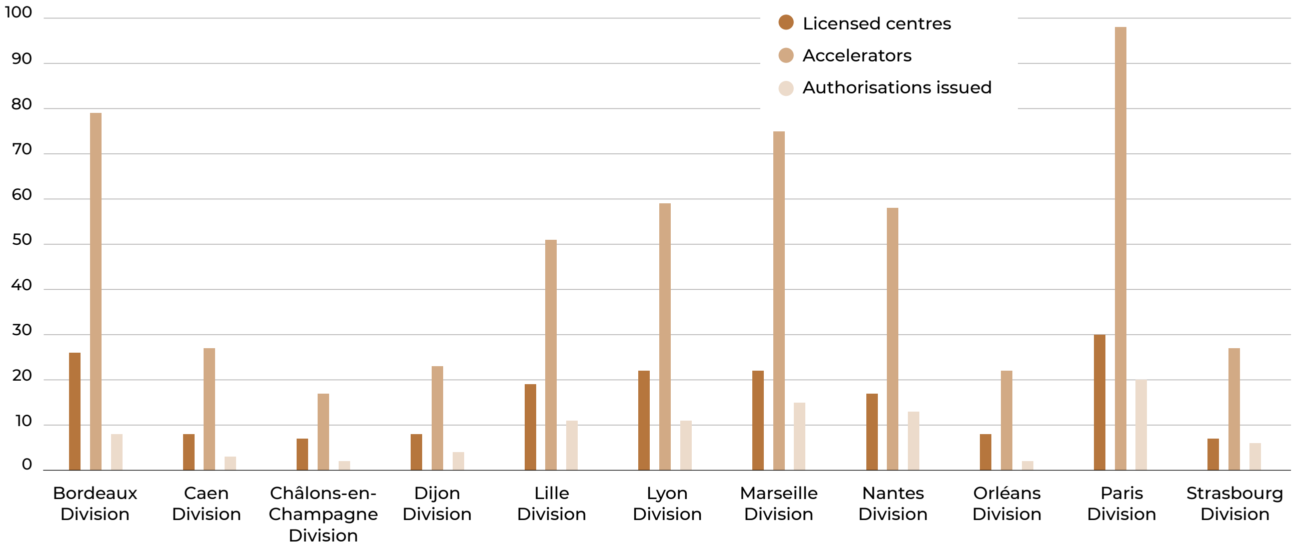
It was originally developed to treat surgically-inaccessible non-cancerous diseases in neurosurgery (artery or vein malformations, benign tumours) and uses specific positioning techniques to ensure very precise localisation of the lesion.

It is used more and more frequently to treat cerebral metastases, but also for extracranial tumours.

3. In 2019, 205,585 people with cancer were treated by radiotherapy in 4,284,242 sessions (source: INCa Observatory).

GRAPH 5

Breakdown, by ASN regional division, of the number of centres and external-beam radiotherapy accelerators inspected and the number of new licenses or license renewals issued by ASN in 2020



This therapeutic technique chiefly uses three specific types of equipment, such as:
- Gamma Knife®, which uses more than 190 cobalt-60 sources. It acts like a veritable scalpel over an extremely precise and delimited zone (5 units in service);
- robotic stereotactic radiotherapy; CyberKnife® is a miniaturised linear accelerator mounted on a robotic arm (19 units in service);
- multi-purpose linear accelerators equipped with additional collimation means (mini-collimators, localisers) that can produce mini-beams.

2.1.4 Radiotherapy using a linear accelerator coupled to a magnetic resonance imaging system

A first linear accelerator coupled to a Magnetic Resonance Imaging (MRI) system was installed in the Paoli-Calmette Institute in Marseille in 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 the IRSN, ASN authorised entry into service of this new technique at the end of 2018.

In 2019, two other centres were licensed to possess and use this type of machine, namely the Georges François Leclerc Centre in Dijon and the Montpellier Cancer Institute (ICM) – Val d'Aurelle in Montpellier. No new devices of this type were installed in 2020.

2.1.5 Contact radiotherapy

Contact therapy or contact radiotherapy is an external-beam radiotherapy technique. The treatments are delivered by an X-ray generator using low-energy beams varying from 50 to 200 kilovolts (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, with the radiation dose being delivered in the operating theatre to the tumour bed during surgical intervention. This technique is used primarily for treating small cancers of the breast.

In April 2016, the French National Authority for Health (HAS) published the results of the assessment of this practice and concluded that the conditions necessary to propose coverage by the state health insurance scheme were not satisfied at the time. It considered that the clinical and medico-economic studies had to be continued in order to acquire clinical data over the longer term. After four years, development of this technique has remained limited and its assessment is continuing.

New intraoperative radiotherapy devices covered by the CE marking have been put on the market. The benefits of using these devices, linked to optimised irradiation of the targeted tumour while preserving the surrounding healthy tissue, and their deployment in France, shall be assessed. Devices of this type are to be examined by the Committee for analysing new practices or techniques using ionising radiation (Canpri) in 2021.

2.1.7 Hadron therapy

Hadron therapy is a treatment technique based on the use of beams of charged particles – protons and carbon nuclei – whose particular physical properties ensure highly localised dose distribution during treatment. Compared with existing techniques, the dose delivered around the tumour to irradiate is lower, therefore the volume of healthy tissue irradiated is drastically reduced. Hadron therapy allows the specific treatment of certain tumours. In June 2016, the INCa published a report on proton therapy treatment indications and possibilities.

Hadron therapy with protons is currently used in three centres in France:
- the Curie Institute of Orsay (equipment modified in 2016);
- the Antoine-Lacassagne Centre in Nice (new equipment installed in 2016);
- the François-Baclesse Centre (ARCHADE project) in Caen (commissioned in 2018).

According to its advocates, hadron therapy with carbon nuclei is more suited to the treatment of the most radiation-resistant tumours and could result in several hundred additional cancer cases being cured each year. The claimed biological advantage is purportedly due to the very high ionisation of these particles at the end of their path, combined with a lesser effect on the tissues they pass through before reaching the target volume.

2.2 Technical rules applicable to external-beam radiotherapy installations

The devices must be installed in rooms specially designed to guarantee radiation protection of the staff, turning them into veritable bunkers (wall thickness can vary from 1 metre (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 must be included in the file submitted to ASN to support the application for a license to use a radiotherapy installation.

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.

In 2019, ASN asked the IRSN to assess the current design requirements for premises housing external-beam radiotherapy facilities, particularly the bunker with shielding baffle. This latter design remains the reference insofar as it reduces the shielding required at the ventilation duct and electrical duct inlets and provides greater security in the event of failure of the door motorisation system or if anyone gets accidentally locked inside. However, if the space available to the licensee is limited, which compromises the installation of the accelerator, a smaller shielding baffle, or even none at all, can be envisaged under certain restrictive conditions.

A new medical device named ZAP-X® is currently undergoing the CE marking procedure. It is intended for "radiosurgery" type intracranial irradiation. The innovative feature put forward by the manufacturer is the self-shielding of this accelerator which, it is claimed, does need to be installed in a bunker. This device has been presented to the Canpri, and further information is awaited, primarily concerning radiation protection of the medical professionals. This device shall also undergo an assessment by the HAS.

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 has been defined for the 2020-2023 period, and its themes have been communicated to the learned societies and government departments concerned.

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 four years (instead of the previous three-yearly frequency);
- by maintaining a higher frequency for the centres displaying vulnerabilities or risks, especially certain centres having required tightened inspections (Lucien Neuwirth Cancerology Institute in Saint-Priest-en-Jarez, the Peupliers Private Hospital in Paris) and the continuation of the tightened monitoring of the Private Radiotherapy Centre of Metz (CPRM), renamed the Private Institute of Radiotherapy of Metz (IPRM) during 2019, following a change of ownership.

The inspection programme was severely impacted in 2020 by the health crisis linked to the Covid-19 pandemic. ASN adapted its oversight in order to be able to continue conducting certain high-stake inspections on site. The other inspections were carried out remotely or postponed until 2021. As a result, ASN carried out 49 of the 73 inspections initially scheduled in 2020, representing 28% of the national installed base. In comparison, 73 inspections were carried out in 2019, representing 42% of the national installed base. Thirteen of the inspections carried out in 2020 were conducted entirely remotely.

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 2020 reveal no major problems in this sector:
- The effective designation of Radiation Protection Advisors (RPA) was confirmed in the majority of the centres inspected.
- The radiation protection technical controls were carried out in about 90% of the centres inspected and were satisfactory.

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 100% of the inspected centres. All the centres have a medical physics organisation plan, but the quality of the plans vary from one centre to another.

The detection of adverse events, their reporting (internally or to ASN) and their recording are deemed satisfactory on the whole. In addition, significant progress is observed in the analysis of these adverse events, the defining of corrective actions and the lessons learned from them: they are satisfactory in 66% of the inspections, compared with 46% in 2019 (see Graph 6).

The improvement in practices through experience feedback and the assessment of the effectiveness of the corrective actions were deemed satisfactory in only 38% of the centres inspected (see Graph 6). This is nevertheless an improvement on 2019, where this proportion was just 27%. In order to be effective, these approaches must bring together representatives of all the professionals involved in the delivery of treatments. The lack of availability of personnel, especially medical, limits their effectiveness.

Enforcement measures and tightened monitoring of centres: improvements observed by ASN

The measures ASN has taken in terms of enforcement (compliance notices) and tightened monitoring of certain radiotherapy centres have brought significant improvements in their situation. Below are three examples of centres faced with organisational malfunctions in preceding years.

Improvement of the situation of the Lucien Neuwirth Cancerology Institute

The Lucien Neuwirth Cancerology Institute (ICLN), situated in Saint-Priest-en-Jarez (Loire *département*), is a public institution specialised in fighting cancer and which exercises external-beam radiotherapy and brachytherapy activities.

Since 2017, ASN has put in place tightened monitoring of this institute, mainly on account of relational difficulties within the radiotherapy department. This monitoring has resulted in the institute undergoing four inspections in two years. The responses obtained further to the inspection of 9 and 10 July 2019 led ASN to give ICLN formal notice on 18 December 2019 to comply with certain regulatory provisions concerning the organisation of human resources and risk management.

The ICLN, represented by its Director and the head of the external-beam radiotherapy department, presented its action plan in response to this compliance notice to ASN General Management on 10 February 2020, and undertook to reduce its activity pending the recruitment and dispensing of the training necessary to acquire the required skills. These provisions were taken up in the licensing decision issued to ICLN in June 2020, the main purpose of which was to transfer responsibility for the nuclear activity from the head of the radiotherapy department to the institute as a legal entity, and to restrict certain activities.

ASN continued its tightened monitoring of the site throughout 2020. The observed improvements enabled the ICLN to gradually resume normal activity in July 2020. An inspection carried out on 28 and 29 September 2020 showed the inspectors that the requirements set in the compliance notice had been satisfied. More generally, improvements have been noted in patient radiation protection, in the organisation of medical physics with appropriate personnel numbers and skills, and effective implementation of the quality approach. Lastly, working relations between the medical staff have improved thanks to collective involvement of all the professions of the radiotherapy department.

ASN will continue to monitor the ICLN in 2021, in order to accompany it in the next phases, particularly the resumption of certain treatments that present greater risks for the patients in the event of an implementation error.

Improvement in the situation of the Peuplier Hospital radiotherapy centre

Further to organisational malfunctions observed during inspections between March and October 2019, the head of external-beam radiotherapy activities at the private Peuplier Hospital of the Ramsay Santé Group, Paris 13th district, was served formal notice on 10 February 2020 to comply with certain regulatory requirements. The measures adopted by the centre to meet the requirements were transmitted to ASN on the set dates and their effective application was checked during a new inspection by ASN on 21 and 22 September 2020, in parallel with a control visit by the Île-de-France Regional Health Agency (ARS).

This inspection revealed a distinct improvement in the situation of the centre. More specifically, the organisation of the medical and medical physics teams, the work of the radiographers and the physicians' assistants have been reorganised. Functions essential for the smooth functioning of the centre and for assisting professionals have been filled by persons involved who have undergone an induction process (deputy director, head radiographer, operational quality manager and quality and risk assistant). Bodies responsible for governance, quality management, consultation and communication have been put in place or revamped, and the associated decisions communicated to the persons concerned. The adverse events internal reporting and analysis system is functioning again, thereby contributing to the continuous improvement of treatment safety. Lastly, activity resumption was organised gradually and as appropriate for the available staff. Lifting of the ASN compliance notice was based on all these points.

ASN will check in 2021 that the new organisation is maintained in a situation of more intense activity.

Follow-ups to the tightened monitoring of the Metz private radiotherapy centre

The technical platform of the Private Radiotherapy Centre of Metz (CPRM) was taken over in May 2019 by Calimetz, a subsidiary of Elsan, a private group of clinics, giving rise to the Private Radiotherapy Institute of Metz (IPRM). The IPRM therefore now holds the license issued by ASN and is responsible for the management of patient and worker radiation protection. Some of the radiotherapist physicians from the CPRM are continuing their medical activity at the IPRM as independent private practitioners.

With this resumption of activity, the new persons in charge have implemented a governance plan that provides for setting up a local management structure, taking control of the quality process and the risk analysis approach, and the overhaul of the information technology resources. Lastly, the centre's organisation has been reviewed and support functions reintroduced internally.

Given this context of significant change, ASN maintained its tightened monitoring of the IPRM's activity in 2019 and 2020, based on regular interchanges and inspections conducted at least annually. ASN's monitoring has confirmed the robustness of the IPRM's approach, which should ultimately meet the conditions needed to lift the tightened monitoring applied to the centre since 2018.

Although particular vigilance is required given the interpersonal relationships, still marked by the past conflicts, and the prospect of the new projects envisaged by the IPRM, such as the implementation of stereotactic techniques, ASN no longer sees any sources of concern for health care safety that would necessitate placing the centre under tightened monitoring.

In order for there to be real continuous improvement in treatment quality and safety, greater efforts must be devoted to regularly assessing the corrective actions put in place, involving all the personnel and using the lessons learned to review the prospective risk analysis, which is mandatory pursuant to the abovementioned ASN resolution 2008-DC-0103 of 1 July 2008.

In addition to the verifications performed, the ability of a centre to deploy a risk management procedure was again subject to specific investigations in 2020. These investigations reveal that:

- Although the requirements for quality and safety management in radiotherapy departments are satisfied on the whole, there are still disparities between centres. The prospective risk analysis for example, which is mandatory, is only available and complete in half of the inspected centres.
- More generally, further to the inspections carried out since 2016, ASN considers that implementation of the risk management procedure is only satisfactory on the whole in half of the inspected centres. These are the centres in which management has defined a policy with shared, assessable and assessed operational objectives, has communicated on the results of this policy and allocated the necessary resources, in particular, to the operational quality manager.

Lastly, ASN still notes in 2020 that the technical, organisational or human changes are not sufficiently planned for in advance. The impact a change can have on the operators' activity is not always analysed, despite the fact that these changes can weaken the existing lines of defence. The lessons learned from the inspections carried out in 2020 show that, when a new technique is deployed,

"Wrong-side" errors, the need to remain attentive throughout the radiotherapy pathway of the patient

So-called "wrong-side" (or laterality) errors are frequent causes of Significant Radiation Protection Events (ESRs) reported to ASN and most often rated level 2 on the ASN-SFRO scale. In 2014 (in collaboration with the professionals), ASN published a *Patient Safety* newsletter dedicated to this type of error (No. 6).

Since then, out of a total of 29 events rated level 2 and two events rated level 2 and higher over the 2014–2020 period, 11 "wrong-side" errors have been reported, 2 of them in 2020.

These errors can occur at various stages from the beginning to the end of a patient's radiotherapy treatment pathway:

- when preparing the medical prescription, whether handwritten or computerised, by failing to consult the documents of the medical file (surgical or anatomy/pathology report) to check the laterality;
- during imaging, due to an error or lack of left/right position indications on the images;
- during dosimetric planning;
- when defining the patient positioning references;
- when carrying out one or more radiotherapy sessions.

To prevent these errors, it is vital to ensure traceability of all the paired organs in all the documents throughout the patients' treatment pathway. Any doubt must be lifted by a collegial review of the radiotherapy file. Lastly, the active participation of the patient or the person accompanying them is key to preventing this type of error.

The importance of taking prior radiotherapy treatments into account: example of a "re-irradiation" due to a second cancer

One Significant Radiation Protection Event (ESR) that occurred in September 2020 provided a reminder of the need to record prior radiotherapy treatments in the patient's computerised medical file. The patient had undergone treatment for a gynaecological cancer in a centre two years previously. Treated in a different centre in 2020 for a lung cancer, the doses delivered during this treatment were duly defined taking into account those delivered during the first treatment. However, when the patient was admitted as an emergency case a few months later for treatment of the lumbar vertebrae, the first treatment was omitted when preparing the third treatment, resulting in overlaps in the fields of irradiation. This error could have been avoided if the treatment data from the first centre had been digitised and integrated in the computerised file of the second centre treating the patient.

The effectiveness of cancer treatments means that more and more patients can receive several radiotherapy treatments in the course of their lifetime, following a relapse, a second cancer or an extension of the disease.

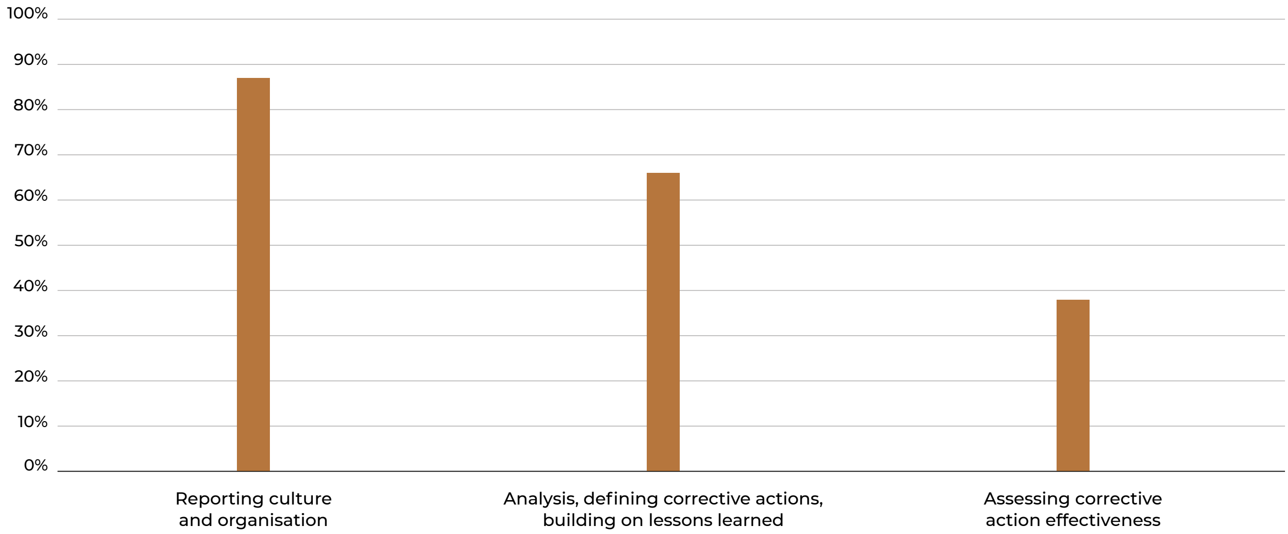
The "re-irradiations" can be staggered over periods ranging from a few weeks to decades, and constitute a new issue in patient radiation protection to which ASN must be particularly attentive. Thirty events have been reported to ASN over the last ten years, some having serious consequences for the patients.

It is sometimes difficult, if not impossible, to identify and take into account a patient's radiotherapy treatment history, depending on how far back the previous treatment dates and the centre in which it was carried out.

Consequently, in June 2020 ASN published a *Patient Safety newsletter* devoted to prior radiotherapy treatments. Good practices and recommendations are set down, especially the need to take into account the prior irradiations in the prospective risk analysis. The importance of having a complete radiotherapy file is also emphasized, as is the need, when a previous irradiation history has been identified, to digitise and integrate in the computerised file all the data concerning the previous irradiations.

GRAPH 6

Percentage of conformity of the facilities concerning the management of events giving rise to corrective actions in 2020



in only 58% of the cases do the centres have adequate command of project management, and in only 69% of the cases do they have adequate command of the installation of the new equipment. These figures nevertheless show distinct progress with respect to 2019, where only 40% and 25% of the departments had an adequate command of project management and the installation of new equipment respectively.

2.3.3 Significant events in external-beam radiotherapy

In 2020, 124 significant radiation protection events were reported in radiotherapy. If the reduction in Significant Radiation Protection Events (ESRs) reported in 2020 can probably be partly attributed to a drop in activity, ASN has noted a distinct reduction in ESRs reported by radiotherapy departments over the last few years. In effect, some 200 ESRs were reported per year in 2014 and 2015.

"Fractionation" errors: example of overdose during a breast cancer treatment

Between 2018 and 2020, ASN received about one hundred reports of Significant Radiation Protection Events (ESRs) linked to a problem of fractionation or protraction of the dose to deliver. The importance of protecting these data in the Record and Verify Systems is all the greater given that the number of hypofractionated stereotactic treatments is bound to increase significantly in the coming years.

ASN published a *Patient Safety* newsletter dedicated to this subject in 2017 (No. 10).

A marking event in 2020 concerning a fractionation error which led to a significant overdose during radiotherapy treatment of a breast cancer was rated level 3 on the ASN-SFRO scale.

The radiotherapist prescribed delivery of a dose of 50 grays (Gy) to the tumour in the right breast, fractionated in 25 sessions.

The administration of a higher dose was detected at the 23rd session, after taking a CT scan to prepare for the end of treatment. At this stage, a dose exceeding 76 Gy had been delivered, instead of the 50 Gy planned for the entire treatment.

There was therefore an over-irradiation of 53% with deterministic effects (oedema of the breast) and an overdose at the right lung which had received more than 20 Gy, a dose beyond which the respiratory capacity is irreversibly diminished. The error resulted from consecutive and discordant manual entries concerning the treatment data. The entry of an incorrect number of sessions in the Treatment Planning Software (TPS)[1] led to the programming of excessively high doses per session. This error was not detected during the transfer and validation of the treatment plan in the Record & Verify software[2], in which the initial prescription was correct.

As soon as this event was reported, ASN immediately initiated an inspection which revealed several contributing factors. Differences were found between practices and the procedures in place, notably concerning the dosimetry validation procedure before the treatment phase, which was not fully adhered to. Furthermore, the risk relating to the manual transcription of the fractionation in the TPS had not been identified in the centre's prospective risks analysis.

1. *The Treatment Planning Software (TPS) enables the medical physicists and dosimetrists, after the target volumes and the organs at risk have been contoured by the radiotherapists, to plan the treatment, that is to say to position the beams such that the tumour is irradiated optimally while preserving the healthy and critical tissues insofar as possible, and perform the provisional calculations of the dose to deliver.*
2. *The Record &Verify software is a medical aid for recording and reducing the risk of errors in the treatment parameters.*

Most of the events reported in 2020 concern patient radiation protection, and the majority of them are not expected to have any clinical consequences.

65% of the events reported in 2020 were rated level 1 on the ASN-SFRO scale. Four events were rated level 2 on the ASN-SFRO scale. They concern two laterality ("wrong-side") errors, one irradiation of a non-targeted area, and one overdose due to a prescription transcription error at the treatment preparation stage. Lastly, one event was rated level 3 on the on the ASN-SFRO scale (see box above).

As in the preceding years, these events always highlight organisational weaknesses concerning:
- 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 a given centre, frequent task interruptions, a heavy and uncontrolled workload having, for example, an impact on treatment amplitudes, or the deployment of a new technique or practice, are all risk factors.

Four ESRs relating to laterality errors were reported to ASN in 2020, two rated level 1 and two rated level 2 on the ASN-SFRO scale.

The level-2 events concerned errors at the target volume contouring stage, the first when treating a head and neck cancer, the second when treating a breast cancer. The following points common to these two events were noted:
- an error occurred at the contouring stage when a radiotherapist defined the volumes to treat;
- the lack of image merging between the diagnostic CT scan performed before surgical ablation of the tumour and the post-surgery CT scan in preparation for external-beam radiotherapy treatment, during the computerised operation which would have made error detection possible;
- the fact that the surgeon did not apply surgical clips after tumoral ablation, which would have provided a landmark;
- the medical file was not verified by the medical physicist at the file validation stage;
- the patients were not questioned on the laterality of their pathology during the first treatment sessions;
- the error was not detected at the medical consultations during of the treatment;
- the error was detected several days after the end of the treatment.

SUMMARY

Even though only 28% of the radiotherapy departments were inspected in 2020, and a quarter of these remotely on account of the health crisis, ASN's radiotherapy inspections confirm that the safety fundamentals are in place (equipment verifications, medical staff training, quality and risk management policy) and the quality assurance procedures are deployed satisfactorily. The prospective risk analyses still remain relatively theoretical and are insufficiently updated prior to organisational and technical changes. Although the inspections frequencies have been reduced in response to the progress made by the radiotherapy centres, some departments presenting vulnerabilities or specific issues will continue to be subject to particular scrutiny and tighter monitoring in 2021. The inspections carried out in 2020 have shown that radiation protection conditions have significantly improved in the centres that have been served a formal compliance notice by ASN or have been subject to tightened monitoring during the preceding years. The occurrence of events such as laterality errors or fractionation errors, sometimes with serious health consequences, reveals persistent organisational weaknesses and the need to assess practices regularly.

3. Brachytherapy

Brachytherapy can be used to treat cancerous tumours either specifically or as a complement to another treatment technique.

Brachytherapy consists in implanting radionuclides, exclusively in the form of sealed sources, either in contact with or inside the solid tumours to be treated.

The main radionuclides used in brachytherapy are iridium-192 and iodine-125.

Brachytherapy uses three techniques (detailed below), depending on the indications.

60 brachytherapy centres are licensed by ASN, and 50 of them use the High Dose-Rate (HDR) technique. ASN issued 13 licenses in 2020. The majority of them were updates to 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 permanently implanted iodine-125 seeds or temporarily implanted caesium-137 seeds.**

Indications:
- Treatment of prostate cancers. Permanent implantation in the patient's prostate gland of seeds with a unit activity of between 10 and 30 megabecquerels (MBq). A treatment requires about 100 seeds, representing a total activity of 1 to 2 gigabecquerels (GBq).
- Treatment of certain eye tumours by temporary implants of iodine-125 placed in a silicone insert (8 to 24 grains per disk), enclosed in a gold-titanium plaque. The seed size is the same as for prostate treatment, but the activity is higher (about 200 MBq per grain). The implants are put in place in the operating theatre under general anaesthetic and the treatment lasts from 1.5 days to one week, with hospitalisation of the patient.
- Treatment of tumours of the endometrium or the uterine cervix by brachytherapy with caesium-137. The treatment is delivered in a shielded hospital room using a caesium-137 afterloader (activity of about 8.2 GBq). The treatment involves 2 to 5 days of hospitalisation. This technique is used very little, pulsed dose-rate brachytherapy being the preferred treatment.

3.1.2 Pulsed Dose-Rate (PDR) brachytherapy

- **delivers dose rates of between 2 and 12 Gy/h;**
- **using sources of iridium-192 with a maximum activity of 18.5 GBq and applied using a specific afterloader.**

Indications: mainly gynaecological cancers, more occasionally bronchus or oesophageal cancer, and exceptionally breast and prostate cancers.

This technique requires patient hospitalisation for several days in a room with radiological protection appropriate to the maximum activity of the radioactive source used. It is based on the use of a single radioactive source which moves in steps, and stops in predetermined positions for predetermined times.

The doses are delivered in sequences of 5 to 20 minutes, sometimes even 50 minutes, every hour for the duration of the planned treatment, hence the name PDR brachytherapy.

Pulsed dose-rate brachytherapy offers a number of advantages with regard to radiation protection:
- no handling of sources;
- no continuous irradiation, which enables the patient to receive medical care without irradiating the staff or having to interrupt the treatment.

However, it is necessary to make provision for accident situations related to the operation of the source afterloader and to the high dose-rate delivered by the sources used.

3.1.3 High Dose-Rate (HDR) brachytherapy

- **delivers dose-rates in excess of 12 Gy/h;**
- **using sources of iridium-192 with a maximum activity of 370 GBq and implemented with a specific afterloader** (some afterloaders use a high-activity cobalt-60 source)

Indications: mainly gynaecological cancers, occasionally the treatment of prostate and bronchus cancers, and exceptionally ear, nose and throat cancers. This technique is also indicated in the treatment of keloid scars.

This technique does not require the patient to be hospitalised in a room with radiological protection; it is performed on an outpatient basis in a room with a configuration comparable to that of an external-beam radiotherapy room. The treatment is performed with an afterloader containing the source and involves one or more sessions lasting a few minutes, spread over several days.

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 (see point 3.3.3).

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.

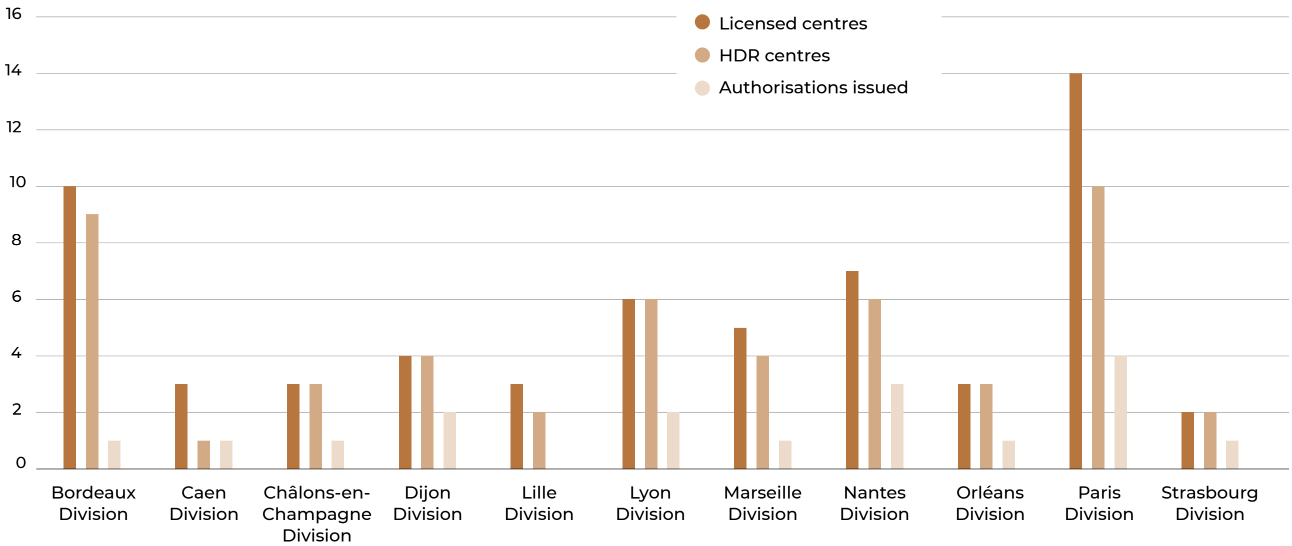
3.3 Radiation protection situation in brachytherapy

In the same way as for external-beam radiotherapy, the safety of brachytherapy treatments has been a priority area of ASN oversight since 2007. The management of high-activity radioactive sources is moreover a specific concern in this activity.

The inspection programme was severely impacted in 2020 by the Covid-19 health crisis. Sixteen inspections were performed out of the 25 initially scheduled, representing about a quarter of the departments. By way of comparison, two-thirds of the departments had been inspected over the last two years. Among the inspections carried out in 2020, seven were conducted remotely, including three with on-site inspection part.

GRAPH 7

Breakdown, by ASN regional division, of the number of brachytherapy centres, of high dose-rate brachytherapy centres and the number of new licenses or license renewals in 2020



3.3.1 Radiation protection of medical professionals

The occupational radiation protection measures deployed in 2020 by the brachytherapy departments were considered satisfactory on the whole, even if these results must be put into perspective given the small number of inspections performed in 2020. Out of the 16 inspected centres possessing high-activity sources, 13 have put in place enhanced training in emergency situations and have organised simulated emergency situation exercises. ASN considers that these efforts must be continued to reinforce the radiation protection training of workers in cases where licenses to hold high-activity sources were delivered in 2020.

3.3.2 Radiation protection of patients

As with external-beam radiotherapy, the radiation protection of brachytherapy patients is assessed from the inspections concerning the implementation of the treatment quality and safety management system.

The presence of medical physicists in sufficient numbers for the activity was observed in all the centres inspected, with one exception where the variations in medical physicist staff numbers led to the postponement of medical procedures. A medical physics organisation plan is also available in all the centres inspected.

The treatment quality and safety management system

The qualitative result of the inspections carried out in 2020 has shown that the majority of brachytherapy departments inspected have deployed the quality management system, with the support of the external-beam radiotherapy departments.

The prospective risks analysis is considered satisfactory in only half of the centres inspected. Although some progress is noted with respect to 2019, the data collected concern fewer centres (a quarter of the centres compared with two-thirds in 2019).

The effectiveness of the corrective actions put in place following adverse events is considered satisfactory in about 45% of the centres inspected, a result comparable with that of 2019. Progress is therefore still required in this respect.

The prior validation of HDR brachytherapy treatments is formalised in 65% of the case, which is a significant improvement on 2019 (52%). While on the subject, ASN underlines the risks associated with the use of high-activity sealed sources (Graph 8).

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, particularly when the sources are replaced. The brachytherapy units rely on these verifications to guarantee correct operation of the devices. Verifications of source activity are also carried out at each source delivery and removal operation.

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 the IRSN and store the sources waiting to be loaded or collected in a suitable place.

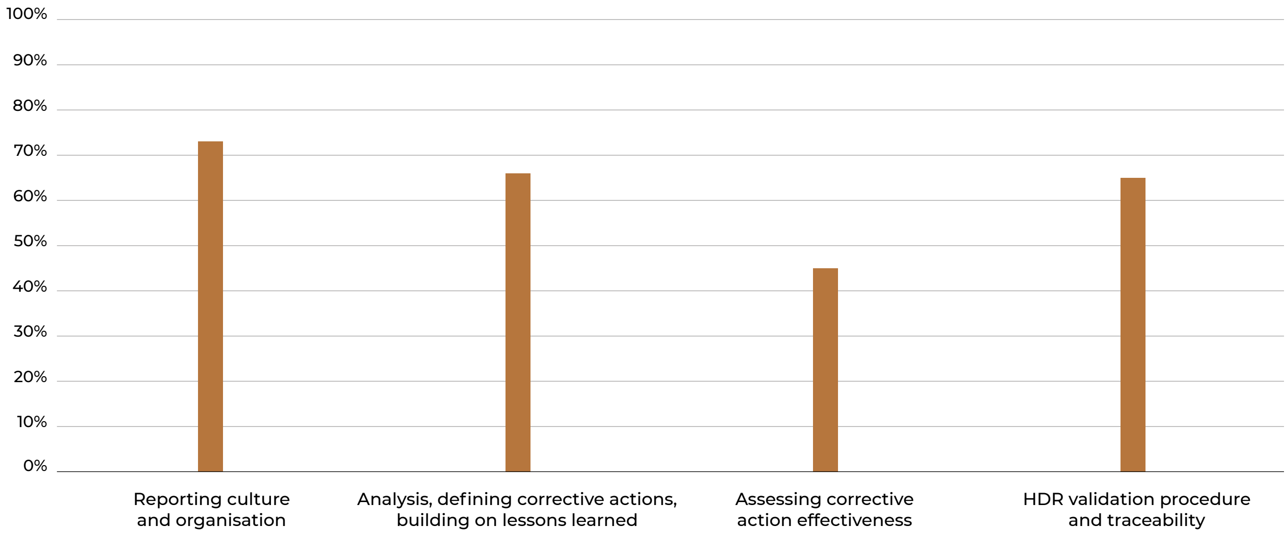
The Order of 29 November 2019 sets the obligations concerning the protection of ionising radiation sources and batches of radioactive sources of categories A, B, C and D against malicious acts The requirements concerning the protection barriers and their resistance time for category A, B and C sources shall be enforceable as from 1 July 2022.

With the exception of just one centre inspected in 2020, the organisational structures in place enable the category of each source or batch of sources to be identified, which is an improvement on 2019. However, the majority of the centres (92%) have still not issued the necessary authorisations to its personnel to access the high-activity sealed sources.

Progress has been noted regarding the safeguarding of access to high-activity sources, with 44% of the centres inspected in 2020 having put in place appropriate measures to prevent unauthorised access to these sources. ASN nevertheless remains attentive to the progress still to be made and inspection of this obligation shall remain a priority in 2021 for the centres holding high-activity sealed sources.

GRAPH 8

Percentage of conformity of the facilities concerning the management of events giving rise to corrective actions in 2020



3.3.4 Emergency situations and management of malfunctions

One event involving the jamming of the source in a PDR applicator was reported in 2020. The event, which occurred when the manufacturer's technician was reloading the applicator, did not lead to personnel or patient overexposure.

This type of event does however provide a reminder of the need to comply with the technical requirements concerning the use of these devices, and the obligations to provide training in emergency situation management and to conduct exercises. The jamming of a source during a maintenance or quality control operation is a precursor event that could arise during a treatment, as happened in 2019.

3.3.5 Significant events in brachytherapy

In 2020, 10 ESRs were reported in brachytherapy, one concerning an overdose during brachytherapy treatment of a keloid scar which was rated level 2 on the ASN-SFRO scale (see box above). In addition, two events having occupational radiation protection consequences resulted from losses of iodine-125 seeds during treatment preparation.

The analysis of these events underlines that the control of risks in brachytherapy must be based on appropriate quality controls and the implementation of organisational measures to better manage the informing of the patient, the sources and emergency situations.

Overdose during brachytherapy treatment of a keloid scar

A patient received brachytherapy treatment for a keloid scar. The dosimetry was approved by the physician and physicist. That same day, two brachytherapy sessions were held five hours apart.

A Significant Radiation Protection Event (ESR) rated level 2 on the ASN-SFRO scale was detected one month after the brachytherapy treatment, when the department physicist compared this patient's file with a similar file.

An error in the irradiation time calculation was discovered, which had led to the patient receiving slightly more than double the prescribed dose. The difference in dose results from choosing the wrong point of dose calculation, set at 1 centimetre (cm) from the catheter instead of 0.5 cm, as provided for in the treatment protocol existing in the department. The patient was informed of the treatment error and is subject to tightened medical monitoring.

The centre has taken the following corrective measures for any keloid scar treatment:
- creation of a check-list for the dosimetry tasks;
- creation of a check-list for medical validation;
- awareness-raising and training on the existing planning protocol.

SUMMARY

With regard to health care safety, the brachytherapy situation appears to be comparable to that of external-beam radiotherapy, but it must be pointed out that ASN could only conduct a few inspections in this area in 2020 on account of the health crisis. 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 securing 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.

A survey conducted in early 2018 with all the nuclear medicine units licensed by ASN was used to establish an inventory of the installed equipment base and its condition, the number of procedures performed using the different technologies, and the human resources. The 2017 data shown below come from that survey.

The total annual number of nuclear medicine procedures in France is about 1,537,000 comprising some 900,000 Single Photon Emission Scintigraphy (SPECT) procedures, 125,000 procedures with semiconductor camera detection and some 500,000 Positron Emission Tomography (PET) procedures (see point 4.1.1).

Nuclear medicine departments

At the end of 2020, this sector of activity comprises 237 nuclear medicine units. The number of ITR rooms nationwide has increased slightly since 2019, going from 155 to 165.

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).

The ASN regional divisions issued 124 nuclear medicine licenses in 2020. They concerned more specifically changes of cameras or license extensions to permit the use of new radionuclides.

Some fifty *in vitro* diagnostic laboratories were inventoried by ASN in 2019, but this number is tending to drop due to the gradual phasing out of this activity in favour of analysis methods that do not use radionuclides.

Medical dispensaries

When a medical dispensary is authorised in a health care centre, the room in the nuclear medicine department in which the radiopharmaceutical drugs are prepared, called the "nuclear pharmacy" or "radiopharmacy", is part of the medical dispensary. In 2019, there were 128 nuclear pharmacies in the nuclear medicine units in public health care institutions and non-profit private health care institutions, such as the cancer centres. The radiopharmacist is primarily responsible for managing the radiopharmaceutical drug circuit (procurement, possession, preparation, control, dispensing and traceability) and the quality of preparation. The radiopharmacist may be assisted by hospital pharmacy dispensers or radiographers.

The equipment

Apart from the cameras used in the nuclear medicine units, some 400 radiation-proof enclosures are installed in the departments, divided roughly equally between "low energy" enclosures (one to two per department) and "high energy" enclosures (one to six per department).

There are also nearly 110 automated or semi-automated devices for preparing radiopharmaceuticals marked with fluorine-18 and about 60 automated injection devices.

Management of effluents from nuclear medicine departments

The management of waste and effluents potentially contaminated by radionuclides must be described in a management plan which includes, more specifically, the conditions of monitoring of discharged effluents in accordance with Article R. 1333-16 of the Public Health Code and ASN resolution 2008-DC-0095 of 29 January 2008. Revision of this resolution began at the end of 2020 and will also lead to an update of ASN Technical Guide No. 18 of 26 January 2012.

One of the 15 recommendations of the working group report[4] "Discharging of effluents containing radionuclides from nuclear medicine units and research laboratories into the sewage network" published in June 2019 on *asn.fr* introduces the notion of setting "contractual" or "management" guidance levels, if applicable, in the discharge license mentioned in Article L. 1331-10 of the Public Health Code.

These guidance levels, whose value would be specific to each centre, are management levels which, in the event of a drift in the measurement results, must trigger an investigation and, if necessary, corrections in the centre's effluents collection and disposal system. ASN called upon the IRSN to propose a measurement protocol and provide each centre with a method for defining their own specific "local" guidance levels. These "local" guidance levels could ultimately figure in the licenses for discharge between the centre generating the wastes and the sewage network managers.

4.1.1 *In vivo* diagnosis

This technique consists in examining an organ or a function of the organism using a specific radioactive substance called a RadioPharmaceutical Drug (RPD) which is administered to a patient. The nature of the RPD depends on the studied organ or function. The radionuclide can be used directly or it can be fixed on 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.

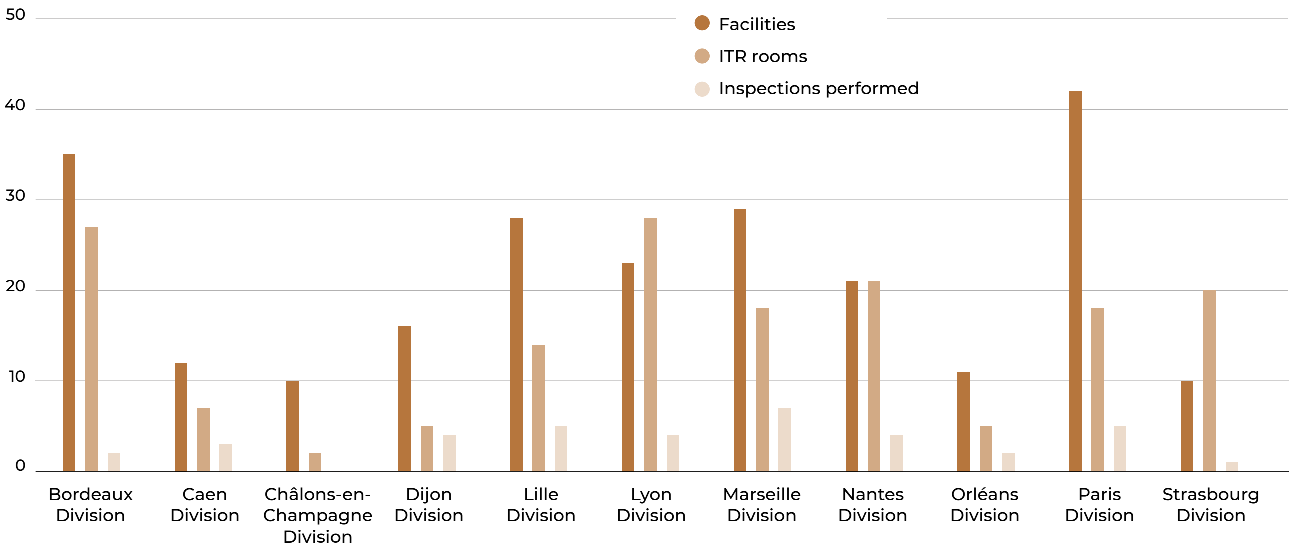
The majority of gamma cameras allow tomographic acquisitions, cross-sectional imaging and a three-dimensional reconstruction of the organs (Single-Photon Emission Tomography – SPECT).

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 RPDs marked with other positron emitters, notably gallium-68, are starting to be used. PET cameras equipped with the Time of Flight (TOF) system allow a lower activity RPD to be injected while still obtaining satisfactory image quality.

4. *asn.fr/Informer/Actualites/Quinze-recommandations-sur-le-deversement-d-eaux-usees-faiblement-contaminees*

GRAPH 9

Breakdown, by ASN regional division, of the nuclear medicine facilities licensed by ASN, the number of hospitalisation rooms dedicated to internal targeted radiotherapy and the number of inspections performed in these facilities by ASN in 2020



Nuclear medicine enables functional images to be produced. It is therefore complementary to the purely morphological images obtained using the other imaging techniques. In order to make it easier to merge functional and morphological images, hybrid appliances have been developed: Positron-Emitting Tomography (PET) scanners are now systematically coupled with a CT scanner (PET-CT) and gamma-cameras can also be equipped with a CT scanner (SPECT-CT).

The installation of semi-conductor cameras (Cadmium Zinc Telluride – CZT), which have very high detection sensitivity, is continuing to develop, particularly in health care centres performing a large number of examinations of the myocardial function. These cameras effectively provide for faster and more comfortable scintigraphic imaging and give a more reliable diagnosis. Research in this area is continuing with the installation in 2020 of two whole body gamma-cameras 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 base of PET cameras comprised:
- 158 PET cameras, all coupled to a CT scanner, accounting for 486,000 procedures per year;
- 4 PET cameras coupled to an MRI scanner, performing some 2,000 procedures 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. Radioimmunology is challenged by techniques that do not use radioactivity, such as immuno-enzymology and chemiluminescence. A few techniques use other radionuclides such as tritium or carbon-14. Here again the activity levels involved are of the order of the kilobecquerel.

4.1.3 Internal targeted radiotherapy

Used for therapeutic purposes, the aim of the administered RPDs is to deliver a high dose of ionising radiation to a target organ for curative or palliative purposes. Two areas of therapeutic application of nuclear medicine can be identified: oncology and non-oncological conditions (treatment of forms of hyperthyroidism, synoviorthesis).

Several types of cancer treatment can be identified:
- treatments administered by nonspecific systemic route, such as thyroid cancer by iodine-131, non-Hodgkin lymphoma by monoclonal antibodies marked with yttrium-90, prostate cancer which has spread to the bones by radium-223, treatment of neuroendocrine or prostate cancers by molecules marked with lutetium-177 (lutetium therapy);
- treatments administered by selective systemic route (treatment of liver cancers by administering microspheres marked with yttrium-90 through a catheter placed in an artery).

Some treatments require patients to be hospitalised for several days in specially fitted-out rooms in the nuclear medicine unit to ensure the radiation protection of the personnel, of people visiting the patients and of the environment. The radiological protection of these rooms is adapted to the nature of the radiation emitted by the radionuclides, and the contaminated urine of the patients is collected in tanks. This is particularly the case with the post-surgical treatment of certain thyroid cancers. The treatments are performed by administering iodine-131 with activities varying from 1.1 GBq to 5.5 GBq.

For therapeutic purposes, there are 165 ITR hospital rooms distributed over 45 nuclear medicine units (see Graph 9).

Other treatments can be administered 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. Radioimmunotherapy can be used to treat certain lymphomas using yttrium-90 labelled antibodies.

Lastly, many patients are treated without being hospitalised, mainly for iodine-131 treatments (other than cancer) and, to a lesser extent, for synoviortheses or palliative treatment of metastatic pains.

4.1.4 Research in nuclear medicine involving humans

Nuclear medicine research conducted on humans has been particularly dynamic in the last few years, with the regular introduction of protocols involving new radionuclides and vectors. Research focusing on the use of new tracers is continuing as much in diagnostic imaging (fluorine-18-fluoroestradiol, development of peptides marked with gallium-68, cardiac applications of iodine-124, exploration of pulmonary ventilation by aerosols marked with gallium-68, etc.) as in therapy (development of new molecules marked with lutetium-177, molecules marked with copper-64, etc.).

The use of new RPDs means that the radiation protection requirements associated with their use must be integrated as early as possible in the process. Indeed, given the activity levels involved, the characteristics of certain radionuclides and the preparations to produce, appropriate measures must be implemented with regard to operator exposure and environmental impact.

To anticipate the impact of these developments in radiation protection, ASN has called upon the IRSN to examine the prospects of using new radionuclides that could be put onto the French market in the years to come. What is expected: a bibliographic study of the radionuclides showing promise for use in humans and those already used in Europe or elsewhere in the world; the clinical application prospects; the radiation

TABLE 3

Main radionuclides used in diverse *in vivo* nuclear medicine explorations

TYPE OF EXAMINATION	RADIONUCLIDES USED
Thyroid metabolism	Iodine-123, technetium-99m
Myocardial perfusion	Thallium-201, technetium-99m, rubidium-82
Lung perfusion	Technetium-99m
Lung ventilation	Technetium-99m, krypton-81m
Osteoarticular process	Technetium-99m, fluorine-18
Renal exploration	Technetium-99m
Oncology – search for metastases	Technetium-99m, fluorine-18, gallium-68
Neurology	Technetium-99m, fluorine-18

Circular letter to medical centres on the management of patients treated with lutetium-177

Lutetium-177 (^{177}Lu) is indicated for the treatment of certain neuroendocrine tumours in the adult and is the subject of much clinical research in the treatment of prostate cancers. Given its therapeutic prospects and the arrival of new vector molecules, the number of patients that could receive this type of Internal Targeted Radiotherapy (ITR) could increase significantly in the years to come.

This is why ASN has updated the licensing conditions, previously formalised in 2014, for the possession and use of lutetium–177 by the nuclear medicine departments.

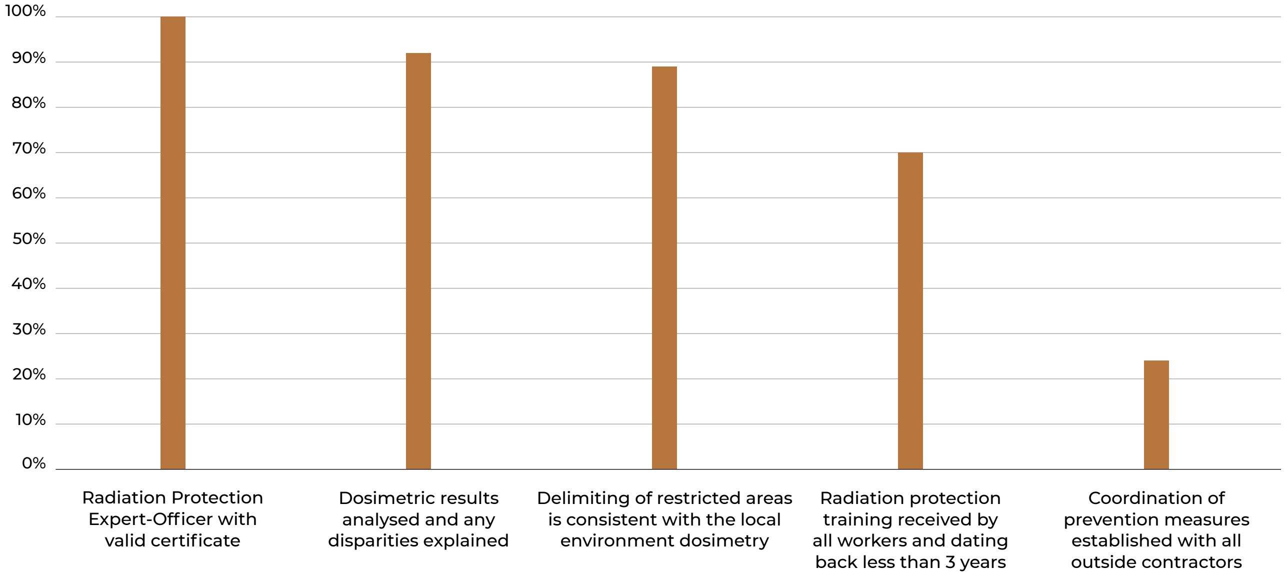
This reassessment of the ASN recommendations concerns the treatment of patients and the management of waste and effluents. It is based on two opinions of the Advisory Committee on Radiation Protection for Forensic and Medical Applications of Ionising Radiation (GPMED) published in 2017 and on the consultation with the stakeholders on this theme. The recommendations resulting from this work were distributed to the heads of nuclear medicine departments, directors of health care institutions, and public sewage system managers by circular letter of 12 June 2020.

Good hospitalisation practices for patients in rooms or premises allowing the collection of contaminated urine in tanks, for a sufficiently long period, are reiterated in this letter. During the time necessary for the construction of appropriate new facilities in the health care centres, treatment on an "out-patient" basis is nevertheless possible within the nuclear medicine department. This temporary arrangement is subject to special precautions and an assessment of the impact of the discharges, which must be less than 1 millisievert (mSv) for all the categories of workers in the sewage system sector. The circular letter also provides details on the management of liquid effluents contaminated by lutetium-177.

ASN points out that the instructions given to the patient when discharged from hospital may be adapted individually, under the responsibility of the physician, while ensuring the radiological protection of the people in the patient's close environment. Lastly, the professionals involved in the treatment of these patients, who do not normally work in a nuclear medicine department, must receive reinforced on-site training in the radiation protection measures. Specifications are provided for this purpose.

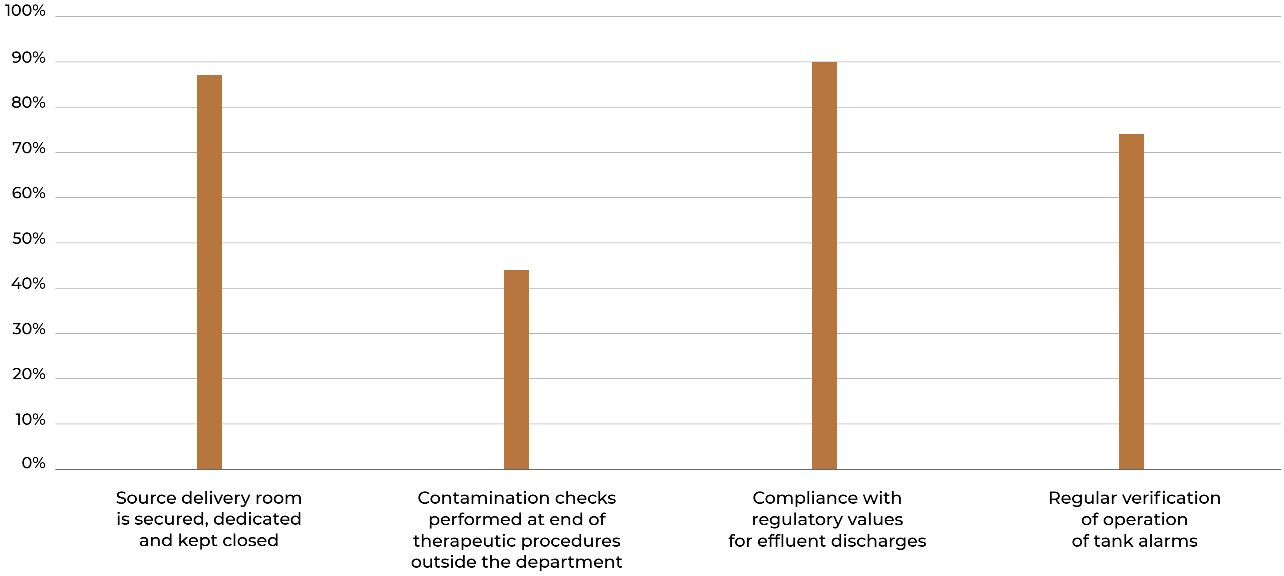
GRAPH 10

Percentage of conformity of the nuclear medicine departments inspected with regard to radiation protection of medical professionals in 2020



GRAPH 11

Percentage of conformity of the nuclear medicine departments inspected with regard to protection of the public and the environment in 2020



protection measures in patients and their family, carers and comforters where applicable, and the workers that will be required to handle the radionuclides, particularly during their preparation in the hospital.

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. Guide No. 32 detailing certain aspects of this resolution was published by ASN in May 2017 and was updated in February 2020.

Compliance with ASN resolution 2017-DC-0591
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[5].

Compliance with ASN resolution 2008-DC-0095
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[6]. 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 for collecting the effluents and wastes produced by nuclear medicine units must be verified regularly (see point 4.3.3.).

4.3 Radiation protection situation in nuclear medicine

37 nuclear medicine departments, which represents 15% of the facilities, were inspected in 2020. As a result of the inspection adaptations due to the pandemic, 13 inspections were carried out remotely, including 5 which nevertheless included a short on-site visit.

4.3.1 Radiation protection conformity of nuclear medicine professionals

From the radiological viewpoint, the personnel are subjected to a risk of external exposure – in particular on the fingers – due to the handling of certain radionuclides (case with fluorine-18, iodine-131 or yttrium-90) when preparing and injecting RPDs, and a risk of internal exposure through accidental intake of radioactive substances.

The results concerning radiation protection of professionals (see Graph 10) show that the radiation protection measures implemented by nuclear medicine departments are generally satisfactory with regard to the appointing of a Radiation Protection Expert-Officer (RPE-O) dedicated to this activity (valid certificate issued by the employer in all the inspected departments), the analysis of the dosimetric results of the medical staff, and the consistency between the delimiting of restricted areas and the results of the working environment verifications.

Two lines for improvement have nevertheless been identified, namely updating of personnel training (in 70% of the departments), all the staff concerned received this training less than three years ago, and coordination with outside contractors (only 24% of the departments have established coordination measures with all outside contractors and 32% with more than 50% of them).

Alongside this, the radiation protection technical verifications have been carried out over the last two years at the regulatory frequency for all the sources and devices and for the radioactivity measuring and detection devices, in nearly 90% of the 37 departments inspected. Only two of the 22 departments concerned by nonconformities had not corrected them.

4.3.2 Radiation protection of nuclear medicine patients

Since ASN resolution 2019-DC-0667 of 18 April 2019 on diagnostic reference levels[7] came into effect, ASN has been assessing the new requirements concerning the quality of collection of doses, their analysis and the optimisation put in place where necessary. The inspections carried out were satisfactory in 54% of the departments. However, 19% of the departments had not optimised their practices even though this was necessary. In four departments the requirements were only partially implemented.

The external quality controls of the last two years have moreover been carried out on all the medical devices at the required regulatory frequency and the nonconformities discovered have been remedied in 92% of the departments. In two departments, not all the devices concerned had undergone the quality controls.

The organisation put in place to integrate medical physicists and specify their duties and time of presence on site is only fully defined in 65% of the departments. In 35% of cases the medical physics organisation described in the Medical Physics Organisation Plan (POPM) was judged insufficient with regard to the risks the activity involves.

4.3.3 Protection of the general public and the environment

Implementation of the requirements concerning protection of the public and the environment is judged acceptable in the majority of the inspected centres (see Graph 11).

Thus, 87% des services have a dedicated and protected deliveries area that complies with the requirements of ASN resolution 2014-DC-0463 of 23 October 2014. In 90% of the departments the activity concentration of the effluents discharged after decay complies with the regulatory limits (10 becquerels per litre – Bq/L – for contaminated effluents after storage, or 100 Bq/L for effluents from the rooms of patients treated with iodine-131).

Nevertheless, progress is expected:
- in non-nuclear medicine departments that use unsealed sources (19 such departments inspected in 2020), given that less than half of them carried out the non-contamination verifications required by the protocol at the end of therapeutic procedures;
- in the verification and traceability of the tank leak detector operating checks which are only fully ensured in 27 of the 37 departments inspected.

4.3.4 Significant events in nuclear medicine

Out of the 37 departments inspected, 64% have a system for recording adverse events. These latter departments analysed the events and reported them to ASN when necessary. Six departments did not have an events recording system, and two had not reported any events.

132 ESRs were reported in 2020, a reduction of nearly a quarter compared with 2019. This drop is probably a consequence of the health crisis, which has led to a reduction in the number of examinations carried out.

As in the preceding years, most of the reported events (70%) concerned the patients who had undergone a nuclear medicine procedure. The majority of the reported events have no expected clinical consequences.

5. ASN resolution 2017-DC-0591 of 13 June 2017 setting the minimum technical design rules to be met by premises in which X-ray emitting devices are used.
6. ASN resolution 2008-DC-0095 of 29 January 2008 setting the technical rules for the elimination of effluents and wastes which are or could be contaminated by radionuclides due to a nuclear activity, taken in application of the provisions of Article R. 1333-12 of the Public Health Code.
7. Order of 23 May 2019 approving ASN resolution 2019-DC-0667 of 18 April 2019, concerning the methods for evaluating ionising radiation doses delivered to patients during a radiology procedure, Fluoroscopy-Guided Interventional or nuclear medicine practices, and the updating of the corresponding diagnostic reference levels.

Transport of radioactive substances: vigilance required from start to finish

The police were alerted on 6 October 2020 by a resident of Châtillon (a municipality in the Hauts-de-Seine *département*) who discovered two packages of radioactive substances on the public highway, one in front of a nursery school, the other a little further along the road. This discovery led to the setting up of a wide security perimeter, triggering of the "Vigipirate" anti-terrorist procedure and evacuation of the children from the nursery school.

The Central Laboratory of the Paris Police Prefecture (LCPP) rapidly informed the ASN Paris division, which went to the scene and confirmed that the two packages contained no radioactivity. The two packages were of the "excepted" type classified under the UN number 2908 corresponding to empty packages having contained radiopharmaceutical products used by a nuclear medicine department for diagnostic examinations, and sent back by this department after use to the supplier of the products.

This event was caused by negligence on the part of the carrier transporting these packages: the driver ended his round without delivering the two packages to the addressee as required by the regulations, leaving them in the vehicle which was broken into during the night, and the following morning he did not notice that the two packages were missing.

Good coordination between the LCPP, the nuclear medicine department that dispatched the packages and ASN enabled the situation to be resolved rapidly. Nonetheless, the following deviations from the requirements of radioactive substance transport regulations were noted concerning this event:

- the marking of the two packages dispatched was noncompliant because they bore the "type A" caption required for packages containing a much larger quantity of radioactive substance, which led to the deployment of a security perimeter that was much wider than necessary around the two empty packages;
- the transport document had not been kept for the minimum period of three months required by the regulations;
- the carrier company had not ensured accurate traceability of the two dispatched packages.

The radioactive substance transport regulations apply to excepted packages classified under UN number 2908, even though they no longer contain radioactive products. To prevent the occurrence of this type of event, the transport carriers must not neglect these rules.

Significant events concerning patients (93 ESRs, i.e. 70% of the reported ESRs)

The majority of the reported ESRs concerning nuclear medicine patients are linked to errors in the administration of an RPD (interchanging of syringes or patients), errors during preparation of the medication (interchanging of bottles), in the scheduling of the examinations, to unnecessary or double exposure of the patient to the CT scanner linked to the non-administration of an RPD or the wrong RPD. One reported event concerned a scintigraphy procedure carried out between two colleagues with no medical prescription whatsoever.

Two events occurred during therapeutic procedures: administration of an iodine-131 capsule of 550 MBq intended for another patient instead of the 370 MBq capsule prescribed, and administration of a lower dose of Lutathera® (about 1,800 MBq) than the prescribed dose (3,900 MBq) due to overflowing of the bottle caused by a system pressure problem (without causing any external contamination).

Significant events concerning medical professionals (20 ESRs, i.e. 15% of the reported ESRs)

Twenty events concerning medical professionals were reported in 2020. They resulted from external contaminations, external exposure to non-decayed or externally contaminated technetium-99m generators. No exceeding of regulatory values was reported in 2020.

Significant events concerning the public (10 ESRs, i.e. 8% of the reported ESRs)

All these events concerned exposure of the foetus in women unaware of their pregnancy. The doses received had no consequences for the child (source: ICRP, 2007).

Three of these events concerned women who received a justified iodine-131 treatment while they were taking a contraceptive and had undergone pregnancy checks that gave a negative result.

Significant events concerning radioactive sources, waste and effluents (9 ESRs, i.e. 7% of the reported ESRs)

The majority of these ESRs are linked to the discovery of radioactive sources and the unauthorised discharge of effluents into the environment (emptying of tanks, etc.). One noteworthy case involved the triggering of a waste disposal site radiation portal monitor by waste from a patient hospitalised in a centre other than that in which they underwent the nuclear medicine procedure. One centre reported the dispersion of effluents caused by a leak in the wastewater drainage pipe from the toilets of the ITR rooms, at the pipe manhole situated below the rooms, inside the centre. Work has been carried out to replace sections of the wastewater drainage network.

SUMMARY

The radiation protection of patients and professionals in the inspected nuclear medicine departments is satisfactory. Progress is nevertheless required in the optimisation of practices and the training of medical professionals in occupational radiation protection must be continued. In addition, the coordination of preventive measures during work by outside contractors (for equipment maintenance, cleaning of the premises, etc.) must be improved. One of the radiation protection challenges is also to ensure good management of the radioactive effluents. This 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. The reported events underline that the radiopharmaceutical drug administration process must be regularly assessed in order to control it, particularly in therapeutic procedures.

5. Fluoroscopy-Guided Interventional practices

5.1 Overview of the techniques and the equipment

FGI practices group all the imaging techniques using ionising radiation to perform invasive medical or surgical procedures for diagnostic, preventive and/or therapeutic purposes, and surgical and medical procedures using ionising radiation for the purpose of guidance or verification.

The equipment

The equipment items used are either fixed C-arm devices installed in the interventional imaging departments in which vascular specialities (neuroradiology, cardiology, etc.) are carried out, or mobile C-arm radiology devices used chiefly in operating theatres in several surgical specialities such as vascular surgery, 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. Practitioners can also use the subtraction method to obtain images, after injecting a contrast agent. Surgeons have recently started to use CT scanners, sometimes mobile or rail-mounted, in the operating theatre. This type of equipment helps the practitioner perform the procedure by providing multi-plane images allowing virtual navigation. These scanners however are not equipped with the latest dose-reduction technologies. The personnel most often work in the immediate proximity of the patient and are also exposed to higher dose levels than in other interventional practices. In these conditions, given the exposure risks for both the operator and the patient, practices must be optimised to reduce doses and ensure the radiation protection of operators and patients alike.

The health care centres

On the basis of the code of the common classification of medical procedures and the activity data reported by the health care centres to the Agency for Information on Hospital Care (AIHC), 903 centres performing FGI practices involving risks (with regard to radiation protection) in one or more disciplines have been inventoried. The distribution of the number of centres by category of Fluoroscopy-Guided Interventional practice is shown in Graph 12.

In 2020, the ASN regional divisions issued 450 acknowledgements of notification of Fluoroscopy-Guided Interventional procedures.

5.2 Technical rules for the fitting out of medical rooms

The rooms in which fluoroscopy-guided intervention procedures are carried out, operating theatres and interventional imaging rooms must be organised in accordance with the provisions of ASN resolution 2017-DC-0591 of 13 June 2017 mentioned in point 4.2.

Few centres are compliant with this resolution because the signalling and safety systems are often absent; as for the technical reports, of those that do actually exist, many are incomplete. ASN has noted that interventional radiology departments comply with this resolution to a greater extent than operating theatres.

5.3 Radiation protection situation in Fluoroscopy-Guided Interventional practices

For several years now, significant radiation protection events have been regularly reported to ASN in the area of FGI 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 under-gone particularly long and complex interventional procedures. In addition to these events, which underline the major radiation exposure risks for the patients, are those concerning professionals, whose exposure can lead to the exceeding of regulatory limits, particularly at the extremities (fingers).

On account of the radiation exposure risks, ASN carries out a large number of inspections in this sector. In 2020, 144 centres representing 238 departments were inspected. These inspections were carried out in interventional imaging departments (rooms dedicated to interventional vascular and osteoarticular radiology, to neuroradiology and to cardiology) and in surgical departments (operating theatre) performing Fluoroscopy-Guided Interventional procedures. 55% of the inspections in 2020 were carried out in operating theatre departments. Fifty-nine centres were inspected entirely remotely and 15 by a remote inspection followed by a short on-site visit.

Characteristics of the inspected departments

238 departments underwent an inspection, with the following breakdown:

- of the 131 operating theatre departments inspected in 2020, 121 had at least one mobile C-arm, 8 had fixed arms and 2 had a mobile CT scanner. To adapt to the departments' organisational constraints on account of the Covid-19 pandemic, ASN inspected 53 departments entirely remotely and 17 by a remote inspection followed by a short on-site visit;
- the 107 interventional imaging departments inspected were broken down as follows: 37 cardiology – coronary angiography departments, 29 cardiology – rhythmology departments, 34 vascular and osteoarticular interventional radiology departments and 7 neuroradiology departments. Eighty-two had at least one fixed C-arm, 14 had mobile C-arms and 11 had fixed CT scanners;
- 42 departments were inspected entirely remotely and 23 by remote inspection followed by a short on-site visit.

More than 76% of the inspected interventional imaging departments have fixed C-arms, whereas in the operating theatres the physicians mainly use mobile C-arms (92%) to guide their surgical procedures. Furthermore, operating theatres are being equipped with ever-more efficient and sophisticated medical devices. These are mobile CT scanners or fixed C-arms in "hybrid" rooms which combine the characteristics of a conventional surgical room with those of an interventional imaging room; this combination enables the surgeon to perform "mini-invasive" surgery with 2D and 3D imaging. Fixed CT scanners coupled to fixed C-arms are also beginning to be installed in health care centres.

5.3.1 Radiation protection of medical professionals

In interventional imaging departments and in operating theatres

The radiation protection of professionals is judged satisfactory, particularly with the appointing of a RPE-O in about 93% of the departments inspected and the implementation of radiological zoning in the facilities in 84% of the services inspected. For the remaining 7%, there is either no internal RPE-O or the external RPE-O is not present during the FGI procedures as required by ASN resolution 2009-DC-0147 of 16 July 2009.

However, the lack of training of the medical professionals in occupational radiation protection, especially practitioners working in operating theatres, is a recurrent inspection finding. Refresher training for all the personnel is provided in just one quarter of the departments inspected.

The occupational radiation protection training of the medical and paramedical professionals who use machines with fixed C-arms in dedicated rooms also remains low, even if they are on the whole better trained.

Although collective radiation protection equipment is available for the interventional imaging departments, it is still too rarely present in the operating theatres.

The coordination of prevention measures with the outside contractors working in the interventional imaging departments and in the operating theatres was clearly inadequate in 2019, with only 26% of the centres having formalised these coordination measures in a prevention plan signed with all the outside contractors. This situation is even less satisfactory in 2020, with only 20% of the inspected centres having formalised their prevention plan with all the outside contractors.

More specifically in the operating theatres

In 76% of the inspected sites the operating theatre professionals have dosimetric monitoring devices that are appropriate for worker exposure and in sufficient quantity. Although this is still insufficient, ASN notes results that are slightly up on 2019.

The lack of appropriate dosimetric monitoring for certain fluoroscopy-guided procedures, particularly at the extremities, and the absence of medical monitoring of the practitioners, make it difficult to assess the radiation protection situation of these professionals in the operating theatres.

There are still organisational difficulties for the RPE-Os, who do not always have sufficient means to perform their duties in full. Furthermore, the time allocated to their duties is not always appropriate, particularly in some centres which rely on the RPE-O to ensure patient radiation protection. ASN notes that the RPE-Os analyse the dosimetric results in order to detect incorrect practices and remedy them. In operating theatres in the private sector, dosimetric monitoring, medical monitoring and, where applicable, employee monitoring, represent a recurrent difficulty.

Radiation protection technical verifications

Radiation protection external technical verifications were carried out in 79% of the interventional imaging departments and about 69% of the operating theatres. When nonconformities were identified, they were already corrected or were being corrected in 72% of the cases when the inspection was carried out, a result that up on 2019 (66%). There is nevertheless still room for progress in meeting the required verification frequencies.

5.3.2 Radiation protection of patients

The findings established on completion of the inspections in 2020 with regard to patient radiation protection confirm the observations made over the last few years (see Graph 14).

ASN thus still observes that little use is made of medical physicists in the departments practicing Fluoroscopy-Guided Interventional procedures, and that the POPMs contain very few details concerning the organisation of medical physics for radio-guided interventional practices (the duties and times of presence of the medical physicist according to the activities are not specified). This slows down implementation of the optimisation principle. Close collaboration between the operator and medical physicist and the regular presence of the latter would allow, among other things, the equipment to be better used, with the application of protocols adapted to the procedures performed, recording of the delivered doses and the evaluation in the light of dosimetric reference levels to be defined locally. When medical centres use outside contractors proposing medical physics services, it is observed that few centres embrace the optimisation approach. These findings have been noted in particular in the operating theatres, where the optimisation approach is rarely put in place, a situation that must be remedied.

In interventional imaging departments and in operating theatres

The observed shortcomings concern firstly the training of medical professionals in patient radiation protection (all the personnel are up to date in their training in 28% of the interventional imaging departments and 9% of operating theatres), and secondly, application of the principle of procedure optimisation, as much in the setting of device parameters and the protocols used as in the practices.

ASN notes that the doses are recorded, analysed and optimised in 33% of the operating theatres and 62% of the interventional imaging departments inspected. Patient monitoring in cases where the exposure threshold for the skin is exceeded, defined by the HAS[8] is not very satisfactory, particularly in operating theatres (65% for operating theatres and 84% for interventional imaging departments).

Reference levels for the most common examinations are being developed locally more and more often. This approach makes it possible, among other things, to set alert levels for triggering appropriate medical monitoring of the patient according to the dose levels delivered to the patient. The patient dose archiving and analysis systems currently being deployed facilitate the development of local reference levels and alert levels per machine and per type of procedure. These systems are an asset for determining the doses previously received by the patient and for monitoring the patient.

The third-party quality controls of the medical devices are generally carried out at the right frequency and on the day of the inspection any previously detected nonconformities had been or were being corrected, equally well in the operating theatres as in the interventional imaging departments.

More specifically in the operating theatres

The medical personnel in the operating theatre has insufficient knowledge of the reference dose levels for the types of procedure performed. The theatre C-arms, due to their mobility, are more rarely connected to the centre's archiving systems than the fixed C-arms of the interventional imaging departments.

5.3.3 Significant events relating to Fluoroscopy-Guided Interventional practices

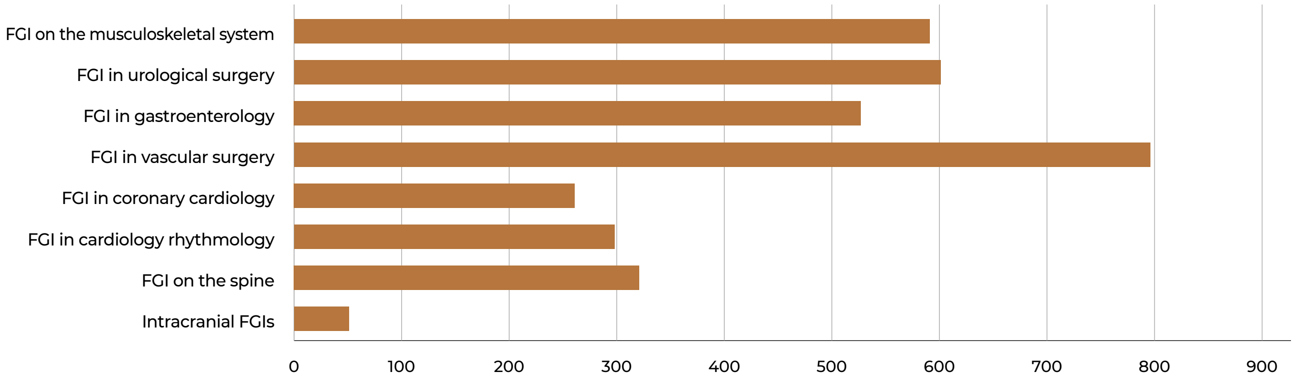
An events recording system is in place in more than 76% of the sites inspected. 28 significant events were reported in this area in 2020, of which 4 also formed the subject of a medical devices vigilance notification:
- 10 concerned overexposure of patients, some of which led to deterministic effects such as transient hair loss (alopecia – three cases) or radiodermatitis (1 case);
- 15 concerned exposure of medical professionals;
- 3 concerned pregnant women exposed during a FGI examination; these women were unaware of their pregnancy at the time of exposure.

For the ESRs concerning patients, most of the overexposures are due to long and complex procedures (in cardiology and

8. *Improving patient monitoring in interventional radiology and fluoroscopy-guided procedures – reducing the risk of deterministic effects of 21 May 2014.*

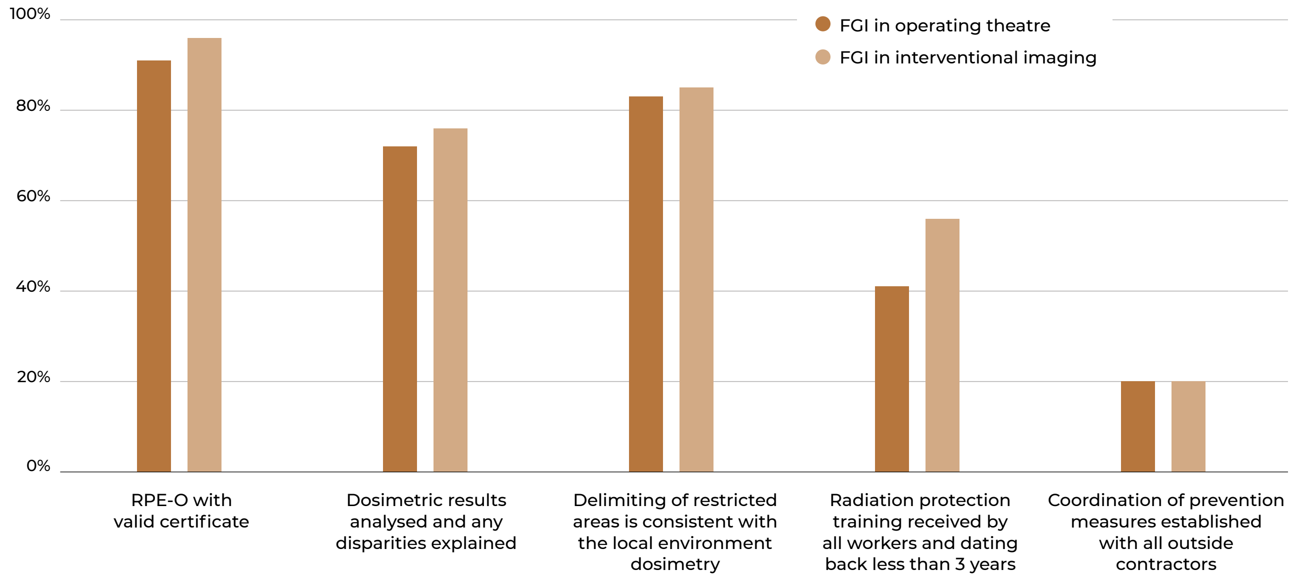
GRAPH 12

Breakdown of the number of centres by category of Fluoroscopy-Guided Interventional practices in 2020



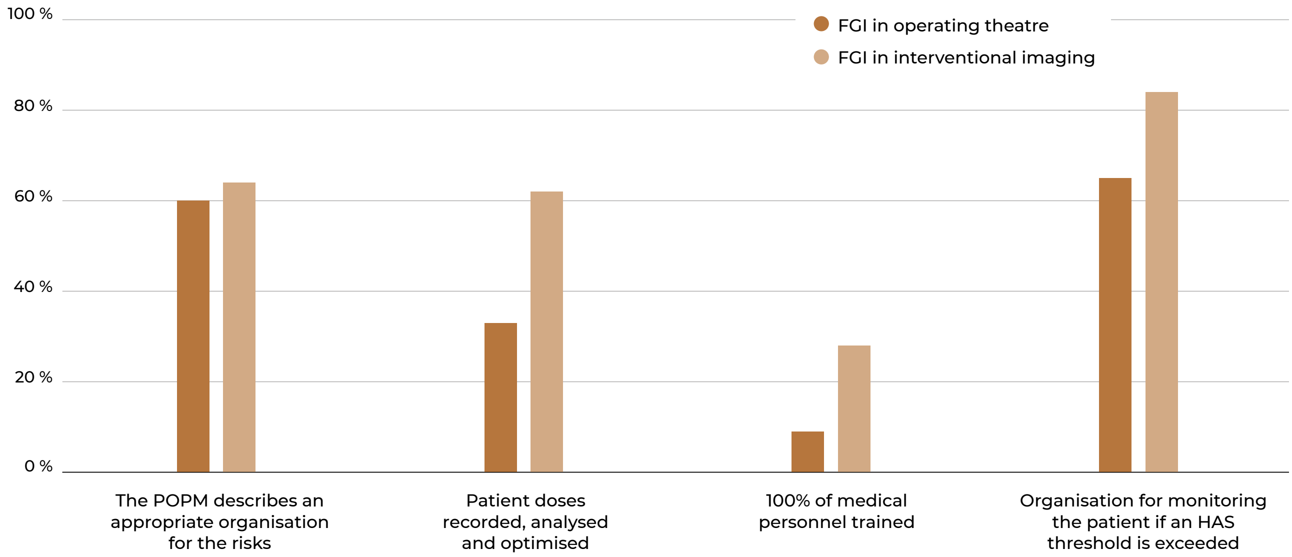
GRAPH 13

Percentage of conformity of the FGI facilities inspected on the theme of radiation protection of medical professionals in 2020



GRAPH 14

Percentage of conformity of the FGI facilities inspected on the theme of radiation protection of patients in 2020



Fluoroscopy-Guided Interventional practices in the operating theatre: the recommendations of the Advisory Committee for Radiation Protection in Medical and Forensic Applications of Ionising Radiation

Fluoroscopy-Guided Interventional (FGI) practices in the operating theatres are in full expansion, in both the diversity of the procedures and the number of specialist areas concerned and the medical devices used. If radiation protection in FGI procedures performed on fixed X-ray equipment has significantly improved in the last decade, ASN inspections highlight shortcomings in procedures performed in the operating theatre. The radiation exposure risks for each patient are usually low. On the other hand, occupational exposure risks are increasing due to the large number of procedures carried out. The risks are primarily linked to a poor culture in the basic rules of radiation protection. Significant progress remains to be made in the context of surgical procedures.

In 2020, ASN published a report setting out recommendations with a view to improving radiation protection during FGI procedures in operating theatres. This report proposes 20 recommendations focusing on four areas:
- quality and risk management;
- the responsibilities of each player;
- radiation protection training;
- the radiation protection tools to develop.

On the basis of these recommendations, a circular letter dated 29 July 2020 was sent to all the health care institutions.

neuroradiology). One of them concerned overexposure linked to a medical device defect. One patient was exposed accidentally by the personnel, the fluoroscopy pedal being blocked in the X-ray emission "mode" under the medical device.

The ESRs reported for medical professionals were due to accidental overexposure. For three professionals, the regulatory limits at the extremities or for the whole body were exceeded. Two events occurred during the stowage of the device emitting ionising radiation (device powered on) or the bio-cleaning.

SUMMARY

In the area of FGI practices, ASN observes that, as in the preceding years, the level of radiation protection of patients and professionals – particularly for surgical procedures performed in operating theatres – is still insufficient. This is why new recommendations to improve radiation protection in the operating theatres were issued in 2020. Deviations from the regulations are still noted frequently during inspections, in the radiation protection of patients and professionals alike, and events are still reported to ASN concerning interventional practitioners having exceeded dose limits. The radiation protection situation is however significantly better in the departments that have been using these technologies for a long time, such as the imaging departments performing interventional cardiology and neurology activities. Extensive work to raise the awareness of all the medical, paramedical and administrative professionals in the centres is still necessary to give them a clearer perception of the risks, especially for operating theatre staff.

Continuous training of medical professionals, especially practitioners, and the involvement of the medical physicist to optimise the radiation protection aspects of intervention protocols, are two key focuses for controlling 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 CT scanner, etc.).

The request for a radiological examination by the physician must be part of a diagnostic strategy taking account of the patient's known medical history, the question posed, the expected benefit for the patient, the examination exposure level and the dose history and the possibilities offered by other non-irradiating investigative techniques. A guide intended for general practitioners (*Guide to good medical imaging examination practices*) indicates the most appropriate examinations to request according to the clinical situations.

6.1.1 Medical radiodiagnosis

Conventional radiology

Conventional radiology (producing radiographic images, or radiographs), if considered by the number of procedures, represents the large majority of radiological examinations performed.

The examinations mainly concern the bones, the thorax and the abdomen. Conventional radiology can be carried out in fixed facilities reserved for diagnostic radiology or, in certain cases, using portable devices if justified by the clinical situation of the patient.

Angiography
This technique, used for exploring blood vessels, involves injecting a radio-opaque contrast agent into the vessels which enables the arterial tree (arteriography) or venous tree (venography) to be visualised. Angiography techniques benefit from computerised image processing (such as digital subtraction angiography).

Mammography
Given the composition of the mammary gland and the fineness of the details required to make a diagnosis, specific devices (mammography units) are used. They operate at low voltage and provide high resolution and high contrast. They are used in particular in the national breast cancer screening programme.

ASN was consulted and gave a favourable opinion on the draft resolution relative to the internal and external quality controls of digital mammography facilities. This resolution updates the checks performed on 2D mammography units and provides for third-party quality controls on the tomosynthesis devices.

Tomosynthesis is a new three-dimensional breast imaging technique that is developing in Europe without any form of quality control. The evaluations of this technique, currently in progress in several European countries, should enable its advantages compared with the traditional planar technique to be determined. At present, this technique is not validated for use in organised breast cancer screening. ASN participates in a working group, coordinated by the HAS, to assess the position of tomosynthesis mammography in the breast cancer screening strategy.

Computed tomography
CT scanners use a beam of X-rays emitted by a tube which moves in a spiral around the body of the patient (spiral or helical CT scanner). Based on a computerised image acquisition and processing system, these scanners produce a three-dimensional reconstruction of the organs with very much better image quality than that of conventional radiology devices. The number of rows of detectors (multidetector-row CT scanner, also known as a multislice or volumetry CT scanner) has been increased in recent machines, enabling thinner slices to be produced. An examination can comprise several helical image acquisitions of a specific anatomical region (with or without injection of a contrasting agent) or of different anatomical regions.

This technique can, like 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 have led to an increase in exploration possibilities (example of dynamic volume acquisitions) and in the indications[9]. The placing of mobile computed tomography systems on the market for intraoperative use is to be underlined, as is the increase in fluoroscopy-guided interventional CT procedures.

On the other hand, these technological developments have led to an increase in the number of examinations, resulting in an increase in the doses delivered to patients and thus reinforcing the need for strict application of the principles of justification and optimisation (see chapter 1). 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 (*e.g.* an emergency doctor), who is not a radiologist, to perform the radiological examination and then send the results to a radiologist in order to obtain an interpretation of the images. If necessary the radiologist can guide the radiological operator during the examination and imaging process. In this case, the doctor on the scene is considered to be the doctor performing the procedure and assumes responsibility for it.
- Tele-expertise, which is an exchange of opinions between two radiologists, where one asks the other – the "expert radiologist" (teleradiologist) – for a remote confirmation or contradiction of a diagnosis, to determine a therapeutic orientation or to guide a remote examination. The data transmissions are protected and preserve medical secrecy and image quality.

Significant events concerning the radiation protection of medical professionals

In 2020, three Significant Radiation protection Events (ESR) concerned workers and formed the subject of an incident notice due to exceeding of the regulatory limit for ionising radiation exposure of the extremities or the whole body. ASN rated these events level 1 on the INES scale (international scale of nuclear and radiological events, graded from 0 to 7 in increasing order of severity).

These ESRs occurred during infiltrations by practitioners in radiology and during fluoroscopy-guided surgical vertebroplasty procedures. Two of the professionals received an equivalent dose exceeding 500 millisieverts (mSv) on the hands over 12 consecutive months, while the third received an effective cumulative dose exceeding 20 mSv.

The exposure of practitioners to ionising radiation during this type of procedure depends on their individual practices, the radiological image acquisition parameters and the use of personal protective equipment.

ASN reminds classified workers of the obligation to wear all their dosimeters and the need to send them to the accredited organisation no later than ten days after the term of the wearing period in order to detect abnormal exposure as soon as possible. The medical professionals must also wear their Personal Protective Equipment (PPE) and apply the optimisation of practices when performing fluoroscopy-guided examinations.

9. *The term indication means a clinical sign, an illness or a situation affecting a patient which justifies the value of a medical treatment or a medical examination.*

07

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 remote interpretation of images. Teleradiology therefore fits into the general health care organisation governed by the Public Health Code and obeys the rules of professional ethics in effect.

The Teleradiology Charter published by the French professional council of radiology (G4) was re-updated in 2020. This fourth version updates the Charter in the light of the practices and regulations in effect, particularly with regard to personal health care data, and the recommendations of the French data protection commission. It details the organisation of the two parts of teleradiology (telediagnosis and tele-expertise). In addition, a guide to good practices concerning the quality and safety of teleimaging procedures was published in May 2019 by the HAS. In this guide the HAS makes important clarifications concerning the proper use of "medical imaging examinations with remote interpretation". It has the particularity of also addressing nuclear telemedicine, deployed with the aim of providing uniform coverage of the country. This guide does not consider mammography, which cannot be done by teleradiology because it necessitates clinical examination of the patient, including palpation.

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 usually associated with a digital system for processing and filing the radiographic image.

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 consolidated by that adopted by the Heads of the European Radiological protection Competent Authorities – HERCA, for which the use of such devices should be reserved for invalid patients, for the forensic medicine sector and for military personnel in the field of action (*Position Statement on Use of Handheld Portable Dental X-ray Equipment* – HERCA, June 2014).

6.2 Technical layout rules for medical and dental radiodiagnosis facilities

Radiology installations

A conventional radiological facility usually comprises a generator (high-voltage unit, X-ray tube), associated with a support (the stand) for moving the tube, a control unit and an examination table or chair.

Mobile facilities, but which are often used in the same given room, such as the X-ray generators used in operating theatres, are to be considered as fixed facilities.

Radiological facilities must be fitted out in accordance with the provisions of ASN technical resolution 2017-DC-0591 of 13 June 2017 mentioned in 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 and excluding any use in fluoroscopy mode. 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.

6.3 Radiation protection situation: spotlight on the CT scanner

The installed base of 1,245 CT scanners is divided among more than 900 facilities which are covered by an ASN license. Graph 15 shows the distribution of CT scanners by geographical zone covered by the ASN regional divisions, and the distribution of the 185 licenses examined in 2020.

In a report published in September 2018, the IRSN notes that the average age of the installed base of CT scanners is higher in the public sector than in the private sector.

ASN carried out 30 inspections in 2020. Eighteen inspections focused specifically on sites with CT scanners used to examine patients arriving in the emergency department or for paediatric patients (whether the scanner is dedicated solely to that use or not). One of these 18 inspections was carried out entirely remotely.

The purpose of these inspections was to verify the requirements defined in ASN resolution 2019-DC-660 of 15 January 2019 relative to quality assurance in medical imaging.

The majority of the centres inspected are in the public sector (11/18). Seven of them have a CT scanner dedicated to the emergency department's activity. According to the information collected, each scanner performs around 8,000 procedures per year on average.

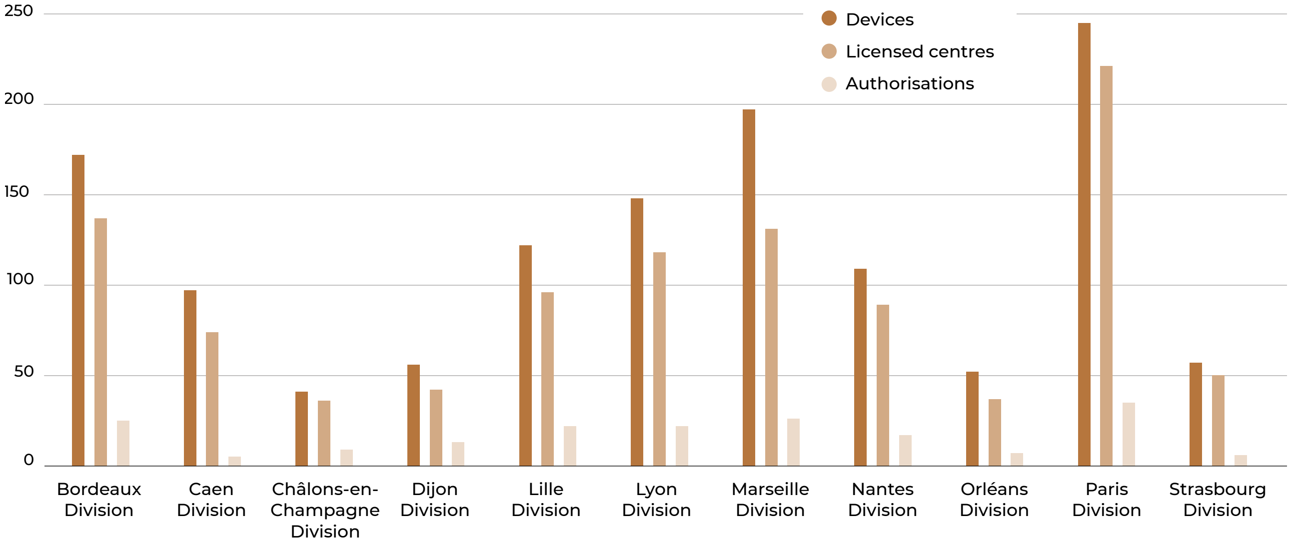
The organisation of the emergency department including access to the CT scanner, particularly in the middle of the night (between midnight and 6 a.m.), is formalised in all the centres. Twelve of the centres have written procedures indicating the patient management actions for patients at risk, while four have verbally communicated procedures and the remaining two have none.

Job sheets exist for each medical professional category in 13 of the 18 centres inspected. Fourteen of the 18 centres have trained more than 85% of their medical staff in radiation protection and two have trained between 65% and 85%. The work station qualification pathway remains to be defined, however.

A request is normally drawn up for each examination and validated by a radiologist or, in the case of one centre, a teleradiologist. However, no procedures are formalised in writing.

GRAPH 15

Breakdown, by ASN regional division, of the number of CT scanners and the number of licenses created or renewed in 2020



The various stages in the verification of the examination requests (reception, prior analysis, validation, substitution, cancellation of the procedure) are formalised in writing by just 9 of the centres. The examination request, however, is validated in 17 of the 18 centres.

The medical physics organisation concerning the CT scanner is described in a POPM by 15 centres, but the time allocated to medical physicists to accomplish their tasks was considered insufficient in 5 cases.

An optimisation procedure is in place (optimised examination protocols, collection and analysis of Diagnostic Reference Levels, etc.), with the utilisation of a Dose Archiving and Communication System (DACS) in 14 of the inspected centres.

The scanner quality controls are carried out at the required frequencies and any nonconformities are corrected.

Radiation protection events are reported and analysed in 13 of the inspected centres.

6.4 Significant events reported in medical and dental radiodiagnosis

238 ESRs were reported in medical and dental radiodiagnosis:
- 73 in conventional radiology, of which 38 concerned women unaware of their pregnancy;
- 165 in computed tomography, of which 76 concerned women unaware of their pregnancy.

The ESR primarily concern women unaware of their pregnancy (114), failings in the patient management process (identity monitoring error, protocols, etc.) and situations of inappropriate exposure of professionals (8). Checks by the medical staff for possible pregnancy in patients must be further increased.

SUMMARY

Diagnostic examinations using computed tomography contribute very substantially to the collective dose received by the public, as medical imaging is the leading source of artificial exposure of the public to ionising radiation. During its inspections, ASN observes a lack of traceability of justification of the examinations and of the difficulties medical professionals encounter in applying the principle. The lack of training of the referring practitioners, the lack of use of the guide to good medical imaging practices, and the lack of justification protocols for the most common procedures partly explain the fact that the justification principle is not always applied. Furthermore, the lack of availability of other diagnostic methods (MRI, ultrasonography) and of health professionals limits the replacement of irradiating procedures by nonirradiating procedures. In July 2018 ASN published a second plan of action for controlling ionising radiation doses delivered to persons during medical imaging. This plan aims to reinforce the justification of the procedures and the optimisation of the ionising radiation doses delivered to the patients.

7. Blood product irradiators

7.1 Description

The irradiation of blood products is used to prevent post-transfusion reactions in blood-transfusion patients. The blood bag is irradiated with a dose of about 20 to 25 grays.

Since 2009, source irradiators have been gradually replaced by X-ray generators, for which notification to ASN has been required since 2015. In 2019, the inventory stood at 29 irradiator devices equipped with X-ray generators.

7.2 Technical rules applicable to facilities

A blood product irradiator must be installed in a dedicated room designed to provide physical protection (against fire, flooding, break-in, etc.). Access to the device, which must have a lockable control console, is limited to the persons authorised to use it.

The fitting out of premises accommodating irradiators equipped with X-ray generators must comply with the provisions of ASN resolution 2017-DC-0591 of 13 June 2017.

8. Synthesis and prospects

The year 2020 was marked by the Covid-19 pandemic which considerably disrupted the health care system. Consequently, ASN reduced the number of inspections in the medical sector and adapted its oversight methods, in particular by deploying remote inspections. Remote inspections account for 26% of the inspections performed, with the highest proportion in nuclear medicine (35%) and the lowest in computed tomography (5%). Consequently, the state of radiation protection in 2020 is based on a significantly smaller number of inspections than in the preceding years (28% fewer).

On the basis of the inspections conducted in 2020, ASN considers that the state of radiation protection in the medical sector is comparable with that of 2019. No major deficiency was detected in the areas of radiation protection of medical professionals, patients, the public or the environment.

Nevertheless, it is still necessary to better anticipate the arrival of new machines, new practices and new radiopharmaceuticals and 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. Furthermore, laterality and fractionation errors in radiotherapy, errors in the administration of radiopharmaceutical drugs in nuclear medicine, exceeding of extremity or whole body dose limits in practitioners during interventional procedures, and contaminations or exposures in nuclear medicine are still reported, reminding us of the need to regularly assess practices.

Updating of the regulatory framework continued in 2020 and early 2021 with the adoption of two ASN resolutions concerning putting in place the new registration administrative system applicable to risk-prone FGI practices and to CT scanners, and the qualification of physicians and dental surgeons who use ionising radiation and the coordinating physician when a legal person is licensed or registered. In addition, two circular letters were issued for the professionals, one concerning radiation protection in the operating theatre and the management of patients, the other concerning waste and effluent management when using lutetium-177 and updating the licensing requirements for nuclear medicine departments.

ASN will continue its inspections in 2021, addressing the radiotherapy, therapeutic nuclear medicine and Fluoroscopy-Guided Interventional practices in priority, drawing on the lessons learned from the new inspection methods used due to the health crisis.

It will also continue to contribute to the regulatory work conducted by the Minister responsible for health concerning the duties of medical physicists, the organisation of medical physics, the reform of the health care activity authorisations and the deployment of clinical audits.

Lastly, putting in place new equipment, new practices and new radiopharmaceuticals remains a priority for ASN. The work to better anticipate and manage the organisational and technical changes in radiotherapy, conducted with the IRSN in collaboration with volunteer radiotherapy centres, hospital federations and health care institutions shall be continued. ASN will also examine the follow-ups to the initial work of the Committee for the Analysis of New Techniques and Practices using Ionising Radiation (Canpri), set up in 2019, concerning a device combining a self-shielding technology with a linear accelerator.

CHAPTER 08

SOURCES OF IONISING RADIATION AND THEIR INDUSTRIAL, VETERINARY AND RESEARCH APPLICATIONS


Présence de radioéléments

08 Sources of ionising radiation and their industrial, veterinary and research applications

The industrial and research sectors have been using sources of ionising radiation in a wide range of applications and locations for many years now. The purpose of the radiation protection regulations is to check that the safety of workers, the public and the environment is properly ensured. This protection involves more specifically ensuring proper management of the sources, which are often portable and used on worksites, and monitoring the conditions of possession, use and disposal, from fabrication through to end of life. It also involves monitoring the main stakeholders, that is to say the source manufacturers and suppliers, and enhancing their accountability.

The radiation sources used are either radionuclides – essentially artificial – in sealed or unsealed sources, or electrical devices generating ionising radiation. The practices/applications presented in this chapter concern the manufacture and distribution of all sources, the industrial, research and veterinary uses (medical activities are presented in chapter 7) and activities not regulated under the Basic Nuclear Installations (BNIs) system (these are presented in chapters 10, 11 and 12).

The ongoing updating of the regulatory framework for nuclear activities established by the Public Health Code is leading to a tightening of the principle of justification, consideration of natural radionuclides, and the implementation of a more graded approach in the administrative systems and measures to protect sources against malicious acts. As of January 2019, the regulation of industrial, research and veterinary activities has been substantially modified by the extension of the notification system to certain nuclear activities that use radioactive sources. Amending the administrative systems continued in 2019 and 2020 with the preparation of texts enabling the new simplified authorisation system called “registration” to enter into effect as of 1 July 2021.

1. Industrial, research and veterinary uses of ionising radiation

1.1 Uses of sealed radioactive sources

Sealed radioactive sources are defined as sources whose structure or packaging, in normal use, prevents any dispersion of radioactive substances into the surrounding environment. Their main uses are presented below.

1.1.1 Verification of physical parameters

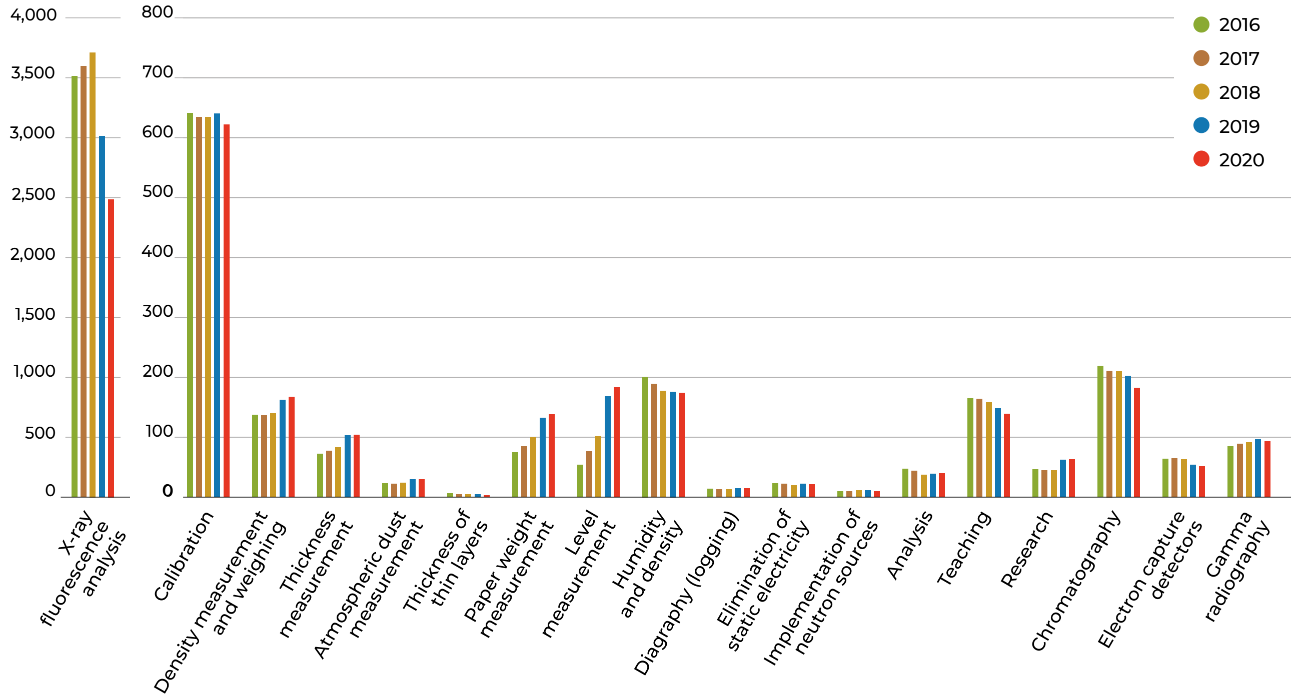
The operating principle of these physical parameter verification devices is the attenuation of the signal emitted: the difference between the emitted signal and the received signal can be used to assess the desired information.

The most commonly used radionuclides are carbon-14, cobalt-60, krypton-85, caesium-137, promethium-147 and americium-241. The source activities range from a few kilobecquerels (kBq) to a few gigabecquerels (GBq).

The sources are used for the following purposes:
- Atmospheric dust measurement: the air is permanently filtered through a tape placed between the source and detector, running at a controlled speed. The intensity of radiation received by the detector depends on the amount of dust on the filter, which enables this amount to be determined. The most frequently used sources are carbon-14 (with an activity of 3.5 megabecquerels – MBq) or promethium-147 (with an activity of 9 MBq). These measurements are used for air quality monitoring by verifying the dust content of discharges from plants.
- Paper weight measurement: a beam of beta radiation passes through the paper and hits a detector situated opposite. The signal attenuation on this detector indicates the density of the paper, and therefore its weight per unit area. The sources used are generally krypton-85 or promethium-147, with activities of 3 GBq at the most.
- Liquid level measurement: a gamma radiation beam passes through the container holding the liquid. It is received by a detector positioned opposite. The signal attenuation measured on this detector indicates the filling level of the container and automatically triggers certain operations (stop/continue filling, alarm, etc.). The radionuclides used depend on the characteristics of the container and the content. The sources generally used are americium-241 (with an activity of 1.7 GBq) or caesium-137 – 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 – barium-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.

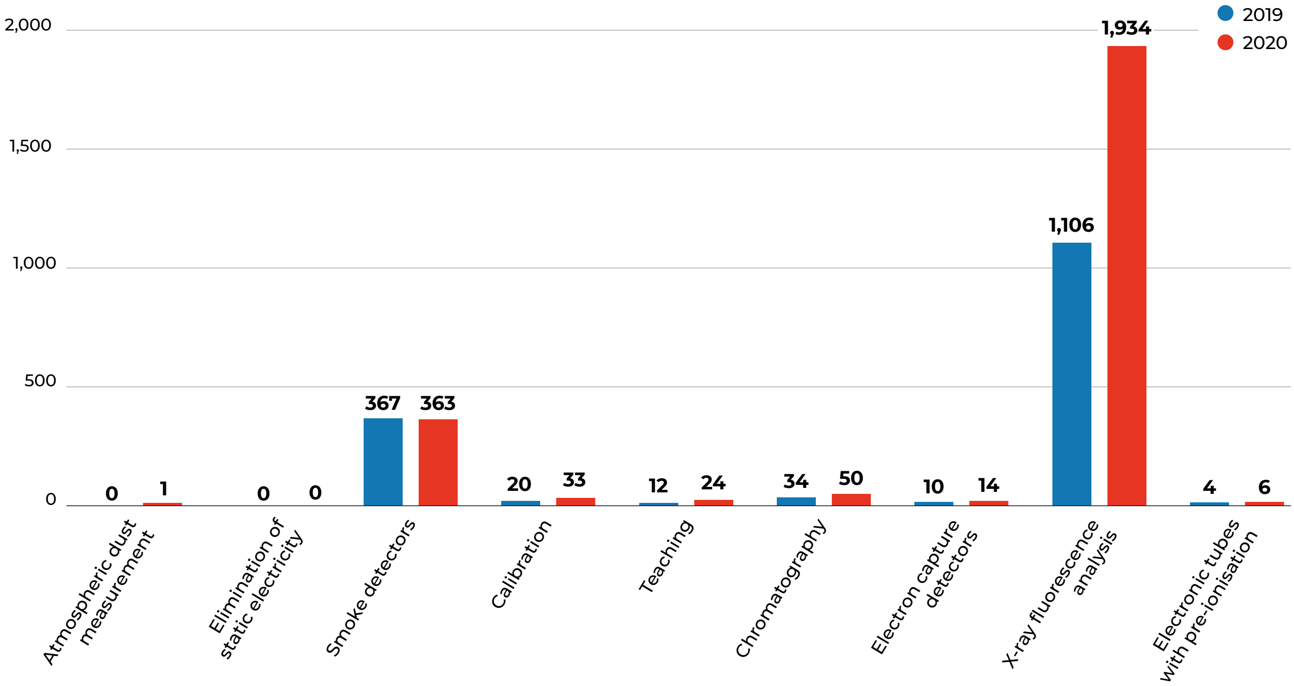
GRAPH 1A

Use of sealed radioactive sources



GRAPH 1B

Breakdown of notifications by end-purpose in 2019 and 2020



1.1.2 Neutron activation

Neutron activation consists in irradiating a sample with a flux of neutrons to activate the atoms in the sample. The number and the energy of the gamma photons emitted by the sample in response to the neutrons received are analysed. The information collected is used to determine the concentration of atoms in the analysed material.

This technology is used in archaeology to characterise ancient objects, in geochemistry for mining prospecting and in industry (study of the composition of semiconductors, analysis of raw mixes in cement works).

Given the activation of the analysed material, this requires particular vigilance with regard to the nature of the objects analysed. Articles R. 1333-2 and R. 1333-3 of the Public Health Code prohibit the use of materials and waste originating from a nuclear activity for the manufacture of consumer goods and construction products if they are, or could be, contaminated by radionuclides, including by activation. Waivers may however be accepted in a very limited number of cases (see point 2.2.1).

1.1.3 Other common applications

Sealed radioactive sources can also be used for:
- industrial irradiation, particularly for sterilization (see point 3.2.1);
- gamma radiography, which is a non-destructive inspection method (see point 3.3.1);
- eliminating static electricity;
- calibrating radioactivity measurement devices (radiation metrology);
- practical teaching work concerning radioactivity phenomena;
- detection by electron capture. This technique uses sources of nickel-63 in gaseous phase chromatographs and can be used to detect and dose various chemical elements;
- ion mobility spectrometry used in devices that are often portable and used to detect explosives, drugs or toxic products;
- detection by X-ray fluorescence. This technique is used in particular for detecting lead in paint. The portable devices used today contain sources of cadmium-109 (half-life 464 days) or cobalt-57 (half-life of 270 days). The activity of these sources can range from 400 MBq to 1,500 MBq. This technique, which uses a large number of radioactive sources nationwide (nearly 4,000 sources), is the result of a legislative system designed to prevent lead poisoning in children by requiring a check on the lead concentration in paints used in residential buildings constructed before 1 January 1949 in case of sale, a new rental contract, or work significantly affecting the coatings in the common parts of the building.

Graphs 1A and 1B show the number of facilities using sealed radioactive sources for the identified applications under the licensing and notification systems respectively. They illustrate the diversity of these applications and their development over the last five years.

It should be noted that:
- a given facility may carry out several activities, and if it does, it appears in Graph 1 and the following diagrams for each activity;
- the breakdown between the licensing system and the notification system (sealed sources and electrical devices emitting ionising radiation) for a given end-use is not yet stabilised, because the changes of administrative system concerning the nuclear activities newly subject to notification since 1 January 2019, will extend through to 31 December 2023 (see point 2.4.2).

1.2 Uses of unsealed radioactive sources

The main radionuclides used in the form of unsealed sources in non-medical applications are phosphorus-32 or 33, carbon-14, sulphur-35, chromium-51, iodine-125 and tritium. They are used in particular in research and in the pharmaceutical sector. They constitute a powerful investigative tool in cellular and molecular biology. Using radioactive tracers incorporated intowv molecules is common practice in biological research. There are also a number of industrial uses, for example as tracers or for calibration or teaching purposes. Unsealed sources are used as tracers for measuring wear, detecting leaks or friction spots, building hydrodynamic models and in hydrology.

As at 31 December 2020, the number of facilities authorised to use unsealed sources stood at 715.

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

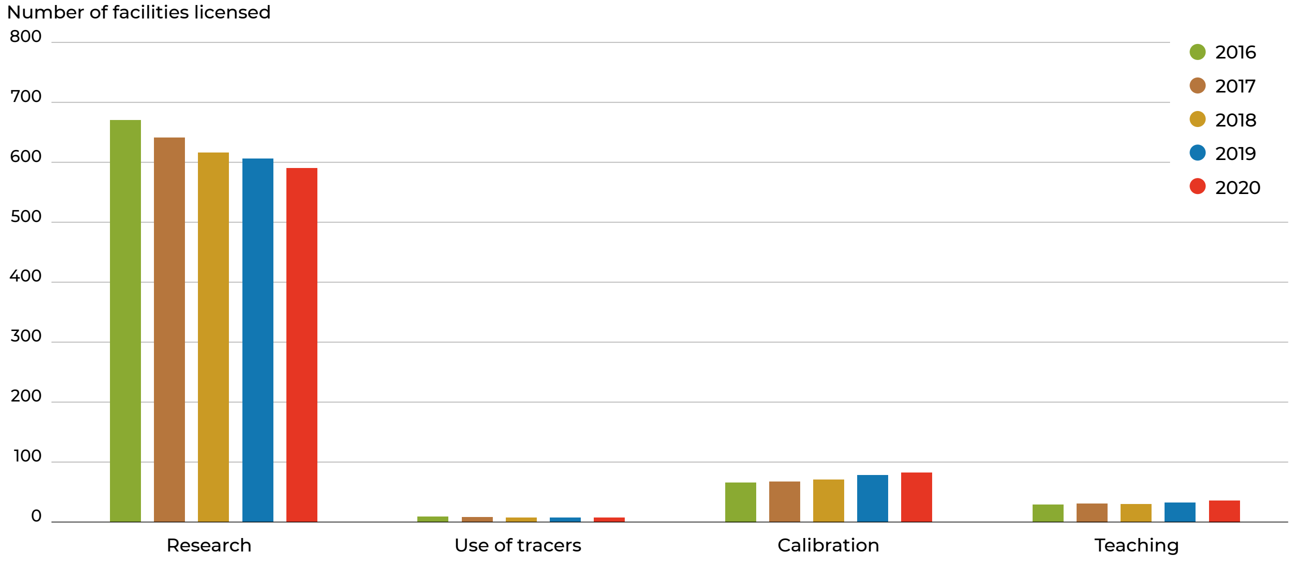
1.3.1 Main industrial applications

In industry, electrical devices emitting ionising radiation are used mainly in non-destructive testing, where they replace devices containing radioactive sources.

Graphs 3A and 3B show the number of facilities using electrical devices generating ionising radiation in the listed applications under the licensing or notification system respectively. They illustrate the diversity of these applications and their development over the last five years. This development is closely related to the regulatory changes which have gradually created a new licensing or notification system concerning the use of these devices.

GRAPH 2

Use of unsealed radioactive sources

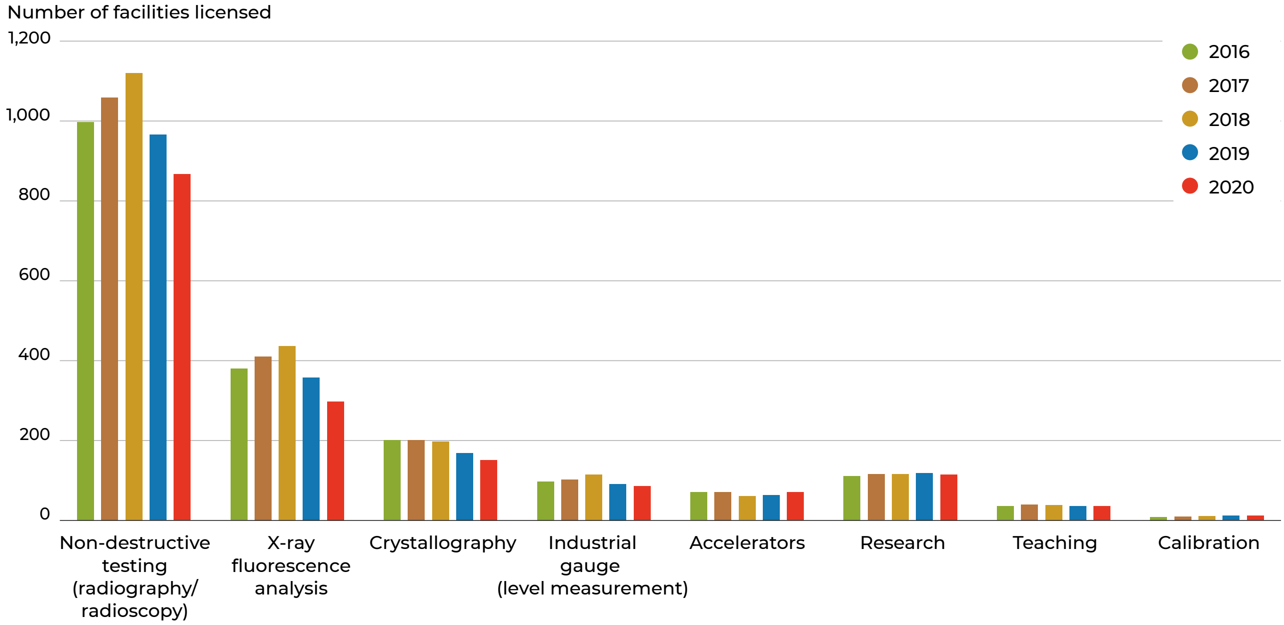


At present, measures to bring the professionals concerned into compliance are very widely engaged in many activity sectors.

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.), checking the quality of weld beads or inspecting materials for fatigue (in aeronautics in particular).

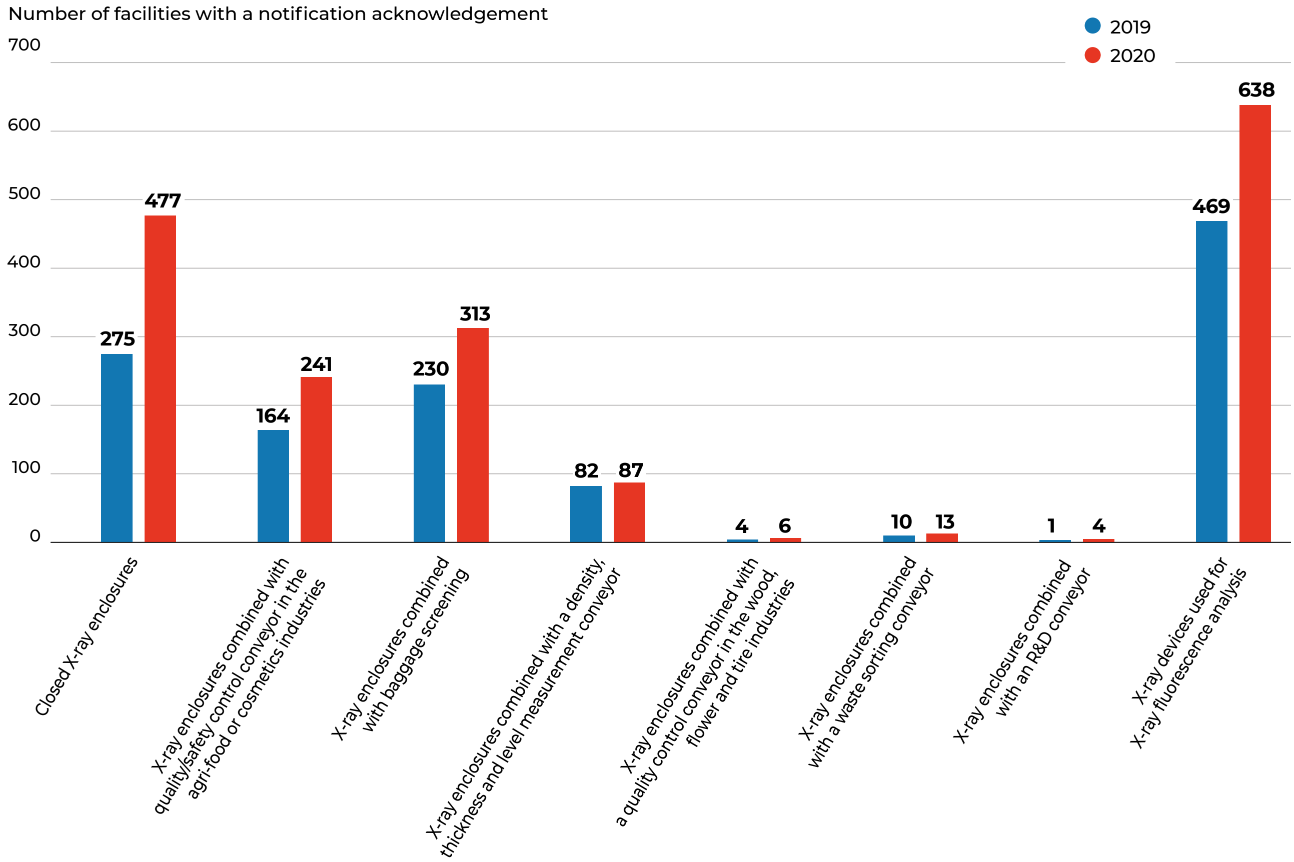
GRAPH 3A

Use of electrical devices generating ionising radiation (veterinary sector excluded)



GRAPH 3B

Breakdown of notifications of ionising radiation generators by end-purpose in 2019 and 2020



These devices, which function using the principle of X-ray attenuation, are used as industrial gauges (measurement of drum filling, thickness measurement, etc.), inspection of goods containers or luggage and also the detection of foreign bodies in foodstuffs.

The increase in the number of types of device available on the market can be explained more particularly by the fact that when possible, they replace devices containing radioactive sources. The advantages of this technology with regard to radiation protection are linked in particular to the total absence of ionising radiation when the equipment is not in use. Their utilisation does nevertheless lead to worker exposure levels that are comparable with those resulting from the use of devices containing radioactive sources.

Baggage inspection
Ionising radiation is used constantly in security screening checks, whether for the systematic verification of baggage or to determine the content of suspect packages. The smallest and most widely used devices are installed at the inspection and screening checkpoints in airports, in museums, at the entrance to certain buildings, etc.

The devices with the largest inspection tunnel areas are used for screening large baggage items and hold baggage in airports, as well as for air freight inspections. These devices are supplemented by tomographs, which give a series of series of cross-sectional images of the object being examined.

The irradiation zone inside these appliances is sometime delimited by doors, but most often simply by one or more lead curtains.

X-ray body scanners
This application is mentioned for information only, since the use of X-ray scanners on people during security checks is prohibited in France (in application of Article L. 1333-18 of the Public Health Code). Some experiments have been carried out in France using non-ionising imaging technologies (millimetre waves).

Inspection of consumer goods
The use of devices for detecting foreign bodies in certain consumer products has developed over the last few years, such as for detecting unwanted items in food products or cosmetics.

X-ray diffraction analysis
Research laboratories are making increasing use of small devices of this type, which are self-shielded. Experimental devices used for X-ray diffraction analysis can however be built by experimenters themselves with parts obtained from various suppliers (goniometer, sample holder, tube, detector, high-voltage generator, control console, etc.).

X-ray fluorescence analysis
Portable X-ray fluorescence devices are used for the analysis of metals and alloys.

Measuring parameters
These devices, which operate on the principle of X-ray attenuation, are used as industrial gauges for measuring fluid levels in cylinders or drums, for detecting leaks, for measuring thicknesses or density, etc.

Irradiation treatment
More generally used for performing irradiations, the self-shielded devices exist in several models that sometimes differ only in the size of the self-shielded chamber, while the characteristics of the X-ray generator remain the same.

Industrial radiography
Radiography for checking the quality of weld beads or for the fatigue inspection of materials is detailed in point 3.1.1.

1.3.2 Veterinary diagnostic radiology

In 2020, the profession counted 18,874 veterinary surgeons, some 13,300 non-veterinarian employees (counted in full-time equivalents) and 6,653 veterinary practices and clinics. Veterinary surgeons use diagnostic radiology devices for purposes similar to those used in human medicine. Veterinary diagnostic radiology activities essentially concern pets.
- some 5,250 veterinary clinics in France have at least one diagnostic radiology device;
- around 60 Computed Tomography (CT) scanners are used in veterinary applications;
- other practices drawn from the medical sector are also implemented in specialised centres: scintigraphy, brachytherapy, external-beam radiotherapy and interventional radiology.

The treatment of large animals (mainly horses) requires the use of more powerful devices installed in specially equipped premises (radiography of the pelvis, for example) and portable X-ray generators, used indoors – whether in dedicated premises or not – or outdoors.

In order to better ensure compliance with regulatory requirements, ASN introduced a notification system in 2009 for what were termed "canine activities" involving less serious radiation risks (see point 2.4.2). This simplification has led to regularisation of the administrative situation of a growing number of veterinary clinics (see Graph 4), with more than 90% of the clinics being notified or licensed.

To further improve the grading of the regulatory requirements in relation to the radiation risks, all activities using electrical devices emitting ionising radiation for veterinary diagnostic radiology, with the exception of pet-care activities which will remain eligible for the notification system, will come under the future registration system (see point 2.4.3) that will be put in place during 2021. Consequently, only a few high-risk activities (scintigraphy, brachytherapy, external-beam radiotherapy and interventional radiology) stemming from the medical sector will remain subject to licensing.

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 clinics, the administrative situation has been continuously improving for a number of years now. At the end of 2020, ASN counted 5,250 notified or licensed facilities, that is to say virtually all of the veterinary clinics identified as using ionising radiation in France.

Among the veterinary activities, those performed on large animals (mainly horses) outside specialised veterinary practices (under "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 (horse owners and stable lads). The inspections carried out by ASN on these veterinary practices over several years have revealed areas for improvement on which ASN remains vigilant when reviewing license applications and performing inspections:
- in-house radiation protection controls and verifications;
- setting up radiological zoning and the monitoring of occupational exposure by active dosimetry. These two findings must nevertheless be put into perspective in view of the regulatory changes introduced by Decree 2018-437 of 4 June 2018 on the protection of workers against ionising radiation, which modified the conditions for setting up and delimiting operation zones;

- the need to increase the radiation protection of people external to the veterinary practice who participate in diagnostic operations involving ionising radiation.

The conventional radiology activities performed on pets (called "canine activities" in France) involve lower radiation risks but represent a very large number of veterinary clinics. As part of its graded approach which consists in adapting the control methods to the radiation risks, ASN conducted an experimental control campaign in 2015 and 2016 which called upon new dematerialised control methods. The campaign was carried out in seven *départements* (Aisne, Allier, Aube, Cantal, Haute-Loire, Pas-de-Calais and Puy-de-Dôme) and addressed 463 veterinary clinics. During this campaign, ASN detected no major shortcomings, save exception, and considers that the organisation of radiation protection in pet care veterinary clinics is satisfactory on the whole. The organisation could nevertheless be improved in the following areas:
- 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 by certain external Radiation Protection Expert-Officers (RPE-Os).

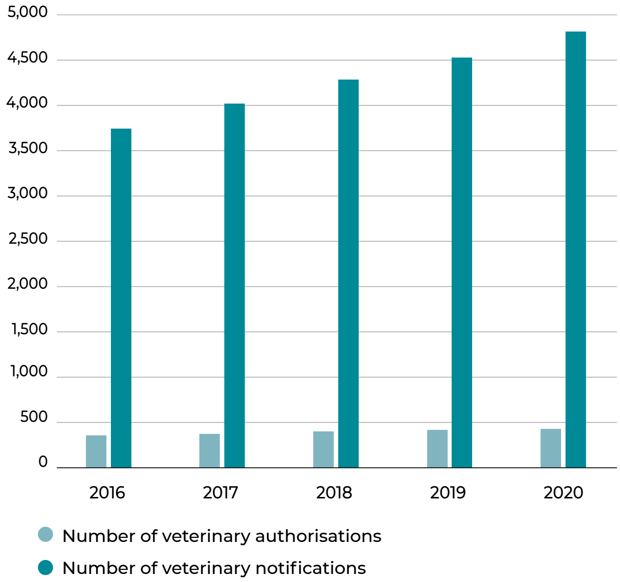
Alongside this, through its various oversight actions, ASN has seen the results of the efforts made by the veterinary professional bodies in the last few years to comply with the regulations and has noted good field practices in the inspected veterinary clinics, and more specifically:
- the presence of in-house RPE-Os in the majority of clinics;
- worker occupational exposure monitoring by passive dosimetry;
- the virtually systematic use of personal protective equipment;
- an approach to optimise the associated operations in nearly all the clinics performing diagnostic radiology on large animals.

Local *in situ* control actions are still carried out regularly by the ASN regional divisions, like the Strasbourg division for example, which in 2019 carried out some ten inspections of veterinary clinics that use ionising radiation.

The extensive nationwide commitment of the profession to harmonising practices, raising awareness, training student veterinary surgeons and drafting framework documents and guides is considered very positive by ASN, which regularly takes part in meetings with the profession's national bodies (more particularly the veterinary radiation protection commission) jointly with the General Directorate for Labour (DGT).

GRAPH 4

Use of electrical devices generating ionising radiation for veterinary activities



1.3.3 The other uses of electrical devices emitting ionising radiation

This category covers all the electrical devices emitting ionising radiation other than those mentioned above and not concerned by the license and notification exemption criteria set out in Article R. 1333-106 of the Public Health Code.

This category includes, for example, devices generating ionising radiation but not used for this property, namely ion implanters, electron-beam welding equipment, klystrons, certain lasers, certain electrical devices such as high-voltage fuse tests.

Lastly, some applications use particle accelerators (see point 3.3.1).

2. Regulation of industrial, research and veterinary activities

2.1 The Authorities regulating the sources of ionising radiation

ASN is the authority that grants the licenses, receives the notifications and will issue the registration decisions, in accordance with the regulatory regime applicable to the nuclear activity concerned.

However, to simplify administrative procedures for licensees already licensed under another system, the Public Health Code makes specific provisions. This concerns more specifically:
- The radioactive sources held, manufactured and/or used in installations licensed under the Mining Code (Article L. 162-1) or, for unsealed radioactive sources, those held, manufactured and/or used in Installations Classified for Protection of the Environment (ICPEs) which come under Articles L. 511-1 to L. 517-2 of the Environment Code, and have a licensing system. The Prefect is responsible for including, in the licenses he delivers, radiation protection requirements for the nuclear activities carried out on the site.
- The installations and activities relating to national defence, for which Defence Nuclear Safety Authority (ASND) is responsible for regulating the radiation protection aspects.
- The installations licensed under the legal system governing Basic Nuclear Installations (BNIs). ASN regulates the radioactive sources and electrical devices emitting ionising radiation necessary for the operation of these installations under this system. Holding and using other sources within the bounds of the BNI remain subject to licensing pursuant to Article R. 1333-118 of the Public Health Code.

These provisions do not exempt the licensee from complying with the requirements of the Public Health Code, and in particular those relative to source acquisition and transfer; they do not apply to the distribution, importing and exporting of radioactive sources, which remain subject to ASN licensing under the Public Health Code.

Since the publication of Decree 2014-996 of 2 September 2014 amending the nomenclature of the ICPEs, some facilities previously licensed by Prefectoral Order under the Environment Code for the possession and use of sealed radioactive sources are now regulated by ASN, under the Public Health Code. The requirements applicable to these installations are now those of the Public Health Code. The transitional period set in Article 4 of the abovementioned Decree, which provided that the license or notification issued under the former section 1715 continued to be valid and deemed a license or notification under the Public Health Code, on condition that no change was made to the nuclear activity, for a maximum period of five years, that is to say until 4 September 2019 at the latest, has now ended. These facilities must therefore have a license or a notification acknowledgement issued under the Public Health Code.

Only the facilities possessing unsealed radioactive substances in quantities exceeding 1 tonne (t) or managing radioactive waste in quantities exceeding 10 cubic metres (m^3) for either of the activities are subject to the system governing ICPE (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 et seq. of the Defence Code. Application of these regulations is overseen by the Minister of Defence for nuclear materials intended for defence needs, and by the Minister in charge of energy for nuclear materials intended for any other use.

2.2 Unjustified or prohibited activities

2.2.1 Application of the ban on the intentional addition of radionuclides in consumer goods and construction products

The Public Health Code states "*that any addition of radionuclides […] to consumer goods and construction products is prohibited*" (Article R. 1333-2). Thus, the trading of accessories containing sources of tritium such as watches, key-rings, hunting equipment (sighting devices), navigation equipment (bearing compasses) or river fishing equipment (strike detectors) is specifically prohibited. Article R. 1333-4 of this same Code provides that waivers to these prohibitions can, if they are justified by the advantages they bring, be granted by Order of the Minister responsible for health and, depending on the case, by the Minister responsible for consumer goods or the Minister responsible for construction, after obtaining the opinion of ASN and of the High Council for Public Health (HCSP). ASN considers that granting waivers to the regulations must remain very limited.

It was implemented for the first time in 2011 for a waiver request concerning the use of a neutron analysis device in several cement works of the Lafarge-Holcim group (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). In 2017, the waiver was renewed for ten years for two cement works, the third cement works mentioned in the initial Order of 2011 having closed (Order of 19 April 2017 of the Ministers responsible for health and construction respectively, ASN opinion 2017-AV-0292 of 7 March 2017). In 2019, another waiver was granted for a third cement works (Order of the Ministers responsible for health and ecological transition of 4 December 2019, ASN opinion 2019-AV-0333 of 1 August 2019). The opinion of ASN was requested in 2020 for a project concerning a waiver for the use of a neutron analysis device in a cement works of the CALCIA group; it is currently under review.

It was also applied in 2014 for light bulbs containing very small quantities of radioactive substances (krypton-85 or thorium-232), serving mainly for applications requiring very high intensity lighting such as public places, work places, or for certain vehicles (Order of 12 December 2014 of the Ministers responsible for health and construction, ASN opinion 2014-AV-0211 of 18 September 2014). The waiver was renewed in 2019 (Order of 25 May 2020 of the Ministers responsible for ecological and solidarity-based transition, for solidarity, health, and the economy and finance (ASN opinion 2019-AV-0340 of 26 September 2019).

A waiver was moreover granted in 2019 to the Tunnel Euralpin Lyon Turin for the use of neutron analysis devices (Order of the Ministers responsible for health and ecological transition of 19 August 2019, ASN opinion 2019-AV-0326 of 21 May 2019).

Conversely, a waiver request to allow the addition of radionuclides (tritium) in some watches was 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).

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 transient period for definitive withdrawal from the market may be necessary, depending on the technical and economic context, particularly when a technological substitution is necessary.

Smoke detectors containing radioactive sources

Devices containing radioactive sources have been used for several decades to detect smoke in buildings as part of the fire-fighting policy. Several types of radionuclides have been used (americium-241, plutonium-238 and radium-226). The activity of the most recent sources used does not exceed 37 kBq, and the structure of the detector, in normal use, prevents any release of radioactive substances into the environment.

New non-ionising technologies have gradually developed for smoke detection. Optical devices now provide comparable detection quality, and can therefore satisfy the regulatory and normative fire detection requirements. ASN therefore considers that smoke detection devices using radioactive sources are no longer justified and that the seven million ionic smoke detectors installed on 300,000 sites (figures estimated in the early 2000's when the public authorities began reflecting on their withdrawal) must be gradually replaced.

The regulatory framework governing their withdrawal was put in place by the Order of 18 November 2011 and the two ASN resolutions 2011-DC-0252 and 2011-DC-0253 of 21 December 2011.

This regulatory framework aimed at:
- planning the removal operations over ten years;
- supervising the maintenance or removal operations, which 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.

Nine years after the implementation of the new regulatory system for Ionisation Chamber Smoke Detector (ICSD) removal and maintenance activities, ASN has, as at 31 December 2020, issued 363 notification acknowledgements and 11 national licenses (issued to industrial groups with a total of 127 agencies) for ICSD removal activities. Among these 11 licenses, eight authorise maintenance operations on fire safety systems and five authorise ICSD dismantling operations, thereby materialising a disposal route for all the existing detectors.

In order to keep track of the pool of ICSDs, the French Institute for Radiation Protection and Nuclear Safety (IRSN) set up in 2105, in collaboration with ASN, 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.

However, although the removal operations have progressed over the last few years, not all the ICSDs will have been removed by the deadline initially set in the Order of 18 November 2011, that is to say the end of 2021. Faced with this situation, ASN is considering, with the professionals, an update of the regulations on the possession of such detectors and their removal and dismantling operations in order to complete the transition of all the fire detection devices to optical technology while at the same time allowing for safe disposition of the removed ICSDs and the radioactive sources they contain.

ASN maintains close relations with Qualdion, an association created in 2011 which labels the companies that comply with the regulations relative to radiation protection and fire safety. The list of Qualdion-labelled companies is available on the Internet. ASN participates with the association in communication campaigns targeting the holders of ionic detectors and the professionals (Expoprotection trade fair, Mayors' trade fair, etc.).

Surge suppressors

Surge suppressors (sometimes called lightning arresters), not to be confused with lightning conductors, are small objects with a very low level of radioactivity used to protect telephone lines against voltage surges in the event of lightning strike. These are sealed devices, often made of glass or ceramic, enclosing a small volume of air containing radionuclides to pre-ionise the air and facilitate electrical sparkover. The use of surge suppressors has been gradually abandoned since the end of the 1970s, but the number remaining to be removed, collected and disposed of is still very high (several million units). When installed, these devices represent no risk of exposure for individuals. However, there can be a risk of exposure and/or contamination, albeit very low, if these objects are handled without precautions or if they are damaged. ASN issued a reminder to the company Orange (formerly *France Télécom*), which has begun an experimental process to identify, remove, sort and dispose of surge suppressors in the Auvergne-Rhône Alpes region and has proposed a national removal and disposal plan. This plan was presented to ASN, and led in September 2015 to the issuing of a license governing the removal of all surge suppressors containing radionuclides present on the Orange network in France and their interim storage on identified sites. The search for a disposal route is in progress in collaboration with the French National Agency for Radioactive Waste Management (Andra). This removal plan is being implemented progressively over an eight-year time frame.

Lightning conductors

Radioactive lightning conductors were manufactured and installed in France between 1932 and 1986. The ban on the sale of radioactive lightning conductors was declared in 1987. This Order did not make the removal of installed radioactive lightning conductors compulsory. Consequently, there is no obligation at present to remove the radioactive lightning conductors installed in France, except in certain ICPEs (Order of 15 January 2008 which set the removal deadline at 1 January 2012) and in certain installations under Ministry of Defence responsibility (Order of 1 October 2007 which set a removal deadline at 1 January 2014).

ASN nevertheless expects all existing radioactive lightning conductors to be removed and transferred to Andra, given the risks they can represent, depending in particular on their physical condition. For several years now ASN has been working to raise professional awareness of the radiation risks for workers and the public. ASN has stepped up its action in this respect by reminding the professionals of their obligations, particularly that of having an ASN license for the removal and storing of lightning conductors pursuant to Articles L. 1333-1 and 2, L. 1333-8, and R. 1333-104 of the Public Health Code. ASN conducts field oversight operations targeting the companies involved in recovering these objects, combined with unannounced inspections on the removal sites.

Andra estimates that some 40,000 radioactive lightning conductors were installed in France. Nearly 11,000 have already been removed and recovered by Andra. The current rate of removal is about 275 per year.

2.3 The regulatory changes

2.3.1 Tightening the regulation of electrical devices generating ionising radiation

ASN considers that the regulatory oversight of suppliers of electrical ionising radiation generators is still insufficient, when the placing of devices on the market is so vitally important for the optimisation of the future radiation exposure of users. The work carried out by ASN in this area, which at present is directed towards the use of these generators, particularly in enclosures, has led to the publication of ASN resolution 2017-DC-0591 of 13 June 2017 setting the minimum technical design rules applicable to facilities that use X-rays.

This resolution came into effect on 1 October 2017. It replaces ASN resolution 2013-DC-0349 of 4 June 2013 without creating additional requirements for already compliant facilities. It concerns facilities in the industrial and scientific (research) sectors, such as industrial X-ray radiography in bunkers and veterinary radiology. It takes account of experience feedback and sets the radiation protection goals by adopting a graded approach to the risks.

ASN considers that these provisions, which are directed exclusively at the use these devices, must be supplemented by provisions concerning their actual design.

This is because, for electrical devices used for non-medical purposes, there is no equivalent of the CE marking that is mandatory for medical devices, certifying conformity with several European standards that cover various aspects, including radiation protection. Furthermore, experience feedback shows that a large number of devices do not have a certificate of conformity to the standards applicable in France. These standards have been mandatory for many years now, but some of their requirements have become partly obsolete or inapplicable due to the lack of recent revisions.

On the basis of the work done in collaboration with the Electrical Certification and Testing Entity for *Bureau Véritas* (LCIE), the Alternative energies and the Atomic Energy Commission (CEA) and the IRSN, draft texts have been produced with the aim of defining minimum radiation protection requirements for the design of X-ray generators; an informal technical consultation of the stakeholders (suppliers, French and foreign manufacturers and the principal users) was conducted in 2015. The various contributions are currently being analysed with the assistance of the 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 supply of devices generating ionising radiation to licensing, in the same way as for radioactive sources. In 2020, ASN continued its work to characterise the advantages, drawbacks and the feasibility of various provisions for regulating the design of industrial radiology devices. Discussions with the General Directorate for Labour (DGT) will be continued.

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 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, supplemented in 2012 by two implementing guides in the Nuclear Security Series relative to the security of radioactive sources and the security of radioactive material transport. As of 2004, 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

Measures implemented to ensure radiation protection, safety, and protection against malicious acts have many interfaces. Generally speaking, ASN's counterparts in other countries are responsible for oversight in these three areas (see Table 2 in chapter 2).

In France, the protection against malicious acts concerning nuclear materials used in certain facilities termed "of vital importance" because they are essential for the functioning of the country, is coordinated by a service under the authority of the Defence and Security High Official (HFDS) of the Ministry of Ecological Transition, responsible for energy.

The changes in regulations adopted since early 2016 have led to an organisation for oversight of the protection of ionising radiation sources against malicious acts which takes into account the existing organisation by entrusting this oversight:
- to the service of the HFDS of the Ministry responsible for energy in installations whose security is already under its control;
- to the Ministry of Defence in the locations placed under its authority;
- to ASN for the other facilities where nuclear activities take place.

The process necessary to set up this oversight, initiated by the Government in 2008 with the assistance of ASN, resulted in Ordinance 2016-128 of 10 February 2016 and then Decree 2018-434 of 4 June 2018 introducing various provisions concerning nuclear activities. These texts, which amend the Public Health Code, divide up the oversight duties in the various installations as indicated above, by including protection against malicious acts in the risks that must be taken into account by those responsible for nuclear activities and by the regulatory bodies when reviewing the licensing applications.

The sources and installations concerned

Oversight of source protection against malicious acts concerns all sources of ionising radiation, that is to say all the devices that could cause exposure to radiation. The majority of the regulatory requirements are however taken to increase the security of the sources presenting the greatest radiological risks: this concerns radioactive sources of categories A, B and C as defined in the Public Health Code, which stems directly from that of the IAEA. The protection requirements are proportionate to the intrinsic dangerousness of the sources. The graded approach therefore implies stricter obligations for the sources (or batches of sources) in category A than in category C. Sources that are not in categories A, B or C are classified in category D.

Some 250 facilities in the civil sector in France hold around 5,200 radioactive sources presenting such security risks. These sources are used essentially for industrial purposes (irradiation, radiography, measurements, etc.) or medical purposes (such as telegammatherapy and brachytherapy. Due to their frequent movements when on worksites, industrial radiography sources present particular security risks.

If sources of different categories are stored together, the lower category sources may be subject to the stricter security measures applicable to the higher category sources.

Regulatory work

The Decree modifying the regulatory part of the Public Health Code taken in application of Ordinance 2016-128 of 10 February 2016 (Decree 2018-434 introducing various provisions with regard to nuclear activities) was published on 4 June 2018. It contains several provisions concerning the protection of sources against malicious acts, and more specifically:
- the classification of ionising radiation sources and 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 their protection against malicious acts (R. 1333-148).

The preparation of the Ministerial Order setting the organisational and technical requirements to protect sources of ionising radiation (or batches of radioactive sources) against malicious acts ended in 2019. The Order was signed on 29 November 2019 and published in the *Official Journal of the French Republic* on 11 December 2019. It entered into force on 1 January 2020 for the sites not licensed on its date of publication (nor being examined on that same date). For already licensed sites, entry into force takes place in two stages: the first, within 6 months (1 July 2020), concerned the organisational and human provisions, the second, 18 months later (1 January 2022) concerned the systems of physical protection against malicious acts. However, due to the health crisis, these two deadlines have been pushed back by 6 months by the Order of 24 June 2020, on which ASN issued an opinion (ASN opinion 2020-AV-0353 of 11 June 2020).

The Order of 29 November 2019 also applies to the transport of category A, B and C sources, whether individually or in batches.

The main requirements of this Order aim, by adopting a graded approach based on categories A, B, C (and D for two items), to have the licensee put in place physical barriers and equipment, along with a policy and an internal organisation, to protect sources against malicious acts. These technical and organisational arrangements are intended to:
- prevent or delay the theft of radioactive sources through access control measures, reinforcement of physical barriers and their openings (doors, windows, etc.), alarms and crossing detection;

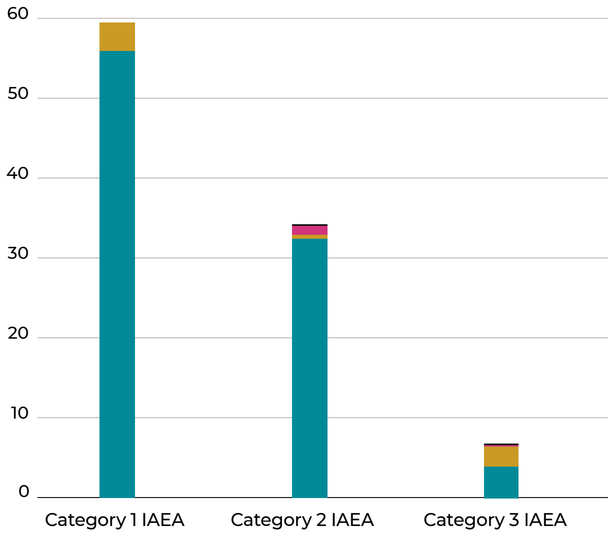
Categorisation of radioactive sources

Radioactive sources have been classified by the International Atomic Energy Agency (IAEA) since 2011 on the basis of predetermined exposure scenarios, in five categories from 1 to 5, according to their ability to create early harmful effects on human health if they are not managed safely and securely. Category-1 sources are considered extremely dangerous while those in category 5 are considered very unlikely to be dangerous. Sources in categories 1 to 3 are considered dangerous for humans to varying degrees.

This categorisation is based solely on the capacity of the sources to produce deterministic effects in certain exposure scenarios and must not under any circumstances be considered as proof that there is no danger in exposure to a category 4 or 5 source, as such exposure could cause stochastic effects in the longer term. The principles of justification and optimisation must therefore be respected in all cases. This IAEA work has been taken up in an Appendix to the Public Health Code amended by Decree 2018-434 establishing various provisions in the nuclear field. Nevertheless, the IAEA categories 4 and 5 have been grouped together in category D of this Code.

GRAPH 5

Breakdown of high-activity sealed sources according to their IAEA category and their oversight authority for protection against malicious acts



● Ministry of Defence
● Defence and Security High Official (HFDS)
● ASN
● ASN and HFDS

The sources in category A of the Public Health Code (PHC) correspond to the IAEA category 1 sources.

The PCH 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.

- protect sensitive information (access limited to duly authorised personnel, promotion of good information technology security practices);
- detect an actual or attempted malicious act (theft in particular) as early as possible;
- take action or alert the local law enforcement agencies after preparing their on-site actions;
- regularly raise awareness, inform and train the personnel on the subject;
- periodically check the effectiveness of the equipment and organise exercises.

For obvious reasons of restricting access to sensitive information, some of the provisions of this Order, detailed in its appendices, were not published in the *Official Journal*. ASN therefore, within its area of competence, sent the relevant appendices by personalised letter to each licensee responsible for nuclear activities concerned.

ASN has also planned to raise awareness on the publishing of the order by actions in the regions at professional events or by holding *ad hoc* meetings with professionals concerned. Due to the Covid-19 health crisis, only one meeting with professionals could be held in 2020, but the action will continue in 2021 as soon as the health conditions so permit.

Alongside the preparation of the order, and to facilitate its practical implementation, a working group has started preparing a joint ASN/SHFDS (Service of the Defence and Security High Official) guide for licensees and for the ASN and SHFDS inspectors. This guide should facilitate common understanding of the requirements of the order by the professionals and inspectors alike. It will present recommendations for the implementation of these requirements and include numerous examples. As it details certain provisions of the appendices to the order, its distribution will be limited. In the second half of 2020, ASN conducted a targeted consultation of professionals on this draft guide. The comments received are currently being addressed and the final version of the guide should be available in 2021.

2.4 Licensing and notification of ionising radiation sources used for industrial, research or veterinary purposes

2.4.1 Integration of the principles of radiation protection in the regulation of non-medical activities

With regard to radiation protection, ASN verifies application of the three major principles governing radiation protection which are written into the Public Health Code (Article L. 1333-2), namely justification, optimisation of exposure and dose limitation.

Assessment of the expected benefit of a nuclear activity and the corresponding health drawbacks may lead to prohibition of an activity for which the benefit does not seem to outweigh the risk. Either generic prohibition is declared, or the license required for radiation protection purposes is not issued or is not extended. For the existing activities, the elements supporting implementation of the justification principle are recorded in writing by the person responsible for the nuclear activity, and are updated every five years and whenever there is a significant change in available knowledge or techniques.

Optimisation is a notion that must be considered in the technical and economic context, and it requires a high level of involvement of the professionals. ASN considers in particular that the suppliers of devices are at the core of the optimisation approach (see point 4). They are responsible for putting the devices on the market and must therefore design them such that the exposure of the future users is minimised. ASN also checks application

International think tank on alternative technologies

Radioactive sources present radiation exposure and safety risks for their users, the general public and the environment, which must be taken into consideration in the reflection phase preceding the deployment of a nuclear activity. Consequently, in France, when technologies presenting lower risks than a nuclear activity are available under technically and economically acceptable conditions, they must be implemented instead of the nuclear activity initially envisaged: this is the principle of justification.

On this basis, as of 2014 and subsequently at the Nuclear Security Summit in Washington in April 2016, France was the initiator of an international initiative now supported by 31 countries and by Interpol. The aim is to support research into and the development of technologies that do not use high-activity sealed radioactive sources and to promote the use of these technologies.

In this context, since April 2015 ASN has, along with the National Nuclear Security Administration (United States), initiated an informal think tank involving several countries working on the subject of replacing high-activity radioactive sources by alternative technologies. The aim of this group, which meets once a year, is to foster greater awareness of the benefits of such alternatives and to share experience feedback from each country in this respect.

ASN has contributed to these meetings by presenting the operations carried out by the French blood transfusion agency, in application of the principle of justification, to replace those of its irradiators that use radioactive sources by electrical irradiators that emit X-rays. ASN also invited the French Confederation for Non-Destructive Tests to present the progress of its work in replacing gamma radiography by other non-destructive testing technologies.

In December 2018, during the International Conference on Nuclear Security organised by the International Atomic Energy Agency (IAEA), the subject of alternative technologies was addressed by several presentations and two panel sessions, and the relevance of this think tank was underlined.

The meetings of the think tank continued in 2019. Other foreign licensees shared their experience, particularly in the use of electrical irradiators emitting X-rays for research activities. These regular meetings provide the opportunity to highlight both successful initiatives in the implementation of alternative technologies and difficulties in the development or implementation of these technologies which must be the subject of further consideration and complementary work. The interchanges had to be interrupted in 2020 due to the Covid-19 pandemic, and should be resumed in 2021.

of the principle of optimisation when examining the license applications, when conducting its inspections, and when analysing reported significant events.

2.4.2 Applicable licensing and notification systems

Applications relating to the possession and utilisation of ionising radiation are examined by the ASN regional divisions, while those concerning the manufacture and supply 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, has introduced 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 by their considerable diversity and the large number of licensees involved. The licensing system is designed to regulate the nuclear activities involving the greatest radiation protection implications, for which ASN checks, when examining the license application, that the applicant has identified the risks and that the measures intended to limit their effects have been studied and planned for. To support this licensing process, ASN has produced licensing application forms adapted to each activity and which are available on *asn.fr*.

These forms are designed for the licensing applications to be formulated by the representative of a legal person, although it is possible for a physical person to apply for a license. These forms list the documents that must be enclosed with the application. All the other documents listed in the appendix to ASN resolution 2010-DC-0192 of 22 July 2010 must be held by the applicant and kept at the disposal of the inspectors in the event of inspection. On completion of the examination, and provided that the measures described by the applicant are satisfactory, a limited-term (usually 5 years) license is issued for the exercise of the nuclear activity.

The notification system

As part of the allocation of the nuclear activity classification into the three administrative systems introduced by the above-mentioned Decree, ASN wanted to implement a more graded approach, proportionate to the risks.

Its initial work focused on the notification system. Notification is a simple procedure which does not require the submission of any supporting documents. It is particularly suited to the nuclear activities that present the lowest risks for people and the environment. Since April 2018, those responsible for a nuclear activity in the industrial, research or veterinary sectors that comes under the notification system, can carry out the notification procedure *via* the ASN "online services" portal.

Through ASN resolution 2018-DC-0649 of 18 October 2018 approved on 21 November 2018, ASN has extended the list of activities subject to notification. The notification system extension should concern about 6,000 companies or individuals which were previously subject to the licensing system. However, it will not be possible to accurately quantify the number of companies or individuals concerned until a five-year term is reached (31 December 2023). This is because, in accordance with the principle of grandfathering, the licenses issued before 1 January 2019 act as notification acknowledgements until the license reaches term, on condition that in the interim there is no change in the nuclear activity. This means that a number of nuclear activities, though now subject to notification, are still regulated by a license.

Administrative tracking of radioactive sources

Articles R. 1333-154, 156 and 157 of the Public Health Code provide for the prior registration by the IRSN (French Institute of Radiation Protection and Nuclear Safety) of transfers of radioactive sources and Article R. 1333-158 for administrative tracking of these sources.

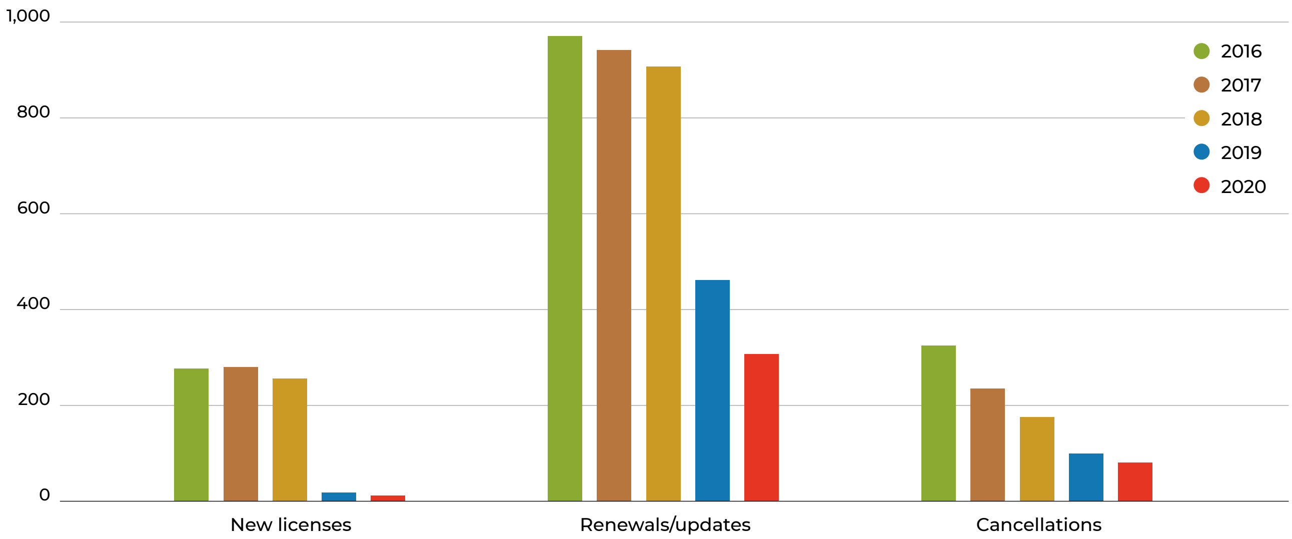
ASN resolution 2015-DC-0521 of 8 September 2015 relative to the tracking and methods of registering radionuclides in the form of radioactive sources and products or devices containing them details the methods of registering transfers and the rules for tracking radionuclides in the form of radioactive sources.

This resolution, applicable as of 1 January 2016, takes into account the existing mode of functioning and supplements it as follows by:

- grading source administrative tracking according to how dangerous the sources are;
- confirming the non-registration of sources whose activity is below the exemption thresholds;
- imposing deadlines between the registering of source transfer and the actual transfer;
- making it an obligation for each source to be accompanied by a "source certificate" indicating all its characteristics and which must be transmitted to the IRSN within two months after receiving the source.

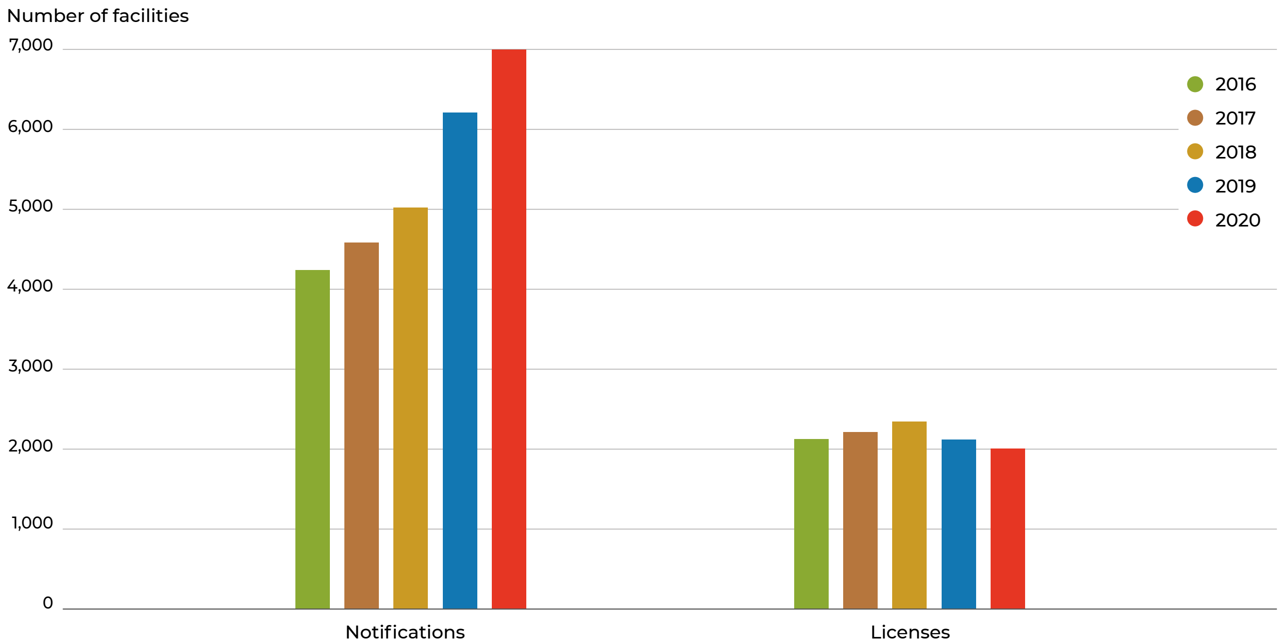
GRAPH 6

Radioactive source "user" licenses and notifications issued each year



GRAPH 7

"User" licenses and notification acknowledgements issued for electrical devices generating radiation



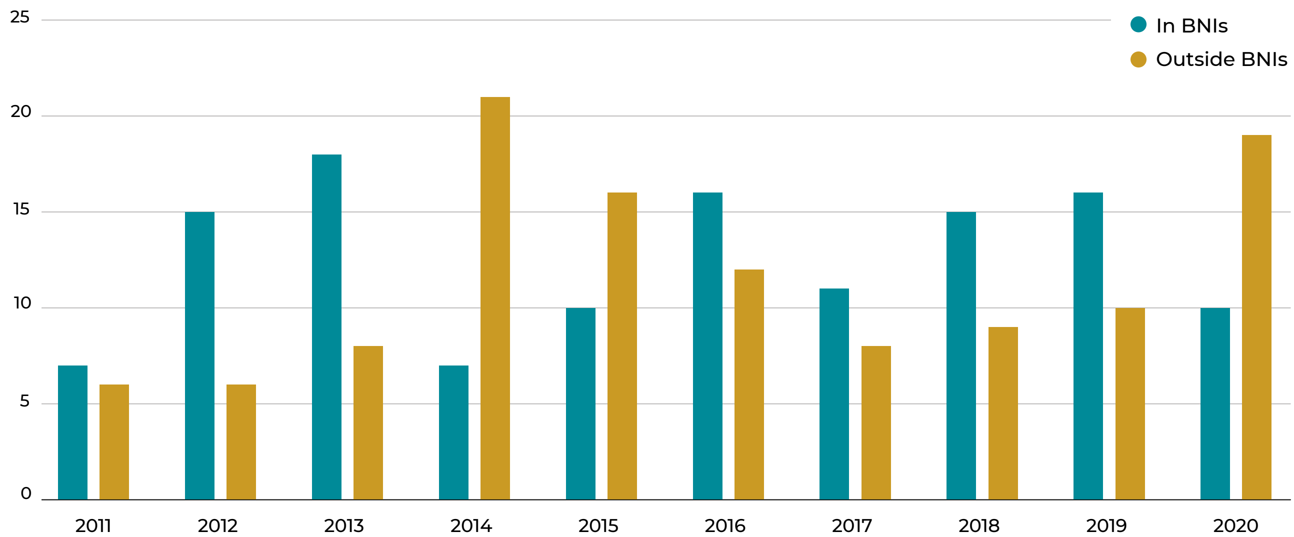
2.4.3 The future registration system (simplified authorisation)

After having drawn up the guiding principles establishing the general framework for the future registration system in 2019, then, in mid-2020, having submitted the draft texts for public consultation, ASN has finished preparing the resolutions concerning this new administrative system. In practice, two resolutions regulate this system: one relative to nuclear activities for medical purposes (see chapter 7, Table 2), the other relative to nuclear activities in the industrial, research and veterinary sectors. ASN resolution 2012-DC-0703 of 4 February 2021 will, subject to ministerial approval, enter into force on 1 July 2021. This system will apply to certain sources of ionising radiation, whether in the form of sealed or unsealed radioactive sources, and X-ray generators, where the risks and drawbacks of possessing or using them can be prevented by complying with the specific general requirements set by the resolution. The resolution therefore defines, apart from the nuclear activities concerned, the content of the simplified authorisation application and the conditions for exercising (specific general requirements) the nuclear activity with which the licensees must comply.

Its entry into effect will mark the second stage – following that of extension of the notification system – of effective implementation of the reform of small-scale nuclear activity regulation, aiming to better materialise a graded approach to the risks. The resolution effectively implies significant alleviations in the administrative procedures compared with those for nuclear activities subject to licensing, such as: a simplified application (both in the information and the substantiation documents to provide), ten-year registration validity by default (and even unlimited validity by default for certain nuclear activities), the possibility of applying for registration *via* the online registration service

GRAPH 8

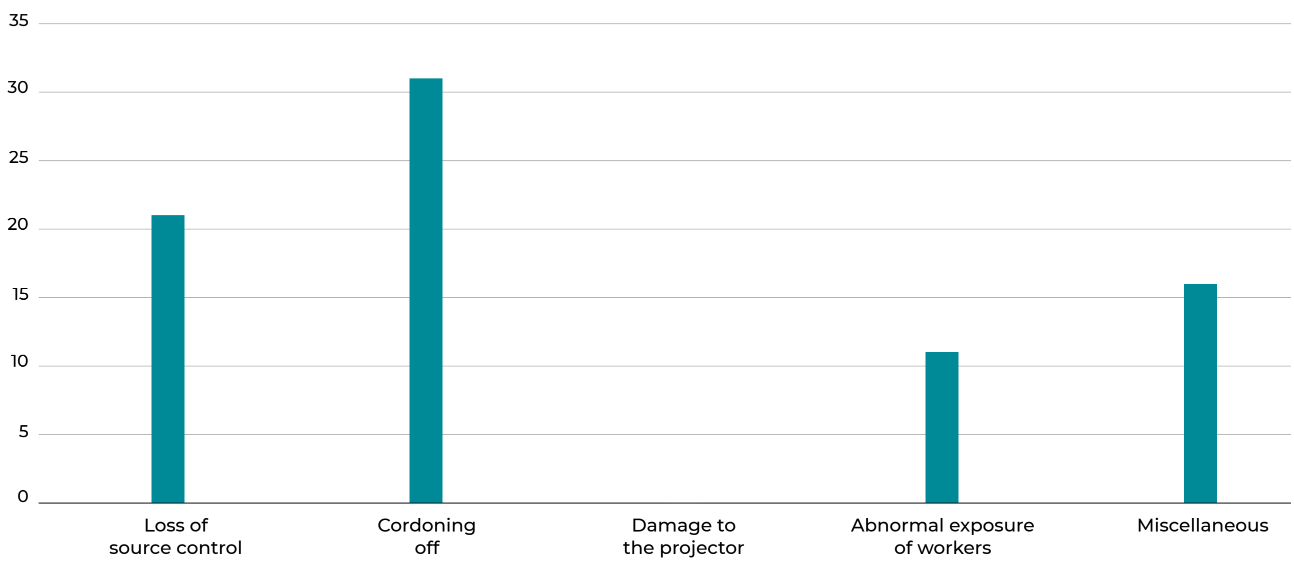
Trend in the number of industrial radiography events reported to ASN



Note: the 24 events of 2018 and the 26 events of 2019 led to 25 and 27 notifications to ASN respectively. In both cases, one event was reported twice by both the ordering customer and the industrial radiography contractor.

GRAPH 9

Main factors contributing to the industrial radiography events reported to ASN over the 2018-2020 period



which will be available on *asn.fr*, review and assessment by ASN within reduced to six months, the with silence after six months being considered as acceptance of registration of the applicant nuclear activity.

Entry into effect of the registration system should ultimately concern between 1,200 and 2,000 licensees in industry, research and veterinary applications, hitherto subject to the licensing system. However, as is the case with the notification system, the number will not be able to be accurately quantified until a five-year period has expired (1 July 2026). This is because, in accordance with the principle of grandfathering, the licenses issued before 1 January 2021 will act as registration until the license reaches term, on condition that in the interim there is no change in the nuclear activity.

2.4.4 Statistics for the year 2020

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 2020, 103 radioactive source supply license applications or license renewal applications were examined by ASN, and 27 inspections were carried out (all ionising radiation sources combined).

Users

The case of radioactive sources

In 2020, ASN examined and notified 12 new licenses, 307 license renewals or updates and 81 license cancellations. Graph 6 shows the licenses issued or cancelled in 2020 and the trend for these data over the last five years. In 2020, ASN also issued 1,218 notification acknowledgements for sealed radioactive sources. The entry into effect of ASN resolution 2018-DC-0649 of 18 October mentioned in point 2.4.2 is the main reason for the very large drop in the number of licenses issued in favour of the issuance of notification acknowledgements, and illustrates the concrete application of the graded approach to risk control.

Once the license or notification acknowledgement is obtained, the holder can procure sources. To do this, it collects supply request forms from the IRSN, enabling the Institute to verify – as part of its duty to keep the national inventory of ionising radiation sources up to date – that the orders are in conformity with the license or notification acknowledgement issued to the user and the license of its supplier. If the order is correct, the transfer is then recorded by the IRSN, which notifies the interested parties that delivery can take place. In the event of difficulty, the transfer is not validated and the IRSN refers the case to ASN (see box page 251).

Cases of ionising radiation generators

ASN has been responsible for the oversight of these devices since 2002, devices for which numerous administrative compliance actions are still required. In 2020, ASN granted 41 new licenses and 174 license renewals or updates for the use of X-ray generators. It also issued 787 notification acknowledgements for devices emitting ionising radiation. As with radioactive sources, the large reduction in the number of licenses issued and, conversely, the significant increase in notification acknowledgements, are direct consequence of the entry into effect of the abovementioned ASN resolution 2018-DC-0649 of 18 October 2018.

A total of 1,995 licenses and 6,980 notification acknowledgements have been issued for devices emitting ionising radiation since 2002. Graph 7 illustrates the trend for the last few years.

3. Assessment of the radiation protection situation in applications involving radiation risks in the industrial, research and veterinary sectors

3.1 Industrial radiography

3.1.1 The devices used

Gamma radiography

Gamma radiography is a non-destructive inspection method used for detecting homogeneity defects in materials such as weld beads. It involves obtaining a radiographic image on silver-based or digital media using the gamma rays emitted by a radioactive source and passing through the object to inspect.

It is widely used in fabrication and maintenance operations in diverse industrial sectors such as boilermaking, petrochemicals, Nuclear Power Plants (NPPs), 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 20 terabecquerels (TBq). 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.

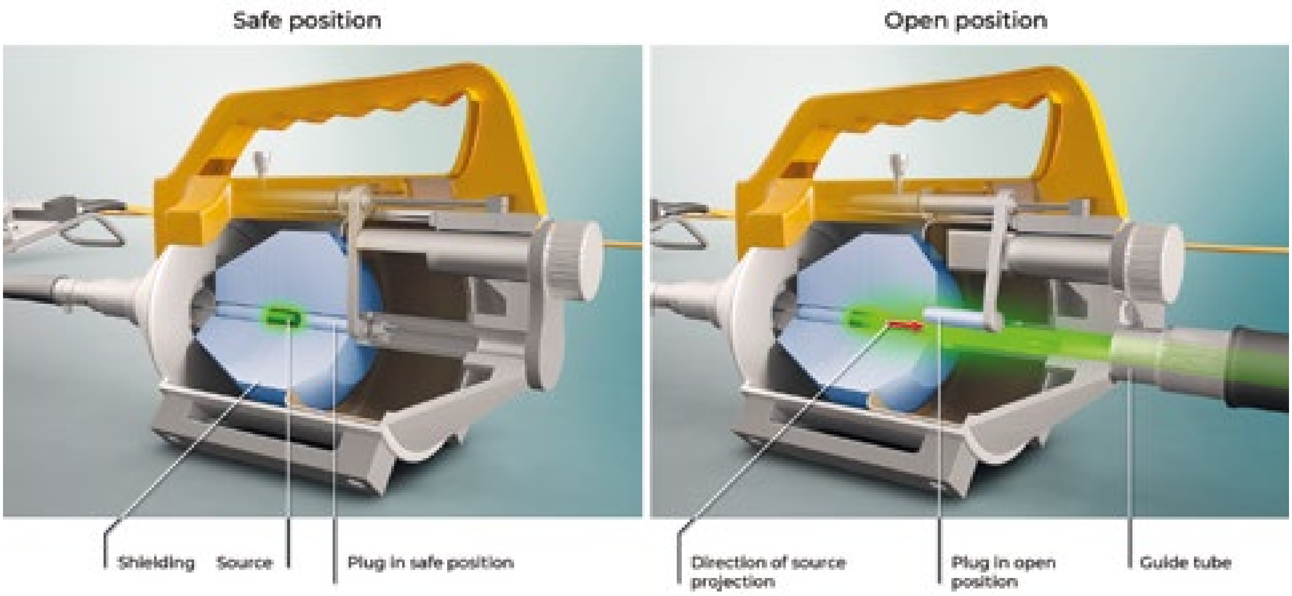
When the source is ejected out of the device, the dose rates can reach several grays per hour at one metre (m) from the device, depending on the radionuclide and its activity level.

As a result of the activity of the sources and the movement of the sources outside the storage container when the device is being used, gamma radiography can entail significant risks for the operators in the event of incorrect use, failure to comply with radiation protection rules, or operating incidents. Furthermore, these gamma radiography activities are often carried out on work sites under difficult conditions (working at night, or in

THE IMPACT OF COVID-19

The Covid-19 pandemic has led ASN, in the industry, research and veterinary sectors, to reduce the initially planned overall inspection programme by about 15% to adapt to the exceptional circumstances, which have had significant effects on the conditions of operation of certain licensees, some of whom have reduced or even temporarily stopped their activities after placing their facilities in safe condition, and to the travel restrictions imposed by the Government. Furthermore, some of the inspections were carried out remotely. This has made comparison with preceding years more difficult. The sections relative to the radiation protection situation of points 3 and 4 below must therefore be read taking into consideration the particular inspection conditions of the year 2020.

Operating schematic of a gamma ray projector



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. This is because the equivalent dose rates are about 55 millisieverts per hour and per terabecquerel (mSv/h/TBq) 1 metre (m) from the source, as opposed to 130 mSv/h/TBq for iridium-192. Yet it can be used in place of iridium-192 in numerous industrial fields, especially the petrochemical or boilermaking industry, and it enables the cordoned-off safety area to be significantly reduced and facilitates intervention in the event of an incident. In France, less than 20% of portable devices are equipped with a selenium-75 source. The deployment of selenium-75 has remained stationary in the last few years. This is because the production plants in Russia have encountered difficulties causing a break in supplies throughout Europe. ASN nevertheless still encourages its use given that the current problems are temporary. Furthermore, the sealed source manufacturers in the United States, who for a long time did not embrace this technology, are now proposing sources of this type. A new manufacturer was thus licensed in 2019.

places that are exposed to the elements, or in cramped spaces). This is therefore an activity with serious radiation protection implications that figures among ASN's inspection priorities.

Industrial X-ray radiography

Industrial X-ray radiography is used for checking the quality of weld beads or for the fatigue inspection of materials.

It is carried out using fixed devices or worksite devices employing directional or panoramic beams which substitute for gamma radiography devices if the conditions of use so permit.

These devices can also be used for more specific and therefore rarer purposes, such as radiography for the restoration of musical instruments or paintings, archaeological study of mummies or the analysis of fossils.

3.1.2 Assessment of radiation protection in industrial radiography activities

Industrial radiology activities are high-risk activities which have been an inspection priority for ASN for several years now.

In 2020, ASN conducted 147 inspections in this area, a number that is stable with respect to 2019 (150). In effect, despite the consequences of the health crisis, ASN maintained its inspection efforts in this area of activity. Even if some inspections procedures were adapted so that all or part of the inspections could be carried out remotely, the ASN inspectors continued to be present at the sites. For example, 59 unannounced worksite inspections, which usually take place at night, were carried out. Furthermore, when inspections were conducted remotely, most were supplemented by targeted on-site inspections, in compliance with Covid-19 prevention and protection measures.

The online notification of worksite schedules for industrial radiography companies put in place by ASN in 2014 facilitates the planning of these inspections. ASN notes that virtually all the licensees concerned generally use this system for the worksite notifications. This being said, the reliability of the information provided is still variable. The points to improve include:
- the updating of schedules when they are changed;
- the accuracy of the worksite location information (not to be confused with the address of the ordering company);
- the completeness of the worksite notification.

From its inspection findings, ASN considers that, on the whole, the risks are properly taken into account – albeit with disparities between companies – with the exception of the cordoning off of work zones at temporary worksites.

ASN finds that the large majority of companies maintained the necessary rigour to meet the regulatory requirements with respect

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 gigabecquerels (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. This situation must nevertheless not be taken for granted and continued vigilance is required. ASN keeps a watchful eye on accidents occurring abroad which have sometimes had serious effects. Examples recently brought to ASN's attention, which confirm the risks to which operators can be exposed as a result of inappropriate actions, include:

- In 2020, in the United States, a radiographer and two assistant-radiographers performing non-destructive tests in an asphalt production unit were exposed to whole body doses of 636, 104 and 26 millisieverts (mSv) respectively while attempting to reintroduce the source into the gamma ray projector after the guide tube had been crushed by a support which fell from a storage tank. The event was rated level 2 on the International Nuclear and Radiological Event Scale (INES scale).
- In 2019, in Spain, an employee of a non-destructive testing company was exposed to about 200 mSv (whole body) by entering a gamma radiography bunker when the iridium-192 source was not in the safe position. The door-opening slaving system for prohibiting access to the bunker during the emission of ionising radiation, did not function due to the failure of the dose rate measuring system. The event was rated level 2 on the INES scale. A similar accident happened the same year in Germany: two employees were exposed to 30 and 100 mSv respectively (whole body) when they entered a gamma radiography bunker when the iridium-192 source was not in the safe position and the radiological environment had not been checked. The event was rated level 2 on the INES scale.
- 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). The event was rated level 2 on the INES scale.
- In 2015, in Iran, two operators were exposed to effective doses of 1.6 and 3.4 Gy. The gamma ray projector source (iridium-192 of 1.3 terabecquerels – 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, five Bulgarian workers were admitted to Percy hospital in Clamart for major treatment following irradiation of 2 to 3 Gy owing to an error in the handling of a gamma ray projector, from which they believed the source had been removed.
- In 2011, in the United States, an apprentice radiographer disconnected the guide tube and noticed that the source was protruding from the source applicator. He tried to push the source into the device with his finger. The estimated dose received at the extremities is 38 Gy.

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.

08

Spotlight on regulatory annual maintenance operations on gamma radiography devices

At the end of 2020, ASN conducted an inspection focusing on the annual maintenance of gamma radiography devices (projectors and accessories) required by the regulations, on the premises of the main supplier of these devices, who is also responsible for these maintenance operations. The purpose of this inspection was to check the management and traceability of the maintenance operations (including the sealed radioactive source loading/unloading operations) performed by the supplier and comparing the information at its disposal with that obtained (mainly maintenance reports) throughout 2020 during the ASN inspections on non-destructive testing sites. On the basis of a sampling inspection of half of the 160 or so maintenance reports collected, the inspectors checked that the information presented by the gamma radiography device users was consistent with the information established by the supplier. The inspectors concluded that the supplier's administrative tracking of all the operations conducted on the gamma ray projectors and their accessories was functional and generally satisfactory.

This inspection formed part of the anti-fraud actions implemented by ASN for several years now to check the veracity of the documents presented by the licensees. No attempt to falsify documents by either the supplier or the users of gamma radiography device supplier was detected.

to the appointing of a Radiation Protection Advisor (RPA – no noncompliance observed) and worker dose monitoring (less than 10% noncompliance observed). The inspectors have also noted that the frequency of gamma radiography device maintenance complies with the regulations. Likewise, all the operators inspected by ASN were, when necessary, in possession of the certificate of aptitude to operate industrial radiology devices (Camari) required by Article R. 4451-61 of the Labour Code.

The inspectors also noted that the efforts made by the companies to train newly-arrived classified workers had been maintained. Thus, in 2020 this information was duly dispensed to the new arrivals in more than 85% of the inspected facilities concerned. However, the periodic refreshing of this training and its content require further improvements.

Conversely, ASN is still concerned by the deviations seen in cordoning off the work zones on temporary worksites. Even if the deviations observed in 2020 are proportionally fewer in number than in 2019, they are still too frequent (one inspection out of four). ASN underlines that the lack of preparation and cooperation between the ordering customers and the radiography contractors before starting temporary worksites (particularly the failure to draw up a precise prevention plan) is one of the causes of these deviations.

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, that the cordoning off must be continuous and that it is essential to have warning lights in sufficient quantity. 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(s). Zoning and cordoning off effectively constitute the main safety barrier in worksite configurations, particularly to prevent unintended exposures. Consequently, ASN remains extremely vigilant regarding this point, which is systematically checked during worksite inspections; moreover, penal enforcement actions have already been proposed for serious breaches.

ASN also notes disparities in the quality of the technical files it has to examine for inspection preparation or follow-up, and those received for license applications. The contractors must in particular be more attentive to the reports establishing the conformity of their facilities with the appropriate technical baseline requirements. ASN still detects errors too frequently, particularly when production of these reports has been subcontracted, and these errors sometimes lead to nonconformities. Furthermore, the inspections carried out in 2020 show that in a quarter of the cases the gamma radiography facility safety devices were not properly installed or verified.

Lastly, the protection of ionising radiation sources against malicious acts (see box on next page) must be further improved. For example, the individual authorisations for access to radioactive sources were correctly drawn up in less than half the inspected sites.

With regard to application of the principles of justification and optimisation, the long-term reflections undertaken by the non-destructive testing professionals have resulted in guidelines which aim to promote the use of alternative methods to industrial radiography. The work is continuing within the professional bodies, in particular with the updating of the construction and maintenance codes for industrial equipment, in order to promote the use of non-ionising inspection methods.

Furthermore, France has a large network of fixed industrial radiography facilities (99 gamma radiography facilities are licensed in France in 2020), enabling 70% of the professionals to propose industrial radiography services in bunkers. ASN considers that the risks of incidents and the workers' occupational exposure are generally well controlled by the licensees when radiography is performed in a bunker complying with the applicable regulations. Despite the availability of such facilities, ASN still observes too often that parts that undergo radiography on worksites, particularly those scheduled at night in workshops, could have been easily moved to a bunker. Apart from optimising doses for the workers, it would also eliminate the risk of having to temporarily shut down the workshop in the event of an incident preventing the radioactive source of the gamma ray projector from returning to the safe position.

ASN considers that the ordering customers have a key role to play to improve radiation protection in industrial radiography, by favouring industrial radiography services in facilities that have a bunker.

Enhancing the awareness of all the players is therefore a priority. The regional initiatives to establish charters of good practices in industrial radiography implemented for several years now at the instigation of ASN and the labour inspectorate, particularly in areas corresponding to the former regions of Provence-Alpes-Côte d'Azur, Haute-Normandie, Rhône-Alpes, Nord-Pas-de-Calais, Bretagne and Pays de la Loire, allow regular exchanges between the various stakeholders. The ASN regional divisions and other regional administrations concerned also regularly organise regional awareness-raising and discussion symposia for which the actors of this professional branch show a real interest.

Inspections relating to the protection of ionising radiation sources against malicious acts: key findings and trends

In 2019 and 2020, during ASN inspections in facilities holding sealed radioactive sources of category A, B or C, either individually or in batches, the first four regulatory provisions applicable since 1 July 2018 relative to their protection against malicious acts were verified in 107 industrial facilities and 27 medical centres.

The classification of radioactive sources or batches of sources into the different categories has been carried out on slightly more than half the facilities (54% [↑][1] for the industrial sector and 59% [↑] for the medical sector), while the remaining facilities have applied the classification only partially (21% [↓] and 33% [↓] respectively), or not at all (24% [↓] and 7% [≈] respectively).

The individual authorisations that the person responsible for the nuclear activity must issue to grant access to these radioactive sources or batches of sources, their transportation or access to the information relative to the means or measures for protecting them, have been granted to only a small extent in the facilities inspected. Only 33% [↑] of the industrial facilities and one medical centre (compared with none in 2019) comply with this requirement as a matter of course. The provisions are partially satisfied in 26% [↑] of the industrial facilities and 33% [↑] of the medical centres: the authorisations are thus only issued to some of the people who need them or without considering the real needs to have them. In the other cases (41% [↓] and 63% [↓] respectively), no authorisation was granted.

Nevertheless, **the measures taken to prevent unauthorised access to the sources** were deemed satisfactory in the large majority of industrial facilities (86% [↓]), whereas in the medical sector less than half of the centres meet the applicable measures at present (43% [↑]).This assessment must however be considered with caution: it is very likely to change once the protection systems (physical in particular) prescribed by the Order of 29 November 2019 relative to the protection of ionising radiation sources and batches of sources in categories A, B, C and D against malicious become applicable.

Lastly, **the majority of the source inventories held by the facilities** are consistent with the national inventory held by the French Institute for Radiation Protection and Nuclear Safety (IRSN) (complete correspondence in 74% [≈] of cases for the industrial sector and 81% [↑] for the medical sector), thus allowing rapid identification of the holding entity and site if necessary.

Between 2019 and 2020, ASN has thus observed a slight improvement in the application of the first four regulatory provisions relative to the protection of category A, B or C radioactive sources against malicious acts in the inspected facilities, except as regards measures to prevent unauthorised access to these sources, which seems to be at a standstill.

The Covid-19 pandemic has reduced the number of inspections performed by the ASN, particularly in the medical centres holding sealed radioactive sources in categories B or C, where inspections dropped by half between 2019 and 2020. Consequently, the change trends for medical centres must be considered with caution.

1. The change in trends between 2019 and 2020 is indicated by the symbols [↑] (rise), [↓] (drop) and [≈] (stable).

Lastly, in 2020 as in the last few years, no cases of overexposure of industrial radiography operators were reported to ASN, even if several significant events linked to loss of source control (source "jamming") did occur during the use of gamma ray projectors. These events were correctly diagnosed by the operators and the persons concerned did not undertake any inappropriate or prohibited operations. For example, the ASN inspectors tasked with checking implementation of protection measures around a defective device pending its placing in safe condition within the Total group's Feyzin oil refinery in the Rhône *département* observed that the situation was correctly managed by those concerned. ASN draws that attention of companies having gamma radiography inspections carried out in their facilities to the consequences of the radioactive source getting jammed outside the gamma ray projector, and especially the setting up of an exclusion zone for the time necessary to definitively place the source in safe condition, which can often be several days.

3.2 Industrial irradiators

3.2.1 The devices used

Industrial irradiation is used for sterilising medical equipment, pharmaceutical or cosmetic products and for the conservation of foodstuffs. It is also a means of voluntarily modifying the properties of materials, for example, to harden polymers.

These consumer product irradiation techniques can be authorised because, after being treated, these products display no residual artificial radioactivity (the products are sterilised by passing through radiation without themselves being "activated" by the treatment).

Industrial irradiators often use cobalt-60 sources, whose activity can be very high and exceed 250,000 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 19 inspections from 2018 to 2020 (of which three were in 2020) in this sector, out of the 25 facilities currently licensed. These inspections show that the radiation protection organisation (in particular the appointing of a RPA), the radiological zoning put in place on the inspected licensees' premises, the informing of new employees and the renewal of verifications are satisfactory, as no significant deviations from the regulations have been observed. The risk is well controlled, in particular thanks to the satisfactory verification, upkeep and maintenance of the facilities in accordance with the provisions described in the licensing applications.

Nevertheless, in one in five inspections ASN found that the verification of the safety systems needed to be improved. Moreover, the findings relative to the verification of the protection of sources of ionising radiation against malicious acts are also valid in this sector. ASN has thus observed that the individual

Initiating trustworthiness checks

The Public Health Code stipulates that the person responsible for the nuclear activities shall issue individual authorisations to the people who need access to the sources or to the information protecting them against malicious acts. To do this, the person may request the opinion of the Command Specialised in Nuclear Security (CoSSeN). This service, which has national competence, is part of the Ministry responsible for energy and the Ministry of the Interior; it is attached to the Director General of the National Gendarmerie.

The CoSSeN's opinion is based on an administrative review intended to check that the behaviour of the persons concerned is not, or has not become, incompatible with the functions or duties exercised. This trustworthiness check is based on the review of police databases and, if the persons are mentioned the said database, additional verifications. The persons concerned must be informed of this trustworthiness check. The conditions of investigation are governed by the Interior Security Code.

This Code also provides the possibility of conducting such trustworthiness check on the person responsible for a nuclear activity, if the activity requires a licence. Performing such checks meets one of the principles of the International Atomic Energy Agency (IAEA) Code of Conduct on the Safety and Security of Radioactive Sources.

ASN considers that is would be illogical for a person responsible for a nuclear activity to be able to request the CoSSeN to perform a trustworthiness check on a member of their staff or their subcontractors' staff without themselves undergoing such a check insofar as they supervise the conditions of exercise of the nuclear activity. At the end of 2020, ASN initiated an experiment in this respect on licensees who are either suppliers of category A, B or C sealed radioactive sources or users of such sources in the Auvergne-Rhône-Alpes region. The preparation of this experiment included numerous interchanges with the CoSSeN.

At the end of this experiment and once any necessary adjustments have been made, ASN plans having trustworthiness check conducted on the already licensed persons responsible for nuclear activities and when an initial licensing application is made or in the event of a change of the person responsible for the nuclear activity (or their representative in the case of a legal person). This trustworthiness check will be carried out at each licensing renewal application.

authorisations for access to sources were duly established in less than half the inspected sites.

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 R. 593-3 of the Environment Code concerning the BNI nomenclature, these facilities are listed as BNIs.

Some applications necessitate the use of beams of photons or electrons produced by particle accelerators. In France, slightly over one hundred particle accelerators, whether linear (linacs) or circular (synchrotrons) are operated in 64 licensed facilities[1] (excluding cyclotrons – see point 4.2 – and excluding BNIs), for highly diverse purposes 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;
- others.

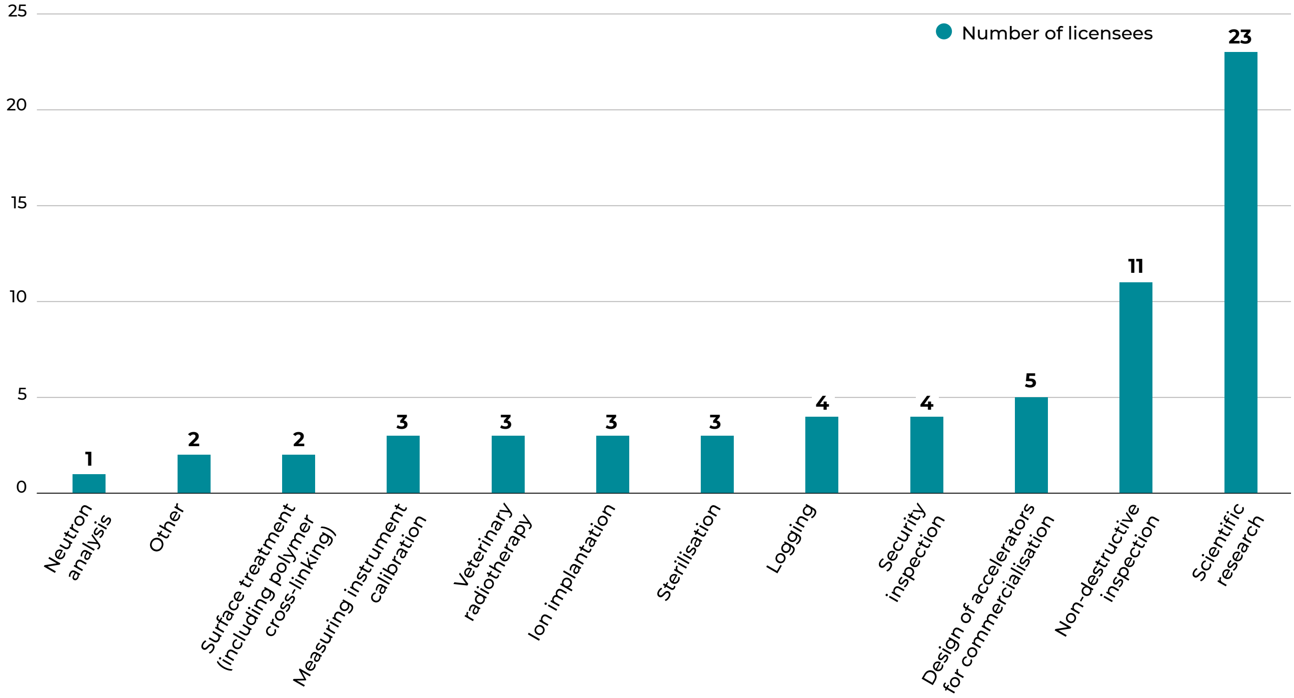
In the field of research, two synchrotron radiation production facilities can be mentioned in France: the European Synchrotron Radiation Facility (ESRF) in Grenoble, and the Soleil (Optimised Source of Intermediate-Energy Light of the Lure Laboratory) synchrotron in Gif-sur-Yvette.

Particle accelerators have been used for several years now in France to fight fraud and large-scale international trafficking. This technology, which the operators consider effective, must however be used under certain specific conditions in order to comply with the radiation protection rules applicable to workers and the public, in particular:
- a ban on activation of construction products, consumer goods and foodstuffs as specified by Article R. 1333-2 of the Public Health Code, by ensuring that the maximum energy of the particles emitted by the accelerators used excludes any risk of activation of the materials being verified;
- a ban on the use of ionising radiation on the human body for purposes other than medical;
- the setting up of procedures to ensure that the checks conducted on the goods or transport vehicles do not lead to accidental exposure of workers or other individuals. The use of ionising technologies to seek out illegal immigrants in transport vehicles is prohibited in France. During customs inspections of trucks using tomographic techniques, for example, the drivers must be kept away from the vehicle and other checks must be performed prior to irradiation to detect the presence of any illegal immigrants, in order to avoid unjustified exposure of people during the inspection.

1. To which must be added 6 licenses to use an accelerator, either under worksite conditions, or for the shared use of a device whose possession is regulated by the other party's license.

GRAPH 10

Distribution of particle accelerators by end-purpose



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.

Between 2018 and 2020, 38 facilities equipped with these devices were inspected by ASN, 12 of them in 2020.

ASN considers the radiation protection situation in the facilities using these devices to be satisfactory on the whole. In effect, the key requirements for conducting this activity with a satisfactory level of radiation protection (organisation of radiation protection, informing and training, technical verifications and design of the premises in which these devices are used) are appropriately implemented by the large majority of the licensees.

Synchrotrons

The synchrotron is a member of the same circular particle accelerator family as the cyclotron (see point 4-2), but is far larger, enabling energies of several gigaelectronvolts to be achieved by means of successive accelerations. Owing to the low mass of the particles (generally electrons) the acceleration created by the curvature of their trajectory in a storage ring, produces an electromagnetic wave when the speeds achieved become relativistic: this is synchrotron radiation. This radiation is collected at various locations called beam lines and is used to conduct scientific experiments.

Nevertheless, these inspections have also identified areas for improvement on which ASN will remain vigilant:

- compliance with the regulations dictating the frequency of technical verifications of work equipment (which under current regulations are carried out by ASN-approved bodies) and the formalised processing of any 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;
- the correct functioning of the audio signal associated with the patrol procedure, which aims to confirm that nobody is in the room before authorising the emission of ionising radiation;
- the availability of radioactivity measurement devices in sufficient quantities for the operators who access these rooms.

Lastly, with regard to experience feedback, no significant radiation protection event was reported to ASN in 2020, apart from the recurrent events associated with the use of particle accelerators in shipment security checks. 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. Although this exposure is unjustified, it nevertheless remains extremely low with effective doses of just a few microsieverts per person.

3.4 Research activities involving unsealed radioactive sources

3.4.1 The devices used

In the research sector, as at 31 December 2020, ASN counted 657 licenses issued under the Public Health Code, of which nearly 90% are issued to public or mixed (public/private) entities. The number of licenses has been decreasing constantly for five years, since about 10 licenses on average are repealed each year. This reduction can essentially be explained by two factors: either the replacement of sources of ionising

Research activities

The use of ionising radiation in research activities extends to various fields such as medical research, molecular biology, the agri-food industry, materials characterisation, etc. It primarily involves the use of unsealed sources (iodine-125, phosphorous-32, phosphorous-33, sulphur-35, tritium-3, carbon-14, etc.). Sealed sources (barium-133, nickel-63, caesium-137, cobalt-60, etc.) are also used in gas chromatographs or scintillation counters or, with higher-activity sources, in irradiators.
X-ray generators rays are used for X-ray fluorescence or X-ray diffraction spectrum analyses. The use of scanners for small animals (cancer research) in research laboratories and faculties of medicine should also be noted. Particle accelerators are used in research into matter or for the manufacture of radionuclides.

radiation by alternative non-ionising technologies (example: immunofluorescent[2] labelling of cells), or the grouping of the licenses of several laboratories into a single license for which the person responsible for the nuclear activity is usually the director of the newly created structure. Added to these factors, since early 2019, is the transfer of certain nuclear activities from the licensing system to the notification system (see point 2.4.2). This reduction should continue in the years to come, with the entry into effect of the new registration system: some nuclear activities in the research sector will come under this system. These facilities and laboratories use mainly unsealed sources for medical and biomedical research, molecular biology, the agri-food business, the sciences of matter and materials, etc. They 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 or X-ray diffraction spectrum analysis. Particle accelerators are used for research into matter or for the production of radionuclides.

3.4.2 The radiation protection situation

In 2020, ASN carried out 43 inspections in this sector[3] (49 inspections per year on average over the 2018-2020 period). Some inspections scheduled for 2020 and considered non-priority were postponed until 2021 on account of the health crisis. Generally speaking, the steps taken in the last few years have brought improvements in the implementation of radiation protection measures in research laboratories, thanks to enhanced overall awareness of radiation protection issues.

Among the observed areas of progress, ASN underlines the strong involvement of the RPAs with the research teams, resulting in better integration of radiation protection, particularly in operations involving ionising radiation sources.

The other notable improvements, already observed in the preceding years, concern the conditions of waste and effluent storage and removal, particularly the setting up of pre-disposal checking procedures. The way this subject is addressed nevertheless varies greatly from one licensee to another and remains a point requiring particular attention in universities which have historically stored their expired /disused sealed radioactive sources and their waste contaminated by radionuclides, sometimes over very long periods of time, rather than disposing of them regularly, which today poses two main problems:

- in view of their diversity, the radioactive waste and expired/disused radioactive sources cannot be further managed without first being precisely identified and characterised;
- the disposal or removal, to which must be added prior characterisation where applicable, represents a significant financial cost which has often been neither foreseen nor budgeted for.

The technical, economic and regulatory difficulties concerning the disposal of legacy sealed sources therefore persist, despite entry into effect on 1 July 2015 of Decree 2015-231 of 27 February 2015 relative to the management of disused sealed radioactive sources. In effect, this text, which aims to facilitate the disposal of sealed sources, gives source holders the possibility of seeking alternative disposal routes with source suppliers or Andra without making it obligatory to return the source to its original supplier.

ASN has identified areas for progress which will be subject to particular scrutiny in the next inspections, such as the individual dose assessment, which remains incomplete, and the classification of people working with ionising radiation, which is generally overestimated by the employers. This nevertheless has no impact on the health of the workers. The defining or updating of radiological zoning must also be improved, particularly by taking into account the actual radiation activities held or used and by performing periodic verifications of the radiological environment.

Concerning the systematic deployment of systems for recording and analysing adverse events and Significant Radiation Protection Events (ESRs), a subject that received close attention in the preceding assessments, it continued to improve in 2020. In effect, among the inspected entities, only 10% still do not have a recording system, compared with 27% in 2019.

In 2020, ASN recorded 21 ESRs concerning research activities (see Graph 12).

The reported ESRs are essentially of three types:

- discovery of sources (48%);
- loss of sources (10%);
- loss of integrity of sealed radioactive sources (10%).

The source losses and discoveries can be explained in particular by poor overall traceability: this often results from the failure to take action to dispose of them when laboratories cease their activity, or from irregular and incomplete keeping of source inventories.

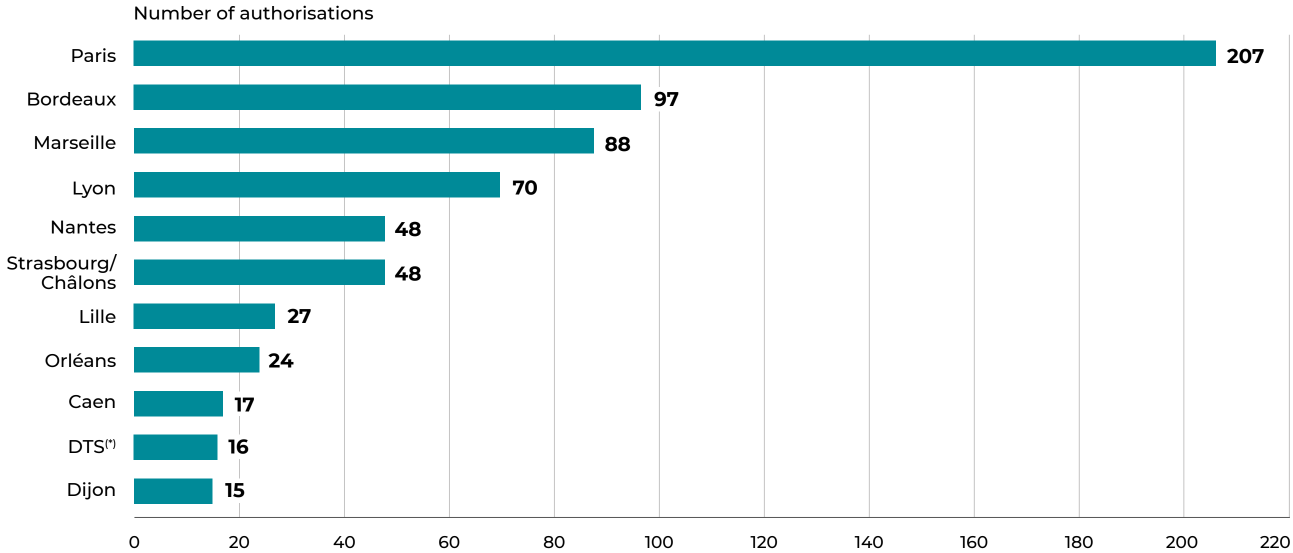
The rare cases of loss of integrity of sealed radioactive sources are linked in particular to shortcomings in performing complete internal radiation protection verifications (non-contamination checks in particular), failure to comply with the required verification frequency and poor traceability of results. These events have had no significant consequences on the personnel or facilities concerned. Ways of having the sources recovered by the initial suppliers are currently being studied.

Lastly, ASN is continuing its collaboration with the General Inspectorate of the National Education and Research Administration (IGAENR), which has competence for labour inspection in the public research sector. An agreement signed in 2014 provides for mutual information sharing, which improves the effectiveness and complementarity of the inspections. An annual meeting is held to assess the functioning of this collaboration.

2. *Immunofluorescence is an immunolabelling technique that uses antibodies and fluorochromes.*
3. *Among these inspections, six focused exclusively on the use of sealed radioactive sources or X-ray emitting devices.*

GRAPH 11

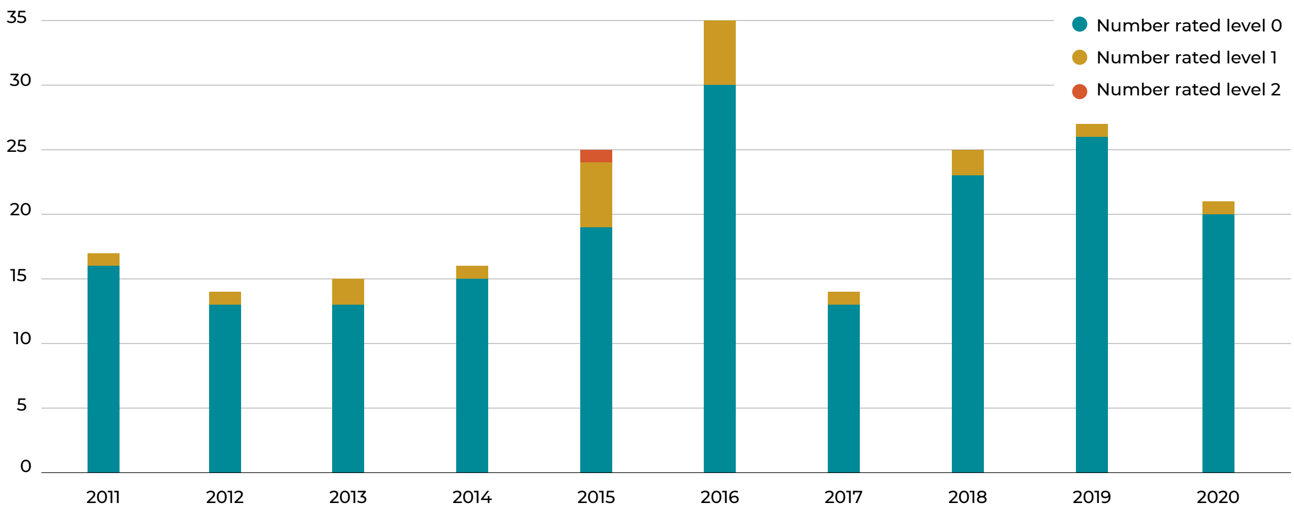
Distribution over the French territory, according to the ASN entity responsible for the licensing of institutions authorised to use unsealed radioactive sources in the research sector in 2020



* The Transport and Sources Department examines the research activities when they are linked to suppliers of ionising radiation sources.

GRAPH 12

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). ASN lists around 150 suppliers with safety-significant business, including 34 low and medium-energy cyclotrons which are currently licensed under the Public Health Code in France.

4.2 Cyclotrons

Functioning

As at 31 December 2020, 4 cyclotrons were "on standby" and 30 were in operation. Among these, 16 are used exclusively for the daily production of radiopharmaceuticals, 7 are used for research purposes and 7 for joint production and research purposes.

In 2020, operation of the 7 cyclotrons (including 1 on standby) of CIS bio international was transferred to the Cyclopharma Laboratories, which were already operating 9 (including 3 in standby status). These 16 cyclotrons are now managed by a single organisation named Curium PET France, with 5 of them being used for joint production and research, while 7 are used only for the production of radiopharmaceuticals.

A slowdown in the production of cyclotrons, particularly that of fluorine-18, was observed in the first half of 2020 on account of the health crisis, which has led to a reduction in medical imaging examination demands.

The assessment of radiation protection in the area of cyclotrons

ASN has exercised its oversight role in this area since early 2010; each new facility or any major modification to an existing facility undergoes a comprehensive examination by ASN. The main radiation protection issues on these facilities must be considered as of the design stage. Application of the relevant standards, in particular standard NF M 62-105 "Industrial accelerators: installations", ISO 106482 "Containment enclosures" and ISO 17873 "Ventilation systems for nuclear installations", guarantees safe utilisation of the equipment and brings a significant reduction in risks.

Facilities that have a cyclotron used to produce radionuclides and products containing radionuclides are subject to gaseous effluent discharge limits specified in their license. The discharge levels depend on the frequency and types of production involved.

Systems for filtering and trapping the gaseous effluents are installed in the production enclosures and in the facilities' ventilation systems in order to minimise the activity discharged at the stack outlet. Some licensees have also installed – as close as possible to the shielded enclosures – systems for collecting and storing the gases to let them decay before being discharged, bringing a substantial reduction in the activities discharged into the environment.

Consequently, the discharged activity levels and the short half-life of the radionuclides discharged in gaseous effluents mean there is no significant impact on the public or the environment.

ASN, jointly with the IRSN, is continuing a study they began in 2016 on the gaseous discharges into the environment from these facilities. The conclusions of the first step, which involved both the IRSN and the licensees, served to establish in 2018 general principles on managing gaseous effluent discharges, the key points of which will be taken up in a draft regulatory text. Alongside this, new assessments of the impacts of discharges from the facilities situated near residential areas have been carried out, using for some facilities modelling tools that are better suited to near-field studies. This work will continue in the coming years.

ASN performs about ten inspections at facilities of this type each year (five in 2020). Aspects related to radiation protection, user safety and the correct operation of cyclotrons and production platforms receive particular attention during the inspections. The scope of the inspections performed includes occupational radiation protection, the management of internal events, monitoring and maintenance of the production equipment, inspection of the surveillance and control systems and the gaseous discharge results. These facilities have a satisfactory radiation protection organisation and good knowledge of the regulations. National action plans have been put into place by the licensees and are monitored by ASN in order to ensure continuous improvement of radiation protection and safety in these facilities.

Fourteen ESRs were reported by the cyclotron licensees in 2020. None of these events led to significant exposure of workers or the public. Most of these events (eight) concerned deliveries of products that had not been ordered by the customer (nuclear medicine department), often due to late cancellations or modifications of medical imaging examinations during the health crisis, which the licensee's planning & scheduling department was unable to process in time. These departments have adjusted their organisation to permit better management of last-minute information concerning orders.

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 the IRSN, to draw up a draft regulatory text on the technical design and operating rules applicable to companies producing radionuclides using a cyclotron. This draft text was made available for consultation by the stakeholders in 2016. A revised version was produced in 2018, taking account of the observations received and including additional chapters on the control and monitoring of gaseous effluent discharges. This second version of this draft underwent a new consultation by the stakeholders in 2019. Preparation of this draft text will continue in 2021, taking into account the discussions held with the DGT in 2019 and information provided by the IRSN in 2020 in order to establish a single regulatory baselinefor the entire sector of activity concerned. The main conclusions of this regulatory work are already being used when examining license applications in order to include appropriate individual licence 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 intend to distribute in France.

In 2020, cyclotrons excluded, 22 inspections were carried out (of which 5 were done remotely[4] at manufacturers/suppliers of sealed or unsealed sources, at companies involved in the dismantling and reconditioning of ICSDs, companies recovering lightning conductors and companies manufacturing and installing X-ray generators – although these devices are not yet subject to a distribution license, their utilisation is regulated, including the commissioning and maintenance operations carried out by the companies that sell them). As a complement to what was done until now, five of the 22 inspections focused on priority themes other than the supply of sources (seeking out cases of fraud, security of sources, maintenance/expert assessment of devices containing sealed radioactive sources). Lastly, some of these inspections (three) focused on foreign companies distributing ionising radiation sources in France.

These inspections have covered about a quarter of the suppliers with safety-significant business on the basis of specific inspection indicators, more specifically linked to the suppliers' responsibilities in the tracking and recovery of disused sealed sources from the users in order to dispose of them as appropriate for the radiation risks they present for people and the environment.

4. *The remote inspections were conducted on suppliers who did not hold physical stocks of sources.*

Cyclotrons

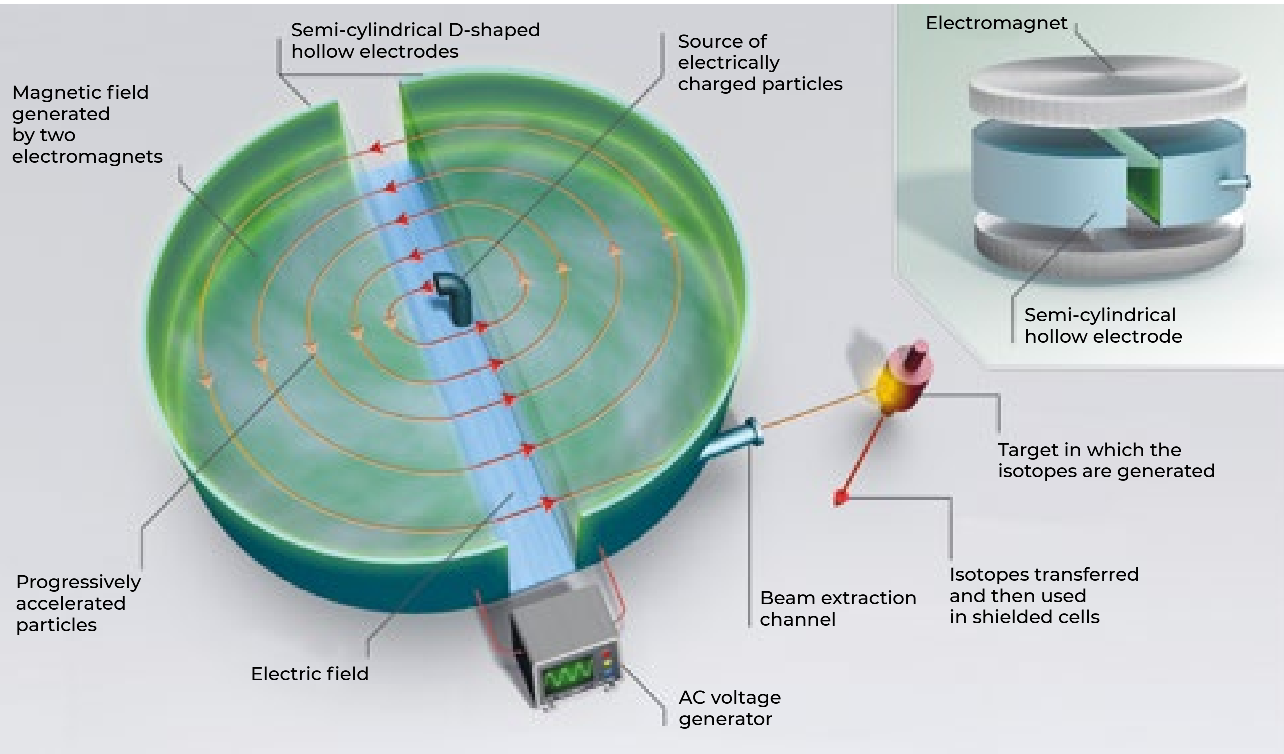
A cyclotron is a device 1.5 to 4 metres (m) in diameter, belonging to the circular particle accelerator family. The accelerated particles are mainly protons, with energy levels of up to 70 megaelectronvolts (MeV). A cyclotron consists of two circular electromagnets producing a magnetic field and between which there is an electrical field, allowing the rotation of the particles and their acceleration at each revolution. The accelerated particles strike a target which is activated and produces radionuclides.

Low and medium energy cyclotrons are primarily used in research and in the pharmaceutical industry to produce positron emitting isotopes, such as fluorine-18 or carbon-11. The radionuclides are then combined with molecules of varying complexity to form radiopharmaceuticals used in medical imaging. The best known of them is ^{18}F-FDG (fluorodeoxyglucose marked by fluorine-18), which is an industrially manufactured injectable drug, commonly used for early diagnosis of certain cancers.

Other radiopharmaceutical drugs manufactured from fluorine-18 have also been developed in recent years, such as ^{18}F-Choline, ^{18}F-Na, ^{18}F-DOPA, along with other radiopharmaceuticals for exploring the brain. To a lesser extent, the other positron emitters that can be manufactured with a cyclotron of an equivalent energy range to that necessary for the production of fluorine-18 and carbon-11 are oxygen-15 and nitrogen-13. 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 gigibecquerels (GBq) per production batch. The positron emitting radionuclides produced for research purposes involve activities that are usually limited to a few tens of gigabecquerels.

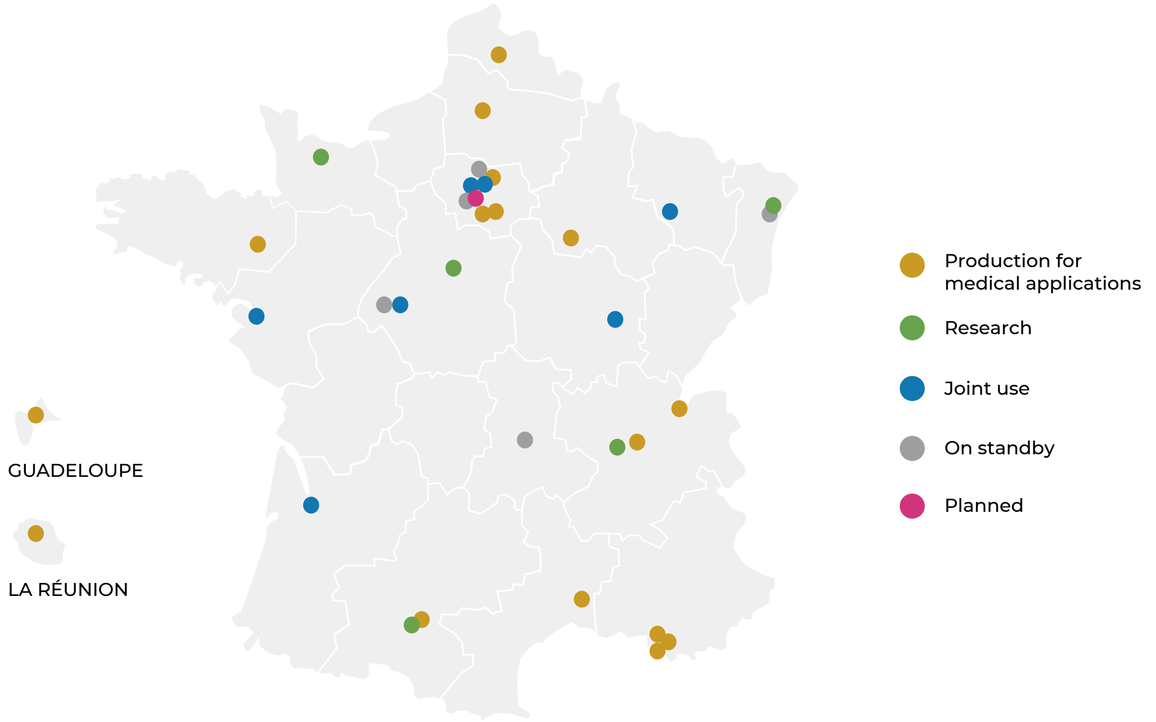
Simplified diagram of the operation of a cyclotron



ASN considers the radiation protection situation associated with the radionuclide distribution activity to be satisfactory on the whole. The large majority of licensees meet the main requirements and assume their responsibilities adequately (verifications prior to supply, technical verifications of the supplied sources, setting up the source recovery streams, transmission of information to the IRSN). These inspections also served to inform source suppliers of forthcoming changes in the regulations, particularly those concerning the protection of radioactive sources they hold, either for their own use of for future supply to customers, against malicious acts.

However, these inspections and the analyses of significant events reports have also revealed points requiring particular attention, including:
- the ability of the suppliers to fully and exhaustively track the sealed radioactive 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 (ten-year administrative limit counting from the date of the first registration figuring on the supply form) are not identified sufficiently far in advance, which slows down the recovery procedure;

Location of cyclotrons in France



- the systematic verifications prior to delivery. These verifications, for which the supplier must take appropriate organisational measures (by computer blocking or verifications during actual preparation of the order), include verification of the existence of a license (or a notification) authorising holding of the source concerned and verification of the fact that the delivery of a source in itself, considering the other sources already delivered by the supplier, will not result in the customer's license limits being exceeded.

5. Conclusion and outlook

Implementation of new administrative systems governing nuclear activities

In 2020, with the aim of stepping up its graded approach to oversight and on the basis of its nomenclature for classifying nuclear activities using ionising radiation, ASN has completed the drafting of resolutions relative to the registration system made possible by the regulatory changes of mid-2018 (Decree 2018-434 of 4 June 2018). With the prospect of this new system coming into effect in mid-2021, ASN will finish developing the online registration service which will be available on its website and will inform the professionals.

Alongside this, to finalise the overhaul of the systems of the Public Health Code as a whole, ASN will start updating the resolution concerning nuclear activities subject to the licensing system; this update will include the part relating to the supply of devices emitting X-rays.

In addition, it will continue its actions to update the regulatory system relative to ICSDs beyond December 2021. Lastly, ASN will work in collaboration with the DGT on the updating of the regulatory framework concerning the technical design rules and the certification procedures for industrial radiography devices (Article R. 4312-1-3 of the Labour Code).

Oversight of the protection of radioactive sources against malicious acts

ASN has been designated as the authority to oversee the provisions to protect the radioactive sources against malicious acts in the majority of facilities. Publication of the above-mentioned Decree brought into effect the first provisions in this respect in mid-2018: those responsible for nuclear activities must more specifically give individual authorisations for access to the most hazardous sources, including for their transport, and for access to sensitive information.

These initial provisions with regard to protection against malicious acts were verified during inspections in 2019 and 2020. The first inspections revealed that this subject is poorly known by licensees and is therefore given little consideration. Over and beyond the fact that these are new regulatory provisions, the licensees must integrate this new dimension in their corporate culture.

A first significant step took place on 1 January 2021, with entry into effect of the requirements on organisational measures provided by the Order of 29 November 2019. The licensee's senior management shall more specifically define and formalise a policy of protection against malicious acts that will be implemented by the person responsible for the nuclear activity, who will be delegated the necessary resources to achieve this.

When examining nuclear activity licensing applications, ASN will ensure that the main provisions have been put in place, in particular by changing the content of the files to be submitted in support of these applications, which should speed up the awareness and assuming of these new responsibilities by the licensees. At the same time, ASN will widen the scope of its inspections to include these additional provisions. It will also adopt an educational approach to introduce these changes to those involved, including by continuing its regular communication targeting the professionals concerned.

ASN will continue the in-house actions it has undertaken to train its staff in the management of this new mission and to provide common aids (especially inspection guides and license application examination guides).

CHAPTER 09

TRANSPORT OF RADIOACTIVE SUBSTANCES

09 Transport of radioactive substances

The transport of radioactive substances is a specific sector of dangerous goods transport characterised by the risks associated with radioactivity. The radioactive substance transports being regulated cover a wide range of activities in the industrial, medical and research sectors. This is based on stringent international regulations.

1. Radioactive substances traffic

The regulations divide the dangerous goods liable to be transported into nine "classes" according to the nature of the corresponding risk (for example: explosive, toxic, flammable, etc. materials). Class 7 covers radioactive substances.

The transport of radioactive substances stands out owing to its considerable diversity. Packages of radioactive substances can weigh from a few hundred grams up to more than 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 very 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.

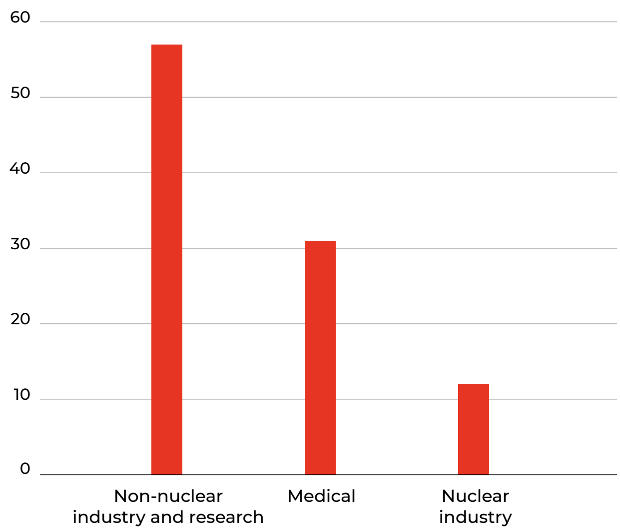
About one third of the packages transported are used in the medical sector: this involves providing health care centres with radioactive sources, for example sealed sources used in radiotherapy, or radiopharmaceutical products, and removing the corresponding radioactive waste. The activity of radio-pharmaceutical 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 necessary to enable the "fuel cycle" to work, owing to the locations of the various facilities and Nuclear Power Plants (NPPs) around the country (see the map opposite). 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 notably the 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:

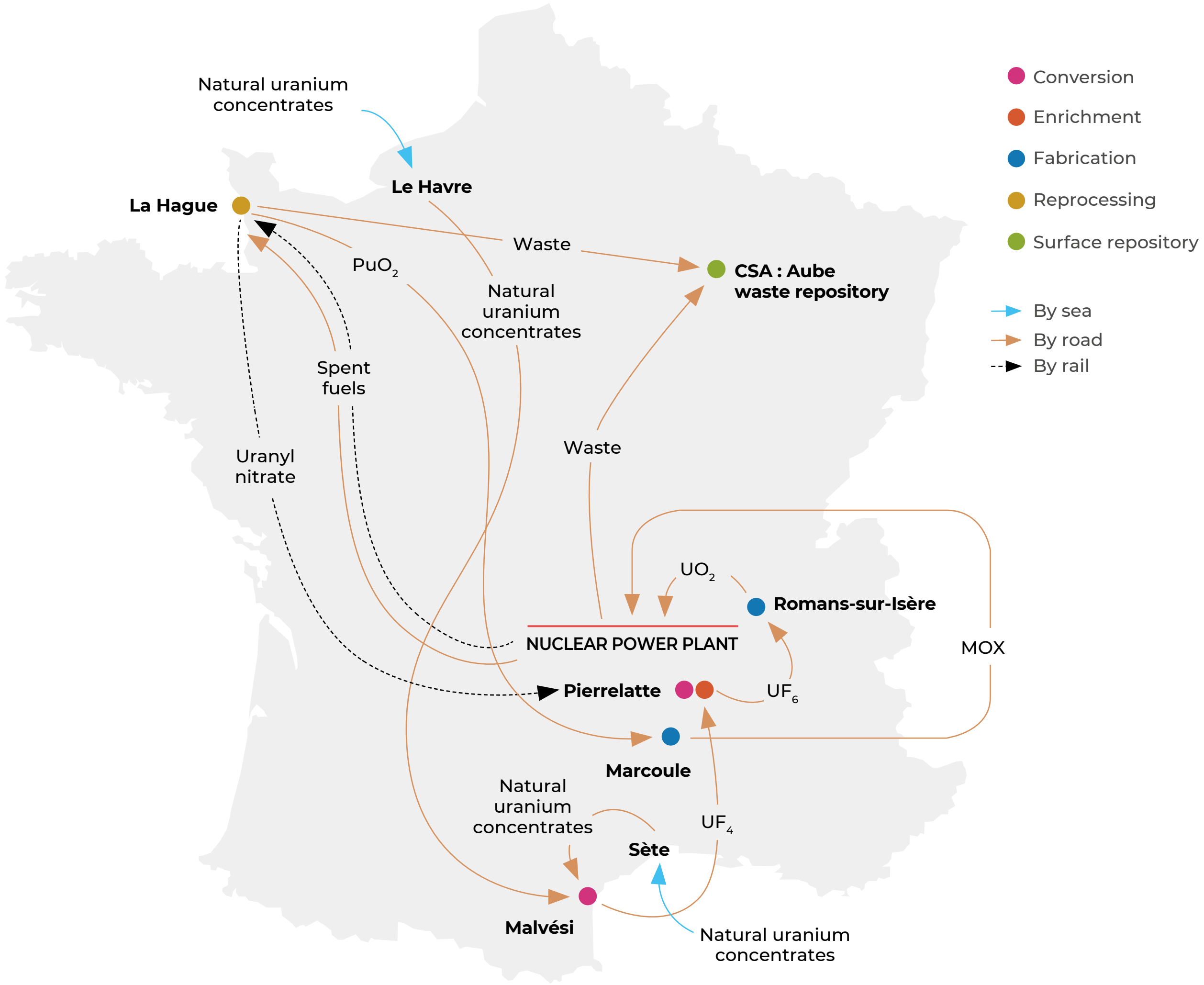
- 200 shipments transporting spent fuel from the NPPs operated by EDF to the Orano reprocessing plant at La Hague;
- about 100 shipments of plutonium in oxide form between the La Hague reprocessing plant and the Melox fuel production plant in the Gard *département*;
- 250 shipments of uranium hexafluoride (UF_6) used for fuel fabrication;

GRAPH 1

Proportion of packages transported per field of activity in %



Transport operations relating to the "fuel cycle" in France



- 400 shipments of fresh uranium-based fuel and some 50 shipments of fresh uranium and plutonium-based "MOX" (Mixed OXydes) fuel;
- 2,000 shipments from or to foreign countries or transiting *via* France, representing about 58,000 packages shipped (industrial, A and B type packages).

The statistical data presented in this chapter come from a study conducted by ASN in 2012. It is based on information collected in 2011 from all the consignors of radioactive substances (Basic Nuclear Installations – BNIs, laboratories, hospitals, source suppliers and users, etc.), as well as on reports from the transport safety advisers. A summary is available on *asn.fr* ("Information" heading).

TABLE 1

Breakdown per mode of transport (rounded figures)

APPROXIMATE NUMBER OF PACKAGES AND SHIPMENTS		ROAD	ROAD AND AIR	ROAD AND RAIL	ROAD AND SEA	ROAD, SEA AND RAIL	ROAD, SEA AND AIR
Packages approved by ASN	Number of packages	18,000	1,300	460	1,900	0	0
	Number of shipments	12,500	1,250	380	390	0	0
Packages not requiring approval by ASN	Number of packages	870,000	47,000	2,900	6,800	34,500	5,300
	Number of shipments	740,000	21,000	530	910	80	5,300

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 radiological shielding provided by the package (material which reduces the radiation in contact with the packages of radioactive substances);
- the risk of inhalation or ingestion of radioactive particles in the event of release of radioactive substances outside the packaging;
- contamination of the environment in the event of release of radioactive substances;
- the initiation of an uncontrolled nuclear chain reaction (criticality risk) that can cause serious irradiation of persons. This risk only concerns fissile substances.

In addition, radioactive substances may also present a chemical risk. This, for example, is the case with shipments of natural uranium with low radioactivity, for which the major risk for humans is related to the chemical nature of the compound, more particularly if it is ingested. Similarly, UF_6, used in the manufacture of fuels for NPPs can, in the event of release and contact with water, form hydrofluoric acid, a powerful corrosive and toxic agent.

By their very nature, transport operations take place across the entire country and are subject to numerous contingencies that are hard to control or anticipate, such as the behaviour of other vehicles using the same routes. A transport accident at a given point in the country cannot therefore be ruled out, possibly in the immediate vicinity of the population. Unlike events occurring within BNIs, the personnel of the companies concerned are generally unable to intervene immediately, or even to give the alert (if the driver is killed in the accident) and the first responding emergency services are not in principle specialists in dealing with a radioactive hazard.

To deal with these risks, specific 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, which helps minimise 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.
- Management of emergency situations, 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 guaranteeing the robustness of the various types of packages

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 radilogical activity, specific activity which represents the degree of concentration of the material, and its physicochemical form.

The regulations define tests, which simulate incidents or accidents, following which the safety functions must still be guaranteed. The severity of the regulatory tests is graded according to the potential danger of the substance transported. Furthermore, additional requirements apply to packages carrying UF_6 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 do not undergo any reference tests. They must nevertheless comply with some general specifications, including regarding radiation protection, to ensure that the level of radiation around the excepted packages remains very low.

TABLE 2

Breakdown of transported packages by type

TYPE OF PACKAGE		APPROXIMATE SHARE OF PACKAGES TRANSPORTED ANNUALLY
Packages approved by ASN	Type B packages, packages containing fissile materials and packages containing UF_6	2%
Packages not requiring approval by ASN	Type A package not containing fissile radioactive substances	32%
	Industrial package not containing fissile radioactive substances	8%
	Excepted packages	58%

2.3.2 Type A packages and industrial packages containing non-fissile substances

Type A packages can, for example, be used to transport radionuclides for medical purposes commonly used in nuclear medicine departments, such as technetium generators. The total activity which can be contained in a type A package is limited by the regulations.

Type A packages must be designed to withstand incidents which could be encountered during transportation or during handling or storage operations (small impacts, package stacking, falling of a sharp object onto the packages, exposure to rain). These situations are simulated by the following tests:
- exposure to a severe storm (rainfall reaching 5 cm/hour for at least 1 hour);
- drop test onto an unyielding surface from a height varying according to the weight of the package (maximum 1.20 metre);
- compression equivalent to five times the weight of the package;
- penetration by dropping a standard bar onto the package from a height of 1 metre.

Additional tests are required if the content of the package is in liquid or gaseous form.

Industrial packages allow the transportation of material with a low specific activity, or objects with limited surface contamination. Uranium-bearing materials extracted from foreign uranium mines are, for example, carried in France in industrial drums with a capacity of 200 litres loaded into industrial packages. Three sub-categories of industrial packages exist according to the hazards presented by the content. Depending on their sub-category, the industrial packages are subjected to the same tests as type A packages, some of the tests or only the general provisions applicable to excepted packages.

As a result of the restrictions on the authorised contents, the consequences of the destruction of a type A package or an industrial package would remain manageable, provided that appropriate accident management measures are taken. The regulations do not therefore require that this type of package be able to withstand a severe accident.

Due to the limited safety implications, type A and industrial packages are not subject to ASN approval: the design of the packages and the performance of the tests are the responsibility of the manufacturer. These packages and their safety case files are subject to spot checks during the ASN inspections.

2.3.3 Type B packages and packages containing fissile substances

Type B packages are those used to transport the most radioactive substances, such as spent fuels or high-level vitrified 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 mainly used by 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 drop 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 9 metres (m) free-fall test, the package reaches the target at about 50 kilometres per hour (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 1 m 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 15 m of water for 8 hours. This test is used to test the pressure-resistance of the package if it 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 consists in immersion under 200 m 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, outside temperature, position of content, etc.).

New 2020 edition of Standard ISO 7195

This Standard:
- clarifies the specifications for the uranium hexafluoride (UF_6) transport cylinders to ensure compatibility between the various users;
- describes the design of the cylinders;
- includes the manufacturing requirements for the procurement of new cylinders designed for the transport of 0.1 kilograms or more of UF_6;
- sets the manufacturing requirements for the procurement of new valves and new plugs;
- defines the requirements concerning the cylinders and valve covers in service.

This third edition supersedes the previous edition ISO 7195:2005. The main changes with respect to the previous edition are:
- the general structure of the document, which has been reorganised for greater clarity and easier comparison with the equivalent American standard ANSI N14.1;
- withdrawal of the 48G cylinder model, replaced by the 30C cylinder;
- introduction of countersunk head plugs for the 30 and 48 inch cylinders, in addition to the hex-head plugs;
- for the 30B, 48X and 48Y cylinders, the possibility of using non-destructive inspections as an alternative to the hydrostatic checks during the periodic inspections, provided that additional inspections are carried out during manufacturing;
- the use of different tightness test methods;
- the ban on reusing valves and plugs previously removed from the cylinders.

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 be shipped. To obtain this approval, the designer of the package model must demonstrate the ability to withstand the above-mentioned tests in the safety case. This demonstration is usually provided by means of tests on a reduced-scale mock-up representing the package and by numerical calculations (to simulate the mechanical and thermal behaviour, or to evaluate the criticality risk).

2.3.4 Packages containing uranium hexafluoride

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 requirements for packages of UF_6. They must meet the requirements of standard ISO 7195 (see box previous page), which governs the design, manufacture and utilisation of packages. These packages are also subject to three tests:

- a free-fall test of between 0.3 and 1.2 m (depending on the weight 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 UF_6, which is a fissile substance, are also subject to the requirements previously presented (see point 2.3.3).

The UF_6 is transported in type 48Y or 30C metal cylinders. In the case of enriched UF_6, this cylinder is transported within a protective shell, which provides the necessary protection for withstanding the tests applicable to packages containing fissile materials. The package models containing UF_6 must also be approved by ASN or a competent foreign authority, before they can be allowed to travel.

2.3.5 Type C packages

Type C packages 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 guaranteeing the reliability of the transport operations

2.4.1 Radiation protection of workers and the public

The radiation protection of workers and the public during shipments of radioactive substances must always be born in mind. The public and non-classified workers must not be exposed to a dose greater than 1 millisievert per year (mSv/year). However, this limit is not intended to be an authorisation to expose the public to up to 1 mSv. Moreover, the justification and optimisation principles applicable to all nuclear activities also apply to the transport of radioactive substances (see chapter 2).

Radiation protection is the subject of specific requirements in the regulations applicable to the transport of radioactive substances. Thus, for transport by road, the regulations stipulate that the dose rate at the surface of the package must not exceed 2 millisieverts per hour (mSv/hour). This limit may be raised to 10 mSv/h in "exclusive use[1]" conditions, because the consignor or consignee can then issue instructions to restrict activities in the vicinity of the package. In any case, the dose rate must not exceed 2 mSv/h in contact with the vehicle and must be less than 0.1 mSv/h at a distance of 2 m from the vehicle. Assuming that a transport vehicle reaches the limit of 0.1 mSv/h at 2 m, a person would have to spend 10 consecutive hours at a distance of 2 m 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[2] principle): for example, lead-lined trolleys could be made available to handling staff to reduce their exposure. This evaluation also

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 creation of a "monitored" or "controlled" zone, depending on the characteristics of the packages carried.

In addition, specific actions are provided for in the Order of 23 October 2020 regarding measurements taken for the assessment of risks and checks on the effectiveness of the prevention means put into place for the protection of workers against the risks from ionising radiation. It requires, among others, that the periodic checks on vehicles used to carry radioactive substances are performed or supervised by the Radiation Protection Advisor. Whereas the first check is carried out before a vehicle is used for carriage of radioactive substances, to ensure the radiological cleanness of the vehicle, the subsequent checks are carried out to ensure that there is no contamination of the vehicle. These checks are performed at a frequency defined by the employer, taking account of the frequency of shipments and their radiological implications, as well as after each transport operation for which a contamination risk has been identified. In any case, the time between two checks shall not exceed three months.

1. *Exclusive use corresponds to cases in which the vehicle is used by a single consignor. This consignor may then give specific instructions for all the transport operations.*
2. *The ALARA (As Low As Reasonably Achievable) principle appeared for the first time in Publication 26 from the International Commission on Radiological Protection (ICRP) in 1977. It was the end-result of a study of the radiation protection optimisation principle.*

Creation of a system of authorisation for security reasons

Pursuant to Articles L. 1333-8 and R. 1333-146 of the Public Health Code, ASN intends in 2021 to revise its resolution 2015-DC-0503 on the system of notification for companies transporting radioactive substances on French territory, so that the transport operations involving the most highly radioactive sources will be subject to authorisation owing to their security implications. Authorisation will therefore be required for the transport of sealed radioactive sources, or batches of category A, B or C sources, as defined in Annex 13-7 to the Public Health Code.

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 begin updating this guide in 2021, to take account of the new provisions of the Labour Code and the Health Code, and their implementing texts, for example the Order of 23 October 2020 (see box), resulting from Directive 2013/59/Euratom (known as the "BSS" Directive). In 2021, it will continue with measures to educate professionals, dealing more specifically with changes to the regulations.

2.4.2 Package and vehicle marking

So that the workers can be informed of the level of risk arising from each package and so that they can protect themselves effectively, the regulations require that the packages be labelled. There are three types of labels, corresponding to different dose rate levels in contact and at 1 m from the package. The personnel working in proximity to the packages are thus visually informed of those which lead to the highest dose rates, and can thus limit the time they spend close to them and can put them as far away as possible (for example by loading them towards the rear of the vehicle).

The packages containing fissile materials must also 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 carry a placard with the radiation trefoil and the word "Radioactive". The purpose of these vehicle markings is to provide the emergency services with the necessary information in the event of an accident.

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 a forwarding agent. The forwarding agent is responsible, on behalf of the consignor or the consignee, for obtaining all the necessary authorisations and for sending the various notifications required by the regulations. 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 good professional practice.
- The carrier and, more particularly, the driver, is responsible for carriage of the shipment to its destination. Their duties include checking the good condition of the vehicle, the presence of the on-board equipment (extinguishers, driver's personal protection equipment, etc.), compliance with the dose rate limits around the vehicle and the display of the orange plates and placards.
- The consignee is under the obligation not to postpone acceptance of the goods, without imperative reason and, after unloading, to verify that the requirements concerning them have been satisfied. It must more specifically perform dose rate measurements on the package after receipt in order to detect any problems that may have occurred during shipment.
- The package owner must set up a maintenance system in conformity with that described in the safety case and the approval certificate in order to guarantee that the elements important for safety are maintained in good condition.

All the transport players must set up a quality management system, which consists of a range of provisions for ensuring compliance with the regulatory requirements and providing proof thereof. This for example consists in performing double independent checks on the most important operations, in adopting a system of checklists to ensure that the operators forget nothing, in keeping a trace of all the operations and all the checks performed, etc. The quality management system is a key element in ensuring the reliability of transport operations.

The regulations also require that all operators involved in transport receive training appropriate to their functions and responsibilities. This training must in particular cover the steps to be taken in the event of an accident.

Contractors which carry, load, unload or handle (after loading and before unloading) packages of radioactive substances on French territory shall declare these transport activities to the ASN, using the ASN online services portal[3], before carrying them out. This online service has been available in English since mid-2019.

The transport of certain radioactive substances (in particular fissile substances) must first be notified by the consignor to ASN and to the Ministry of the Interior, seven days prior to departure. This notification stipulates the materials carried, the packagings used, the transport conditions and the details of the consignor, the carrier and the consignee. It is a means of ensuring that the public authorities have rapid access to useful information in the event of an accident.

In 2020, 1,385 notifications were sent to ASN.

2.5 Preparedness and response to emergency situations

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 cooperate with the public authorities to assist with the response operations, including by providing all pertinent information in their possession. This in particular concerns the carrier and the consignor who have information about the package and its contents that is of great value for determining the appropriate measures to be taken. To meet these regulatory obligations, ASN recommends that the parties involved develop emergency response plans allowing the organisation and tools to be defined in advance, enabling them to react efficiently in the event of an actual emergency.

The driver may be unable to give the alert, if injured or killed in the accident. In this case, recognizing the radioactive nature of the consignment would be the entire responsibility of the first responder emergency 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 within 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. The French Institute for Radiation Protection and Nuclear Safety (IRSN) assists ASN in this role, 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, etc.). The fire service teams specialising in the radioactive risk (the Mobile Radiological Intervention Units – CMIR) would be called on, along with the IRSN's mobile units; the Prefect could also, if necessary, requisition the mobile units of certain nuclear licensees (such as the Alternative Energies and Atomic Energy Commission – CEA, or EDF), even if the shipment in question does not concern these licensees.

As with other types of emergency, communication is an important factor in the event of a transport accident so that the population can be informed of the situation and be given instructions on what to do.

In order to prepare the public authorities for the eventuality of an accident involving a shipment of radioactive substances, exercises are held to test the entire response organisation that would be put into place.

ASN will continue in 2021 to support adequate preparedness by the public authorities for emergency situations involving a transport operation, in particular by promoting the performance of local emergency exercises and issuing recommendations on the steps to be taken in the event of an accident.

Finally, ASN intends 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 adequately assessed, to enable the licensees to define any relevant measures needed to reduce them, under the supervision of the Prefect. It will also tie in with the assessments of the consequences of 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 an improbable accident but one which could have major consequences for public health and safety and protection of the environment. As radioactive substances are transported on the public highway, the possibility of an accident of an intensity exceeding the package design criteria set by the regulations cannot be ruled out. For packages carrying the most dangerous contents, the consequences for persons and the environment could be significant.

ASN recommendations in the event of a transport accident

The response by the public authorities in the event of a transport accident comprises three phases:
- The emergency services reach the site and initiate "reflex" measures to limit the consequences of the accident and protect the population. The radioactive nature of the substances involved is discovered during this phase;
- The entity coordinating the emergency response confirms that the substances are indeed radioactive, alerts ASN and the IRSN

3. *teleservices.asn.fr*

and gives more specific instructions to the responders, pending activation of the national emergency centres.
- Once the ASN and the 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 the IRSN and the national Nuclear Risk Management Aid commission (MARN), ASN produced a document to help direct the actions of the emergency services. It contains general information about radioactivity, general recommendations for the emergency services so that their response can take account of the specific nature of radioactive substance transports, plus sheets organised per type of substance, providing more detailed information and advice for the emergency response coordinator during phase 2.

2.6 Regulations governing the transport operations within the perimeter of nuclear facilities

Dangerous goods transport operations can take place on the private roads of nuclear sites, in what are referred to as “on-site transport operations”. Such operations are not subject to the regulations governing the transport of dangerous goods, which only apply on public roads. However, these operations present the same risks and detrimental effects as dangerous goods transports on the public highway. The safety of these operations must thus be overseen with the same rigour as for any other risk or detrimental effect created within the perimeter of BNIs.

This is why the on-site transport of dangerous goods is 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 baseline safety requirements for BNIs.

The Environment Code, supplemented by ASN resolution 2017-DC-0616 of 30 November 2017, defines the on-site transport operations for which authorisation must be requested from ASN. In addition, in 2017, ASN published Guide No. 34 providing the licensees with recommendations for implementing the regulatory requirements concerning on-site transport operations.

Finally, in 2020, ASN extended the online notification and online submission functions to deal with applications for implementing noteworthy changes to on-site transports as set out in Articles R. 593-59 and R. 593-56 of the Environment Code.

3. Roles and responsibilities in regulating the transport of radioactive substances

3.1 Regulation of nuclear safety and radiation protection

In France, ASN has been responsible for regulating the safety and the radiation protection of transports of radioactive substance for civil uses since 1997, while the Defence Nuclear Safety Authority (ASND) fulfils this role for transports relating to national defence. Within its field of competence, ASN is responsible, in terms of safety and radiation protection, for the regulation and oversight of all steps in the life of a package: design, manufacture, maintenance, shipment, actual carriage, receipt and so on.

3.2 Protection against malicious acts

The prevention of malicious acts consists in preventing sabotage, losses, disappearance, theft and misappropriation of nuclear materials (as defined in Article R*. 1411-11-19 of the Defence Code) that could be used to manufacture weapons. The Defence and Security High Official (HFDS), under the Minister responsible for energy, is the Regulatory Authority responsible for preventing malicious acts targeting nuclear materials.

In the field of transport security, the IRSN Transport Operations Section (EOT) is responsible for managing and processing applications for approval of nuclear material shipments, for supervising these transports and for notifying the authorities of any alerts concerning them. This security duty is defined by the Order of 18 August 2010 relative to the protection and regulation of nuclear materials during transport. Thus, prior to any transport operation, the Defence Code obliges the carriers to obtain a transport authorisation. The EOT reviews the corresponding application files. This review consists in checking the conformity of the intended provisions with the requirements defined by the Defence Code and the above-mentioned Order of 18 August 2010.

ASN has initiated the process to update its resolution 2015-DC-0503 of 12 March 2015 relative to the notification system for companies transporting radioactive substances on French soil. This update aims to introduce an authorisation system for the transport of the most radioactive sources, in the light of their security implications.

In 2019, ASN held a public consultation on the orientations it was planning to adopt for this update. In 2021, ASN will complete this update, paying attention to the interface between the provisions established in the new regulations on the protection of ionising radiation sources and batches of category A, B, C and D radioactive sources against malicious acts (Order of 29 November 2019, amended) 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 Unit (MTMD) of the Ministry responsible for the environment. This entity is tasked with 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 (standing sub-committee in charge of dangerous goods transport, within the High Council for the Prevention of Technological Risks), that is consulted for its opinion on any draft regulations relative to the transport of dangerous goods by rail, road or inland waterway. Field inspections are carried out by land transport inspectors attached to the Regional Directorates for the Environment, Planning and Housing (Dreals).

For the regulation of dangerous goods to be as consistent as possible, ASN collaborates regularly with the administrations concerned.

In 2021, as was the case in 2019, ASN will take part in the training of the General Directorate for Civil Aviation (DGAC) inspectors responsible for the inspection of air transport of dangerous goods in order to present them with the specificities of class 7 and to share experience feedback from ASN’s inspections on these subjects.

The breakdown of the various inspection duties is summarized in Table 3.

4. ASN action in the transport of radioactive substances

4.1 Issuance of approval certificates and shipment approvals

The type B and C packages, as well as the packages containing fissile materials and those containing more than 0.1 kilogramme of UF_6 require an ASN approval certificate in order to be transported. The designers of the package models who request approval from ASN must support their application with a safety case demonstrating the compliance of their package with all the regulatory requirements. Before deciding whether or not to issue an approval certificate, ASN reviews these safety cases, drawing on the expertise of IRSN, in order to ensure that the safety cases are pertinent and conclusive. If necessary, the approval certificate is issued with requests in order to further improve the safety cases.

In some cases the IRSN appraisal is supplemented by a meeting of the ASN Advisory Committee for Transports (GPT). The opinions of the Advisory Committees are always published on *asn.fr*. The approval certificate specifies the conditions for the manufacture, utilisation and maintenance of the transport package. It is issued for a package model, independently of the actual shipment itself, for which no prior ASN opinion is generally required. This shipment may however be subject to security checks (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 m drop, a compensatory measure may be to reduce the speed of the vehicle, have it escorted and choose a route avoiding such a drop height. The probability of a serious accident, and thus of a violent shock on the package, is thus considerably reduced. A shipment under special arrangement is only possible with the approval of the competent authority, which then issues approval for shipment under special arrangement, stipulating the compensatory measures to be applied.

In the case of certificates issued abroad, the international regulations provide for their recognition by ASN. In certain cases, this recognition is automatic and the foreign certificate is directly valid in France. In other cases, the foreign certificate is only valid if endorsed by ASN, which then issues a new certificate. In 2020, 39 approval applications were submitted to ASN by the manufacturers.

ASN issued 32 approval or shipment authorisation certificates, for which the breakdown according to type is presented in Graph 2. The nature of the transports and packages concerned by these certificates is presented in Graph 3.

In 2019, Robatel initiated the development of a new packaging, called R85, designed for the road or rail transport of irradiated and contaminated control rod cluster guide tubes from French NPPs. Before shipment, the package may be stored for several years. In mid-2020, ASN issued a favourable opinion on the safety options for this new package model, after considering the new provisions of the 2018 edition of IAEA's SSR-6 regulations. In 2021, it will examine the approval certificate application received at the end of 2020.

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 2020, ASN carried out 62 inspections in the field of radioactive substances transport (all sectors considered). The follow-up letters to these inspections are available on *asn.fr*.

4.2.1 Regulation of package manufacturing

The manufacture of transport packaging is subject to the regulations applicable to the transport of radioactive substances. The manufacturer is responsible for producing packagings in accordance with the specifications of the safety case, demonstrating regulatory compliance of the corresponding package model. To do this, it implements a quality management system covering all the operations from procurement of parts and raw materials up to final inspections. Furthermore, the manufacturer must be able to prove to ASN that it complies with the regulatory provisions and, in particular, that the as-built packagings are compliant with the specifications of the safety case.

The inspections carried out by ASN in this field aim to ensure that the manufacturer satisfactorily fulfils its responsibilities.

In 2020, ASN carried out four 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 (to immobilise the contents), etc.

During these inspections, ASN reviews the quality management procedures implemented for the manufacture of a packaging on the basis of the design data and verifies their effective implementation. ASN ensures that the inspections performed by or on behalf of the manufacturer and any 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. For example, on 10 and 11 December 2019, in a plant in Germany, ASN and the German competent authority for transport (*Bundesanstalt für Materialforschung und Prüfung* – BAM), jointly inspected the manufacture of new DN 30 overpacks used to transport UF_6 in 30 B cylinders. One point investigated by the inspectors was how Daher, the ordering customer, monitored its subcontractor.

ASN may also inspect the manufacture of the specimens used for the drop tests and fire tests required by the regulations. The objectives are the same as for the series production model because the specimens must be representative and comply with the maximum requirements indicated in the mock-up manufacturing file, which will determine the minimum characteristics of the actual packaging to be manufactured.

In 2021, ASN intends to continue spot-check inspections of transport packaging manufacturing. This is because the irregularities detected at the Creusot Forge plant, some of which affected certain transport packagings, confirmed the importance of inspecting the packaging manufacturing and maintenance operations.

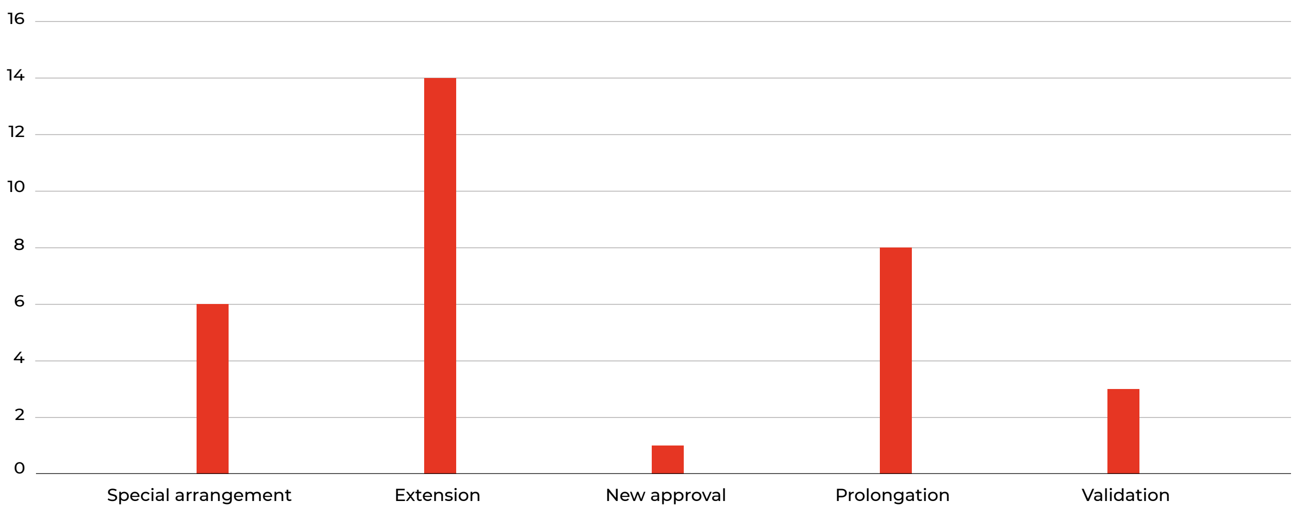
TABLE 3

Administrations responsible for regulating the mode of transport and the packages

MODE OF TRANSPORT	REGULATION OF MODE OF TRANSPORT	PACKAGE REGULATION
By 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.
By road, rail and 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.
By 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 is in close collaboration with ASN for radioactive substances packages.

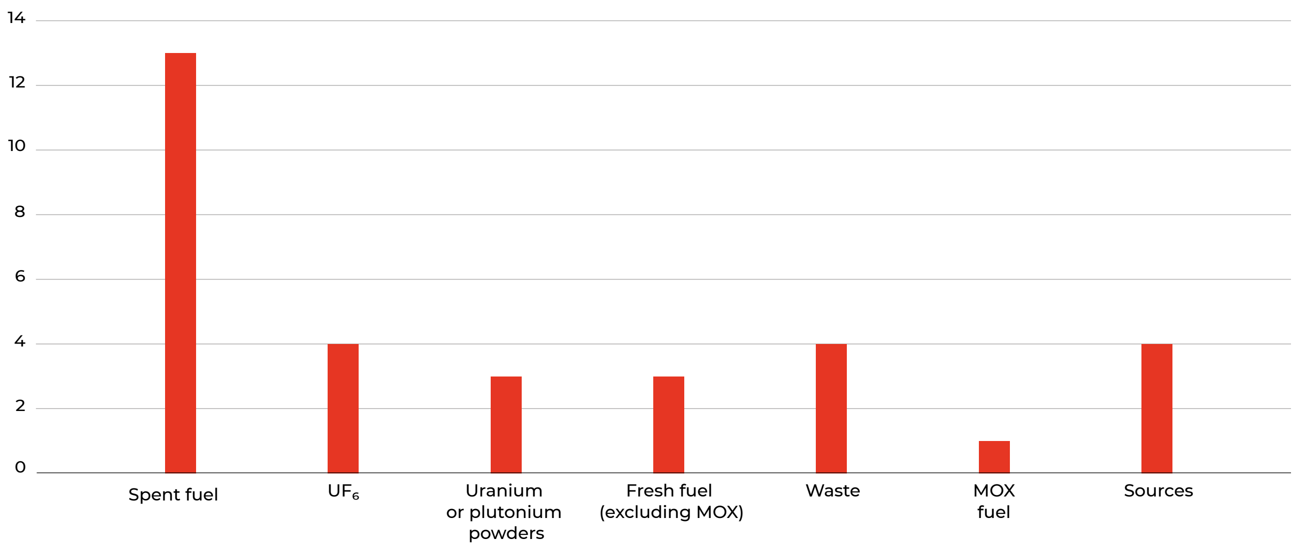
GRAPH 2

Breakdown of number of approvals according to type, in 2020



GRAPH 3

Breakdown of number of approvals according to content transported, in 2020



Approval certificate for the TN Eagle package

On 21 December 2020, ASN issued a type B(U) fissile materials approval certificate for a new package model developed by Orano NPS (formerly TN International). This new package model, called TN Eagle, is designed for exclusive-use land and sea transport of spent fuel assemblies, as well as for their interim storage. The issue of this approval is aimed at transport operations and in no away anticipates the subsequent outcome of a request for dry storage of spent fuels in such packages, in France.

4.2.2 Packaging maintenance inspections

The consignor or user of a packaging loaded 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 inspections carried out by ASN focus on, for example, the following maintenance activities:
- the periodic inspections of the components of the containment system (screws, welds, seals, etc.);
- the periodic inspections of the securing and handling components;
- the 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.

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 (safety case) demonstrating that the model meets the regulatory requirements, including that the model withstands the specified tests, along with a declaration of conformity delivered by the manufacturer attesting full compliance with the model specifications, must be kept at the disposal of ASN.

The various inspections carried out in recent years confirm progress in compliance with this requirement and in implementation of the ASN recommendations detailed in its guide concerning packages which are not subject to approval (Guide No.7, volume 3).

This Guide, updated in 2016, proposes a structure and a minimum content for the safety cases demonstrating that packages which are not subject to approval do comply with all the applicable requirements, along with the minimum content of a declaration of conformity of a package design with the regulations.

ASN thus noted improvements in the content of the 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 shortcomings in the demonstration by some of the players (designers, manufacturers, distributors, owners, consignors, companies performing the regulatory drop tests, package maintenance, etc.) of package conformity with the regulations. The areas for improvement include the following points:
- the description of the authorised contents per type of packaging;
- the demonstration that there is no loss or dispersion of the radioactive content under normal conditions of transport;
- compliance with the regulatory requirements regarding radiation protection, more specifically the demonstration, as of the design stage, that it would be impossible to exceed the dose rate limits with the maximum authorised content.

Inspection of package shipment to the Taishan NPP

On 29 September 2020, the ASN inspectors went to the port of Sète (Hérault *département*) to control the shipment of FCC4 packages loaded with uranium oxide fresh fuel assemblies to the Taishan NPP in China. They observed the arrival of the road convoys and the loading of the maritime flats containing the packages onto a ship. They examined the handling means used and checked the compliance of the vehicles, the placarding and the labelling, as well as the qualification of the drivers. They also checked that the packages were in good condition and observed the package handling operations from the road vehicles into the ship's hold.

The inspectors also reviewed the transport documents to verify the traceability of package conformity as of departure, as well as the emergency protocol and the function sheets of those involved in the transport operations. One of the inspectors inspected the ship's hold to check stowage of the packages and reviewed the loading plan and the handling resources available on the ship.

The inspectors were accompanied by the French Institute for Radiation Protection and Nuclear Safety (IRSN) experts, who took radiological measurements, both on the packages and on the road vehicle, in order to check compliance with the regulation limits.

No non-compliance was found as a result of these measurements. The inspectors found no noteworthy deviation as a result of their checks. They inspectors consider that the safety of the transport operations and its organisation were satisfactory.

4.2.4 Monitoring the shipment and transportation of packages

The scope of ASN inspections includes all regulatory requirements binding on each of the transport players, that is compliance with the requirements of the approval certificate or declaration of conformity, training of the personnel involved, implementation of a radiological protection programme, satisfactory stowage of packages, dose rate and contamination measurements, documentary conformity, implementation of a quality assurance programme, etc.

More particularly with respect to transports concerning small-scale nuclear activities, the ASN inspections confirm significant disparities from one carrier to another. The differences most frequently identified concern quality management, actual compliance with the procedures put into place and radiation protection of the workers.

Knowledge of the regulations applicable to the transport of radioactive substances seems to be sub-standard in the medical sector in particular, where the procedures adopted by some hospitals or nuclear medicine units for package shipment and reception need to be tightened. Their quality management system has not yet been formally set out and deployed, more specifically with regard to the responsibilities of each member of staff involved in receiving and dispatching packages.

More generally, in transport operations for small-scale nuclear activities, the radiological protection programmes and the safety protocols have not yet been systematically defined. ASN also found that checks on vehicles and packages prior to shipment could be improved. The inspections concerning the transport of gamma ray projectors regularly reveal inappropriate stowage or tie-down.

In the BNI sector, ASN considers that the consignors must improve how they demonstrate that the content actually loaded into the packaging complies with the specifications of the approval certificates and the corresponding safety cases, including if this demonstration is provided by a third-party. In this latter case, the consignor's responsibilities then require that it verify that this demonstration is appropriate, and that it monitor the third-party company in accordance with the usual methods of a quality assurance system.

As BNI licensees are increasingly using contractors to prepare and ship packages of radioactive substances, ASN is paying particularly close attention to the organisation put into place to monitor these contractors.

Finally, with regard to on-site transports within NPPs, ASN considers that the licensees must remain vigilant to the application of package stowage rules.

4.2.5 Oversight of preparedness for emergency situations management

In order to enhance the preparedness of the transport operators (mainly consignors and carriers) for emergency situations management, ASN published Guide No. 17 in December 2014 on the content of accident and incident management plans concerning the transport of radioactive substances. This Guide recommends the production of plans to prepare for emergency situations management and stipulates their minimum contents.

4.2.6 Analysis of transport events

The safety of the transport of radioactive substances relies in particular on the existence of a reliable system for detecting and processing anomalies, deviations or, more generally, any abnormal events that could occur. Therefore, once detected, these events must be analysed in order to:

- prevent identical or similar events from happening again, by taking appropriate corrective and preventive measures;
- prevent a more serious situation from developing by analysing the potential consequences of events which could be precursors of more serious events;
- identify the best practices to be promoted in order to improve transport safety.

The regulations also requires online notification to ASN of the most significant 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 (see box page 282).

As required by Article 7 of the Order of 29 May 2009, amended, concerning the transport of dangerous goods by land, any significant event concerning the transport of radioactive substances, whether the consequences are actual or potential, must be notified to ASN within four working days, as stipulated in its Guide No.31 on the notification of events. This Guide, which was entirely revised in 2017, is available on *asn.fr*. After notification, a detailed report of the event must be sent to ASN within two months.

Events notified in 2020

In 2020, in the field of the transport of radioactive substances, ASN was notified of 71 events rated 'level 0' on the International Nuclear and Radiological Event Scale (INES scale) and 4 events rated 'level 1'. A slight drop in the number of 'level 0' events is observed by comparison with 2019, whereas the number of 'level 1' events remains stable. Graph 4 shows the variations in the number of significant events notified since 2003.

ASN was also notified of 33 Events of Interest for the Safety of Transports (EIT), a figure which is stable by comparison with 2019. Because they have no actual or potential consequences, these events are not rated on the INES scale. There is thus no obligation to notify ASN, but the latter does encourage periodic information so that it has an overview of the EITs and can detect any recurrence or trends which could be indicative of an issue.

Sectors concerned by these events

Most of the significant events notified concern the nuclear industry. Only just over 10% concern transports related to the non-nuclear industry (primarily the transport of gamma ray projectors). Nearly one quarter concern the transport of pharmaceutical

Inspection of a fresh fuel shipment en route for the Flamanville EPR reactor

In preparation for the future commissioning of the new EPR reactor at Flamanville, EDF has started to receive the first fresh fuel assemblies in the installation (fuel building pool). At the end of 2020, this involved a number of road shipments from the Framatome plant at Romans-sur-Isère.

The inspections concerning this type of transport operation are generally carried out on departure from the plant or at arrival in the Nuclear Power Plant (NPP); they can however be performed at another point along the route.

A team of ASN inspectors thus performed an unannounced evening inspection when the convoy stopped for the night along the route. This was an opportunity to inspect the compliance of the transport operations, of the vehicles and of the qualification of the drivers. ASN also checked correct implementation of the regulation regarding radiological zoning that is applicable during this type of prolonged stay. This inspection revealed no significant deviations from the regulations in force. The operator of the stopover site was also notified of a few points meriting minor improvement.

Inspection of Isovital activities concerning the transport of radiopharmaceuticals

On 19 October 2020, ASN carried out an inspection of the activities of Isovital, focusing on the radiation protection of workers and the environment, the services of radiation protection advisor and transport safety advisor. This inspection showed that radiation protection issues are not satisfactorily addressed by the company. The radiation protection organisation put into place by the company needs to be clarified both internally and for its radiation protection advisor services. In addition, the individual evaluations of exposure to ionising radiation and the risk assessments are not detailed enough to be able to justify the dose constraints defined and the classification of workers.

Finally, several major shortcomings with respect to transport regulations were also found, notably a faulty quality management system, leading to certain documents being unavailable for inspection, no processing of deviations detected by ASN during the inspections, or the use of carriers not declared with ASN for subcontracted transport of radioactive substances. ASN will make sure that these shortcomings are corrected.

products, three of which were notified as being level 1 on the INES scale. These consisted in workers exceeding the applicable regulatory occupational exposure limit. The fourth event rated 'level 1' on the INES scale was an excepted package, carrying contaminated equipment and tools, with a contact dose rate exceeding the applicable regulatory limit.

Graph 5 shows the breakdown of significant events notified per notification criterion and Graph 6 presents the breakdown according to content and mode of transport.

ASN observes that most EITs are notified by nuclear industry players, with few notifications from players in the medical and non-nuclear industry sectors despite the transport traffic concerned. ASN does however point out that notification of EITs is not a regulatory obligation.

Causes of events

The recurring causes of the Significant Events (EST) notified in 2020 include the following:
- non-conformities affecting a package: these mainly concern errors in calculation of the transport index leading to incorrect labelling and non-compliance with certain provisions indicated in the safety case or the user's instructions. These events had no actual consequences for safety or radiation protection. However, in certain conditions, in the event of an accident, the strength of the package could be reduced;
- conveyance placarding faults or deficiencies in the transport documents;
- the presence of contamination spots exceeding the regulatory limits, mainly detected on conveyances which have been used to transport spent fuel packages. With regard to radiation protection, the impact of these events is low because the contamination spots detected were inaccessible;
- stowage errors concerning contaminated equipment and tools transported in containers;
- delivery errors or temporarily mislaid packages.

The EIT of which ASN was notified are primarily deviations relating to incorrect labelling of packages, the absence of transport documents, as well as minor traffic accidents which did not compromise the safety of the package being transported.

4.3 Participation in drawing up the regulations applicable to the transport of radioactive substances

4.3.1 Participation in the work of the International Atomic Energy Agency

ASN represents France on the IAEA Transport Safety Standards Committee (TRANSSC) which brings together experts from all countries in order to review the IAEA Safety Standards constituting the basis of regulations concerning the transport of radioactive substances. With a view to constant improvement of the safety level, ASN played, for example, an active part in drafting the 2018 edition of this document, SSR-6, a French translation of which has been available since mid-2019. The publication of the IAEA guide for application of the radioactive materials transport regulation (SSG-26) is expected in 2021.

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. ASN therefore sits on the High Council for the Prevention of Technological Risks, which is required to issue an opinion on any draft regulation for the transport of dangerous good by rail, road and 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 2020, ASN thus issued an opinion on a draft Order modifying the Orders of 23 November 1987 and 29 May 2009.

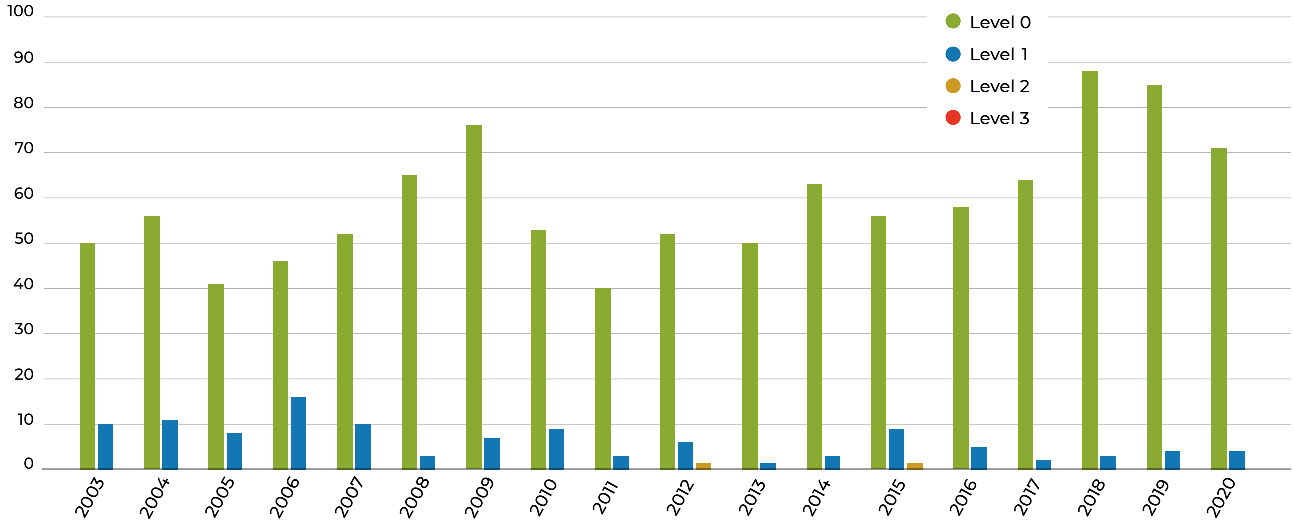
Finally, the regulatory framework for the protection of radioactive substances against malicious acts, excluding nuclear materials already covered by a specific regulation, was reinforced in 2019: ASN more specifically ensured that transport operations, during which the substances are particularly vulnerable, were suitably incorporated into the Order of 29 November 2019 concerning the protection of ionising radiation sources and batches of category A, B, C and D radioactive sources against malicious acts.

4.4 Contributing to public information

Ordinance 2012-6 of 5 January 2012, modifying Books I and V of the Environment Code, extends the obligations for public information to the persons responsible for nuclear activities. Article L. 125-10 of the Environment Code sets the thresholds beyond which the person responsible for transport must communicate the information requested by a citizen. The thresholds are defined as being those "*above which, in application of the international conventions and regulations governing the transport of dangerous goods, of the Code of Transport and of their implementing texts, the transport of radioactive substances is subject to the issuance – by ASN or by a foreign Authority competent in the field of radioactive substance transport – of an approval of the transport package design or a shipment approval, including under special arrangement*". Any citizen may therefore ask the persons in charge of transport

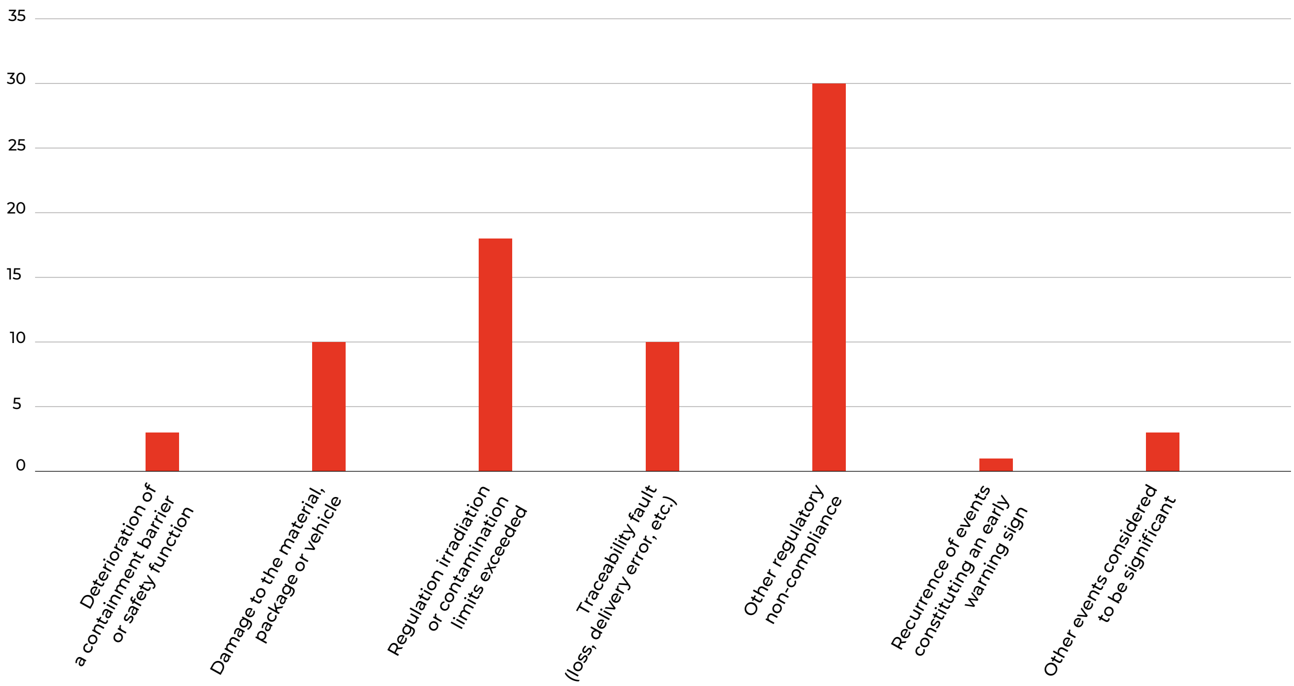
GRAPH 4

Trend in the number of significant events affecting the transport of radioactive substances notified between 2003 and 2020



GRAPH 5

Breakdown of significant events notified in 2020 by notification criterion



for information on the risks presented by the transport operations referred to in the Environment Code.

On *asn.fr*, ASN has also published information presenting the transport of radioactive substances.

4.5 Participation in international relations in the transport sector

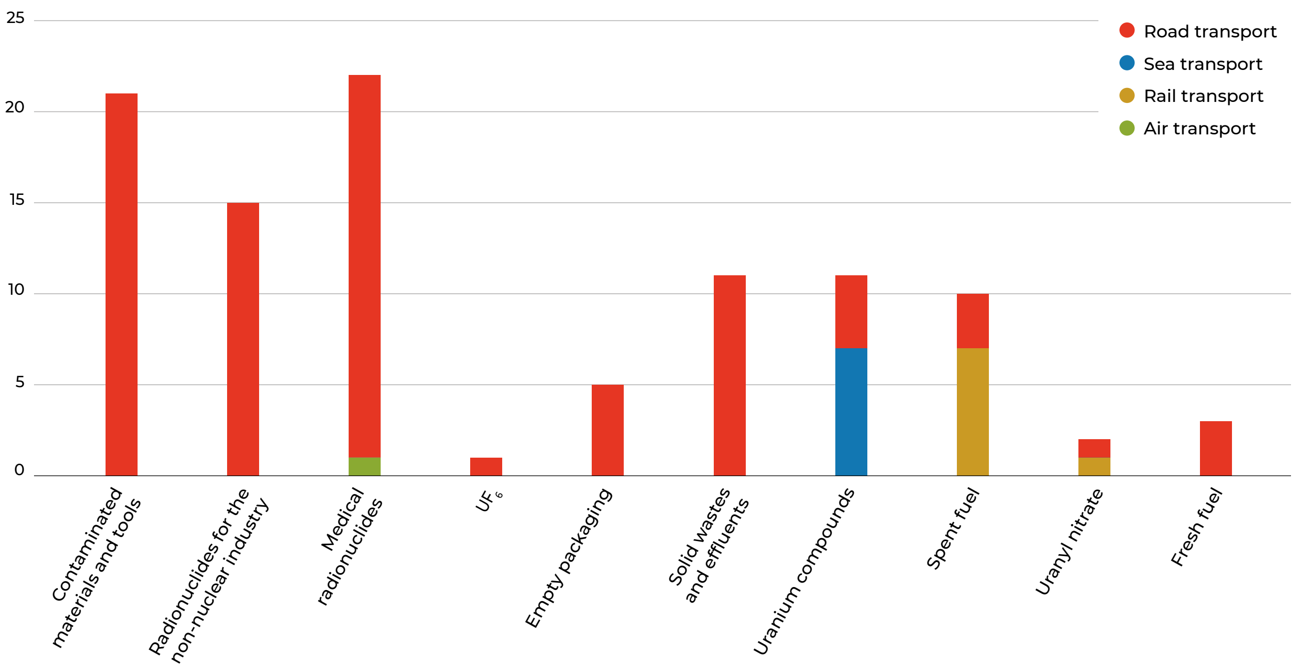
International regulations are drafted as a result of fruitful exchanges between countries, with such exchanges also addressing their implementation. These exchanges are part of a process of continuous improvement of the safety of radioactive substance transports, and ASN encourages exchanges with its counterparts in other States.

4.5.1 Work of the European Association of Competent Authorities on transport

The European Association of Competent Authorities on the Transport of Radioactive Material (EACA) was created in December 2008. Its purpose is to promote the harmonisation of practices in the regulation of the safety of transport of radioactive substances, and to encourage exchanges and experience feedback between the various Authorities. France, which initiated the creation of this association, plays an active part in its work,

GRAPH 6

Breakdown of notified transport events by content and mode of transport in 2020



including by presenting its views on the regulatory changes that may be needed, in particular on the occasion of the association's annual meeting.

4.5.2 Bilateral relations with ASN's foreign counterparts

ASN devotes considerable efforts to maintaining close ties with the competent authorities of the countries concerned by the numerous shipments to and from France. Prominent among these are Germany, Belgium, the United Kingdom and Switzerland.

Germany

In 2016, the French and German Authorities decided to meet regularly to discuss a range of technical subjects. ASN also participates in the Franco-German technical committees concerning the programme for returning German spent nuclear fuel reprocessing waste. A new packaging 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 the nuclear production of electricity in Belgium, French-designed packagings are sometimes used for shipments necessary for the "fuel cycle". In order to harmonise practices and achieve progress in the safety of these shipments, ASN and the competent Belgian Authority (Belgian Federal Nuclear Regulating Agency – AFCN) regularly exchange know-how and experience. The exchanges more particularly concern the review of safety cases for French package models for which approval is validated in Belgium and inspection practices in each country.

Online notification of transport events

The publication of the Order of 11 December 2018 modifying the Order of 29 May 2009 concerning the transport of dangerous goods by road, makes the use of ASN's online services portal mandatory from 1st January 2019, for the notification of significant events concerning the transport of radioactive substances on the public domain. With a view to harmonisation, the online services portal was also extended in mi-2019 to the notification of on-site transport events concerning dangerous goods within Basic Nuclear Installations (BNIs).

Notification of an event as stipulated in ASN Guide No. 31 does not replace the obligation to alert ASN immediately in the case of an emergency situation.

Events related to the transport of ore from third-party countries

Recurring deviations have been observed in "fuel cycle" natural uranium ore transports from mines in Central Asia, Africa and Australia: on their arrival in France, contamination spots exceeding the regulation limits and damaged drums are discovered. ASN found a slight improvement in the situation by comparison with 2017 but, together with the transport stakeholders and ordering parties, is continuing to work to improve the transport conditions for these packages.

United Kingdom
ASN and the British regulator (Office for Nuclear Regulation – ONR) share many subjects of interest, notably with regard to validation of English approvals by ASN and vice-versa. Bilateral contacts are therefore held regularly to ensure good communication between these two Authorities.

Switzerland
In 2012, ASN began bilateral exchange on transports with the Swiss Federal Nuclear Safety Inspectorate (IFSN – called *Eidgenössisches Nuklearsicherheitsinspektorat* (ENSI) in German). Since then, ASN and IFSN have met annually in order to discuss the packaging model safety cases and the checks on the requirements associated with the correct utilization of these transport packages.

2018 edition of the IAEA Regulations for the Safe Transport of Radioactive Materials (SSR-6)

The main changes introduced into the 2018 edition of the transport regulations by comparison with the previous 2012 edition, concern:
- improved management of the packages used both for carriage and storage operations (dual-purpose cask or DPC);
- the creation of SCO-III objects for the transport of unpackaged voluminous items;
- greater account being taken of ageing mechanisms when designing packages;
- reinforced protection of the plugs of UF_6 cylinders;
- cessation of the leaching test for LSA-III materials.

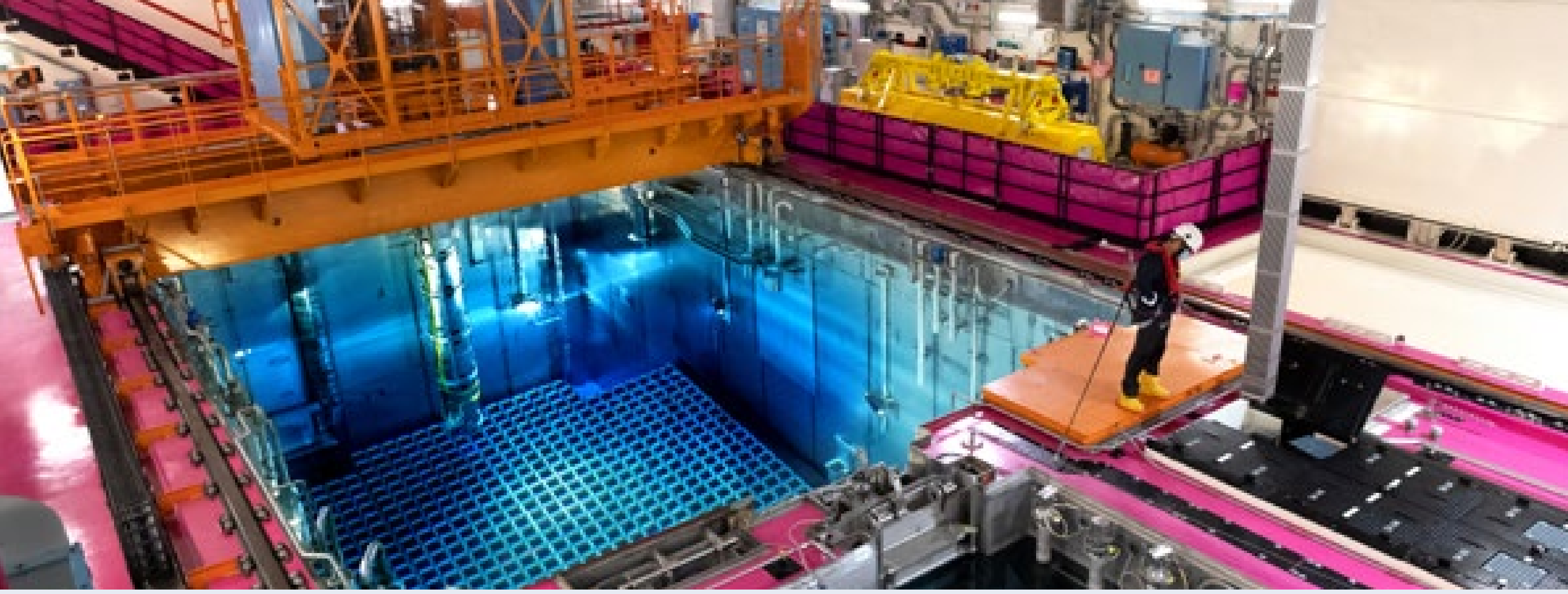
THE IMPACT OF COVID-19

France has adopted a number of measures to deal with the consequences of the health crisis. On 19 March 2020, it first of all signed the M324 multilateral agreement for an exceptional extension until 30 November 2020 of the validity of the training certificates for Drivers and Safety Advisors appointed within companies (CST), which was reaching its expiry date. On 26 October 2020, it again signed the M330 multilateral agreement to postpone this expiry date to 28 February 2021.

Finally, the Order of 10 December 2020 introduced exemptions to certain provisions of the Order of 29 May 2009 concerning the carriage of dangerous goods by land (called the “TMD Order”). This Order relaxes certain constraints applying to CSTs and to inspection bodies approved for quality assurance inspections concerning packaging manufacturing, because of the lockdown measures and the physical distancing rules imposed owing to the health crisis caused by the Covid-19 pandemic.

CHAPTER 10

THE EDF NUCLEAR POWER PLANTS



10 The EDF Nuclear Power Plants

The electricity generating reactors are at the heart of the nuclear industry in France. Many other installations described in other chapters of this report produce the fuel intended for the Nuclear Power Plants (NPPs) or reprocess it, dispose of the waste from the NPPs or study physical phenomena related to the operation or safety of these reactors.

The French reactors are technically very similar and thus form a standardised fleet operated by EDF. Although this uniformity means that the licensee and the French Nuclear Safety Authority (ASN) have extensive experience of their operation, it also means that there is a higher risk if a generic design, manufacturing or maintenance flaw is detected on one of these installations, as it could then affect all the reactors. ASN thus requires a high degree of reactivity and rigour on the part of EDF when analysing the generic nature of these flaws and their consequences for the protection of people and the environment, as well as when processing them.

ASN exercises extremely stringent oversight of safety, of environmental protection and radiation protection measures in the NPPs and continuously adapts it, in particular in the light of experience feedback from the design, manufacture, operation and maintenance of NPP reactor components. To monitor the safety of the reactors in operation, under construction or being planned, ASN mobilises nearly 200 staff on a daily basis in the Nuclear Power Plant Department (DCN), the Nuclear Pressure Equipment Department (DEP) and its regional divisions, and can draw on nearly 200 experts from the French Institute for Radiation Protection and Nuclear Safety (IRSN).

ASN develops an integrated approach to the oversight of the facilities. It intervenes at all stages in the life of the NPP reactors, from design up to decommissioning and delicensing. Through its expanded scope of intervention it examines the fields of nuclear safety, environmental protection, radiation protection, occupational safety and the application of labour laws, at all stages. For each of these fields, it monitors all aspects, whether technical, organisational, or human. This approach requires that it take account of the interactions between these fields and that it define its monitoring actions accordingly. The resulting integrated overview enables ASN to fine-tune its assessment of the state of nuclear safety, radiation protection, environmental protection and worker protection within the NPPs.

1. General information about Nuclear Power Plants

1.1 General presentation of a Pressurised Water Reactor

By transferring heat from a hot source to a heat sink, an electricity generating thermal power plant produces mechanical energy that it converts into electricity. Conventional thermal power plants use the heat given off by the combustion of fossil fuels (fuel oil, coal, gas). NPPs use that given off by the fission of uranium or plutonium atoms. The heat produced in a Pressurised Water Reactor (PWR) leads to the creation of steam, which does not come into contact with the nuclear fuel. The steam is then expanded in a turbine which drives a generator producing a three-phase electric current with a voltage raised to 400,000 volts (V) by a transformer. After expansion, the steam passes through a condenser where it is cooled on contact with tubes circulating cold water from the sea, a water course (river) or an atmospheric cooling circuit. The condensed water is reused in the steam production cycle.

Each reactor comprises a nuclear island, a conventional island, water intake and discharge structures and possibly a cooling tower.

The nuclear island mainly comprises the reactor vessel, the reactor coolant system, the Steam Generators (SG) and the systems ensuring reactor operation and safety: the chemical and volumetric control, residual heat removal, safety injection, containment spray, SG feedwater supply, electrical, Instrumentation and Control (I&C) and reactor protection systems. These elements are also associated with systems providing support functions: monitoring and processing of primary effluents, water supply, ventilation and air conditioning, back-up electricity supply (diesel electricity generating sets).

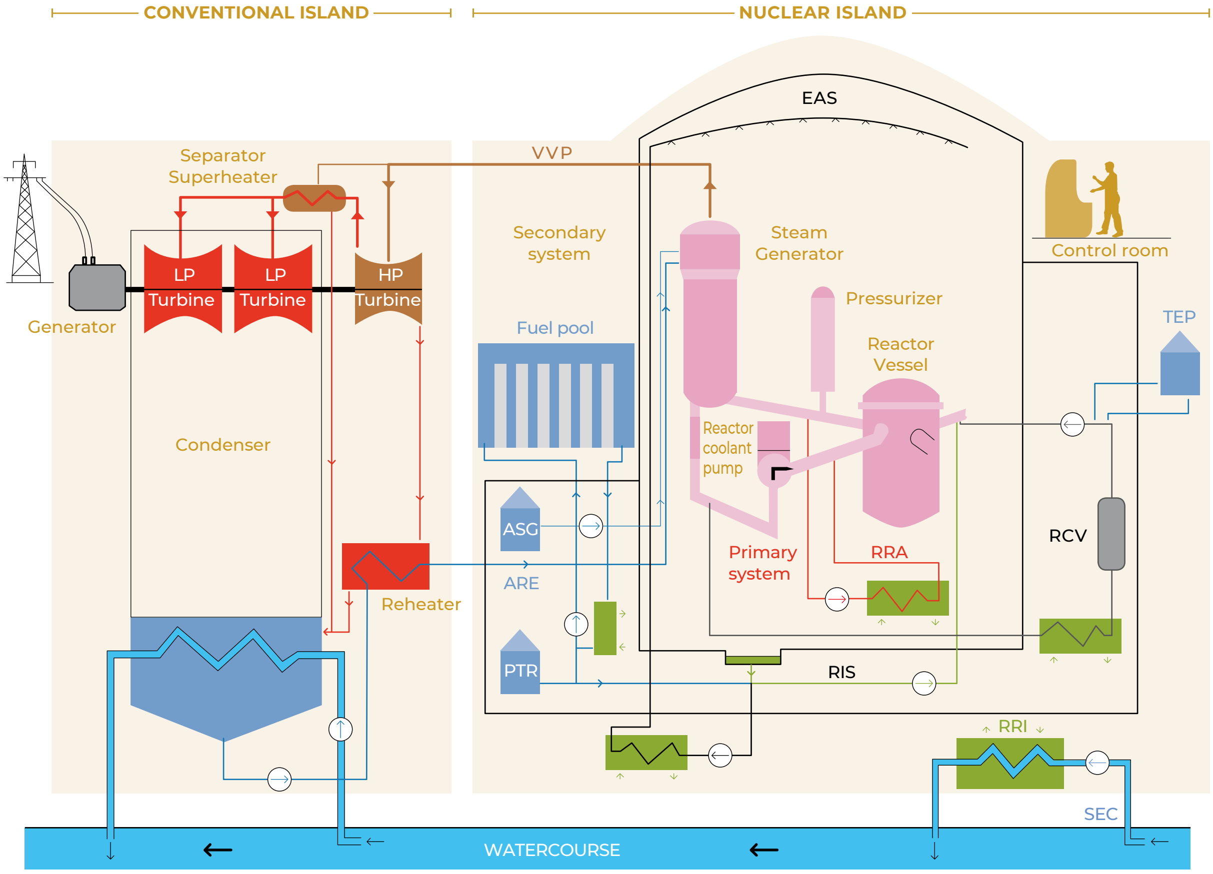
The nuclear island also comprises systems for the evacuation of steam to the conventional island, as well as the building housing the fresh and spent fuel storage and Cooling Pool (BK). When mixed with boric acid, the water in this pool helps absorb the neutrons emitted by the nuclei of the fissile elements in the spent fuel, to avoid sustaining nuclear fission, to cool the spent fuel and to provide the workers with radiological protection.

The conventional island notably comprises the turbine, the generator and the condenser. Some components of these items take part in reactor safety. The secondary systems are partly in the nuclear island and partly in the conventional island.

1.2 The core, fuel and its management

The reactor core consists of fuel assemblies made up of “rods” comprising “pellets” of uranium oxide and depleted uranium oxide and plutonium oxide (for Mixed OXydes fuels – MOX), contained in closed metal tubes, called “cladding”. When fission occurs,

Pressurised Water Reactor operating principle



ARE: Feedwater Flow Control System
ASG: Steam Generators Auxiliary Feedwater System
EAS: Reactor building 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 Turbine
VVP: Main Steam Systems

the uranium or plutonium nuclei, said to be “fissile”, emit neutrons which in turn trigger other fissions: this is the chain reaction. The nuclear fissions give off a large amount of energy in the form of heat. The water in the reactor coolant system, which enters the lower part of the core at a temperature of about 285°C, heats up as it rises along the fuel rods and comes out through the top at a temperature of close to 320°C.

At the beginning of an operating cycle, the core has a considerable energy reserve. This gradually decreases during the cycle, as the fissile nuclei are consumed. The chain reaction and thus the power of the reactor is controlled by:
- the insertion of “control rod clusters” containing neutron-absorbing elements into the core to varying extents. This enables the reactor’s reactivity to be controlled and its power adjusted to the required production of electricity. Gravity dropping of the control rods is used for emergency shutdown of the reactor;
- adjustment of the concentration of boron (neutron absorbing element) in the reactor coolant system water during the cycle according to the gradual depletion of the fissile elements in the fuel;
- the presence of neutron-absorbing elements in the fuel rods which, at the beginning of the cycle, compensate the excess core reactivity after partial renewal of the fuel.

At the end of the cycle, the reactor core is unloaded so that some of the fuel can be replaced.

EDF uses two types of nuclear fuel in the PWRs:
- uranium oxide (UO_2) based fuels enriched with uranium-235 to a maximum of 4.5% by mass. These fuels are fabricated in several French and foreign plants, by Framatome and Westinghouse;
- fuels consisting of a mixture of depleted MOX. MOX fuel is produced by Orano’s Melox plant. The maximum authorised plutonium content is currently set at 9.08% (average per fuel assembly) giving an energy performance equivalent to UO_2 fuel enriched to 3.7% uranium-235. This fuel can be used in the twenty-four 900 Megawatts electric (MWe) reactors, for which the Creation Authorisation Decrees (DAC) authorise the use of plutonium fuel.

EDF has standardised how the fuel is used in its reactors, referred to as “fuel management”. Fuel management, which concerns similar reactors, is more particularly characterised by:
- the nature of the fuel and its initial fissile material content;
- the maximum burnup of the fuel when removed from the reactor, characterising the quantity of energy extracted per ton of material, expressed in gigawatt days per tonne (GWd/t);
- the duration of a reactor operating cycle;

- the number of new fuel assemblies loaded following each reactor refuelling outage (generally one third or one quarter of the total number of assemblies).

1.3 The primary system and the secondary systems

The primary system and the secondary systems transport the energy given off by the core in the form of heat to a turbine generator set which produces electricity.

The reactor coolant system comprises cooling loops, of which there are three for a 900 MWe reactor and four for the 1,300 MWe, 1,450 MWe or 1,650 MWe Evolutionary Power Reactor (EPR) type reactors. The role of the reactor coolant system is to extract the heat given off by the core by means of circulating pressurised "primary water" or "reactor coolant". Each loop, connected to the reactor vessel containing the core, comprises a circulating pump, called the "reactor coolant pump" and a SG. The reactor coolant, heated to more than 300°C, is maintained at a pressure of 155 bar by the pressuriser, to avoid boiling. The primary system is entirely situated within the containment.

The primary system coolant transfers its heat to the water of the secondary systems in the SGs. The SGs are heat exchangers which, depending on the model, contain from 3,500 to 5,600 tubes through which the reactor coolant circulates. These tubes are immersed in the secondary system water, which thus boils without coming into contact with the reactor coolant.

Each secondary system primarily consists of a closed loop through which water passes, in the form of liquid in one part and in the form of steam in the other. The steam produced in the SGs is partially expanded in a high-pressure turbine and then passes through moisture separator-reheaters before entering the low-pressure turbines for final expansion, from which it passes to the condenser. Once condensed, the water is then sent to the SGs by the extraction pumps, followed by the feedwater pumps after passing through the reheaters.

1.4 The secondary system cooling system

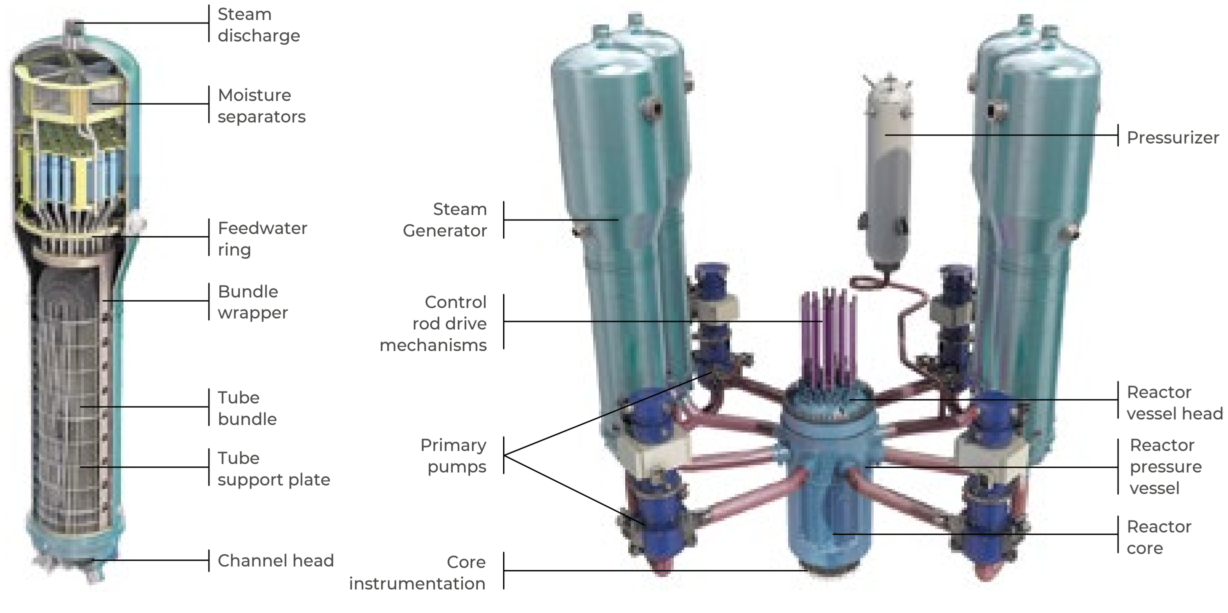
The function of the secondary system cooling system is to condense the steam exiting the turbine. To do this, it has a condenser comprising a heat exchanger containing thousands of tubes through which cold water from outside (sea or river) circulates. On contact with these tubes, the steam condenses and can be returned in liquid form to the SGs (see point 1.3). The water in the cooling system heats up in the condenser and is then either discharged into the environment (once-through circuit) or, if the river discharge is too low or the heating too great for the sensitivity of the environment, is cooled in a Cooling Tower (TAR) – semi-closed or closed circuit.

The cooling systems are environments favourable to the development of pathogenic micro-organisms. Replacing brass by titanium or stainless steel in the construction of riverside reactor condensers, in order to reduce metal discharges into the natural environment, requires the use of disinfectants, mainly by means of biocidal treatment. The copper contained in brass has bactericidal properties that titanium and stainless steels do not. Air cooling towers can contribute to the atmospheric dispersal of legionella bacteria, whose proliferation can be prevented by stricter maintenance of the works (descaling, implementation of biocidal treatment, etc.) and monitoring.

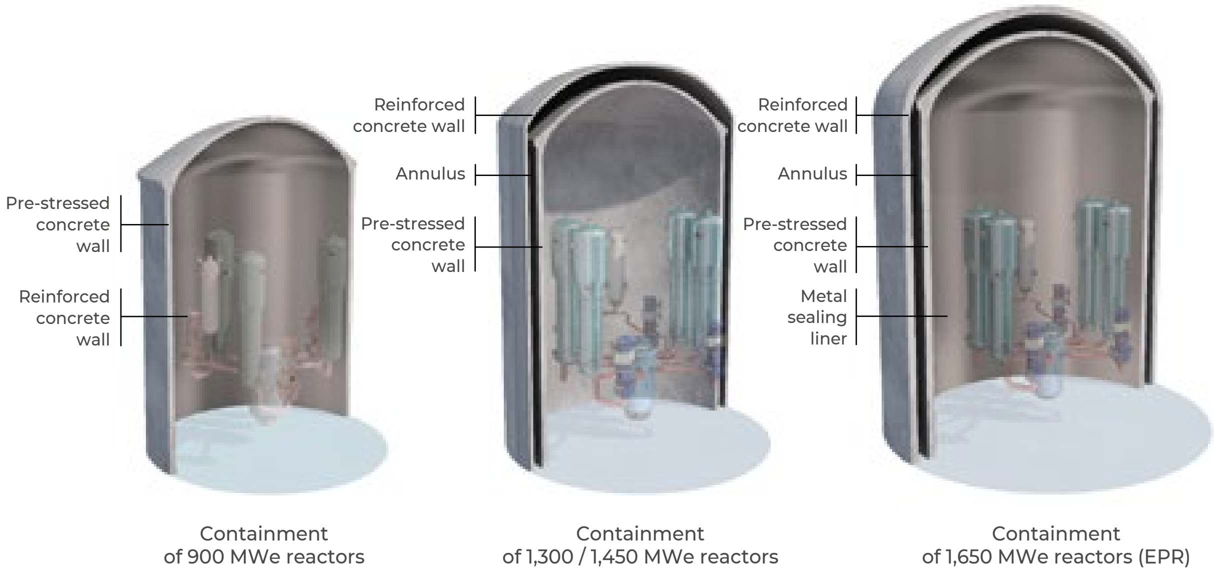
1.5 The containment

The PWR containment performs two functions:
- the containment of radioactive substances liable to be dispersed in the event of an accident; to do this, the containments were designed to withstand the temperatures and pressures that would result from the most severe loss of coolant accident (double-ended circumferential rupture of a reactor coolant system pipe) and to ensure satisfactory leaktightness in these conditions;
- reactor protection against external hazards.

A Steam Generator and a main primary system for a 1,300 MWe reactor



Reactor containments



There are three containment model designs:

- Those of the 900 MWe reactors comprise a single pre-stressed concrete wall (concrete comprising steel tendons tensioned to compress the structure in order to increase its tensile strength). This wall provides mechanical pressure resistance and ensures the integrity of the structure in the event of an external hazard. Tightness is provided by a metal liner covering the entire internal face of the concrete wall.
- Those of the 1,300 MWe and 1,450 MWe reactors are made of two walls: the inner prestressed concrete wall and the outer reinforced concrete wall. Leaktightness is provided by the inner wall and the Ventilation System (EDE) which, between the two walls, collects and filters residual leaks from the inner wall before discharge. Resistance to external hazards is primarily provided by the outer wall.
- That of the Flamanville EPR consists of two concrete walls and a metal liner covering the entire internal face of the inner wall.

1.6 The main auxiliary and safeguard systems

In normal operating conditions, at power, or in reactor outage states, the auxiliary systems control nuclear reactions, remove heat from the primary system and residual heat from the fuel and provide containment of radioactive substances. They mainly comprise the reactor's chemical and Volumetric Control System (RCV) and the reactor's Residual heat Removal System (RRA).

The role of the safeguard systems is to control and limit the consequences of incidents and accidents. This chiefly concerns the following systems:

- the Safety Injection System (SIS), the role of which is to inject water into the primary system in the event of it leaking;
- the reactor building Containment Spray System (EAS), the role of which is to reduce the temperature and thus the pressure in the containment, in the event of a major primary system leak;
- the Steam Generators Auxiliary feedwater System (ASG), which supplies water to the SGs if the normal feedwater system is lost, thus enabling heat to be removed from the primary system. This system is also used in normal operation during reactor outage or restart phases.

1.7 The other systems important for safety

The other main systems or circuits important for safety and required for reactor operation are:

- the Component Cooling System (RRI) which cools a certain number of nuclear equipment items. This system functions in a closed loop between the auxiliary and safeguard systems on the one hand and the systems carrying water from the river or sea (heatsink) on the other;
- the Essential Service water System (SEC) which cools the RRI system with water from the river or sea (heatsink). This is a backup system comprising two redundant lines. In certain situations, each of its lines is capable of removing heat from the reactor to the heatsink;
- the Reactor Cavity and Spent Fuel Pit Cooling and Treatment System (PTR), which in particular removes residual heat from the fuel elements stored in the fuel building pool;
- the ventilation systems, which contain radioactive materials by creating negative pressure in the rooms and by filtering discharges;
- the fire-fighting water systems;
- the I&C system, which processes the information received from all the sensors in the NPP. It uses transmission networks and sends orders to the actuators from the control room, through the programmable logic controllers or operator actions. Its main role with regard to reactor safety is to monitor reactivity, control the removal of residual heat to the heatsink and take part in the containment of radioactive substances;
- the electrical systems, which comprise sources and electricity distribution. The French nuclear power reactors have two external electrical sources: the step-down transformer and the auxiliary transformer. These two external sources are supplemented by two internal electrical sources: the backup diesel generators. 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. Finally, following the Fukushima Daiichi NPP accident (Japan), these resources were supplemented by an "ultimate back-up" diesel generator set for each reactor.

2. Oversight of nuclear safety

2.1 Fuel

2.1.1 Changes to fuel and fuel management in the reactor

In order to increase the availability and performance of the reactors in operation, EDF and the nuclear fuel manufacturers are developing improvements to be made to the fuels and to how they are used in the reactors.

EDF has standardised its fuel management methods. ASN ensures that each change to fuel management undergoes a specific safety demonstration 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.

As fuel behaviour is a key element in the safety of the core in a normal or accident operating situation, its reliability is crucial. Thus, the leaktightness of the cladding of the fuel rods, tens of thousands of which are present in each core and which constitute the first containment barrier, receives particularly close attention. In normal operation, leaktightness is monitored by EDF through permanent measurement of the activity of the radionuclides contained in the primary system. Any increase in this activity beyond predetermined thresholds is a sign of a loss of leaktightness in the fuel assemblies. During each shutdown, EDF must look for and identify the assemblies containing leaking rods, which must not then be reloaded. If the activity of the primary system becomes too high, the General Operating Rules (RGE) require shutdown of the reactor before the end of its normal cycle.

ASN ensures that EDF looks for and analyses the causes of the loss of leaktightness observed, notably by examining the leaking rods in order to determine the origin of the failures and prevent them from reoccurring. The preventive and corrective measures may concern the design of the rods and assemblies, their manufacture or the reactor operating conditions. In addition, the conditions of fuel assembly handling, of core loading and unloading, as well as preventing the presence of foreign objects in the systems and pools are also covered by operating specifications, some of which contribute to the safety case and for which EDF's compliance is spot-checked by ASN during inspections. ASN also carries out inspections to check the nature of EDF's monitoring of its fuel suppliers. Finally, ASN periodically consults the Advisory Committee for Nuclear Reactors (GPR) concerning the lessons learned from fuel operating experience feedback.

2.1.2 Assessment of the condition of the fuel and its management in the reactor

ASN considers that in 2020, EDF's management of the integrity of the first barrier, that is the fuel rod cladding, was on the whole satisfactory for all the NPPs.

The progress observed in 2019 with regard to the risk of foreign material entering the primary system, which could then damage the first containment barrier, continued in 2020.

The number of reactors with one or more assemblies with cladding defects was similar to the previous year. ASN will be attentive to the results of the investigations carried out by EDF on the fuel assemblies concerned and to ensuring that lessons are learned in order to improve their design, manufacture and operation.

In dealing with the obsolescence of the sipping machines in the fuel buildings, in which the assemblies are checked, ASN will also be attentive to the correct performance of all the maintenance operations performed on this equipment. This attention will be maintained until the deployment of new mobile sipping machines currently being designed.

As in 2019, ASN observes that few events were reported during the fuel handling operations in 2020. ASN continues to pay particular attention to correct application of the improvement measures implemented on all the sites following the snagging of a fuel assembly during the Tricastin unloading operations in 2019.

By comparison with 2019, ASN observes that in 2020, fewer reactors carried out a long power increase after refuelling, requiring a modification of their operating baseline requirements. The reactors concerned operated for a prolonged period of time at intermediate power, which increases the risk of rupture of the first barrier in certain accident situations. These extended power increase durations were, in the cases encountered in 2020, caused by incidents on certain secondary system equipment. ASN considers that EDF must ensure that its facilities are available, more specifically the secondary system, before carrying out the divergence and power increase transients.

At unloading of Paluel NPP reactor 2 at the end of 2019, EDF observed the presence of a corrosion deposit on more than one third of the core fuel assemblies. This deposit was observed on a French NPP reactor for the first time and is due to the replacement of the Steam Generators during the previous outage. This operation led to a high concentration of corrosion products in the primary system. These corrosion products, which are usually neutralised and removed, were deposited on the core, notably owing to a first slow power increase after refuelling. Several analyses aimed at characterising the phenomenon were carried out in 2020 and will continue in 2021.

With regard to the fabrication of fuel assemblies, ASN is maintaining its vigilance following the anomalies encountered in 2017 on MOX fuel (presence of large-sized plutonium enriched islands) which reoccurred in 2019, despite the steps taken in Orano's Melox plant. EDF's notification of a significant event regarding the rising neutron flux phenomenon at the bottom and top of the fissile column of MOX fuel assemblies led ASN to ask the licensee to adopt compensatory measures in 2018, pending the deployment of a change to the design of these assemblies.

Finally, in 2020, a generic anomaly on the fuel assemblies designed by Westinghouse was brought to light. One of the grids of these assemblies experienced damage during operation, generating migrating objects. Pending additional technical data and the replacement of these grids by reinforced grids for the next assemblies, ASN asked EDF to perform additional tests on the reactors concerned, to ensure that the safety functions remain available.

2.2 Nuclear Pressure Equipment

2.2.1 Monitoring of the design and manufacturing conformity of Nuclear Pressure Equipment

ASN assesses the regulatory compliance of the Nuclear Pressure Equipment (NPE) most important for safety, referred to as "level N1", corresponding to the reactor pressure vessel, the SGs, the pressuriser, the primary circuit pumps, the piping, as well as the safety valves.

These regulations are a guarantee of their safety. They are defined by a European Directive on NPE and are supplemented by requirements specific to NPE.

Fault in implementation of a post-weld heat treatment process during manufacture of the Framatome Steam Generators

Assembling components by welding creates mechanical stresses in the welded areas. To reduce these stresses, the manufacturer applies a Post-Weld Heat Treatment (PWHT), which consists in heating the material for several hours to a temperature of several hundred degrees. This heating can be carried out on the complete part in a furnace if the size of the part so permits, or locally by using heating devices such as electrical heating elements. The treatment temperature and duration must be controlled in order firstly to remove the stresses resulting from the welding, and secondly to avoid altering the mechanical properties of the material.

In 2019, the manufacturer Framatome brought to light the fact that certain processes used in its Saint-Marcel plant or in the Nuclear Power Plants (NPPs) to assemble components or install the Steam Generators (SGs), had led to insufficient control of the temperatures around the circumferences of the treated welds.

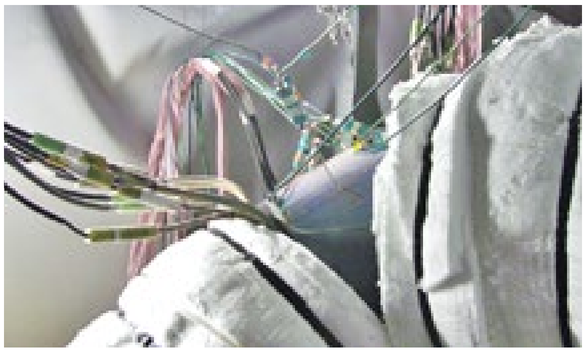
This deviation concerns 177 of the 192 SGs installed in EDF's reactors in operation. EDF justified the continued integrity of the equipment concerned, by drawing on the results of tests performed on representative mock-ups, on material test coupons and on numerical temperature prediction models. During each reactor outage, the welds concerned are specifically checked (thickness measurements and defect search). ASN checks the justifications provided by EDF for each reactor before it is restarted.

At the same time, EDF has set up a programme of detailed characterisation based on mock-ups and material tests.

ASN rated this event level 1 on the International Nuclear and Radiological Event Scale (INES scale).

In addition, equipment currently being manufactured by Framatome is also concerned: 22 SGs intended for reactors in operation, as well as the SGs, pressuriser and secondary system lines for the Flamanville Evolutionary Power Reactor (EPR). Framatome is defining the appropriate treatment strategies for each of the equipment items concerned. This includes repair studies, test mock-ups and digital simulation studies to assess the impact of the deviations on the required mechanical properties.

ASN questioned the other manufacturers of large equipment items (Westinghouse and MHI), in order to check that they correctly implement the post-weld heat treatment processes.



This conformity assessment concerns the equipment intended for the new nuclear facilities (more than 200 equipment items are concerned on the Flamanville EPR) and the spare equipment intended for nuclear facilities already in service (notably the replacement SGs). ASN can be assisted in this task by organisations that it approves. These latter can be mandated by ASN with performance of some of the inspections on the "level N1" equipment and are tasked with assessing the regulatory compliance of the NPE less important for safety, said to be "level N2 or N3". The oversight by ASN and the approved organisations is carried out at the different stages of the design and manufacture of the NPE. It takes the form of an examination of the technical documentation of each equipment item and inspections in the workshops of the manufacturers, as well as at their suppliers and subcontractors. Four inspection bodies or organisations are currently approved by ASN to assess NPE compliance: Apave SA, Bureau Veritas Exploitation, Vinçotte International and the inspection body of the EDF users.

In 2020, the approved organisations carried out 2,750 inspections on the design and manufacture of the NPE intended for the Flamanville EPR and 5,000 inspections for the replacement NPE intended for the NPP reactors in operation. These inspections are performed under ASN supervision.

2.2.2 Assessment of the design and manufacturing of Nuclear Pressure Equipment

Actions focusing on detection and processing of deviations and implementation of improvement plans in the fabrication plants

2020 saw extensive mobilisation of the resources of the manufacturer Framatome for continued examination of the deviations detected, in particular those which had affected the post-weld heat treatment of the connecting welds for replacement SG components, produced at the Framatome Saint-Marcel plant.

2020 was also marked by the continued implementation of the improvement plan for the Creusot Forge plant, which notably includes reinforcing the safety culture, improved management of the industrial tools and consolidation of technical skills. In the light of the results obtained, ASN gave a favourable opinion for the resumption of manufacturing of the shells intended for the SG replacement programme. Framatome will be required to maintain efforts to ensure that a long-term, robust and efficient organisation tailored to the safety issues is maintained within the Creusot plant. ASN will maintain particular surveillance of this plant.

The manufacturer Westinghouse continued to apply its improvement plan in its SG manufacturing plant in Italy, with regard to the internal monitoring quality system. The conditions were thus defined for lifting the reinforced surveillance in place.

Processing of the irregularities reported at the end of 2018 by the supplier of special alloys and steels, Aubert & Duval, is also continuing. The investigations carried out have not yet identified any consequences for the safety of the facilities.

At the same time, the organisations, manufacturers and licensees are developing an organisation and the corresponding resources within their own structures, in order to prevent and detect the risk of fraud. Although progress has been observed, improvements are still needed in the implementation of the technical procedures.

Reinforcing justification of the design of NPE

ASN has regularly observed that the justifications and demonstrations provided by the manufacturers with regard to the regulations applicable to NPE, notably in terms of the good design of this equipment, are unsatisfactory. The industrial firms, EDF and Framatome in particular, therefore took fundamental measures as of the first half of 2015 to change their practices and bring them into line with the regulatory requirements. ASN monitored these actions, most of which were carried out within the framework of the French Association for NSSS Design, Construction and Monitoring Rules (AFCEN) and involved the majority of the profession. ASN considers this approach to be a positive one and, for most of the problems identified in 2015, considers that the AFCEN guides and methods published are appropriate. This approach was repeated for the years 2019 to 2022, so that the profession continues to make progress on certain topics and in order to learn the lessons from the initial applications of the guides and methods created and the deviations observed during ongoing manufacturing.

2.2.3 Monitoring the operation of Pressure Equipment

The reactor Main Primary and Secondary Systems (MPS and MSS), which contribute to the containment of the radioactive substances, to cooling and to controlling reactivity, operate at high temperature and high pressure.

The monitoring of the operation of these systems is regulated by the Order of 10 November 1999 relative to the monitoring of operation of the main primary system and the main secondary systems of nuclear pressurized water reactors. These systems are thus the subject of monitoring and periodic maintenance by EDF. This monitoring is itself checked by ASN.

These systems are subject to periodic re-qualification every 10 years, which comprises a complete inspection of the systems involving non-destructive examinations, pressurised hydrotesting and verification of the good condition and good operation of the over-pressure protection accessories.

Nickel-based alloy zones

Several parts of the PWRs are made of nickel-based alloy. This type of alloy is chosen for its resistance to generalised or pitting corrosion. However, in the reactor operating conditions, one of the alloys chosen, Inconel 600, has proven to be susceptible to stress corrosion. This particular phenomenon occurs in the presence of significant mechanical stresses. It can lead to the appearance of cracks, as observed on certain SG tubes in the early 1980s or, more recently in 2011, on a vessel bottom head penetration in Gravelines NPP reactor 1 and in 2016 on a vessel bottom head penetration in Cattenom NPP reactor 3.

These cracks require that the licensee repair the zones concerned or isolate the part of the system concerned.

At the request of ASN, EDF adopted an overall approach to monitoring and maintenance for the zones concerned. Several zones of the main primary system made of Inconel 600 alloy are thus subject to specific monitoring. For each of them, the in-service monitoring programme, defined and updated annually by the licensee, is submitted to ASN, which checks that the performance and frequency of the checks carried out by EDF are satisfactory and able to detect the deteriorations in question.

The strength of reactor pressure vessels

The reactor pressure vessel is an essential component of a PWR and contains the reactor core and its instrumentation. For the 900 MWe reactors, the vessel is 14 meters (m) high, 4 m in diameter, 20 centimeters (cm) thick and weighs 330 tonnes (t). 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 t.

In normal operating conditions, the vessel is entirely filled with water, at a pressure of 155 bar and a temperature of 300°C. It is made of ferritic steel, with a stainless steel inner liner.

Regular inspection of the condition of the vessel is essential for two reasons:
- The vessel is a component for which replacement is not envisaged, owing to both technical feasibility and cost.
- Monitoring contributes to the break preclusion approach adopted for this equipment. This approach is based on particularly stringent design, manufacturing and in-service inspection provisions in order to guarantee its strength throughout the life of the reactor, including in the event of an accident.

During operation, the vessel's metal slowly becomes brittle, under the effect of the neutrons from the fission reaction in the core. This embrittlement more particularly makes the vessel more susceptible to thermal shocks under pressure, or to sudden pressure rises when cold. This susceptibility is aggravated by the presence of technological flaws, which is the case for some vessels with manufacturing defects under their stainless steel liner.

ASN regularly examines the evidence to substantiate the in-service resistance of the vessels transmitted by EDF, to ensure that it is sufficiently conservative.

Maintenance and replacement of Steam Generators

The SGs comprise two parts, one of which is a part of the main primary system and the other a part of the main secondary system. The integrity of the main components of the SGs is monitored, more specifically the tubes making up the tube bundle. This is because any damage to the tube bundle (corrosion, wear, cracking, etc.) can lead to a primary system leak to the secondary system. Rupture of one of the tube bundles would lead to bypassing of the reactor containment, which is the third containment barrier. The SGs are the subject of a specific in-service monitoring programme, defined by EDF and periodically revised and examined by ASN. Following the inspections, those tubes which are too badly damaged are plugged, to remove them from service.

Clogging of the tubes and internals of the secondary part of the Steam Generators

Over time, the SGs tend to become clogged with corrosion products from the secondary system exchangers. This leads to a build-up of soft or hard sludge at the bottom of the SGs, fouling of the tube walls and clogging of the tube bundle tube support plates. The corrosion products form a layer of magnetite on the surface of the internals. The layer of deposits (fouling) that forms on the tubes reduces the heat exchange capacity. On the tube support plates, the deposits prevent the free circulation of the water-steam mixture (clogging), which creates a risk of damage to the tubes and the internal structures and which can degrade the overall operation of the SG.

To prevent or mitigate the clogging effects described above, various solutions can be implemented to limit metal deposits: preventive chemical cleaning or remedial mechanical cleaning (using hydraulic jets), replacement of material (brass by stainless steel or titanium alloy, which are more corrosion-resistant) in certain secondary system exchanger tube bundles, modification of the chemical products used for conditioning of the systems and an increase in the pH of the secondary system. Some of these operations require a license for the discharge of some of the products used.

Some chemical cleaning processes are still being tested to confirm that the chemical products utilised are harmless.

Replacement of the Steam Generators

Since the 1990s, EDF has been running a programme to replace the SGs with the most severely damaged tube bundles, with priority being given to those made of non-heat-treated Inconel 600 alloy (600 MA), and then those made of heat-treated Inconel 600 alloy (600 TT).

The campaign to replace SGs with a tube bundle made of 600 MA – some 26 reactors – was completed in 2015 with that of the Blayais NPP reactor 3. It is continuing with replacement of SGs in which the tube bundle is made of 600 TT – that is 26 reactors.

Monitoring methods applied to main primary and secondary system Pressure Equipment

The Order of 10 November 1999 specifies that the non-destructive testing processes used for in-service monitoring of the Pressure Equipment (PE) of the main primary and secondary systems of nuclear power reactors must be qualified before they are used for the first time. This qualification is granted by a body comprising experts from both inside and outside EDF whose expertise and independence are verified by the French accreditation Committee (Cofrac).

Qualification is a means of guaranteeing that the non-destructive testing process actually achieves the anticipated level of performance as described in specifications drawn up beforehand.

Owing to the radiological risks associated with radiographic inspection, ultrasound inspections are preferred, provided that they offer equivalent inspection performance.

To date, more than 90 non-destructive test processes have been qualified for the in-service inspection programmes. New development and qualification processes to address new needs are in progress.

With regard to the Flamanville EPR, virtually all of the test processes for in-service monitoring of the main primary and secondary systems PE were qualified ahead of the Pre-Service Inspection (VCI) of the main primary and secondary systems, corresponding to more than 30 qualified processes specific to the EPR.

2.2.4 Assessment of Pressure Equipment in operation

The reactor pressure vessels

As part of the preparation for the fourth periodic safety reviews of the 900 MWe reactors (see point 2.10.3 and Notable Events in the introduction to this report), EDF sent ASN a dossier in 2017 substantiating the in-service strength of these reactors after 40 years of operation. The generic approach adopted by EDF consists in conservatively considering the mechanical properties of the vessel experiencing the worst-case irradiation embrittlement for the 900 MWe reactors. EDF carried out fast fracture resistance studies taking account of the changes in the properties of the materials and will carry out inspections to check there are no prejudicial defects in the steel during the ten-yearly outage of each reactor.

The principles of the reactor vessels in-service strength demonstration

The regulations in force require in particular that the licensee:

- identify the operating situations with an impact on the vessel;
- take measures to understand the effect of ageing on the properties of the materials;
- deploy resources to enable it to ensure sufficiently early detection of defects prejudicial to the integrity of the structure;
- eliminate all cracks detected or, if this is impossible, provide appropriate specific justification for retaining such a type of defect as-is.

This generic approach was submitted to the Advisory Committee for Nuclear Pressure Equipment (GPESPN) for its opinion on 20 November 2018, 15 October 2019 and 8 September 2020. The examination concerned the defects analysed, the estimated irradiation ageing of the metal of the vessel, the thermo-mechanical analyses and the studies assessing the margin with respect to fast fracture of the vessels, the classification of small primary break transients and justification of the level of residual stresses in the circumferential welds of the core shells.

The studies carried out conclude that the vessels with no faults are capable of functioning for a further ten years.

For the reactor vessels on which previous inspections showed that there were manufacturing flaws, specific studies will be performed before the ten-yearly outage of each of the reactors concerned. This was notably the case for Tricastin NPP reactor 1.

Cast elbow assemblies

Cast elbow assemblies are piping components installed on PWR main primary systems. They are installed on the hot and cold legs.

The cast elbow assemblies installed on the 900 MWe reactors were made of austenitic-ferritic stainless steel. The ferritic phase experiences ageing under the effect of temperature. Certain alloy elements present in the material accentuate this susceptibility to ageing. The result is a deterioration of certain mechanical properties, such as toughness and resistance to ductile tearing.

In addition, these elbow assemblies comprise shrinkage clusters or filaments, or solidification cracks, inherent in the static casting manufacturing method, which could, when combined with thermal ageing, increase the risk of fast fracture.

EDF has carried out extensive work to learn more about these materials, their ageing kinetics and to assess the fast fracture margins.

The dossier produced by EDF was examined by ASN with production of an opinion from the GPESPN on 23 May 2019. Following this analysis, ASN sent EDF requests for additional substantiation of the predicted behaviour of the aged material, identification of the flaws present in the cast elbow assemblies, analysis of the fast fracture margins of the elbow assemblies and in-service monitoring of these components.

Regulatory reference files
The licensee is required to keep and update the regulatory reference files required by the above-mentioned Order of 10 November 1999 with regard to MPS and MSS monitoring. These files consist of design, manufacture, overpressure protection files, materials files, in-service observations and, as applicable, deviations processing files. The licensee is required to update these files as often as necessary and at periodic requalification of the main primary and secondary systems. Owing to the standardised nature of the French NPP reactors, EDF can perform a generic update of these files. For the fourth periodic safety reviews of the 900 MWe reactors, EDF carried out this update, which is particular in that the design hypotheses were initially produced for 40 years of operation.

ASN thus examined the hypotheses and methods used by EDF for updating the equipment files. The entire analysis was the subject of an opinion from the GPESPN on 8 October 2019. ASN also examined all the monitoring programmes scheduled for the MPS and MSS equipment. Following this examination, ASN considered that the overall approach adopted by EDF is satisfactory, while nonetheless asking it to reinforce certain examinations.

Operation of Pressure Equipment
ASN considers that the situation of the second containment barrier is a point requiring continued vigilance in 2020, the year having been marked by the detection of significant levels of fouling in the SGs on some reactors, liable to impair their operating safety. This finding revealed the inability of maintenance to guarantee a satisfactory level of cleanness. The monitoring strategy for the secondary part of the SGs deployed by EDF was revised in mid-2020 to better prevent these situations.

In addition to its assessment of this situation, ASN notes that replacement of the SGs for Gravelines NPP reactor 6 had to be postponed again because of deviations affecting the manufacture of this equipment.

The in-service monitoring of the other MPS equipment, pursuant to the Order of 10 November 1999, is carried out appropriately. In 2017, the detection of a crack in a reactor vessel bottom head penetration on the Cattenom NPP reactor 3, the cracking of two plugs installed on the SG of the Paluel NPP reactor 1 in 2016, the perforation of five SG tubes on reactors 2 of the Belleville-sur-Loire and Flamanville NPPs in 2019, the perforation of an SG tube on the Belleville NPP reactor 1 and detection of a boiler effect in an SG of the Nogent-sur-Seine NPP reactor 1 in 2020, illustrate the risk of further deterioration associated with the ageing of the installations. In response to the situations encountered in 2020, EDF reinforced its maintenance and inspection provisions, by increasing the level of stringency and developing new repair processes.

2.3 The containments

2.3.1 Monitoring the containments

The containments are monitored and tested to check their compliance with the safety requirements. More specifically, their mechanical behaviour must guarantee good tightness of the reactor building if the pressure inside it were to exceed atmospheric pressure, which can happen in certain types of accidents. This is why, at the end of construction and then during the ten-yearly inspections, these tests include an inner containment pressure rise with leak rate measurement. These tests are required by the Order of 7 February 2012, setting the general rules concerning Basic Nuclear Installations (BNIs).

2.3.2 Assessment of the condition of the containments

Overall management of the containment function
ASN observes occasional but recurring unavailability of certain equipment participating in the containment function, such as the points of access to the interior of the containment (airlocks and equipment hatch), the circuit depressurising the annulus between the double-wall containments or the control room ventilation system. These unavailabilities will require an analysis and discussions with EDF in 2021 in order to identify any improvements needed.

Since 2016, EDF has also been carrying out an action plan with the main aim of guaranteeing that the flowrates in the ventilation systems meet the safety requirements both for the containment and for thermal conditioning of the installations, in the light of the changes made to the reactors since they were built. In order to achieve this goal, the action plan is being deployed, reactor by reactor, on all the ventilation systems concerned, and includes an inventory of the condition of the equipment and ducts. Whenever necessary, EDF is carrying out repairs and improvements and making the necessary adjustments to the ventilation flowrates. In order to check correct implementation of this plan and attainment of the corresponding safety objectives, ASN will be conducting a campaign of dedicated inspections in 2021.

Single wall containments with an internal metal sealing liner
The ten-yearly tests on the 900 MWe reactor containments carried out since 2009 for their third ten-yearly inspections did not generally bring to light any particular problems liable to compromise their operation.

The containment of Bugey NPP reactor 5 did however need to be repaired, following damage to the tightness of its metal liner at the lower part of the reactor building, observed in 2015. EDF implemented specific monitoring. The tightness of this containment will receive particularly close attention during the fourth periodic safety review of this reactor in 2022.

The results of the tests on the containments of the 900 MWe reactors, carried out for the first time during their fourth ten-yearly outage on Tricastin NPP reactor 1 and Bugey NPP reactor 2, were satisfactory.

Monitoring of the containments was examined by ASN as part of the generic phase of the fourth periodic safety review of the 900 MWe reactors. ASN considers that monitoring must also cover the cleanness of the containment domes and that EDF must provide appropriate means of investigation for the pre-stressing tendon anchor zones on these domes.

Double-wall containments
The tests on 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 a loss of pre-stressing of certain tendons that was greater than anticipated at the design stage.

EDF then initiated major work consisting in locally applying a resin sealing coating to the interior and exterior surfaces of the inner wall of the containments of the most severely affected 1,300 MWe reactors, as well as to the 1,450 MWe reactors. This work continued in 2020. The tests performed since completion of this work have all complied with the leak rate criteria.

ASN remains vigilant with regard to changes in the leaktightness of these containments and to maintaining the long-term effectiveness of the coatings.

During the 2013 examination on the effectiveness of the double-wall reactor containment function, ASN noted that the characteristics of some containments were liable to create internal swelling of the concrete prejudicial to its tightness in the long-term. Since this examination, EDF has initiated measures to characterise and monitor the phenomena which could affect the concrete of the containments. The analyses carried out by EDF notably showed that the kinetics of the development of these phenomena are very slow and that the containments concerned suffer from no structural damage. ASN remains vigilant with regard to the medium to long-term development of the phenomena involved.

Modelling of the containments of the 1,300 MWe and 1,450 MWe reactors in a severe accident situation show particular behaviour, which leads to a risk of cracking in part of the thickness of the dome, in certain accident scenarios. In 2019, EDF transmitted data concerning this behaviour, and they are currently being examined by ASN.

2.4 Risk prevention and management

2.4.1 Monitoring the drafting and application of the General Operating Rules

The General Operating Rules (RGE) cover the operation of nuclear power generating reactors. These are drafted by the licensee and are the operational implementation of the hypotheses and conclusions of the safety assessments constituting the nuclear safety case. They set the limits and conditions for operation of the installation.

Normal and degraded mode operation

Operating Technical Specifications

The Operating Technical Specifications (STE), which constitute Chapter III of the RGE, define the normal operating conditions based on the facility's design and sizing hypotheses and require the systems needed for maintaining the safety functions, in particular the integrity of the radioactive substance containment barriers and the monitoring of these functions in the event of an incident or accident. They also stipulate the action to be taken in the event of temporary failure of a required system or if a limit is exceeded, situations which constitute "degraded mode" operation.

The STEs evolve to integrate the lessons learned from their application and the modifications made to the reactors. The licensee can also modify them temporarily if need be, for example to carry out an operation in conditions that differ from those initially considered in the nuclear safety case. It must then demonstrate the relevance of this temporary modification and define adequate compensatory measures to control the associated risks.

Depending on their significance, STE modifications that could affect safety require either submittal of an authorisation application to ASN or notification to ASN before they are implemented.

During NPP inspections, ASN verifies that the licensee complies with the STE and, as necessary, the compensatory measures associated with any temporary modifications. It also checks the consistency between the modifications made to the facilities and the normal operating documents, such as operational control instructions and alarm sheets, and the training of the persons responsible for applying them.

Periodic tests

The Protection Important Component (PIC) of persons and the environment undergo qualification to guarantee their ability to perform their assigned functions in the situations where they are needed. The periodic tests of these equipment items help check their continued qualification and regularly verify that they will be available when required. The periodic test rules for equipment important for safety are incorporated into the general operating rules of the reactors. They set the nature of the technical checks to be performed, their frequency and the criteria for determining the satisfactory nature of these checks.

ASN ensures that the periodic tests on the equipment important for safety are pertinent and are continuously improved. It carries out this verification when examining the reactor commissioning authorisation application and then the applications for authorisation to modify the RGE. During inspections, it also verifies that these periodic tests are carried out in accordance with the test programmes stipulated in the RGE.

Core physics tests

The core physics tests contribute to the first two levels of Defence in Depth. Their purpose is, on the one hand to confirm that the core in operation is compliant with the design baseline requirements and the safety case and, on the other, to calibrate the automatic control and protection systems. These tests, prescribed in the RGE, are performed periodically.

The physics tests at restart are comparable to requalification tests following reloading of the core. The physics tests during the cycle and for the cycle extension guarantee the availability and representativeness of the instrumentation as well as the performance of the core in operation.

The modifications to the RGE concerning core physics tests are made using a process similar to that for STE modifications and generally require ASN authorisation.

During the on site inspections, ASN checks the conformity of the tests performed (compliance with procedures and criteria to be verified) and EDF's organisation during these particular operating phases.

Operating rules in the event of an incident or accident

Operation in the event of an incident or accident

The strategies and reactor operating rules for an incident or accident situation are defined in the RGE. These evolve notably to take account of experience feedback from incidents and accidents, to correct the anomalies detected during their application or to take account of modifications made to the facilities, in particular those resulting from the periodic safety reviews. Most of these modifications require ASN authorisation.

ASN regularly checks the processes to draft and validate the incident or accident operating rules, their pertinence and how they are implemented.

To do this, ASN can place the facility's control teams in a simulated situation to check how they apply the above-mentioned rules and manage the specific equipment used in accident operating situations. It in particular ensures correct application of the emergency teams organisation principles described in the EDF baseline requirements validated by ASN. This organisation more particularly requires that each emergency team member take part in an exercise at least once a year.

Operation in a severe accident situation

Following an incident or accident, if the safety functions (control of reactivity, cooling and containment) are not guaranteed owing to a series of failures, the situation is liable to develop into a severe accident following severe fuel damage. When faced with such unlikely situations, the installation control strategies place emphasis on preserving the containment in order to minimise releases into the environment. The implementation of these strategies mobilised the expertise of the local and national emergency teams. These teams draw on the On site Emergency Plan (PUI) plus the severe accident intervention guide and the emergency teams action guides in particular.

THE IMPACT OF COVID-19

The Covid-19 pandemic health crisis required the adoption of special measures to guarantee the safety of EDF's Nuclear Power Plants (NPPs).

The travel restrictions put in place by the Government in the spring of 2020 at first severely reduced EDF's ability to carry out scheduled maintenance work during the reactor refuelling outages. Faced with this situation, EDF decided to extend the theoretical duration of all the scheduled outages and to postpone or cancel certain others. ASN made sure that the maintenance and outage operations were pushed back by EDF in compliance with the applicable safety rules.

In terms of organisation, EDF adopted measures to guarantee the safety of the installations, while complying with the health rules in force. Many members of staff were assigned to home-working. For the persons required to be physically present in the NPPs, notably for the control teams, steps were taken to minimise contacts within the teams and avoid crossovers between the various teams. Steps were taken to guarantee a response capacity in an emergency.

ASN found that EDF paid particular attention to ensuring that the safety of the facilities remained the number one priority for everyone. Special attention will also need to be given to prioritisation and correct performance of the activities which were postponed for several months owing to the health crisis; these postponements entail an increase in the activities to be performed in the coming months and provisions will be required to ensure that this can be done in compliance with the safety rules.

ASN asked EDF to draw conclusions from this period, notably with regard to the resulting organisational changes.

ASN periodically examines the strategies developed by EDF in these documents, in particular for the reactor periodic safety reviews.

2.4.2 Assessment of reactor operations

Normal and degraded operation

ASN observes that the vast majority of NPPs made significant progress in 2020 with respect to the rigorousness of monitoring in the control room and control of the installations. In most cases, this progress was accompanied by a clear reduction in the number of unauthorised excursions from the operating range and the number of failures to comply with the operating control rules. This improvement could be the result of the implementation on certain sites of action plans to reinforce rigorousness and process safety difficulties identified. It could also be explained by the measures adopted by EDF to manage the Covid-19 pandemic: organisational changes were made to the working of the operating teams and, in order to limit contacts, this involved keeping access to the control room by other personnel to a minimum. This led to a calmer environment in the control rooms.

ASN will be monitoring development of the situation with interest over the coming years and will continue to check deployment of the action plans initiated on this subject.

However, on the majority of sites, ASN does observe an increase in the number of significant events. An analysis of their causes reveals that inappropriate documentation was used by the control team or that this documentation was incorrectly used. ASN also observes a significant rise in the average time taken to detect non-compliance with the operating technical specifications. The steps taken by EDF to manage the Covid-19 pandemic mentioned in the previous paragraph led to a degree of isolation of the various actors and could be one of the causes of these developments.

ASN will thus be reinforcing its vigilance with regard to the quality of the operating documentation and its correct use by the operating teams. The root causes of the delays in detecting non-compliances with the operating rules will have to be identified and dealt with.

In 2020, the periodic tests were the cause of several generic significant events, owing to inappropriate implementation of the testing rules in the operating documents or test rules that are inconsistent with the rest of the general operating rules. ASN will be attentive to ensuring that EDF learns the appropriate lessons from these events.

Operation in an incident, accident, or severe accident situation

ASN carried out several inspections in 2020 on the organisational and technical arrangements made by EDF to deal with an incident and accident situation. Despite the health context, most of these inspections were carried out on site. A tightened inspection was in particular carried out in the Cattenom NPP.

During these inspections, ASN checked application of the operating instructions applicable to an incident or accident situation. These inspections almost always include a simulation involving the EDF teams.

During these inspections, management of operation in an incident or accident situation was considered to be satisfactory. However, as in 2018 and 2019, ASN found that certain operating documents contained errors, inaccuracies, or even instructions that were impossible to carry out. EDF is correcting the errors and inaccuracies detected within time-frames that are on the whole satisfactory, except when this correction depends on the EDF national engineering teams.

In 2020, EDF activated its PUI for a fire outside the controlled area in the Belleville-sur-Loire NPP. The situation did not require any population protection measures.

In 2020, a limited number of inspections on the emergency organisation and resources were carried out owing to the health situation. They did however confirm the findings in previous years, that is a satisfactory level of assimilation of the organisation, preparedness and management principles for emergency situations.

Finally, in 2021, ASN will continue to check the application of the provisions of its resolution 2017-DC-0592 of 13 June 2017 concerning the obligations on BNI licensees in terms of preparedness for and management of emergency situations and the content of the PUI. Work to ensure compliance with the provisions of this resolution is continuing, with deadlines staggered until 1 January 2022. ASN will continue to check the steps taken by EDF with regard to emergency organisation in the event of an external hazard of extreme intensity.

2.4.3 Monitoring maintenance of the facilities

Preventive maintenance is an essential line of defence in maintaining the conformity of a facility with its baseline safety requirements. This is an important topic, checked by ASN during its inspections in the NPPs.

In order to improve the reliability of the equipment important for safety but also industrial performance, EDF is optimising its maintenance activities, drawing on practices used in conventional industry and by the licensees of NPPs in other countries.

Since 2010, EDF has thus initiated the deployment of a new maintenance methodology, called AP-913, developed by the American nuclear licensees. The main interest of this method is to make the equipment more reliable through in-service monitoring, allowing improvements to preventive maintenance.

Deployment of this maintenance methodology is based on implementation of the following six processes:
- identification of critical equipment and definition of the associated maintenance and monitoring programmes;
- definition of equipment monitoring and maintenance requirements;
- equipment and systems performance analysis;
- definition and oversight of corrective measures;
- continuous improvement of baseline requirements and oversight of reliability;
- equipment lifecycle management.

After an AP-913 deployment review in 2016, EDF developed its practices in order to guarantee the quality of maintenance work, refocus performance monitoring on the most important equipment and systems and optimise the volume of maintenance operations.

2.4.4 Assessment of maintenance

The organisation in most NPPs for successfully carrying out large-scale maintenance was satisfactory in 2020, including in a context made complicated by the Covid-19 pandemic. However, ASN regularly identifies points for improvement concerning reactor maintenance, such as taking account of the various hazards, the preparation of activities or the traceability of the work done. The procurement of non-conforming spare parts once again this year led to faults in the management of the activities. Incorrectly applied national EDF documents or incorrect operational documents are also the cause of inappropriate maintenance operations or maintenance quality defects. Poor performance of the work is sometimes detected belatedly, in other words only during the operations to requalify the equipment after the maintenance work. Finally, ASN observed that the requalification tests are not always able to detect equipment defects following maintenance or modification work.

In 2020, ASN confirms the improvement in the technical oversight of contractor operations and monitoring, particularly through the use of computerised tools recently deployed in the NPPs. However, the root cause of several significant events is still maintenance non-quality undetected by monitoring or by first level analyses.

In 2019, ASN asked EDF for a review of its maintenance policy and the adaptations made. In 2021, ASN will examine the replies provided by EDF in 2020, in particular with regard to the observations that it regularly issues.

In the context of the continued operation of the reactors, the “major overhaul” programme and all the modifications made as a result of the lessons learned from the accident at the Fukushima Daiichi NPP, ASN considers that it is important for EDF to continue with its efforts to remedy the difficulties encountered and improve the quality of its maintenance activities.

The Independent Safety Organisation

At EDF, the 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 Nuclear Power Plant, the FIS comprises safety engineers and auditors, who conduct a daily check on the safety of the reactors. The working of each FIS is checked and evaluated at a national level by the FIS of EDF’s Nuclear Production Division. Finally, the EDF internal inspectorate, in particular the general inspector reporting to the Chairman of the EDF group, assisted by a team of inspectors, represents the highest level of independent verification of nuclear safety within the EDF group.

2.4.5 Preventing the effects of internal and external hazards

Fire risks

In the same way as the other BNIs, NPPs are covered by ASN resolution 2014-DC-0417 of 28 January 2014, relating to the rules applicable to BNIs for controlling fire risks.

The way the fire risk is taken into account in the NPPs is based on the principle of defence in depth built around three levels, that is the design of the facilities, fire prevention and firefighting.

Design rules must prevent a fire from spreading and mitigate its consequences; they are based primarily on “fire sectorisation”. This involves dividing the facility into sectors and containment areas designed to keep the fire within a given perimeter bounded by items (doors, walls and fire dampers) offering a specified fire resistance duration. The main purpose is to prevent a fire spreading to two redundant equipment items performing a fundamental safety function.

Prevention primarily consists in:
- ensuring that the nature and quantity of combustible material in the premises remains below the hypotheses adopted for fire sectorisation;
- identifying and analysing the fire risks in order to take steps such as to avoid them. More specifically, for all the work liable to generate a fire, a “fire permit” must be issued and protective measures taken.

Finally, the detection of an outbreak of fire and fire-fighting should enable a fire to be brought under control and then extinguished within a time compatible with the fire resistance duration of the sectorisation elements.

ASN checks that the fire risk is taken into account in the NPPs, notably through an analysis of the licensee’s baseline safety standards, monitoring of significant events reported by the licensee and inspections performed on the sites.

The important risks associated with fire have been the subject of numerous ASN requests since 2003 and ASN thus reminded EDF in 2016 that, for the purposes of the fourth periodic safety review of the 900 MWe reactors, it expected a well-structured and robust safety case based on a Defence in Depth approach. ASN is examining the justification methods produced by EDF. These were submitted to the GPR for analysis in 2019. This examination showed that the changes proposed by EDF represented considerable improvements to the safety case (for example, sectorisation resistance studies, account taken of the effect of smoke). In addition, the new methods adopted identified sectorisation aspects for which correct working is particularly important. For example, the fire doors which are required to be closed were identified and will be subject to specific monitoring.

Explosion risks
An explosion can damage the items essential for maintaining safety or lead to rupture of the containment and the dispersal of radioactive materials into the facility, or even into the environment. Steps must thus be taken by the licensee to protect the sensitive parts of the facility against explosions.

ASN checks these prevention and monitoring measures, paying particular attention to ensuring that the explosion risk is taken into account in EDF's baseline safety requirements and organisation. ASN also ensures compliance with the "Explosive Atmospheres" (ATEX) regulations to ensure worker protection.

Internal flooding risks
An internal flood, in other words which comes from within the facility, may lead to failure of equipment necessary for reactor shutdown, fuel cooling and containment of radioactive products. Steps are therefore taken to prevent internal flooding (maintenance of piping carrying water, etc.), or mitigate its consequences (presence of floor drains and water extraction pumps, installation of sills or leaktight doors to prevent the flood from spreading, etc.). These measures are regularly inspected by ASN.

ASN remains vigilant with regard to the risks of internal flooding as a result of an earthquake, as well as with regard to the integration of operating experience feedback, in particular the processing of deviations affecting certain internal flooding protection measures.

External flooding risks
Following the partial flooding of the Blayais NPP in December 1999, the licensees, under the supervision of ASN, reassessed the safety of their facilities in the face of this risk, in conditions that were more severe than before, and made numerous safety improvements, according to a schedule defined according to the risks. In accordance with the ASN requirements, EDF completed the required work on all its nuclear power reactors in 2014.

At the same time, to ensure more exhaustive and more robust integration of the flooding risk, as of the facilities design stage, ASN published Guide No. 13 in 2013 concerning BNI protection against external flooding. For the existing facilities, ASN asked EDF in 2014 to take account of the recommendations of the Guide on all its reactors:
- for the 1,300 MWe reactors, ASN asked EDF to give priority to the third periodic safety review;
- for the other reactors in service, EDF will give priority to the next periodic safety reviews (fourth reviews for the 900 MWe reactors and second reviews for the 1,450 MWe reactors).

Following the stress tests performed in the wake of the Fukushima Daiichi NPP accident, ASN considered that with regard to flooding protection, the requirements resulting from the complete reassessment carried out following the flooding of the Blayais NPP in 1999 would be able to provide the NPPs with a high level of protection against the external flooding risk. However, ASN issued several resolutions in June 2012 asking the licensees:
- to reinforce NPP protection against certain hazards, such as intense rainfall and earthquake-induced flooding;
- to define and implement a "hardened safety core" of material and organisational measures to control the fundamental safety functions in extreme situations and in particular in the case of flooding beyond the design-basis safety requirements (see point 2.9).

Seismic risks
Although seismic activity in France is moderate or slight, EDF's inclusion of this risk in the safety case for its nuclear power reactors is the subject of constant attention on the part of ASN, given the potential consequences for the safety of the facilities. Seismic protection measures are designed into the facilities. They are periodically reexamined in the light of 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 used to determine the seismic risk for surface BNIs (except for radioactive waste long-term disposal facilities).

This Basic Safety Rule is supplemented by ASN Guide 2/01 of May 2006 which defines acceptable calculation methods for a study of the seismic behaviour of nuclear buildings and particular structures such as embankments, tunnels and underground pipes, supports or tanks.

The design of the buildings and the equipment important for safety in the NPPs must thus enable them to withstand earthquakes of an intensity greater than the strongest earthquakes that have occurred in the region. EDF's NPPs are thus designed for seismic levels incorporating the local geological features specific to each one.

As part of the periodic safety reviews, the seismic reassessment consists in verifying the adequacy of the seismic design of the facility, taking account of changing knowledge about seismic activity in the region of the site or about the methods for assessing the seismic behaviour of elements of the facility. The lessons learned from international experience feedback are also analysed and integrated into this framework.

Changing knowledge leads EDF to reassess the seismic hazard during the periodic safety reviews.

Following the Fukushima Daiichi NPP accident, ASN instructed EDF to define and implement a "hardened safety core" of material and organisational measures to control the fundamental safety functions in extreme situations comparable, in the French context, 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 those adopted in the design or periodic safety review of the installations.

In order to define this exceptional level earthquake, ASN asked EDF to supplement the deterministic approach to defining the seismic hazard with a probabilistic approach, which would be more closely in line with international best practices.

Heatwave and drought risks
During the heat waves in recent decades, some of the watercourses used to cool NPPs experienced a reduction in their flow rate and significant warming. Significant temperature rises were also observed in certain NPP premises housing heat-sensitive equipment.

EDF took this experience feedback into account and initiated reassessments of the operation of its facilities in air and water temperature conditions more severe than those initially included in the design. In parallel with development of these "extreme heat" baseline safety requirements, EDF initiated the deployment of a number of priority modifications (such as the increase in the capacity of certain heat exchangers) and implemented operating practices optimising the cooling capacity of the equipment and improving the resistance of equipment susceptible to high temperatures.

For the periodic safety review of its reactors, EDF has initiated a modifications programme on its facilities designed to provide protection against heat wave situations. The capacity of certain

Operation of nuclear reactors during heat waves

The temperatures considered in the nuclear reactors safety case are regularly reassessed, notably during the periodic safety reviews. These reassessments take account of climate change.

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

1. **The operation of safety systems during a heat wave:**
   - In a heat wave, ventilation and air-conditioning systems are needed to guarantee the operation of the safety systems of the nuclear reactors.
   - Since the heat waves of 2003 and 2006, EDF has reinforced the ventilation and air-conditioning capacity of the premises containing the safety systems. These systems undergo preventive servicing, monitoring and maintenance and the general operating rules for the reactors make provision for steps to be taken in the event of failure of this equipment. This entails taking special measures, or even shutting down the reactor, as necessary.
   - In addition, EDF sets out special operating rules which, between April and October of each year, adapt the level of deployment of the internal organisations on the basis of the weather forecasts.
2. **Reactor cooling and effluent management in the event of drought or low water levels:**
   - Nuclear reactors must be permanently cooled in order to remain safe. Water is thus taken for this purpose from a watercourse or from the sea.
   - A period of drought can lead to a drop in the level and discharge of a watercourse. The licensee must permanently ensure that these remain sufficient to cool the safety systems. These parameters are specific to each nuclear reactor.
   - The discharge of the watercourse also affects the dispersal of liquid effluents from the nuclear reactors. For each Nuclear Power Plant (NPP), ASN sets a minimum watercourse discharge value at which effluent discharges are possible. Below this discharge rate (low water situation), effluent discharges are prohibited and the licensee has to store the effluents produced.
3. **Controlling thermal discharges:**
   - The water intake from watercourses or the sea to cool the reactor is generally speaking discharged at a higher temperature, either directly, or after cooling in the cooling towers, enabling some of the heat to be dissipated into the atmosphere.
   - In the case of NPPs using a watercourse, ASN has for each site defined the conditions for discharge of the water used for cooling. In order to protect the environment, the ecosystem in particular, limit values are set for the heating of the watercourse as a result of operation of the NPP, as well as for the temperature of the water downstream of the plant. If these limit values are exceeded, the licensee shall reduce the power of the reactor or shut it down. Since 2006, ASN has incorporated measures into the regulations covering NPP discharges, to define the operations of NPPs in exceptional climatic conditions leading to significant warming of the watercourse. These provisions are however only applicable if the security of the electricity grid is at stake. Temporary relaxation of the limit values for the thermal discharges may also be authorised by ASN, on the basis of a justified request from EDF, if there is a risk to the security of the electricity grid, as was the case during the heat waves of 2003 and 2006. In this case, environmental monitoring is reinforced.
   - During the heat waves of 2019, EDF had to shut down several reactors and reduce the power of some others.

cooling systems for equipment required for the nuclear safety case will in particular be improved.

EDF has also initiated a climatic monitoring programme to anticipate climate changes which could compromise the temperature hypotheses adopted in its baseline requirements.

ASN asked EDF to take account of the operating experience feedback from the heatwaves of 2015, 2016 and 2019, and their effects on the facilities.

Other hazards

The safety case for the EDF NPPs also takes account of other hazards such as high winds, snow, tornados, lightning, cold air temperatures, man-made hazards (transport of dangerous goods, industrial facilities, airplane crashes, etc.), and hazards affecting the heatsink.

2.4.6 Assessment of the risk prevention measures relating to hazards

The Fukushima Daiichi NPP accident led EDF to reinforce its organisation for the management of risks relating to extreme hazards. More specifically, networks of coordinators were set up for all the NPPs to oversee the implementation of the actions defined to deal with these hazards. Annual reviews are also held to improve this organisation.

Fire risks

ASN observes that management of the fire risk needs to be improved, with a number of outbreaks of fire recorded in 2020 comparable to that observed in 2018, whereas it had been lower in 2019.

The findings made in previous years are still relevant with regard to some of the sites inspected:
- deviations in management of equipment stores, which have high calorific potentials;
- deviations in the use of fire permits and management of the compensatory measures defined in the fire risk assessments that could be improved;
- deviations linked to the management of fire detection inhibitions;
- premises sectorisation anomalies management that could be improved in order to prevent the spread of a fire;
- firefighting equipment availability not guaranteed.

In 2020, ASN carried out inspections on the topic of fire management on all the NPPs, despite the constraints arising from the health situation and asked for corrective measures to be taken to remedy the findings made.

ASN observes the efforts made by certain sites to take the corrective measures needed, with the deployment of tools and

The defined requirements

The Order of 7 February 2012 states that a defined requirement is a "*requirement assigned to a Protection Important Component (PIC) of persons and the environment, so that it can, with the expected characteristics, perform the function stipulated in the safety case mentioned in the second paragraph of Article L. 593-7 of the Environment Code, or to an Activity Important for the Protection (AIP) of persons and the environment, so that it can meet its objectives with regard to this safety case*".

For the PIC, 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 PIC.

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.

action plans, but considers that if they are to be effective, the personnel must be given greater support with implementing them. ASN thus observed that in 2020, EDF had continued its actions to reduce errors in fire risk management in the premises identified as being particularly susceptible to this hazard.

In addition, the time taken to remedy certain deviations or to take corrective actions as a result of experience feedback needs to be reduced.

Finally, following an ASN request in 2019, EDF initiated a review to improve its firefighting organisation, notably by reinforcing the capacity of its response resources to deal with an established fire.

Explosion risks

Despite the steps taken by EDF, management of the explosion risks is not yet satisfactory on all the nuclear reactors. Certain maintenance work and inspections required by EDF's internal doctrine are not always carried out satisfactorily. Furthermore, ASN observes that the updating of certain documents (notably the procedures for periodic tests or for checks on piping carrying hazardous fluids), the integration of operating experience feedback, the processing of certain deviations and the deployment of certain modifications are sometimes postponed and this is not always justified given the potential safety consequences.

ASN notes the efforts made by EDF to reduce these deviations through the implementation of reinforced monitoring and deployment of action plans. Furthermore, in 2020, EDF worked on updating documents concerning protection against explosions, required by the regulations concerning the risks involved in the formation of ATEX and conducts conformity audits on equipment that is supposed to comply with the requirements of these regulations. This process should be continued in the coming years. ASN thus considers that EDF must continue to pay particular attention to this point and ensure that the explosion risk prevention approach is implemented with all necessary rigour on all the sites.

Internal flooding risks

Considerable efforts are required on most sites to improve control of the flooding risk, in particular with respect to:
- the maintenance of the necessary equipment (piping, floor drains, etc.);
- the risk assessments during maintenance operations and in the event of detection of a malfunction of a necessary equipment item;
- the compliance with the corrective action deadlines identified by the annual reviews;
- the training of the coordinators and awareness-raising among the EDF and contractor personnel.

In 2019, ASN thus sent requests to EDF asking it to supplement the approach adopted for improved control of the internal flooding risk, to ensure the correct operation of the floor drains, to reinforce maintenance of the piping liable to lead to internal flooding and to ensure improved management of their ageing.

EDF has initiated field visits to identify the piping which could cause internal flooding in the electrical buildings, which are particularly vulnerable to this risk, in order to assess the need to reinforce their maintenance. In accordance with ASN's requests, EDF will extend these surveys to the other buildings. ASN sees as positive the fact that EDF has initiated the refurbishment of the circuits of certain cooling systems that are particularly susceptible to corrosion.

Finally, for the fourth periodic safety review of the 900 MWe reactors, EDF has updated its safety case regarding internal flooding risks, notably by considering several possible water flow routes.

Seismic risks

The inspection programmes implemented by EDF lead it to regularly report significant safety events owing to the lack of seismic resistance of certain equipment. These events are the result of targeted inspections gradually being deployed by EDF. These non-compliances can have serious consequences in the event of an earthquake and they are thus systematically analysed. For example, in 2020, EDF reported a significant event, rated level 2 on the International Nuclear and Radiological Event Scale (INES scale) by ASN (see box page 302), owing to the lack of seismic resistance of equipment necessary for the correct functioning of the emergency diesel generator sets on several NPPs.

An earthquake occurred on 11 November 2019 in the municipality of Le Teil (Ardèche *département*). Following this earthquake, EDF implemented the operating procedure required in the event of an earthquake on the Cruas-Meysse NPP. This was because the seismic motion detected on this site reached the level requiring shutdown of the reactors so that checks could be carried out. An inspection programme was then defined and carried out before the reactors were restarted. In November 2019, ASN asked EDF to determine whether this earthquake should lead to a revision of the seismic levels to be adopted for protection of the Tricastin and Cruas-Meysse NPP sites. EDF's answer transmitted in 2020 is currently being examined.

Risks linked to extreme temperatures

The inspections concerning the risks associated with extreme temperatures show that EDF's organisation must be improved on the majority of sites. On several sites, ASN more particularly found a lack of forward planning in preparing the facility for the summer or winter configuration.

In 2020, at ASN's request, EDF ran operating tests on the emergency diesel generator sets during a period of high temperatures. The purpose of these tests is to confirm the qualification demonstration of this equipment.

Lightning risks

The inspections relating to lightning reveal the need on all sites to set up reinforced organisation and oversight to improve the integration of the regulatory requirements associated with the management of this hazard.

The lightning risk assessments may be based on information which does not actually reflect the real situation on the facilities. Despite a few improvements in 2020, ASN observed a significant delay in the performance of the work identified in the technical studies. ASN also regularly finds that the deadlines for performance of the periodic checks on the lightning protection systems by the competent inspection organisations are not adhered to. These points were the subject of requests for corrective action. EDF has defined a programme of work to improve the situation.

2.4.7 Monitoring facilities compliance with the requirements

Maintaining the conformity of the facilities with their design, construction and operating requirements is a major issue insofar as this conformity is essential for ensuring compliance with the safety case. The processes employed by the licensee, notably during reactor outages, contribute to maintaining the compliance of the facilities with the requirements resulting from this safety case.

Reactor outages

The nuclear power reactors must be periodically shut down for replacement of the fuel depleted during the electricity production cycle. One third or one quarter of the fuel is thus renewed at each outage.

These outages allow temporary access to certain parts of the facility which are not accessible during production, although with specific radiation protection precautions. They are thus put to good use for verifying the condition of the equipment by carrying out checks, tests and maintenance, as well as for performing works on the facility.

These refuelling outages can be of several types:

- Refuelling Outage (ASR) and Maintenance Outage (VP): these outages, which last a few weeks, are devoted to replacing a part of the fuel and to carrying out a verification and maintenance programme, which is more extensive during a VP than during an ASR.
- Ten-yearly outage (VD): this is an outage involving a programme of in-depth verification and maintenance. This type of outage, which lasts several months and takes place every ten years, enables the licensee to carry out large-scale operations such as the complete inspection and hydraulic testing of the reactor coolant system, hydrotesting of the containment or incorporation of design changes resulting from the periodic safety reviews.

These outages are scheduled and prepared by the licensee several months in advance. ASN checks the steps taken by the licensee to ensure the safety of the facility, environmental protection and radiation protection of the workers during the outage, as well as the safety of the reactor for the next production cycle.

Processing of deviations

A deviation is a non-compliance with a defined requirement or a requirement set by the licensee's integrated management system. A deviation may thus affect a structure, a system or a component of the facility. It may also concern compliance with an operating document or the working of an organisation.

The regulations require that the licensee identify all deviations affecting its facilities and process them. The activities related to the processing of deviations are activities important for the protection of persons and the environment. They are thus subject to oversight and monitoring requirements, the implementation of which is regularly checked by ASN.

In the light of the provisions of its resolution 2014-DC-0444 of 15 July 2014 concerning PWR shutdowns and restarts, the monitoring performed by ASN primarily concerns:

- during the outage preparation phase, the content of the outage programme drawn up by the licensee. As necessary, ASN may ask for additions to this programme;
- during the outage, through regular briefings and inspections, the implementation of the programme and the handling of any unforeseen circumstances;
- at the end of the outage, when the licensee presents the reactor outage review, the condition of the reactor and its suitability for restart. It is after this inspection that ASN may or may not approve reactor restart;
- after reactor restart, the results of all the tests performed during the outage and in the restart phase.

The identification and processing of deviations

The checks initiated by EDF within the framework of its operating baseline requirements and the additional verifications requested by ASN, on the basis more particularly of operating experience feedback, can lead to the detection of deviations from the defined requirements, which must then be processed. These deviations can have a variety of origins: design problems, construction errors, insufficient expertise in maintenance work, deterioration through ageing, organisational shortcomings, etc.

The steps taken to detect and correct deviations, specified in the Order of 7 February 2012, play an essential role in maintaining the level of safety of the facilities.

"Real-time" checks

Carrying out periodic test and preventive maintenance programmes on the equipment and systems contributes to identifying deviations. Routine visits in the field and technical inspection and verification of activities considered to be important for the protection of persons and the environment are also effective means of detecting deviations.

Verifications during reactor outages

EDF takes advantage of nuclear reactor outages to carry out maintenance work and inspections which cannot be performed when the reactor is generating electricity. These operations more particularly correct deviations already known, but can also lead to the detection of new ones. Before each reactor restart, ASN asks EDF to identify any anomalies not yet remedied, to take appropriate compensatory measures and to demonstrate the acceptability of these anomalies with respect to the protection of persons and the environment for the coming production cycle.

Check on conformity of the electrical power sources

In resolution 2019-DC-0662 of 19 February 2019, ASN instructed EDF to carry out checks on the conformity of the electrical power sources for its reactors, in particular the ultimate diesel backup generator sets.

During these checks, EDF detected seismic resistance anomalies on 37 reactors. These defects concern the incorrect installation of the elastomer couplings on piping, the corrosion of certain portions of pipes or their supports, connection errors in certain electrical cabinets and electrical cabinet or cooling tower anchor defects.

ASN rated this event level 1 or 2 on the International Nuclear and Radiological Event Scale (INES scale) depending on the reactor concerned, according to the nature of the defects encountered and the number of emergency diesel generating sets affected. This event had no consequences on the personnel, nor on the environment.

All of the defects detected were repaired by EDF or, with regard to the incorrect installation of certain elastomer couplings, were subject to reinforced monitoring until the next reactor outage, when they will be replaced.

In accordance with resolution 2019-DC-0662, the checks on the Nuclear Power Plant (NPP) electrical power sources will continue until the beginning of 2022, notably for those checks which can only be carried out during reactor refuelling outages.

Ten-yearly verifications: conformity checks

EDF carries out periodic safety reviews of the nuclear reactors every ten years, in accordance with the regulations (see point 2.10.2). EDF then carries out an in-depth review of the actual state of the facilities by comparison with the applicable safety requirements, more particularly on the basis of the in-service monitoring hitherto carried out, and lists any deviations. These verifications can be supplemented by a programme of additional investigations, the aim of which is to check the parts of the facility which are not covered by a preventive maintenance programme.

The additional verifications in response to ASN requests

In addition to the steps taken by EDF with regard to its operating baseline requirements, additional checks are carried out at the request of ASN, whether, for example, with regard to operating experience feedback about events which have occurred on other facilities, after inspections, or after examination of the provisions proposed by the licensee within the context of the periodic safety reviews.

Information of ASN and the public

When a deviation is detected, EDF, in the same way as any BNI licensee, is required to assess the impacts on nuclear safety, radiation protection and protection of the environment. If necessary, EDF then sends ASN a significant event notification. As of level 1 on the INES scale, the public is informed of the events thus reported on *asn.fr*

ASN requirements concerning repairs

For the most important deviations, ASN published its Guide No. 21 on 6 January 2015 regarding the handling of conformity deviations. This Guide specifies ASN's requirements concerning the correction of non-conformities and presents the approach expected of the licensee in accordance with the principle of proportionality. This is based more specifically on an assessment of the potential or actual consequences of any deviation identified and on the licensee's ability to guarantee control of the reactor in the event of an accident, by taking appropriate compensatory measures. The Guide also recalls the principle of correction of compliance deviations as soon as possible and in any case defines the maximum times allowed.

Significant events

EDF is required to notify ASN of and then analyse any significant events occurring in its NPPs (see chapter 3, point 3.3). Each significant event is, whenever appropriate, rated by ASN on the INES scale. This process of notification and analysis of significant events contributes to operating experience feedback and to the continuous improvement approach for the protection of the interests mentioned in Article L. 593-1 of the Environment Code.

At the local and national levels, ASN examines all significant events notified (a summary of their analysis for 2020 is given in point 2.4.8) and checks that these events have been processed by EDF. The significant events deemed noteworthy due to their severity or their recurrent or generic nature, undergo an in-depth analysis by ASN.

During inspections in the NPPs and the EDF head office departments, ASN checks the licensee's organisation and the steps taken to learn the technical and organisational lessons from operating experience feedback.

2.4.8 Assessment of facilities compliance with the applicable requirements

ASN has regularly pointed out to EDF that the organisational measures adopted to deal with deviations contained shortcomings, that the traceability of the steps taken to process deviations was insufficient and that the time taken to characterise, check and process deviations and inform ASN did not always comply with the requirements of the Order of 7 February 2012. In 2019, EDF therefore revised its internal baseline requirements regarding the management of deviations, in order to improve their processing and ensure that ASN is informed reactively and in a manner proportionate to the safety issues. In 2020, ASN found that the situation was continuing to improve. More specifically, EDF further improved its ability to correct deviations rapidly, even if efforts are still needed on this point.

In 2020, EDF again reported several significant events concerning the emergency diesel generators, revealing defects present since they were installed or related to in-service monitoring problems. In this respect, ASN instructed EDF to carry out complete conformity checks on the emergency diesels in a resolution of 19 February 2019 (see box). On this point, some checks will continue to be carried out until the beginning of 2022, given the scheduling of reactor outages enabling them to be performed.

In addition to the emergency diesel generating sets, the most significant deviations found in 2020 concerned the seismic resistance of the reactor safeguard and cooling equipment.

In 2020, ASN was also particularly vigilant with respect to controlling the conformity of the facilities during the fourth ten-yearly inspection of the Bugey NPP reactor 2. EDF's monitoring programme was the subject of specific inspections.

ASN will continue to be particularly attentive to the conformity of the facilities in 2021 and will in this respect continue its inspections of the condition of equipment and systems.

Finally, ASN observes that certain systems linked to the "support", "reactivity control" and "cooling" safety functions are subject to recurring unscheduled unavailability. This is notably the case with the reactor component cooling systems, post-accident monitoring, reactor nuclear power measurement and SG back-up feedwater supply. These unavailabilities will require an analysis and discussions with EDF in 2021 in order to identify any improvements needed.

Notification of significant events by EDF

Pursuant to the rules for the notification of significant events (see chapter 3, point 3.3), ASN received 740 Significant Safety Event (ESS) reports from EDF in 2020, along with 174 Significant Radiation Protection Event (ESR) reports and 61 Significant Environmental Protection Event (ESE) reports. The number of significant events fell by about 2.4% in 2020 by comparison with the previous year. This drop is the result of a significant fall in the number of ESE (83 ESEs in 2019).

Graph 1 shows the trend since 2010 in the number of significant events notified by EDF and rated on the INES scale.

Graph 2 shows the trend since 2010 in the number of significant events according to the notification field: ESS, ESR and ESE. Events not rated on the INES scale are also taken into account.

Significant events affecting several nuclear reactors are grouped under the term generic significant events. Twenty-six events of this type were reported in 2020 in the field of nuclear safety.

Reactor outages

The reactor outages schedule for 2020 was extensively disrupted by the health crisis. The travel restrictions put in place by the Government in the spring of 2020 at first severely reduced EDF's ability to carry out scheduled maintenance work during the reactor refuelling outages. EDF decided to prolong the theoretical durations of all the scheduled outages and to postpone or cancel some of them. ASN made sure that the maintenance and outage operations were pushed back by EDF in compliance with the applicable safety rules.

The conditions in which EDF carried out its activities were made more complicated by the implementation of barrier measures to prevent the spread of the disease.

2.5 Prevention and management of environmental and health impacts

2.5.1 Monitoring of discharges and of waste management

Monitoring the management of water intake and environmental discharges

The Environment Code gives ASN competence to issue binding requirements regarding BNI water intake and effluent discharges (see chapter 3, point 4.1). The laws and regulatory texts for protection of the environment that apply to French NPPs comprise generic texts, mainly the Environment Code, the Order of 7 February 2012 and ASN resolutions 2013-DC-0361 of 16 July 2012 relating to control of the detrimental effects and health and environment impacts of BNIs, and 2017-DC-0588 of 6 April 2017, concerning the methods of water intake and consumption, effluent discharges and environmental monitoring of PWRs, as well as regulatory texts specific to each of the NPPs:

- decisions setting the procedures for water intake and consumption and environmental discharges of liquid and gaseous effluents (chemical and radioactive);
- decisions setting the environmental discharge limits for liquid and gaseous effluents (chemical and radioactive); these decisions are approved by the Minister responsible for nuclear safety;
- the Orders of the Prefect authorising water intake and discharges of liquid and gaseous effluents: pre-dating November 2006, they contain binding requirements concerning the discharge procedures and limits specific to a nuclear site. In order to apply the new regulatory architecture to all the French NPP reactors, revision of the orders has led to them being repealed, with the adoption of ASN resolutions.

For each site, ASN sets the limit values for emissions, water intake and discharge of effluents on the basis of the best available technologies in technically and economically acceptable conditions, taking into consideration the characteristics of the installation, its location and the local environmental conditions.

ASN also sets the rules concerning the control of detrimental effects and the impact of PWRs on health and the environment. These requirements are notably applicable to the management and monitoring of water intake and effluent discharge, to environmental monitoring and to information of the public and the authorities (see chapter 3, point 4.1).

In setting these requirements, ASN uses operating experience feedback from all the reactors as the basis, while also taking account of operational changes (change in conditioning of systems, anti-scaling treatment, biocidal treatment, etc.) and changes to the general regulations.

Finally, every year, the NPP licensees send ASN an annual environmental report which notably contains a summary of the intakes from and discharges into the environment, any impacts they may have, the significant events which have occurred and the future outlook.

The impact of thermal discharges from the Nuclear Power Plants

NPPs discharge hot effluents into watercourses or the sea, either directly, from those NPPs operating with "once-through" cooling, or after cooling of these effluents in cooling towers, enabling some of the heat to be dissipated to the atmosphere. Thermal discharges from NPPs lead to a temperature rise between the points upstream and downstream of the discharge which, depending on the reactors, can range from a few tenths of a degree to several degrees. These thermal discharges are regulated by ASN resolutions.

Since 2006, provisions have been incorporated into these resolutions for advance definition of the operations of NPPs in exceptional climatic conditions leading to significant warming of the watercourse. These special provisions are however only applicable if the security of the electricity grid is at stake.

Monitoring of waste management

The management of the conventional and radioactive waste produced by the NPPs falls within the general framework of BNI waste management. The legal framework for the management of waste applicable to the NPPs comprises legislative and regulatory texts of general scope, notably the Environment Code, the Order of 7 February 2012 and ASN resolution 2015-DC-0508 of 21 April 2015 concerning the study of waste management and the inventory of waste produced in BNIs.

In compliance with the Environment Code, EDF carries out waste sorting at source, differentiating in particular between waste from nuclear zones and other waste. For all the waste, ASN examines the study produced by the licensee regarding waste management. This document is specific to each facility, as required by the regulations (see "Regulation" heading on *asn.fr*). This document more specifically presents a description of the operations which are the cause of production of the waste, the characteristics of the waste produced or to be produced, an estimation of the waste traffic volumes and a waste zoning plan.

Waste storage in the Blayais NPP

In addition, every year, each site sends ASN a summary report on its production of waste and the corresponding disposal routes, a comparison with the results of previous years, a summary of the site organisation and the differences observed with respect to the management procedures specified in the waste management study, the list of significant events which have occurred and the outlook for the future.

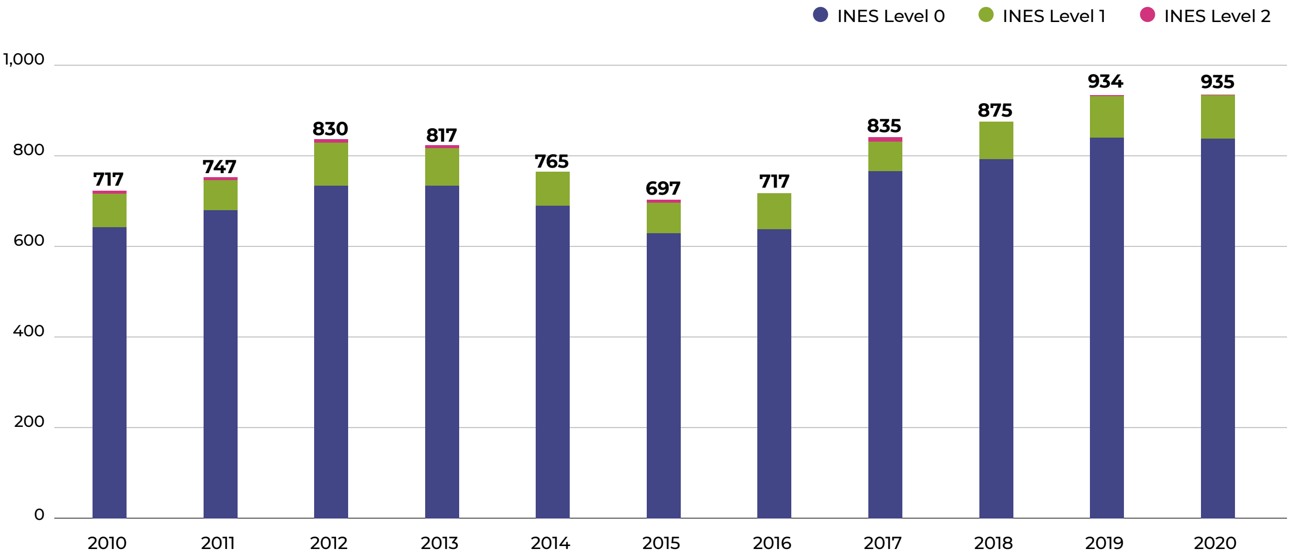
2.5.2 The prevention of health impacts and soil pollution

Prevention of pollution resulting from accidental spillage of dangerous substances

As on numerous industrial sites, the operation of an NPP involves the handling and storage of "dangerous" chemical substances. The management of these substances and the prevention

GRAPH 1

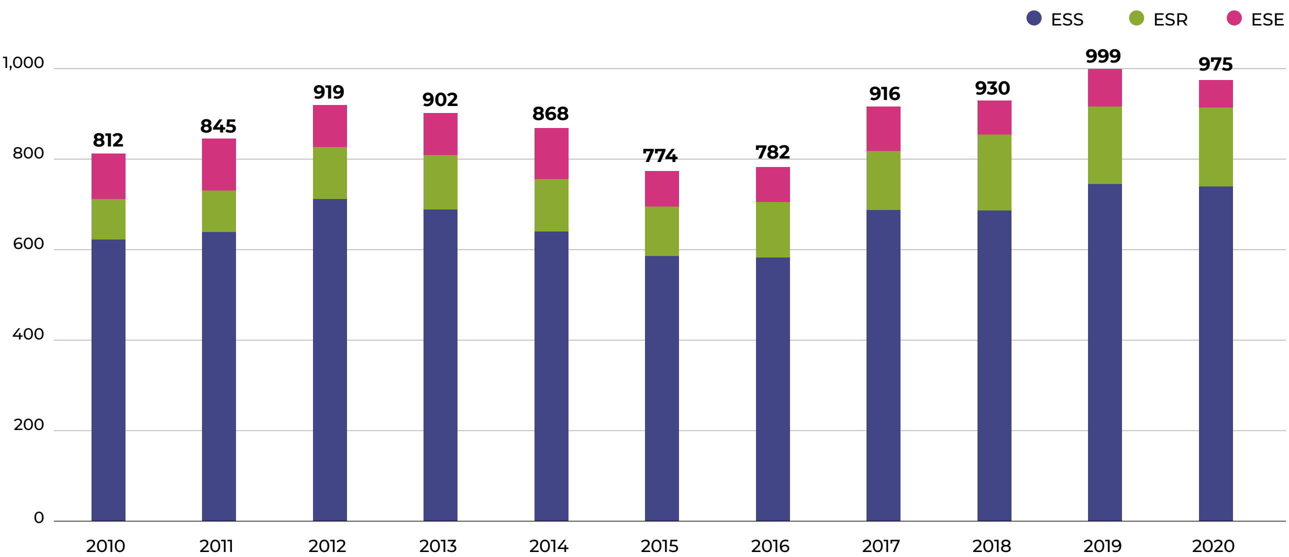
Trend in the number of significant events rated on the INES scale in the EDF Nuclear Power Plants between 2010 and 2020



This Graph includes radiation protection data for the Fessenheim NPP.

GRAPH 2

Trend in the number of significant events by domain in the EDF Nuclear Power Plants between 2010 and 2020



This Graph includes radiation protection data for the Fessenheim NPP.

of pollution, which are the responsibility of the licensee, are regulated by ASN resolution 2013-DC-0360 of 16 July 2013 and the Order of 7 February 2012 and must also comply with the requirements of the European texts. The licensee has obligations regarding the operational management of these substances and the identification of the corresponding potential hazards. It must also be able to take the necessary steps in the event of any incident or accident situations which would lead to pollution.

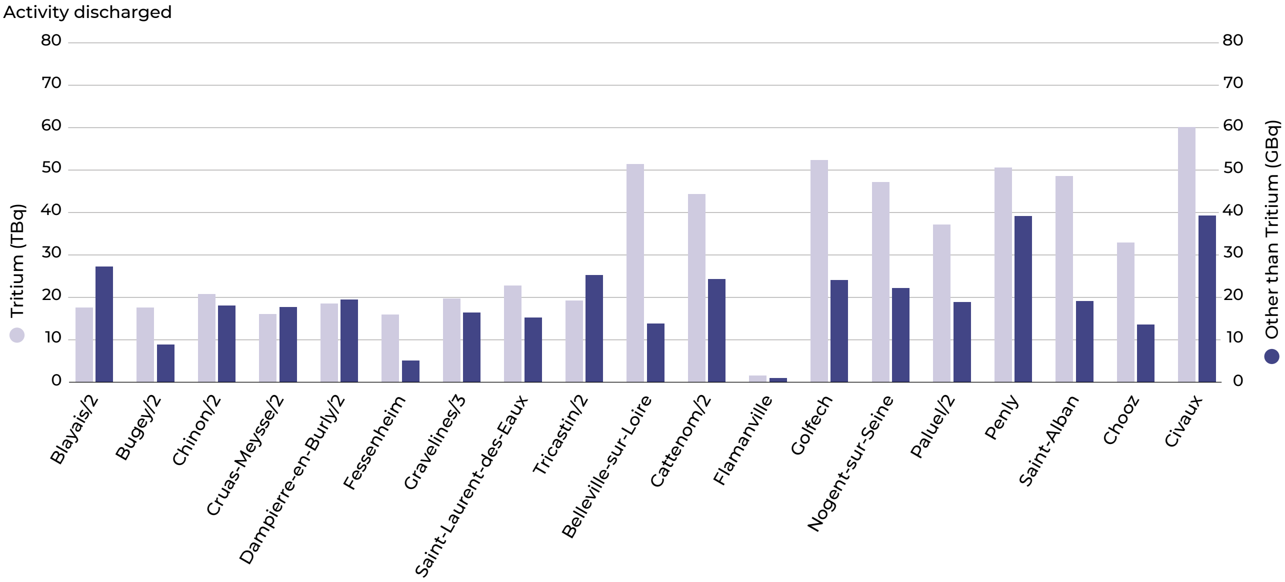
The licensee must thus for instance precisely identify the location of each dangerous substance on its site, along with the corresponding quantities. Drums and tanks must be labelled in compliance with the European Classification, Labelling, Packaging (CLP) regulation and there must be retention areas designed to collect any spills. The NPPs must also adopt an organisation and resources to prevent pollution of the natural environment (groundwater, river, soil).

For several years and at the request of ASN, EDF has been carrying out steps to improve its management of the pollution risk by working to improve the confinement of dangerous liquid substances on its sites.

Through its field inspections, ASN is closely monitoring the organisational and material provisions adopted by EDF to manage the dangerous substances present in its facilities and to deal with any pollution.

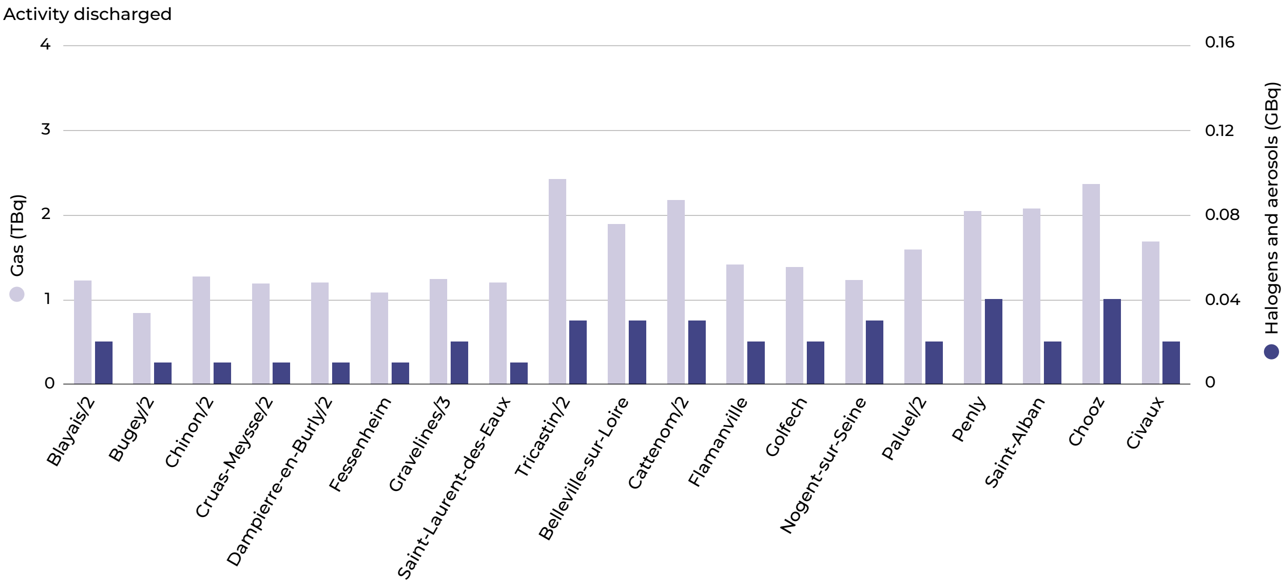
GRAPH 3

Liquid radioactive discharges for the Nuclear Power Plants in 2020 (per pair of reactors)



GRAPH 4

Gaseous radioactive discharges for the Nuclear Power Plants in 2020 (per pair of reactors)



As there can be a different number of reactors on each site, the results are given "per pair of reactors", to enable a comparison to be made from one site to another. This for example entails: keeping the results as they are for the Golfech site, which has two reactors; dividing by two those of Chinon, which has four reactors (Chinon/2); dividing by three those of Gravelines, which has six reactors (Gravelines/3). Moreover, the discharge data for each site, sent to ASN by EDF, are not representative of the operating time of the facilities or activities.

Prevention of the health impacts caused by the growth of legionella and amoeba in certain cooling systems of the Nuclear Power Plant secondary systems

Certain NPP cooling systems constitute environments favourable to the development of legionella and amoeba (see point 1.4).

ASN resolution 2016-DC-0578 of 6 December 2016 on the prevention of risks resulting from the dispersal of pathogenic micro-organisms (legionella and amoeba) by PWR secondary system cooling installations sets requirements concerning:

- the design, upkeep and monitoring of the facility;
- the maximum legionella concentrations in the water in the facility and downstream of it with regard to amoeba;
- the steps to be taken in the event of proliferation of micro-organisms in the systems, or infection, identified in proximity to the facility;
- information of the public and the administrations in the event of proliferation of micro-organisms.

Through file reviews and its field checks, ASN closely monitors the preventive or remedial measures taken by EDF to reduce the risk of the proliferation of these micro-organisms and the results of these actions, including the chemical discharges resulting from biocidal treatment.

2.5.3 Assessment of control of detrimental effects and impact on the environment

Assessment of prevention of detrimental effects, control of environmental discharges and waste management

In 2020, 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.

EDF's organisation for controlling the detrimental effects and impact of NPPs on the environment needs to be improved on most sites and ASN considers that the licensee needs to raise its level of vigilance on this topic.

Although ASN observes improved assimilation by the sites of the methodical analyses of the microbiological risks and efforts to improve the containment of dangerous liquid substances on certain sites, it nonetheless considers that corrective measures are still needed with respect to pollution prevention and waste management. EDF has defined a national action plan on this latter subject.

Inadequacies in the containment of dangerous liquid substances, observed during inspections in 2018 and 2019, led ASN to ask EDF for a review of all the NPPs. The information communicated offers a satisfactory level of detail on the current situation of the sites. ASN asked EDF to inform it of the steps it intends to take to improve the situation on each of the sites.

In 2020, as in previous years, ASN observed that discharges are well managed on most of the sites. However, certain events indicate occasional weaknesses

In January 2020, ASN served EDF with formal notice to transmit certain data required by its resolution 2013-DC-0360 concerning the Blayais, Bugey, Chinon, Chooz, Cruas-Meysse, Gravelines and Saint-Laurent-des-Eaux sites. EDF had not enclosed the following with the concluding report for the periodic safety review of certain installations:

- an analysis of the performance and the means for preventing and mitigating impacts and detrimental effects of the installation in the light of the effectiveness of the best available techniques;
- an analysis of the chemical and radiological status of the environment of the installation and its immediate vicinity.

EDF met the 2020 deadlines stipulated in this formal notice.

2.6 The contribution of man and organisations to safety

The contribution of people and organisations to the safety of NPPs is a decisive factor in all steps of the plant lifecycle (design, construction, commissioning, operation, decommissioning). ASN therefore focuses on the conditions which are favourable or prejudicial to the contribution to NPP safety by the operators and worker groups. It defines the Organisational and Human Factors (OHF) as being all the aspects of working situations and the organisation which will have an influence on the work done by the operators.

2.6.1 Monitoring how organisations work

The Integrated Management System

The Order of 7 February 2012 stipulates that the licensee must in particular have the technical skills needed to manage the activities involved in operation. Of these, the processing of significant events requires an in-depth analysis of the organisational and human causes in addition to the technical causes.

Furthermore, the above-mentioned order requires that the licensee define and implement an Integrated Management System (IMS) to ensure that the requirements concerning the protection of interests are systematically considered in any decision concerning the facility. This IMS must specify the steps taken with regard to organisation and to resources of all kinds, in particular those adopted to control the activities important for the protection of persons and the environment.

ASN oversight of the working of the organisations set up by EDF aims to check the IMS implementation procedures. ASN more particularly ensures that the design or modification approach adopted by the engineering centres at the moment of the design of a new facility or a modification to an existing facility takes account of the users' needs and does not compromise compliance with the defined requirements.

More broadly, ASN monitors the organisation put into place by EDF to manage the resources needed to perform these activities.

Management of subcontracted activities

Maintenance and modification activities on French reactors are to a large extent subcontracted by EDF to outside contractors. EDF justifies the use of subcontracting by the need to call on specific or rare expertise, as well as the highly seasonal nature of reactor outages and thus the need to absorb workload peaks.

EDF's decision to resort to subcontracting must not compromise the technical skills it must retain in-house in order to carry out its responsibility as licensee with regard to the protection of persons and the environment and to be able to effectively monitor the quality of the work performed by the subcontractors. Poorly managed subcontracting is liable to lead to poor quality work and have a negative impact on the safety of the facility and the radiation protection of the workers involved.

EDF takes the necessary steps to control the risks associated with the subcontracted activities and regularly updates them. EDF has thus reinforced the preparation of outages, more particularly to guarantee the availability of human and material resources.

ASN checks the conditions surrounding the preparation for (schedule, required human resources, etc.) and performance of the subcontracted activities (relations with the licensee, monitoring by the licensee, etc.). It also checks that the workers involved have the means needed (tools, operating documentation, etc.) to perform their tasks, in particular when these means are made available by EDF.

2.6.2 Assessment of the working of the organisations and control of activities

The overall organisation

ASN considers that EDF correctly managed the changes to its organisations made necessary by the health measures linked to the Covid-19 pandemic. Some of these changes were even beneficial to safety. This is the case with the steps taken to limit contacts with the control operators, which created a calmer atmosphere in the control rooms, and to extend the scheduled reactor outage durations, the effect of which was to reduce activity scheduling problems on certain sites.

Over and above the particular problem of the health crisis, ASN carried out a campaign of "explanatory" interviews in 2020, during which the inspectors urged the site personnel to discuss their experience and their day-to-day working conditions. During the course of these discussions, ASN found that the personnel were on the whole satisfied with their working conditions, but it did identify recurrent failings liable to degrade the quality of the work done (schedule changes increasing the time pressure or waiting times, logistics problems, problems with the provision of tools and spares, inappropriate operational documentation, rooms and equipment to which access was sometimes difficult, etc.). In some cases, ASN observed working groups that were in difficulty, notably with regard to maintaining a balance between workload and resources, as well as the management of interfaces with the other disciplines (operating and maintenance disciplines, for example). In 2021, ASN will remain vigilant with regard to these points. It will ensure that these difficulties experienced on a day to day basis by certain personnel do not cause them to lose sight of the meaning of their activity and the contribution of their actions to safety, notably through a process whereby certain deviations gradually become the norm.

Management of skills, training and qualifications

The organisation put into place on the sites to manage skills, qualifications and training remained on the whole satisfactory in 2020, despite the difficulties linked to the Covid-19 pandemic.

ASN observed robust implementation and assimilation of the discipline baseline requirements on the sites (baseline requirements identifying the duties of each discipline and the corresponding training path) and relatively good working by the specific training programming and follow-up entities (common training service, training committees at several levels of the organisation). Integration into the site departments of various profiles dedicated to skills management ("training support", "discipline coordinators", etc.) is an efficient system for supporting and advising the managers.

However, in 2020, ASN regularly found failings in the field of skills, notably with regard to assimilation of operational processes and documents, and the technical skills of certain personnel and monitoring supervisors (lack of technical familiarity with the equipment on which the contractors work). These shortcomings are particularly noticeable on the sites where there is significant workforce turnover. The scheduled ASN inspections in 2021 on the subject of skills will focus on these failings.

Monitoring of subcontracted activities

ASN considers that the quality of monitoring of subcontracted activities remained on the whole stable in 2020 for all the sites, by comparison with 2019. The progress observed on certain sites in terms of preparation for and application of the monitoring programmes is partly due to the correct assimilation of the new tool helping with the definition of monitoring programmes and performance of the monitoring actions. However, the monitoring procedures still reveal difficulties on certain sites (shortcomings in the monitoring of technical operations, difficulties with the transmission of defined requirements to certain contractors or, more generally, with making them aware of the issues linked to the sensitive activities). These difficulties imply that monitoring is not always an effective line of defence against potential failures by the contractors. They will remain a point of particular attention for ASN in 2021.

Management of operational documentation

ASN considers that the operational documentation could still be extensively improved in 2020. This is a recurring fundamental problem. Numerous analyses of significant events reported in 2020 still show problems relating to the operational documentation, regardless of the discipline concerned. The sites are still experiencing difficulties with providing the high-quality documents needed for satisfactory performance of the activities (inappropriate ergonomics, operating documents that are incomplete, overly generic or not up-to-date, operating procedures which do not take account of reactor states or site specificities, etc.). These weaknesses can be found in various operating domains, notably incident or accident operations, with regard to which significant improvements must be made to the documentation. On numerous sites, ASN also observes failings in the utilisation of the operational documentation (insufficient assimilation of the files, incomplete work follow-up files, incomplete lock-out conditions, risk assessments not covering the risks specific to the activity, etc.).

These failings are to a large extent related to organisational malfunctions in the documentation creation and update process and they potentially compromise the documentary support line of defence. In 2021, ASN will remain vigilant with regard to these problems.

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. By comparison with 2019, ASN observes some progress, but considers that this organisation must be further improved on the majority of sites. Failing persist in terms of detecting, reporting and processing difficulties encountered in the field, notably with respect to early warning signs. As in 2019, the encouragement given to the contractors to report positive or negative findings *via* the debriefings and dedicated tools remains insufficient and needs to be reinforced on a majority of sites.

The analyses conducted by the sites further to significant events are generally relevant and the identification of organisational causes is progressing. However, as in 2019, the analysis of the root causes still all too often leads to relatively unambitious corrective measures, with no actual changes to the organisations. Finally, too many sites are still particularly limited when it comes to assessing the effectiveness of the corrective measures.

In 2021, ASN will be particularly attentive to the operating experience feedback approach to be implemented by the licensee concerning its health crisis management and the conclusions that will be drawn with regard to the long-term adoption of certain new practices. The organisation of numerous disciplines, including operations, was indeed modified, entailing significant adaptations in the day-to-day activities and operations.

2.7 Personnel radiation protection

2.7.1 Monitoring of personnel radiation protection

Exposure to ionising radiation in a nuclear power reactor comes primarily from the activation of corrosion products in the primary system and fission products in the fuel. All types of radiation are present (neutrons, α, β and γ), with a risk of internal and external exposure. In practice, more than 90% of the doses received come from external exposure to ß and γ radiation. Exposure is primarily linked to maintenance operations during reactor outages.

ASN monitors compliance with the regulations relative to the protection of workers liable to be exposed to ionising radiation in NPPs. In this respect, ASN is attentive to all the workers on the sites, both EDF personnel and those of contractors.

This oversight is carried out during inspections (specifically on the topic of radiation protection, one to two times per year and per site, during reactor outages, following incidents, or more occasionally in the EDF head office departments and engineering centres), and on the occasion of the review of files concerning occupational radiation protection (significant events, design, maintenance or modification files, EDF documents implementing the regulations, etc.) with the support of the IRSN as applicable.

Periodic meetings are held with EDF as part of the technical dialogue with the licensee. They enable ASN to check the progress of technical or organisational projects being run to improve radiation protection.

Significant contamination events

The number of significant contamination events concerning workers in the NPPs operated by EDF remained at a high level in 2020: eight events (including one concerning the Fessenheim NPP) were reported in 2020, as compared with seven events in 2019 and two in 2018. These events, which led to exposure greater than one quarter the annual regulation limit per square centimetre of skin, were rated level 1 on the INES scale. The procedure adopted by EDF, which consists in removing the contaminating particles with a wipe as soon as they are detected was implemented in most of these cases and helped reduce the time the workers were exposed.

ASN also observes that the wearing of surgical masks, made mandatory owing to the health situation, is liable to increase the number of reflex hand movements towards the face and thus the risk of transferring a radioactive particle to the face or neck of the workers.

ASN will continue its inspections on this topic in 2021, more particularly with regard to the procedures for providing care for those contaminated and preventing the dissemination of radioactive contamination.

2.7.2 Assessment of personnel radiation protection

The collective dose on all the reactors fell in 2020 by comparison with 2019 (Graph 5), as did the average dose received by the workers for one hour of work in the controlled area (Graph 7). The doses received by the workers are broken down as illustrated below in Graphs 3 and 4.

Graph 6 shows the breakdown of the workers according to whole body external dosimetry. It can be seen that the dosimetry for 75% of the exposed workers is less than 1 mSv (millisievert) for the year 2020, 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 2020.

Graph 7 shows the trend in whole body average individual dosimetry according to the categories of workers in the NPPs. The most exposed worker categories in 2020 are personnel in charge of heat insulation, welding, monitoring, mechanical work and ancillary systems. The doses recorded by the most exposed workers are down on 2019.

Despite these results, ASN found that the regression in worker radiation protection already observed in 2019, worsened in 2020. This notably concerns the application of radiation protection rules and the consideration of worker protection when planning the activities. Shortcomings are in particular observed in the implementation of processes for access to and demarcation of operation areas and prohibited areas, in which the dose equivalent rate is liable to be higher than 100 millisieverts per hour (mSv/h). They reflect an inadequate perception of the radiological risks and an inappropriate radiation protection culture. During the inspections carried out during reactor outages, the ASN inspectors repeatedly submit requests regarding the availability of radiation protection equipment, and regarding risk and dose optimisation assessments. They nonetheless underline the fact that steps have been taken to remedy the deviations observed, notably with regard to dose optimisation.

The drop in the standard of radiation protection is particularly flagrant in certain NPPs. For these NPPs, ASN has reinforced its monitoring. It observes that the steps taken by EDF are not fully bearing fruit, notably with regard to the correction of organisational deviations. ASN will be remaining vigilant on these issues during the course of 2021.

2.8 Labour Law in the Nuclear Power Plants

2.8.1 Oversight of Labour Law in the Nuclear Power Plants

ASN is responsible for labour inspectorate duties in the 18 NPPs, the EPR reactor under construction at Flamanville and 11 other installations, most of which are reactors undergoing decommissioning. The workforce in an NPP varies between 800 and 2,000 people. The total number of staff assigned to all the nuclear sites is about 24,000 for the employees of EDF, and 23,000 for the employees of the subcontractors, who more specifically take part in maintenance during reactor outages.

The role of the labour inspectorate is to ensure that the Labour Code as a whole is applied by the employers, whether EDF or its contractors.

The labour inspectorate takes part in the integrated vision of oversight sought by ASN and carries out its monitoring work in conjunction with the other activities to monitor and oversee the safety of facilities and radiation protection.

In 2020, the ASN resources for its labour inspectorate duties were:
- 15 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 regulations

Throughout the year 2020, and more particularly during the lockdown periods, the ASN labour inspectors were in great demand from the employers, the staff, the EDF or contractor personnel representatives, regarding the protection measures to be implemented on the workplace to deal with the health crisis, and the conditions for the continuity of their activities on the sites. The labour inspectorate provided considerable support by supplying information and explanations regarding the Government measures to the employers and the health, safety and working conditions commissions of the social and economic committees.

Specific actions were taken on the sites and notably concerned:
- monitoring of the updating of the activity continuity plans and the consolidated occupational risk assessment documents;
- monitoring of the quality of the protection masks and personal protection equipment made available to the staff;

- monitoring of the psychosocial risk cases within the context of the health crisis and the alerts reported by the social and economic committees at EDF and the contractors.

Even if, at the beginning of the first lockdown, problems were noted with defining and implementing appropriate protection measures, EDF was able to mobilise organisational and material resources to combat the spread of the virus on its sites.

With regard to occupational health and safety, the ASN labour inspections more specifically covered the following topics in 2020:
- the use of electrical installations. The inspectors are continuing to monitor the measures taken by EDF to ensure compliance with the provisions of the Labour Code;
- the worksites with asbestos risks. The labour inspectors are particularly vigilant during their inspections with regard to preventing the risk of inhalation of these fibres;
- the conformity of the working equipment and more specifically the lifting gear. The labour inspectors are still finding shortcomings;
- the fire and explosion hazards, for which the ASN inspectors revealed non-conformities. ASN provides coordinated oversight to take account of all aspects of these hazards, which are important both for worker safety and for nuclear safety (see point 2.4.6);
- improvement of the ventilation conditions in the workplace.

Finally, the labour inspectors systematically initiate an inquiry in the event of a severe accident or severe near-accident.

International subcontracting and provision of services
Steps were taken in 2020 regarding the monitoring of notifications and the conditions for the secondment of staff from foreign companies, notably on the Chooz decommissioning site.

Several inquiries regarding the transfer of labour contracts were also carried out when the contractors on the sites were changed.

Criminal and administrative procedures in progress
With regard to illegal working, ASN closely monitors the criminal proceedings instigated in previous years, more specifically through regular contacts with the Public Prosecutor's offices.

In terms of health and safety, the work by the ASN labour inspectorate led to ten criminal procedures being opened against EDF or contractors in 2020, with regard to non-conformity of personal protection equipment, the working of the personnel representative bodies or the secondment of staff from foreign companies. Administrative penalty procedures for violations of working hours regulations were initiated by the labour inspectors and monitored by the Regional Directorates for Enterprises, Competition, Labour and Employment, who have the power to issue sanctions in this area.

2.8.2 Assessment of health and safety, professional relations and quality of employment in the Nuclear Power Plants

Certain occupational risk situations, such as the risks linked to working equipment and more particularly to lifting gear, explosion and fire risks and electrical risks, are still subjects of concern and must be significantly improved. EDF has however put measures in place to correct these situations. The labour inspectorate also still observes occasional situations in which the risk linked to the presence of asbestos is not considered prior to the work, in order to avoid accidental exposure.

Finally, progress is still required in the management of joint contractor working (quality of prevention plans in particular), the use of subcontracting and foreign staff secondment situations.

2.9 Lessons learned from the accident in the Fukushima Daiichi NPP

Following the accident in the Fukushima Daiichi NPP, ASN adopted a range of resolutions dated 5 May 2011, requiring the licensees of the major nuclear facilities to carry out stress tests.

The conclusions of these stress tests led to an ASN position statement on 3 January 2012, which was itself peer reviewed in April 2012, under the European stress tests programme.

On the basis of the opinion of the Advisory Committees and the conclusions of the European stress tests, ASN issued a range of resolutions dated 26 June 2012, instructing EDF to implement:
- a range of corrective measures or improvements, notably the acquisition of additional communication and radiological protection means, the implementation of additional instrumentation, the extensive consideration of internal

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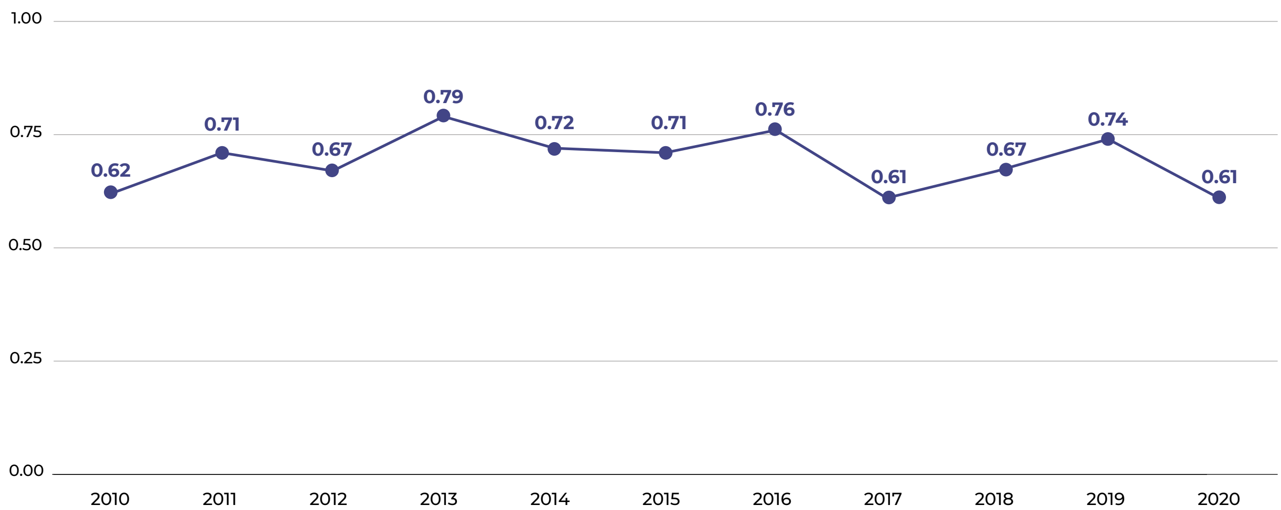
GRAPH 5

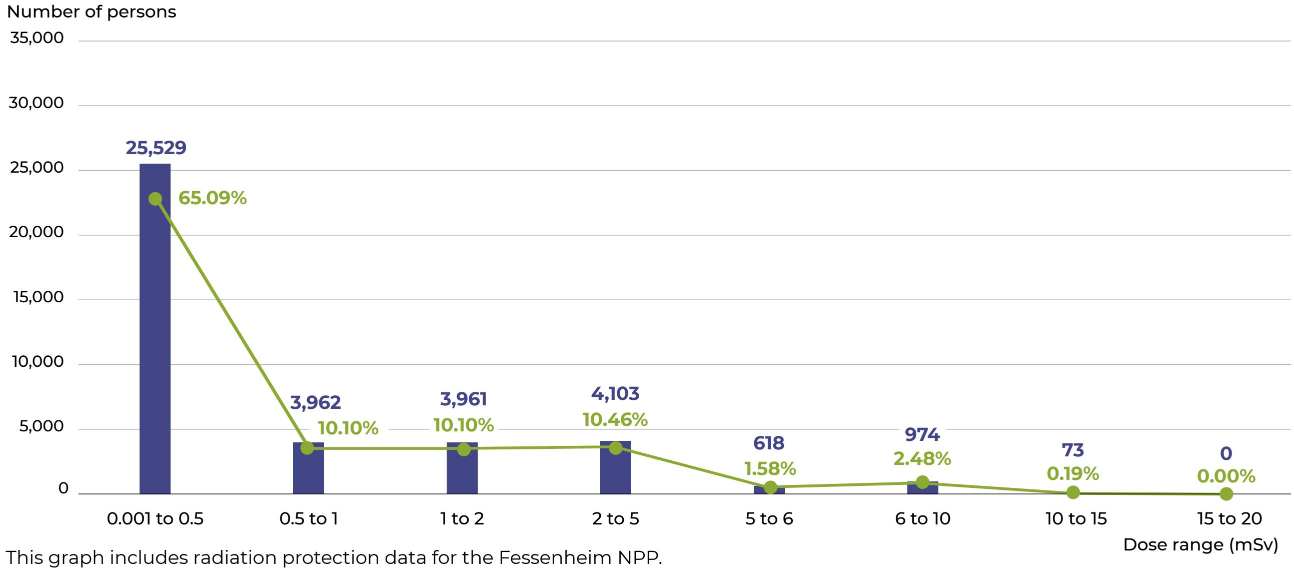
Mean collective dose per reactor (Man-Sv/reactor)



This graph includes radiation protection data for the Fessenheim NPP.
Source: EDF.

GRAPH 6

Number and percentage of workers per dose range (in mSv) for 2020

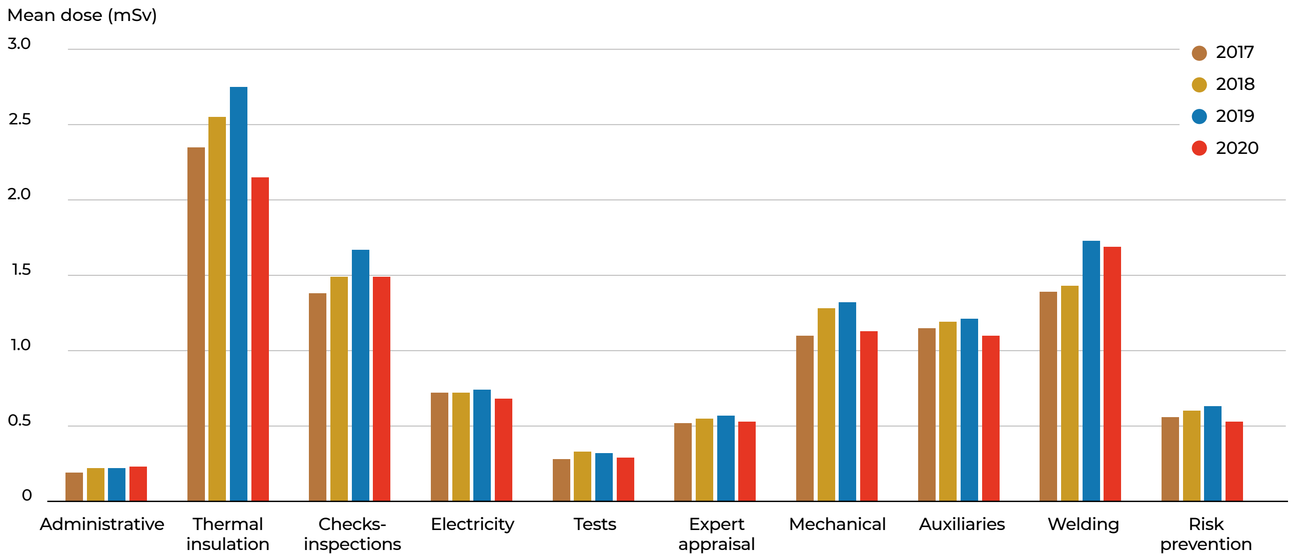


This graph includes radiation protection data for the Fessenheim NPP.

Source: EDF.

GRAPH 7

Trend in mean individual dose according to the categories of trades of the workers in the Nuclear Power Plants



This graph includes radiation protection data from the Fessenheim NPP.

Source: EDF.

and external hazard risks, improvements in the handling of emergency situations;
- a Nuclear Rapid Intervention Force (FARN) which, using mobile means external to the site, can intervene on a nuclear site in a pre-accident or accident situation;
- a local emergency centre allowing emergency management of the nuclear site as a whole in the event of an extreme external hazard;
- a "hardened safety core" of material and organisational measures which, in the event of an extreme external hazard, is designed to:
  - prevent an accident with fuel melt, or limit its progression;
  - limit large-scale radioactive releases;
  - enable the licensee to carry out its emergency management duties.

ASN added to its requests with a range of resolutions dated 21 January 2014 aiming to clarify certain design provisions for the "hardened safety core", in particular the definition and justification of the extreme external natural hazard levels to be considered for the "hardened safety core".

More generally, ASN's requests are also part of a continuous process to improve safety with regard to the targets set for the third-generation reactors, and aim in addition to be able to cope with situations far beyond those normally considered for this type of installation.

These requests are issued in application of the "Defence in Depth" approach and as such concern measures to prevent and mitigate the consequences of an accident, based on both additional fixed means and external mobile means planned for all the installations on a site beyond their initial design basis.

Given the nature of the works requested, the licensee must carry out studies for the design, construction and installation of new equipment which first of all require time and secondly a schedule to optimise their implementation on each NPP. Indeed, insofar as these major works are carried out on nuclear sites which are in service, it is also necessary to ensure that their performance does not degrade the safety of the NPPs.

In 2015, EDF completed the deployment of temporary or mobile measures to enhance how the main situations of total loss of the heat sink or electrical power supplies are addressed. More particularly, connection means were installed so that, in the event of an emergency, the mobile systems can be connected to provide water. Furthermore, the FARN, which is one of the main emergency management means, was set up. Since 31 December 2015, the FARN teams have had the capacity for simultaneous intervention on all the reactors of a site in less than 24 hours (up to six reactors in the case of the Gravelines site). These provisions are in response to the recommendations resulting from the European peer review in April 2012 as part of the European stress tests.

EDF has also started the deployment of certain permanent resources robustly designed and organised with regard to extreme hazards in order to deal with the main situations of loss of heat sink or of electrical power supplies, beyond the safety baselines currently in force, and with core melt accidents.

The most important measures are:
- installation of a large-capacity Ultimate Backup Diesel-generator set (DUS), requiring the construction of a dedicated building to house it. Owing to the industrial difficulties encountered by EDF in the construction, unforeseen events during the commissioning tests and difficulties arising from the specific measures implemented to limit the spread of the Covid-19 pandemic, ASN decided in 2019, and then in 2020, to modify the deadlines for commissioning of these DUS. In parallel with this rescheduling, with the deadline now being pushed back to 28 December 2021, ASN issued binding requirements for an increase in the robustness of the existing electricity sources. At the end of 2020, 54 of the 56 DUS had been commissioned by EDF;
- the creation of an ultimate water source. On 31 December 2020, EDF installed the ultimate water sources for Flamanville reactors 1 and 2, Bugey reactor 2 and Tricastin reactor 1. EDF also initiated the installation of those for the other sites and intends to complete the works between 2021 and 2023, depending on the sites;
- construction on each site of a local emergency centre capable of withstanding extreme external hazards (functionally independent in an emergency situation). In 2019, EDF completed the construction of the local emergency centre on the Flamanville site and commissioned it in 2020. For the other sites, EDF plans completion of the works between 2022 and 2026, depending on the site.

These measures will also be supplemented during the periodic safety reviews by implementation of the "hardened safety core". These resources were partially deployed on the Tricastin NPP reactor 1 and on the Bugey NPP reactor 2, during their fourth ten-yearly inspections.

The most important measures are:
- addition of a new makeup pump to the primary system;
- completion of connection by fixed backup water supply systems for the SG and ultimate water make-up for the fuel storage pool;
- installation of an ultimate instrumentation & control system and the definitive instrumentation of the "hardened safety core";
- the installation of an ultimate containment cooling system, to prevent opening of the filtered vent on this containment in the event of a severe accident;
- the adoption of measures to stabilise the corium on the basemat, in the event of an accident with core melt and reactor vessel melt-through.

With a view to implementation of the "hardened safety core", ASN is examining the design hypotheses for the material provisions and checking that the solutions proposed by EDF can meet the safety objectives set.

On the basis of the files transmitted by EDF and the studies carried out, ASN asked the GPR for its opinion on the more important points of these files.

2.10 Continued operation of the Nuclear Power Plants

2.10.1 The age of the Nuclear Power Plants

The NPPs currently in service in France were built over a relatively short period of time: 45 nuclear power reactors representing nearly 50,000 MWe, or three-quarters of the power output by all the French nuclear power reactors, were commissioned between 1980 and 1990, and seven reactors, representing 10,000 MWe, between 1991 and 2000. In December 2019, the average age of the 56 reactors in operation, calculated from the dates of first divergence, can be broken down as follows:
- 38 years for the 32 nuclear power reactors of 900 MWe;
- 33 years for the 20 nuclear power reactors of 1,300 MWe;
- 23 years for the four nuclear power reactors of 1,450 MWe.

2.10.2 The periodic safety review

The principle of the periodic safety review

The periodic safety reviews of nuclear power reactors comprise the following two parts:
- A check on the condition and conformity of the facility: this step aims to assess the situation of the facility with respect to the rules applicable to it. It is based on a range of inspections and tests in addition to those performed in real-time. These verifications may comprise checks on the initial design studies as well as field inspections of the equipment, or even ten-yearly tests such as the containment hydrotests. Any deviations detected during these investigations are then restored to conformity within a time-frame commensurate with their potential consequences. Ageing management is also incorporated into this part of the review.
- The safety reassessment: this step aims to improve the level of safety, notably taking account of the experience acquired during operation, changing knowledge, the requirements applicable to the more recent facilities and international best practices. Following these reassessment studies, EDF identifies the changes it intends to make to its facilities in order to enhance safety.

The review process for the EDF nuclear power reactors

In order to fully benefit from the standardisation of the nuclear power reactors operated by EDF, these two parts of the periodic safety review are first of all covered by a generic studies programme for a given type of reactor (900 MWe, 1,300 MWe or 1,450 MWe reactors). The results of this programme are then applied to each nuclear power reactor on the occasion of its periodic safety review. EDF more particularly carries out a large part of the checks and modifications related to the periodic safety reviews during the ten-yearly inspections of its reactors.

In accordance with the provisions of Article L. 593-19 of the Environment Code, following this periodic safety review, the licensee sends ASN a periodic safety review concluding 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 by the Environment Code.

ASN analysis

The guidelines of the generic programmes proposed by EDF for verification of the status of the facility and reassessment of safety are the subject of an ASN position statement issued following consultation of the GPR and possibly of the GPESPN. On this basis, EDF carries out safety reassessment studies and defines the modifications to be made.

Following consultation of the Advisory Committees at the end of the periodic safety review generic phase, ASN issues a position statement on the results of the reassessment studies and on the modifications to allow the safety improvements envisaged by EDF.

ASN then informs the Minister responsible for nuclear safety of its analysis of the review concluding report for each nuclear power reactor, mentioned in Article L. 593-19 of the Environment Code, and may issue new binding requirements regarding its continued operation.

The Energy Transition for Green Growth Act 2015-992 of 17 August 2015 supplemented the framework applicable to the periodic safety reviews on nuclear power reactors. It more specifically requires ASN authorisation, following a public inquiry, of the provisions proposed by the licensee during the periodic safety reviews beyond the 35th year of operation of a nuclear power reactor. Five years after submitting the periodic safety review report, the licensee also submits an interim report on the condition of the equipment, in the light of which ASN may supplement its binding requirements.

The main challenges in managing ageing

As with all industrial facilities, NPPs are subject to ageing. ASN ensures that, in line with its general operating and maintenance strategy, EDF takes account of ageing-related phenomena in order to maintain a satisfactory level of safety in the installations for their operating lifetime.

To understand the ageing of an NPP, over and above simply the time that has passed since it was commissioned, a certain number of factors must be considered, more specifically the existence of physical phenomena which can degrade the characteristics of the equipment according to its usage or its conditions of use.

Deterioration of replaceable items

Equipment ageing is the result of phenomena such as the hardening of certain steels under the effect of irradiation or temperature, the swelling of certain concretes, hardening of polymers, corrosion of metals, etc. This deterioration is generally incorporated as of the design and manufacture of the facilities and then in a programme of monitoring and preventive maintenance, as well as of repair or replacement if necessary.

The lifetime of non-replaceable items

Non-replaceable items, such as the reactor pressure vessel (see point 2.2) and the containment (see point 2.3), are subject to close monitoring in order to check that they age as anticipated and that their mechanical characteristics remain within the limits allowing satisfactory behaviour.

Obsolescence of equipment and its components

Before it is installed in the NPPs, some equipment undergoes a qualification process designed to ensure that it is able to perform its functions in the stress and atmosphere conditions corresponding to the accident situations in which it would be required. The availability of spares for this equipment is heavily dependent on any changes in the industrial network of suppliers. The end of manufacturing of certain components or the closure of the manufacturing company can lead to supply difficulties. Prior to their installation, EDF must check that new spares that are different from the original parts do not compromise the qualification of the equipment on which they are to be installed. Given the time required for this procedure, EDF must anticipate well in advance.

The nuclear power reactors ageing management process

The approach adopted by EDF to manage the ageing of its facilities is built around three key points:

- Anticipate ageing as of the design process: at design and during manufacture of the components, the choice of materials and the installation arrangements must be appropriate to the planned operating conditions and take account of the known or presumed degradation kinetics.
- Monitor the actual condition of the facility: during operation, degradation phenomena other than those considered in the design can be discovered. The periodic test and preventive maintenance programmes, the additional investigation programmes as well as examination of operating experience feedback (see points 2.4.3, 2.4.4, 2.4.7, 2.4.8 and 2.6.1) must enable these phenomena to be detected sufficiently well in advance.
- Repair, renovate or replace the equipment: given the operating constraints that such routine or exceptional maintenance operations are liable to generate, especially when they can only be performed during nuclear power reactor outages, EDF must seek to anticipate them, in particular to take account of the time taken to procure new components, the time taken to prepare for and carry out the work, the risk of obsolescence of components and the loss of technical skills on the part of the workforce.

At the request of ASN, EDF established a methodology for managing the ageing of its nuclear power reactors beyond 30 years of operation, the aim of which is to demonstrate their ability to continue to function until their fourth periodic safety review in satisfactory conditions of safety, on the one hand in the light of the understanding of and ability to manage the mechanisms and kinetics of the damage modes linked to ageing and, on the other, according to the condition of the facilities observed during their third periodic safety review.

This methodology comprises a first generic phase which aims to determine how ageing is taken into account for a set of similar reactors. Subsequently, on the occasion of the third periodic safety review of each nuclear power reactor, a summary file specific to the reactor is drawn up in order to demonstrate management of the ageing of the equipment and the reactor's ability to continue to function for the ten-year period following its third ten-yearly inspection.

To ensure continued operation of the nuclear power reactors beyond their fourth ten-yearly inspection, EDF reuses this type of approach, which is applied not only to all the systems, structures and components important for managing radiological risks, but also conventional risks.

Time-line of first criticality of the French nuclear power reactors

Date of first criticality	Reactors	Total power
1977	Fessenheim 1, Fessenheim 2	1,800 MWe
1978	Bugey 2, Bugey 3	1,800 MWe
1979	Bugey 4, Bugey 5	1,800 MWe
1980	Tricastin 1, Gravelines 1, Tricastin 2, Tricastin 3, Gravelines 2, Dampierre 1, Gravelines 3, Saint-Laurent B1	7,200 MWe
1981	Dampierre 2, Saint-Laurent B2, Blayais 1, Dampierre 3, Tricastin 4, Gravelines 4, Dampierre 4	6,300 MWe
1982	Blayais 2, Chinon B1	1,800 MWe
1983	Cruas 1, Blayais 4, Blayais 3, Chinon B2	3,600 MWe
1984	Cruas 3, Paluel 1, Cruas 2, Paluel 2, Gravelines 5, Cruas 4	6,200 MWe
1985	Saint-Alban 1, Paluel 3, Gravelines 6, Flamanville 1	4,800 MWe
1986	Paluel 4, Saint-Alban 2, Flamanville 2, Chinon B3, Cattenom 1	6,100 MWe
1987	Cattenom 2, Nogent 1, Belleville 1, Chinon B4	4,800 MWe
1988	Belleville 2, Nogent 2	2,600 MWe
1990	Cattenom 3, Penly 1, Golfech 1	3,900 MWe
1991	Cattenom 4	1,300 MWe
1992	Penly 2	1,300 MWe
1993	Golfech 2	1,300 MWe
1996	Chooz B1	1,450 MWe
1997	Chooz B2, Civaux 1	2,900 MWe
1999	Civaux 2	1,450 MWe

● 900 MWe ● 1,300 MWe ● 1,450 MWe

Source: ASN.

2.10.3 Current periodic safety reviews in the Nuclear Power Plants

The 900 MWe reactors

The third periodic safety review

In July 2009, ASN issued a position statement on the generic aspects of continued operation of the 900 MWe reactors beyond their third periodic safety review. 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 concluding report for the reactor submitted by EDF.

At the beginning of 2021, 33 of the 34 reactors of 900 MWe had carried out their third periodic safety review and have incorporated the improvements resulting from this review.

In 2020, ASN also sent the Minister responsible for nuclear safety its analysis of the periodic safety review concluding report for the Tricastin NPP reactor 4. On the basis of this analysis, ASN did not identify any elements compromising EDF's ability to ensure the safety of this 900 MWe reactor up until the next periodic safety review. Pursuant to Article L. 593-19 of the Environment Code, ASN took this opportunity to issue additional binding requirements designed to reinforce the safety of this reactor.

The fourth periodic safety review

A review with major implications

The 34 EDF 900 MWe reactors were commissioned between 1977 and 1987 and the first of them are approaching their fourth periodic safety review. The conditions for the continued operation of these reactors, except for the two reactors of the Fessenheim NPP, which were definitively shut down in 2020, will therefore be defined within this framework. These two reactors will be the subject of a specific periodic safety review.

For the other 32 reactors, there are a number of particular implications in this fourth periodic safety review:

- Some items of equipment are reaching their design-basis lifetime. The studies concerning the conformity of the installations and the management of equipment ageing therefore need to be reviewed to take account of the degradation mechanisms actually observed and the maintenance and replacement strategies implemented by EDF.
- The modifications associated with this periodic safety review will enable the integration of the modifications specified by ASN following the Fukushima Daiichi NPP accident to be completed on these reactors.
- The safety reassessment of these reactors and the resulting improvements must be carried out by comparison with the new-generation reactors, such as the EPR, the design of which meets significantly reinforced safety requirements.

ASN's position statement on the generic phase of the periodic safety review

In 2013, EDF sent ASN its proposed 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 the 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.

In 2020, with the support of the IRSN, ASN finalised its examination of the generic studies linked to this review. In 2018 and 2019, ASN more particularly obtained the opinion of its Advisory Committees on:
- the management of ageing and obsolescence;
- the mechanical strength of the reactor pressure vessels (see point 2.2.4);
- NPE;
- the accident studies in the safety case;
- the ability of the installations to withstand internal and external hazards;
- the probabilistic safety assessments;
- the management of accidents with core melt.

It again asked for their opinion in 2020 with regard to the mechanical strength of the reactor vessels core zone and the results of the generic phase of this periodic safety review.

At the beginning of 2021, ASN issued a position statement on the conditions for continued operation of the reactors (see Notable events).

2020: submission of the concluding report on the periodic safety review of the first reactor

Tricastin NPP reactor 1 and Bugey reactor 2 underwent their fourth ten yearly outages in 2019 and 2020 respectively. These outages were a major step in their fourth periodic safety reviews. During these outages, EDF carried out a significant part of the required inspections and deployed most of the safety improvements associated with the review. ASN will issue a position statement on the continued operation of Tricastin NPP reactor 1 in 2022, after its position statement on the generic studies and its examination of the periodic safety review concluding report for this reactor, submitted by EDF in February 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 Safety (HCTISN), in the form of a consultation on the measures planned by EDF to meet these objectives. At the end of 2020, ASN also consulted the public on its draft resolution specifying the conditions for continued operation of these reactors. Pursuant to the law, a public inquiry will then be held, reactor by reactor, after submission of the periodic safety review concluding report for each reactor.

The 1,300 MWe reactors

The third periodic safety review

At the beginning of 2015, ASN issued a position statement on the generic aspects of the continued operation of the 1,300 MWe reactors beyond 30 years of operation. ASN considers that the steps taken or planned by EDF to assess the state of its 1,300 MWe reactors and manage their ageing up to the fourth periodic safety review are acceptable. ASN also considers that the modifications identified by EDF following this study phase will help to significantly improve the safety of these installations. These improvements in particular concern reinforcing protection of the facilities against hazards, reducing releases of radioactive substances in the event of an accident, with or without core melt, and preventing the risk of uncovering of the fuel assemblies stored in the spent fuel pit or during handling.

To help conclude the generic phase of this review, ASN intends to issue additional requests in 2021 applicable to all the 1,300 MWe reactors, with the aim of reinforcing their safety.

The reactors of the NPPs at Flamanville, Saint-Alban, Paluel, Belleville-sur-Loire, Nogent-sur-Seine, as well as the Cattenom NPP reactors 1 and 2, carried out their third ten-yearly outages between 2015 and 2020. The third ten-yearly outages on the other 1,300 MWe reactors will take place up until 2024.

The fourth periodic safety review

In July 2017, EDF presented a file giving the orientations envisaged for the generic phase of the fourth periodic safety review of the 1,300 MWe reactors. In 2019, ASN issued a position statement on these orientations, after consultation of the GPR on 22 May 2019. ASN considers that the general objectives set by EDF for this review are acceptable in principle. However, following on from its requests regarding the fourth periodic safety review of the 900 MWe reactors, ASN asks EDF to modify or supplement these general objectives for this safety review, to consider certain baseline requirements for reassessment of the safety of its facilities and to add study topics to its review programme.

In 2020, ASN initiated the first expert assessments for the generic phase of this periodic safety review. They more specifically concerned the methods to be used during this review for the study of certain accidents.

EDF will carry out the first ten-yearly outage associated with this periodic safety review in 2026.

The 1,450 MWe reactors

The second periodic safety review

In 2011, EDF transmitted its proposed orientations for the generic study programme of the second periodic safety review for the 1,450 MWe reactors. After consulting the GPR in 2012, EDF supplemented its generic studies programme with a number of measures and clarified some of its proposals. ASN issued a position statement in February 2015 on the guidelines for this second periodic safety review and considered that the safety objectives to be adopted for the second periodic safety review of the 1,450 MWe reactors should be defined in the light of the objectives applicable to the new nuclear power reactors and asked EDF to study measures liable to meet this requirement as rapidly as possible, with the aim of implementing them as of the second periodic safety reviews of the 1,450 MWe reactors.

The examination of the generic phase of this periodic safety review should be concluded in 2021 and ASN aims to issue a position statement on this generic phase at the end of 2021.

Chooz NPP reactors B1 and B2 carried out their second ten-yearly outages in 2019 and 2020. The ten-yearly outages for the two Civaux reactors will be completed in 2022.

Ageing management

With a view to continued operation beyond the fourth periodic safety review of the 900 MWe nuclear power reactors, EDF intends to continue to use the ageing management approach applied since the third periodic safety review of its reactors, while reinforcing its equipment renovation and replacement projects. Ageing management, in particular for non-replaceable items, such as the reactor pressure vessel (see point 2.2) and its containment (see point 2.3), as well as obsolescence management, are essential for maintaining a satisfactory level of safety.

After considering that the steps taken or planned by EDF, notably for identifying the various equipment degradation modes, implementing the corresponding countermeasures and integrating operating experience feedback, were on the whole satisfactory, in 2013 and then again in 2016, ASN – with the support of the IRSN – once more examined the ageing and obsolescence management approach and in March 2018 obtained the opinions of the GPR and GPESPN.

ASN notes that EDF has taken account of the requests it made in 2013 and 2016. ASN considers that the steps taken or planned to ensure management of the ageing and obsolescence of the structures, systems and components of the 900 MWe reactors and thus contribute to maintaining their compliance beyond their fourth periodic safety review, supplemented by the undertakings made following the examination, are satisfactory.

The programmes for equipment qualification for accident conditions are pertinent and enable this qualification to be extended beyond the fourth ten-yearly outage. Actions are still in progress to cover all the equipment concerned.

The envisaged exceptional maintenance operations (replacements, repairs or renovations scheduled during or after the fourth ten-yearly outages) are consistent with the ageing assessments.

The improvements identified for dealing with obsolescence are such as to guarantee satisfactory and lasting management of obsolescence.

The programme of additional investigations defined by EDF and the planned procedures for processing the results are deemed to be on the whole 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 assessments and the assimilation by the NPPs of the demonstration of the suitability for continued operation.

Finally, ASN considers that, without delaying their decommissioning, the final shutdown of the Fessenheim NPP reactors should be used as an opportunity to check the absence of any unexpected degradation or ageing phenomena, in particular on those parts of the installation that are hard to access.

Moreover, the first Topical Peer Review, required by Council Directive 2014/87/Euratom of 8 July 2014, amending Directive 2009/71/Euratom establishing a community framework for the nuclear safety of nuclear installations, on the subject of ageing management, confirmed that the ageing management approach adopted for EDF's nuclear reactors is appropriate. The national action plan drawn up to address the conclusions of this review was implemented in 2020, notably with regard to incorporation of the specific aspects of the sites in their local ageing management programme and the inspections on buried piping. In early 2021, ASN expects EDF to transmit information regarding the ageing management programme during the lengthy construction phases of new facilities and prolonged reactor outage periods.

2.11 Flamanville EPR

The EPR is a PWR using a design that has evolved from that of the reactors currently in operation in France. It meets the following reinforced safety objectives: reduction in the number of significant events, limitation of discharges, reduced volume and activity of waste, reduced individual and collective doses received by the workers (in normal operation and incident situations), reduced overall frequency of core melt, taking account of all types of failures and hazards and reduced radiological consequences of any accidents.

After a period of a decade during which no nuclear reactors were built in France, in May 2006 EDF submitted a creation authorisation application with the Ministers responsible for nuclear safety and for radiation protection, for an EPR type reactor with a power of 1,650 MWe on the Flamanville site, which was already home to two 1,300 MWe reactors.

The Government authorised its creation through Decree 2007-534 of 10 April 2007, after a favourable opinion issued by ASN following the examination process. This Decree was modified in 2017 and in 2020, to extend the time allowed for commissioning of the reactor.

After the issue of this Creation Authorisation Decree and the building permit, construction of the Flamanville EPR reactor began in September 2007. The first concrete was poured for the nuclear island buildings in December 2007.

EDF aims to load fuel and start up the reactor at the end of 2022. This takes account of the time needed on the one hand to repair certain welds on the MSS and, on the other, to allow the end of the erection and testing operations.

2.11.1 Examination of the authorisation applications

Examination of the commissioning authorisation application

In March 2015, EDF sent ASN its commissioning authorisation application for the installation, including the safety analysis report, the general operating rules, a study of the facility's waste management, the PUI, the decommissioning plan and an update of the facility's impact assessment. Following a preliminary examination, ASN considered that all the documents required by the regulations were officially present, but it decided that additional justifications were needed if ASN was to be able to reach a final decision on the commissioning authorisation application. ASN began the technical examination of the subjects for which most of the information was available, although it did submit some requests on certain points.

In June 2017, ASN received updated versions of the commissioning authorisation application files. Some elements still need to be provided before ASN is able to issue a position statement on the commissioning authorisation application file. In 2018, ASN more particularly issued requests for additional information regarding the general operating rules.

ASN also obtained the opinion of the GPR on 4 and 5 July 2018 concerning the safety analysis report for the Flamanville EPR reactor. This meeting was devoted in particular to the action taken following the previous GPR sessions devoted to this reactor since 2015. The Advisory Committee considers that the reactor's safety case is on the whole satisfactory and points out that some additional information is still required concerning how the fire risk is addressed and the behaviour of the fuel rods which have experienced a boiling crisis. The GPR also considers that the design and dimensioning of the back-up systems and auxiliary safety systems are on the whole satisfactory and observes that additional information is still required concerning the breaks liable to affect the fuel storage pool cooling system. In 2019, ASN submitted requests for supplements to the safety case that are needed for a final decision to be reached on the commissioning authorisation application. Finally, in 2020, ASN specified the required additions to the commissioning authorisation application so that it includes the conclusions of the technical examinations conducted.

Authorisation for reception and storage of nuclear fuel on the Flamanville EPR reactor site

Arrival of nuclear fuel on the Flamanville EPR reactor site

On 8 October 2020, ASN authorised the arrival of nuclear fuel on the Flamanville Evolutionary Power Reactor (EPR) reactor site. Since then, EDF has received the first fuel assemblies and stored them in the specific pool in the building.

ASN carried out an inspection on the Flamanville site on 18 and 19 August 2020 in order to evaluate the licensee's readiness for the fresh fuel reception, handling and storage operations.

The checks carried out during this inspection showed that the state of the installation and the licensee's readiness for arrival of the fuel on the site were satisfactory.

If an assembly were to be dropped when being handled during reception and storage of fresh fuel, there is a risk of dispersal of radioactive substances. ASN considers that the steps taken by EDF to prevent this accident scenario and mitigate the consequences were it to happen are satisfactory.

ASN also authorised the use of radioactive gases to carry out the effectiveness tests on certain filter systems.

This authorisation is one of the steps prior to commissioning of the Flamanville EPR reactor. The commissioning of the installation, that is loading of fuel into the reactor vessel, remains subject to authorisation by ASN.

Partial commissioning authorisation for arrival of the fuel
EDF sent an application for partial commissioning of the installation to allow the arrival of fuel on the site, so that the fuel assemblies to be used for future operation could be safely received and stored. This partial commissioning is one of the steps prior to commissioning of the Flamanville EPR reactor, but in no way prejudges this commissioning, which is the subject of a separate examination. After examination of the application file and the supplements requested during the investigation, and further to consultation of the public, ASN authorised this partial commissioning on 8 October 2020.

2.11.2 Monitoring of construction, start-up tests and preparation for operation

ASN is faced with numerous challenges concerning oversight of the construction, start-up tests and preparation for operation of the Flamanville EPR reactor. These are:
- checking the quality of equipment manufacturing, installation construction, radiation protection and environmental protection, in a manner commensurate with the safety implications, in order to be able to issue a position statement on the ability of the installation to meet the defined requirements;
- ensuring that the start-up tests programme is satisfactory, that the tests are correctly performed and that the required results are obtained;
- ensuring that the various stakeholders learn the lessons from the construction phase and the performance of the start-up tests, including the upstream phases (selection and monitoring of contractors, construction, procurement, etc.) which will enable the as-built installation to comply with the safety case for the duration of the project;
- ensuring that the licensee takes the necessary steps so that the teams in charge of operating the installation after commissioning are well-prepared.

To do this, ASN has set binding requirements regarding the design, construction and start-up tests for the Flamanville EPR reactor and for operation of the two Flamanville 1 and 2 reactors close to the construction site. Compliance with these requirements is regularly checked by ASN through inspections and through examination of the commissioning authorisation application. As this is a nuclear power reactor, ASN is also responsible for labour inspection on the construction site. Lastly, ASN ensures oversight of the manufacture of the NPE that will be part of the primary and secondary systems of the nuclear steam supply system. The main steps taken by ASN in 2020 are described below.

Oversight of the construction, assembly and test activities on the Flamanville EPR reactor site
ASN carried out 13 EDF inspections on the Flamanville EPR reactor construction site in 2020.

In its construction site oversight activities, ASN devoted particular attention to the following subjects in 2020:
- preparation for and performance of the initial repairs of the main steam letdown line welds. ASN more particularly checked the production of the corresponding documentation, management of the skills of the workers involved and the supervisors of these operations, and checked compliance with the welding procedures;
- the preparation for and performance of the start-up tests for the various systems of the installation and EDF's organisation for management of the overall tests;
- preparation for partial commissioning to allow the arrival of nuclear fuel within the perimeter of the installation and operation of the installation following this partial commissioning. ASN also carried out checks on the transport of fresh fuel assemblies;
- application of the strategy for the conservation, maintenance and testing of the equipment and structures present on the construction site until the reactor is commissioned. Owing to the postponements to reactor commissioning announced by EDF, ASN makes sure that EDF continues to pay close attention to defining and complying with the requirements corresponding to the conservation, maintenance and testing of the equipment already installed and the structures built;
- protection of the environment and more particularly the follow-ups to the tightened inspections performed on the subject in 2019;
- the radiation protection of workers during radiographic inspection of welds.

Oversight of the Flamanville EPR reactor engineering activities

In 2020, ASN carried out two inspections in EDF's engineering departments regarding the performance of activities important for protection and their monitoring when performed by outside contractors. These inspections were carried out on the sites where these activities are performed.

In January 2020, ASN thus conducted an inspection in the premises of Framatome, where the reactor protection system software is developed. During this inspection, ASN examined skills management, as well as the process for managing changes and deviations.

In addition, in October 2020, ASN carried out an inspection in the premises of Edvance, where it examined the process for production and management of the documentation for incident and accident control.

Labour inspection on the Flamanville EPR reactor construction site

The actions carried out by the ASN labour inspectors in 2020 consisted in:
- performing checks on the contractors working on the site;
- answering direct queries from the employees;
- carrying out inquiries following occupational accidents;
- investigating requests for exemptions to provisions under the labour regulations.

Application of the safety rules was regularly checked.

Oversight of NPE design and manufacturing for the Flamanville EPR reactor

During the course of 2020, ASN continued to assess the conformity of the design of the NPE of the main primary and secondary systems.

Having observed inadequate justification and incomplete design files for this equipment, more specifically with regard to the risk assessments, choice of materials and in-service inspectability of the equipment, ASN held numerous technical meetings with Framatome (formerly Areva NP) in 2013 and 2014 in order to define the additional data to be provided. In 2015, Framatome began a revision of all technical design documentation for this

Welds on lines of the main secondary systems of the Flamanville EPR reactor

Implementation of the orbital TIG process – weld on the main secondary system

Major repairs are required on the welds on lines of the main secondary systems of the Flamanville EPR reactor. Some of these welds are located on the main steam lines, which are subject to a "break preclusion" approach, which assumes mechanical properties and a level of manufacturing quality that are particularly high.

Eight of these welds are located in the annulus between the two containment walls of the reactor building. The difficult access conditions required the development of special intervention means and the qualification of specific welding, inspection and heat treatment processes. In 2020, ASN initiated its examination of the qualifications of these various processes and will issue a position statement on initiation of the welding operations at the beginning of 2021.

Most of the other welds on the main steam lines to be repaired, of which there are about 50, are located in an environment with no access difficulties. In 2020, ASN initiated its examination of the qualification of the repair processes. EDF was able to initiate the repair of seven welds as of the summer of 2020. ASN is attentive to ensuring that the number of repairs made in parallel is compatible with the organisation of worksite surveillance. This work will continue until 2022.

At the same time, EDF evaluated the quality of the other welds, in particular the Steam Generator (SG) feedwater lines. This work led EDF to decide to repair ten or so additional welds. ASN will issue a position statement on the scope of the welds to be repaired once EDF has submitted all the justifications.

equipment. This latter must be substantiated to take account of the deviations observed.

With regard to the monitoring of NPE manufacturing, the action taken by ASN in 2020 mainly concerned the preparation for and performance of repairs of welds on the main steam letdown lines subject to the break preclusion requirements (see box page 317).

ASN also initiated an analysis of the deviations which affected the post-weld heat treatment of the connection welds on the SG and pressuriser components carried out in Framatome's Saint-Marcel plant.

If the design and manufacturing checks prove to be satisfactory in the light of the regulatory requirements, ASN issues certification of NPE compliance. Over the previous years, ASN issued the very first certificates, including that for the reactor pressure vessel. The compliance evaluation of the other NPE or level N1 nuclear assemblies will continue in 2021.

2.11.3 Assessment of construction, start-up tests and preparation for operation of the Flamanville EPR reactor

ASN considers that the design of the Flamanville EPR reactor should be able to achieve the ambitious safety objectives set for the third generation reactors. It should also lead to a significant reduction in the probability of core melt and radioactive releases in the event of an accident, by comparison with the second generation reactors. The EPR reactor design in particular includes systems for managing severe accidents and is able to withstand extreme external hazards. This design only required very minor changes to take account of the lessons learned from the accident at the Fukushima Daiichi NPP.

However, a number of important technical subjects are still being examined. This is notably the case with the design of the safety valves on the primary system, the general operating rules that will apply as of commissioning and the lessons learned from commissioning of the first EPR reactors abroad.

Oversight of construction also regularly brought to light construction quality flaws, which required corrective action and led EDF to conduct additional checks, which are the subject of discussions with ASN. ASN considers that EDF must supplement the programme of additional inspections scheduled as part of the quality review of equipment other than pressure equipment.

EDF has carried out most of the tests needed prior to start-up of the installation. The in-depth analysis of the results will verify that the as-built installation complies with the safety case.

2.12 Studies on reactors of the future

The EPR 2 reactor

In April 2016, EDF asked ASN for its opinion on the safety options for a PWR reactor project called "EPR New Model" (EPR NM), being developed by EDF and Framatome.

This project aims to meet the general safety objectives for third-generation reactors. It aims to integrate the lessons learned from the design, construction and commissioning of the EPR reactors at Flamanville 3, Olkiluoto 3, Taishan 1 and 2 and Hinkley-Point C, along with operating experience feedback from existing reactors. In addition, the design of this reactor will incorporate all the lessons learned from the Fukushima Daiichi NPP accident. This more specifically entails reinforcing the design against natural hazards and consolidating the independence of the installation and the site in an accident situation (with or without core melt) until such time as the off-site resources can intervene.

ASN examined the Safety Options Dossier (DOS) for the EPR NM with the support of the IRSN, taking account of the recommendations of Guide No. 22 on PWR design. At the request of ASN, the GPR met in January 2018 to examine this dossier.

In 2018, EDF sent ASN its decision to upgrade the technical configuration of the EPR NM to a new version, called "EPR 2".

On 16 July 2019, ASN thus published its opinion on the safety options proposed for the EPR NM reactor and its EPR 2 configuration upgrade. ASN considers that the general safety objectives, the safety baseline requirements and the main design options are on the whole satisfactory. ASN's opinion identifies the subjects to be considered in greater depth prior to submitting a reactor creation authorisation application. Additional justifications are in particular needed on the break preclusion approach for the main primary and secondary piping, the approach for dealing with hazards, fire and explosion in particular, and the design choices for certain safety systems. In 2020, EDF provided additional information on these subjects. It is currently being examined.

Small Modular Reactors

Several Small Modular Reactor (SMR) projects are currently being developed around the world. These are reactors with a power of less than 300 MWe, built in a factory and delivered to their installation site. A French SMR project involving EDF, Technicatome, the Alternative Energies and Atomic Energy Commission (CEA) and Naval Group is currently at the preliminary design stage. ASN considers that these projects are opportunities to develop reactors with significant nuclear safety improvements.

Generation IV reactors

Since 2000, in partnership with EDF and Framatome, the CEA has been examining fourth-generation reactors, notably within the "Generation IV" International Forum (GIF). Given that the CEA's Astrid project has been abandoned, the industrial deployment of Generation IV reactors cannot be envisaged before the end of this century.

3. Outlook

In 2021, ASN actions in the field of NPP oversight will more specifically concern the following topics.

The periodic safety reviews
After issuing a position statement on the generic conditions for the continued operation of the 900 MWe reactors beyond their fourth periodic safety review, ASN will examine the periodic safety review concluding reports for the first reactors concerned.

ASN will also continue to examine the generic phase of the fourth periodic safety review of the 1,300 MWe reactors.

Compliance of the facilities with their baseline design, construction and operating requirements
ASN will continue to be particularly attentive to the conformity of the facilities in 2021 and will in this respect continue its inspections of the condition of equipment and systems. It will ensure that the new EDF baseline for processing deviations is able to satisfactorily meet the regulatory obligations linked to the detection and processing of deviations and reporting to ASN.

ASN will also be particularly vigilant to EDF's correct performance of the facilities compliance inspection programme during the fourth ten-yearly outages of several 900 MWe reactors.

Oversight of the Flamanville EPR reactor
ASN will continue to oversee the preparation of the various documents supporting operation, equipment conservation measures and the conditions for the preparation and performance of secondary system weld repairs. The nuclear safety inspectors will continue with inspections at a sustained rate.

ASN will continue to examine the commissioning authorisation application, will examine the start-up test results and will continue with its assessment of the compliance of the NPE most important for safety.

Oversight of Nuclear Pressure Equipment
In recent years, oversight of NPE has been marked by a number of major events: the detection of problems linked to carbon segregation in certain forged components, irregularities that could be considered to be falsifications, notably at Framatome's Creusot Forge plant and on the Ancizes site of Aubert et Duval, and problems with quality control on the welds of the Flamanville EPR reactor and heat treatment of the SG welds.

In 2021, ASN will carry out work to monitor these events and will also continue with work to prevent such problems from happening again.

CHAPTER 11

“NUCLEAR FUEL CYCLE” INSTALLATIONS

11 "Nuclear fuel cycle" installations

The "nuclear fuel cycle" begins with the extraction of uranium ore and ends with the packaging of the various radioactive wastes from spent fuel for subsequent disposal. In France, the last uranium mines were closed in 2000, so the fuel cycle concerns the fabrication of the fuel and then its reprocessing once it has been used in the nuclear reactors.

The licensees of the fuel cycle plants are part of the Orano or EDF (Framatome) groups: Orano operates Melox in Marcoule, the La Hague plants, all the Tricastin plants, as well as the Malvési facilities. Framatome operates the facilities on the Romans-sur-Isère site.

The French Nuclear Safety Authority (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 plants in Malvési and Tricastin. These plants, which are regulated under the legislation for Installations Classified for Protection of the Environment (ICPEs) use natural uranium in which the uranium-235 content is around 0.7%.

Most of the world's nuclear power reactors use uranium slightly enriched with uranium-235. The Pressurised Water Reactor (PWR) series for example requires uranium enriched with isotope-235. In France, UF_6 enrichment between 3% and 6% is carried out by ultracentrifuges in the Georges Besse II plant in 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 inserted into the reactor core, where they deliver energy, notably by fission of uranium-235 nuclei. Before it is used in the reactors, fresh 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 recycling 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 fresh fuels. EDF announced its intention to resume its use in 2023, after re-enrichment of the reprocessed uranium in Russia.

The plutonium resulting from the reprocessing of uranium oxide fuels is used in the Orano plant in Marcoule, called "Melox", to fabricate MOX fuel (mixture of uranium and plutonium oxides) which is used in certain 900 Megawatts electric (MWe) nuclear power reactors in France. The MOX nuclear fuels are not currently reprocessed after being used in the reactors. Pending reprocessing or disposal, the spent MOX fuels are stored at the La Hague plant.

The main material flows for the fuel cycle are presented in Table 1.

Other facilities are needed for the operation of the Basic Nuclear Installations (BNIs) mentioned above, more particularly the "Socatri" facility, which is responsible for the maintenance and decommissioning of nuclear equipment, as well as the treatment of nuclear and industrial effluents from the Orano platform in Tricastin.

1.1 Front-end fuel cycle

Before fuels are fabricated for use in the reactors, the uranium ore must undergo a number of chemical transformations, from the preparation of the "yellow cake" through to conversion into UF_6, the form in which it is enriched. These operations take place primarily on the Orano 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 operates:

- the former Comurhex facility (BNI 105) for converting uranium tetrafluoride (UF_4) into UF_6, which contains the Philippe Coste plant;
- 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 (ICPE within the perimeter of BNI 155) for converting depleted UF_6 into U_3O_8;

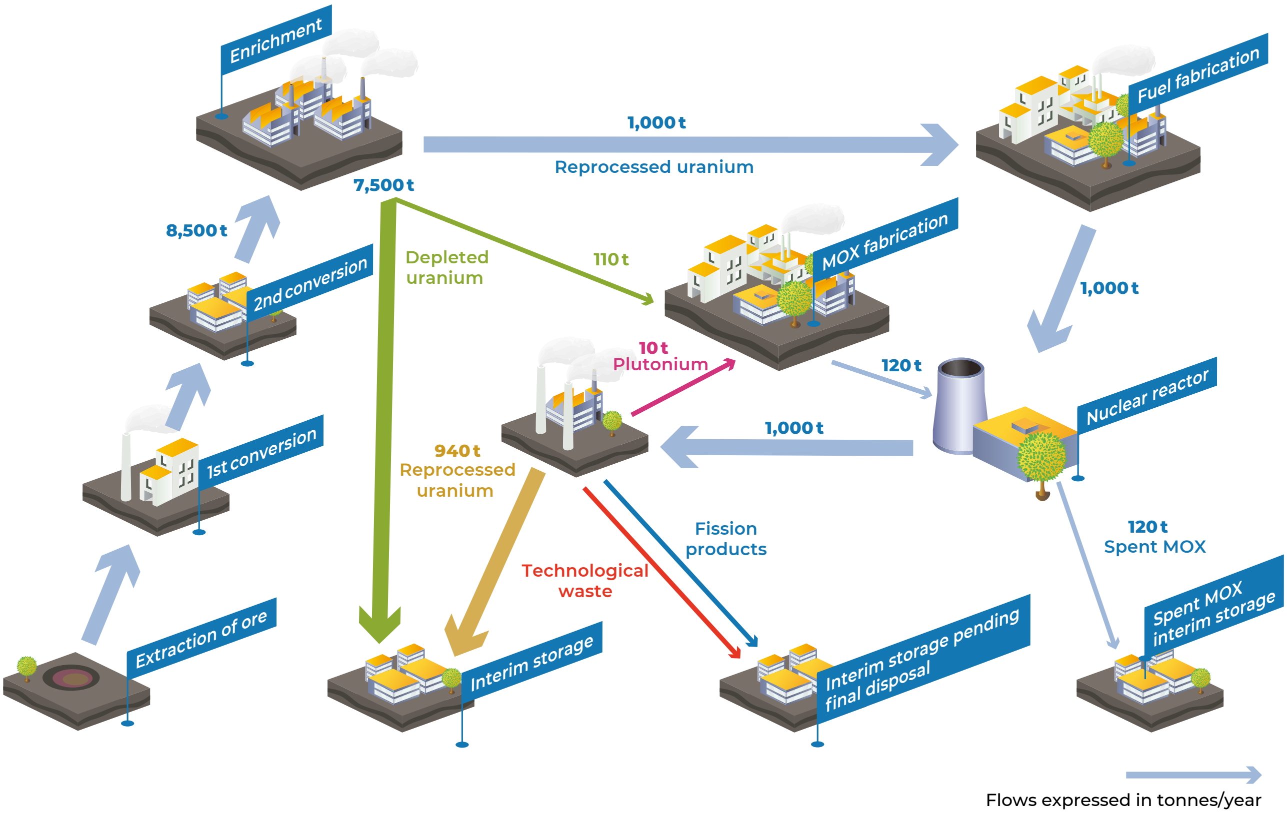
1. *Transuranic elements are chemical elements heavier than uranium (atomic number 92). The main ones are neptunium (93), plutonium (94), americium (95), curium (96). In a reactor, they are derived from uranium during secondary reactions other than fission.*

TABLE 1

Fuel cycle industry movements in 2020

	PRODUCT PROCESSED			PRODUCT OBTAINED		PRODUCT SHIPPED	
INSTALLATION	ORIGIN	PRODUCT PROCESSED	TONNAGE HEAVY METAL	PRODUCT OBTAINED	TONNAGE HEAVY METAL	DESTINATION	TONNAGE HEAVY METAL
Orano Ex-Comurhex Tricastin	ICPE Malvési	UF_4	1,704	UF_6	3,581	Orano storage areas Tricastin	3,581
Orano TU5 Unit Tricastin	Orano La Hague	Uranyl nitrate	4,480	U_3O_8	1,303	Orano storage areas Tricastin	1,303
Orano W unit Tricastin	GB II	UF_6 depleted	8,154	U_3O_8	6,510	Orano storage areas Tricastin	6,510
Orano GB II Tricastin	Orano Tricastin or Cameco (Canada)	UF_6	10,146 (of which 3,038 from Cameco)	UF_6 depleted	8,671	Defluorination	8,671
				UF_6 enriched	1,410	Fuel manufacturers	1,410
Framatome Romans	GB II Tricastin	UF_6 enriched	614	Assemblies based on enriched natural uranium	705	South Africa	26
						EDF	615
	Urenco (United Kingdom)		106			China	38
						Tihange (Belgium)	28
	Framatome Lingen (Germany)	UO_2 rods based on natural uranium	10	UO_2 and U_3O_8 powder based on enriched natural uranium	4.5	CEA	5
						Areva NP Richland (United States)	2.5
Orano Marcoule Melox	Framatome Lingen (Germany)	UO_2 depleted	80	Fuel elements MOX	79	EDF	71
	WSE vasteras (Sweden)		1				
	Orano La Hague	PuO_2	7			EPZ (Netherlands)	12
Orano La Hague	Fuels reprocessed in the La Hague plant						
	EDF and other licensees	UOX and MOX	1,035	Uranyl nitrate	1,068	Orano Tricastin	1,131
	Reactor BR2 Mol	RTR	0.03	PuO_2	12	Melox Marcoule	9
	Fuels stored in the La Hague plant pools						
	EDF and other licensees	Irradiated fuel elements	9,955	-	-	-	-

Fuel cycle diagram



- areas for the storage of uranium and thorium in various forms (BNIs 93, 178 and 179);
- the Atlas analysis laboratory (BNI 176);
- a Defence Basic Nuclear Installation (DBNI) which more particularly operates the radioactive substances storage areas, virtually all of which are for civil uses;
- the Socatri facility (BNI 138) which manages waste from the Tricastin site and carries out nuclear equipment maintenance and decommissioning.

The TU5 facility and the Orano W plant – BNI 155

BNI 155, called TU5, can handle up to 2,000 tonnes (t) of uranium per year, enabling it to reprocess all the uranyl nitrate ($UO_2(NO_3)_2$) produced by the Orano 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 reprocessed uranium is placed in storage on the Tricastin site.

The Orano 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).

The Philippe Coste plant is located inside its perimeter and is devoted to the fluorination of UF_4 into UF_6, to allow its subsequent enrichment in the Georges Besse II plant (GB II). Each year, it produces about 14,000 t of UF_6 from the UF_4 coming from the Orano facility in Malvési. It has ICPE status subject to authorisation with institutional controls ("Seveso" class installation) and is monitored by ASN accordingly.

The Georges Besse II ultra-centrifuge enrichment plant – BNI 168

BNI 168, called Georges Besse II (GB II), for which creation was authorised in 2007, is a plant enriching uranium by means of gas ultra-centrifugation. This process involves injecting UF_6 into a cylindrical vessel rotating at very high speed. Under the centrifugal force, the heavier molecules (containing uranium-238) are separated from the lighter ones (containing uranium-235). By combining several centrifuges, creating a cascade, it is then possible to recover a stream enriched with fissile U-235 isotope and a depleted stream. GB II comprises two enrichment units (South and North units) and a support unit, the REC II.

At the beginning of 2009, ASN authorised commissioning of the South unit, comprising eight modules, followed in 2013 by the North unit, comprising six modules, the first two of which are designed to enrich the uranium from spent fuel reprocessing. ASN authorised commissioning of the support unit in 2014. Enrichment of the uranium resulting from reprocessing, requiring prior authorisation from ASN, has not been implemented.

The Atlas facility – BNI 176

The purpose of the Atlas facility is:
- to carry out industrial physico-chemical and radio-chemical analyses;
- to monitor liquid and atmospheric discharges and monitor the environment of the Tricastin facilities.

The Atlas facility, which complies with the most recent safety requirements, is robust to external hazards. ASN authorised its commissioning on 7 March 2017.

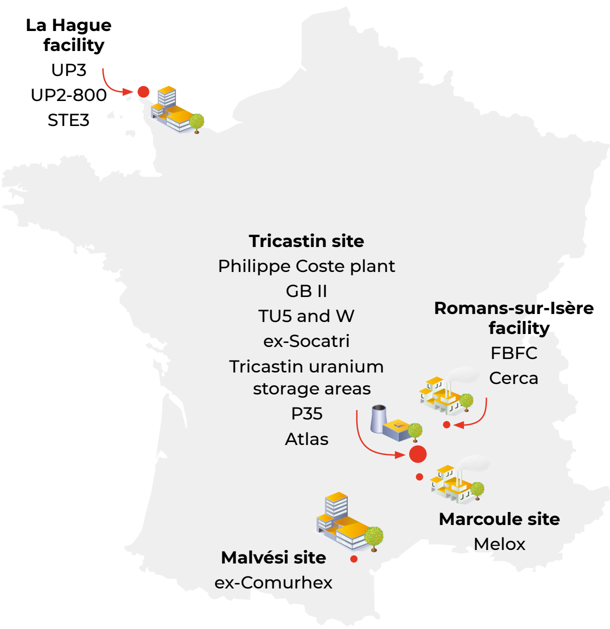
The Tricastin uranium storage facility – BNI 178

Following the delicensing of part of the Pierrelatte DBNI by decision of the Prime Minister, BNI 178 – or the Tricastin uranium storage facility – was created. This facility groups the uranium storage facilities and the platform's new emergency management premises. ASN registered this facility in December 2016.

The P35 facility – BNI 179

Following on from the delicensing process for the Pierrelatte DBNI by decision of the Prime Minister, BNI 179, known as "P35" was created. This facility comprises ten uranium storage buildings. ASN registered this facility in January 2018.

Installations of the fuel cycle in operation or undergoing decommissioning



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 the fuel assemblies.

The fuels used in the experimental reactors are more varied and, for example, some of them for example use highly-enriched uranium in metal form. These fuels are fabricated in the Framatome plant at Romans-sur-Isère usually called Cerca (BNI 63).

The MOX fuel is fabricated in BNI 151 Melox, operated by Orano and located on the Marcoule nuclear site.

1.3 The back-end fuel cycle – reprocessing

The Orano 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.

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 (t/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 t/year. The limits and conditions for discharges and water intake by the site are defined by two ASN resolutions of 22 December 2015 (resolution 2015-DC-0535 and resolution 2015-DC-0536).

Operations carried out in the plants

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

When the spent fuel assemblies arrive at the plants in their transport casks, they are unloaded either "under water" in the spent fuel pool, or dry in a leaktight shielded cell. The fuel assemblies are then stored in pools for cooling.

The fuel assemblies are then sheared and dissolved in nitric acid to separate the pieces of metal cladding from the spent nuclear 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 packaging 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 as uranyl nitrate $UO_2(NO_3)_2$. It will then be converted into a solid compound (U_3O_8) called "reprocessed uranium" in the TU5 facility on the Tricastin site.

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

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

The liquid effluents are 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 other effluents are routed 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 level and intermediate-level, short-lived waste (LLW/ILW-SL) repository at Soulaines (see chapter 14) or stored on the Orano site at La Hague, pending a final disposal solution (in particular the CSD-V and CSD-C). In accordance with Article L. 542-2 of the Environment Code, 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 originates. In order to guarantee an equitable distribution of the waste resulting from the reprocessing of the fuels of its various customers, the licensee has proposed an accounting system that tracks the entries into and exits from the La Hague plant. This system, called Exper system, was approved by the Order of the Minister responsible for energy of 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, Framatome, EDF and Andra.

ASN monitors the overall consistency of the industrial choices made with regard to fuel management and which could have consequences for safety. In this context, ASN periodically asks EDF to submit a "Cycle Impact" file prepared jointly with the fuel cycle stakeholders and presenting the consequences – for each step of the "nuclear fuel cycle" – of EDF's strategy for use of the different types of fuel in its reactors.

The last "Cycle Impact 2016" file, for the period 2016-2030, produced in collaboration with Framatome, Orano and Andra, more particularly identifies the maximum thresholds (capacity saturations, maximum isotope content of fuel reached, etc.) foreseeable until 2040, on the basis of various energy mix 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 for designing and building any new facilities identified as being necessary for implementation of the strategy.
- Radioactive substances transport contingencies were explicitly taken into account.
- Nuclear reactor closures were studied for the period of time considered, in particular assuming stable electricity demand until 2025, to take account of the planning provisions included in the Energy Transition for Green Growth Act 2015-992 of 17 August 2015.
- The strategy for managing and storing spent fuels pending reprocessing or disposal was explained.

After examination, ASN delivered its opinion on 18 October 2018, the main conclusions of which are as follows.

ASN considers that the "Cycle Impact 2016" file provides a satisfactory presentation of the consequences on the nuclear facilities, transport operations and waste of the various "nuclear fuel cycle" evolution scenarios. However, the consequences of the contingencies 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. This for example entails ensuring that – given the incompressible development times for industrial projects – the need for the creation of 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 of nuclear reactors and of La Hague), 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 very significantly greater than the current and projected capacities, or to be able to use MOX fuel in reactors other than the 900 MWe reactors, which are the oldest. The time-frame required for the design and production of these options is about ten years. ASN therefore asks the industrial players to start examining these two options without delay.

Every five years, the Government updates the Multi-year Energy Plan (MEP). The functioning of the "nuclear fuel cycle" is liable to evolve according to the orientations thus defined. ASN therefore urges the industrial players to study the safety and radiation protection consequences of implementing the MEP on the "nuclear fuel cycle", and its consistency, at each of its revisions.

Further to this examination, the year 2020 was marked by several events which disrupted the balance of the cycle:

- The Melox plant again experienced difficulties in producing MOX fuel of the required quality and quantity for the EDF fleet of reactors, although to a lesser extent than in 2019. The new production process in fact leads to a greater disparity in the size of the depleted uranium grains and thus a higher discard rate. This led EDF to reduce the number of MOX assemblies present in the core of certain reactors. This situation also leads to a lesser consumption of the plutonium produced by the La Hague plants and a larger number of spent fuel assemblies in the pools. The excess plutonium under the responsibility of Orano, and the non-conforming MOX, will eventually have to be resorbed.
- A fission products evaporator-concentrator at La Hague reached a level of corrosion requiring increased surveillance of its thickness, so as to guarantee its ability to withstand the pressure in an earthquake situation. In 2020, ASN thus authorised particular surveillance methods for this evaporator, which apply to its final operating phase. If the evaporator is shut down before it is replaced, this will lead to a reduction in the reprocessing capacity of the La Hague plants.

These disruptions of the cycle back-end plants confirm the need for countermeasures identified by ASN in its opinion of 18 October 2018 should commissioning of the EDF centralised storage pool occur after saturation of French spent fuel storage capacity.

1.5 Outlook: planned facilities

New uranium storage facility project on the Tricastin site

In February 2015, Orano 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 undertook work to optimise the existing storage facilities on the site in order to push back their saturation date from 2019 to 2021 and in November 2017 submitted a creation authorisation application for new storage buildings. In 2018, ASN informed the Minister responsible for nuclear safety that the content of the creation authorisation application was sufficient for its examination to take place. A public inquiry was held on this subject at the end of 2020. The project should receive an authorisation decree in 2021.

"New concentration of fission products" project on the La Hague site

In order to replace the fission products evaporator-concentrators at La Hague, which are suffering from a more advanced stage of corrosion than imagined in the design, Orano is building new units, called "NCPF", comprising six new evaporators. This particularly complex project required several authorisations and was the subject of an ASN resolution in 2020, concerning the process of three of these evaporators (NCPF T2). The authorisations for connection of this new equipment to the existing units will be the subject of other resolutions and authorisations in the coming months.

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 also requested a modification of the UP3-A plant Creation Authorisation Decree so that CSD-C storage could be extended. This extension, for which ASN issued a favourable opinion on 8 September 2020, was authorised by the Decree of 27 November 2020.

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 submitted the safety options file in 2016 for a new special fuels reprocessing unit. This unit would comprise new shearing and dissolving equipment. In March 2017, ASN informed the licensee that the safety options for this new unit were on the whole satisfactory. Orano however encountered technical difficulties in developing the process, which led to a significant change in the initial design options. In the light of this, ASN granted Orano more time to submit the authorisation application for this unit. The licensee transmitted new safety options for this project in January 2020. ASN released its observations on this file on 9 December 2020.

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 (PNGMDR), instructed EDF "*to send ASN the technical and safety options for the creation of new storage capacity before 30 June 2017*".

EDF opted for a centralised storage pool, which should allow storage of spent fuels for which reprocessing or disposal can only be envisaged in the long-term future. The envisaged operating life for this storage facility is about a century. In 2017, EDF transmitted the safety options file for this project, the siting of which has not yet been specified.

Following examination of the safety options file transmitted by EDF, ASN issued its opinion in July 2019. It considered that the general safety objectives and the design options adopted are on the whole satisfactory. Additional studies and demonstrations are however required, notably concerning the design and the control of manufacturing, in order to guarantee the long-term leaktightness of the pool, as well as the external hazard levels adopted once the actual site of the facility has been identified.

In 2020, EDF reported a delay concerning this storage pool project, which would be located on the La Hague site but which would not be commissioned before 2034.

As of 2018, ASN had asked EDF to present the counter-measures it envisaged for this situation, given the possible saturation of French spent fuel storage capacity by the time of this commissioning.

The countermeasures envisaged by EDF, together with Orano, are to increase the density in the La Hague pools, increase the use of MOX in the 900 MWe reactors and use dry storage of spent fuels.

With regard to the increased density in the La Hague pools, Orano submitted a safety options file in November 2020. This file was presented to the PNGMDR working group and will be examined by ASN.

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

At each step in the fuel cycle, the potential risks in the facilities are different:

- The conversion and enrichment facilities mainly entail toxic risks (owing to the chemical form of the radioactive substances they use), criticality risks (when they use enriched materials) and the risk of dissemination of radioactive substances (in powder, liquid or crystallised form).
- The fuel fabrication facilities mainly entail toxic risks (when they have conversion units), criticality, fire or explosion risks (in the ceramic plants which use heating processes), the risk of dissemination of radioactive substances (powder or crystals) and of exposure to ionising radiation (when they use reprocessed substances).
- The spent fuel reprocessing facilities mainly entail risks of dissemination of radioactive substances (the substances used are mainly liquids and powders), of criticality (the fissile substances employed change geometrical shape) and exposure to ionising radiation (the fuels contain highly irradiating substances).

Their common point is that they never seek to create chain reactions (prevention of the criticality risk) and that they use dangerous substances in industrial quantities. Conventional industrial risks are therefore particularly present. Certain plants, Orano at Tricastin and La Hague or Framatome at Romans-sur-Isère, are in this respect subject to the Seveso Directive.

ASN endeavours to apply oversight that is proportionate to the potential risks of each facility, which 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, reinforcing the inspections and the scope of the reviews carried out by ASN for the higher risk facilities.

When the installations are substantially modified or when they are finally shut down, ASN is in charge of examining these modifications, which are the subject of an amending decree from the Government, after prior consultation of ASN. ASN also establishes binding requirements for these main steps. Finally, ASN also reviews the safety files justifying the operation of each BNI.

For each facility, ASN monitors the organisation and means chosen by the licensee to enable it to assume its responsibilities in terms of nuclear safety, radiation protection, emergency management in the event of an accident and protection of nature, the environment and public health and safety. ASN monitors the working of the organisations put into place by the licensees mainly through inspections, more specifically those devoted to safety management. In this respect, Orano submitted applications for a change of licensee concerning all its BNIs, in February 2020. The purpose of this project, called "PEARL", is to separate the group's activities into three separate subsidiaries dealing with the cycle front-end, the cycle back-end and decommissioning. ASN's examination of this application showed that it led to a change in organisation in the Orano group BNIs undergoing decommissioning, liable to compromise the principle set out in the Environment Code, whereby operational responsibility for a BNI lies with its nuclear licensee. Orano thus submitted a request for a waiver to this principle in December 2020 and ASN will issue a position statement on it in 2021.

2.2 Lessons learned from the Fukushima Daiichi accident

Priority was given to integrating the lessons learned from the Fukushima Daiichi Nuclear Power Plant (NPP) accident (in Japan) 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 and Framatome facilities assessed in 2011, in the light of the conclusions of the stress tests. These requirements more specifically stipulate the deployment of a "hardened safety core" of material and organisational provisions designed to prevent a severe accident or limit its spread, mitigate large-scale releases and enable the licensee to fulfil its emergency management duties.

Generally speaking, Orano and Framatome designed and implemented new means to deal with extreme situations in their facilities in good time.

More specifically, the Local Emergency Command Posts (PCD-L) on the Romans-sur-Isère and Tricastin sites were relocated to new emergency management buildings designed to withstand extreme hazards. These buildings more specifically contain a ventilation system with filtration enabling the personnel present to be protected against a toxic release from the site's facilities, neighbouring facilities or, on the Tricastin site, a radioactive release from the neighbouring NPP.

With regard to the La Hague site, Orano carried out work and deployed means to ensure significant water reserves in the event of an extreme situation, and means to ensure recirculation of water under the storage pools and thus maintain a minimum water level above the fuel assemblies in the event of a leak. Finally, the site's new PCD-L emergency building, which is robust to extreme hazards, has been operational since 2019.

On the Marcoule site, Orano has begun the construction of its new emergency building, designed to withstand extreme hazards. This construction site is however considerably behind schedule owing to recurring difficulties between the licensee and its civil engineering contractor and it might not be completed before the end of 2021.

ASN nonetheless considers that the progress of the post-Fukushima work and the organisational measures adopted are satisfactory at Orano 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 reviews concerned 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 these periodic safety reviews confirmed that the subjects to be examined by the licensee during the periodic safety reviews, along with the required methodologies, should be defined during what is referred to as the orientation phase. In addition, probabilistic analyses must be added to the safety cases for all the BNIs. Following the periodic safety review of plant UP2-800 (BNI 117), Orano established an ambitious safety analysis methodology based on methods applied to Installations Classified for Protection of the Environment and presented it to ASN in 2020 with a view to extending it to all of its BNIs. Its implementation for the forthcoming periodic safety review of BNI 116 will represent significant progress for analysis of the complex accident sequences to be examined by ASN.

The periodic safety review of BNI 98 (FBFC) comprises safety improvements to the facility, notably with regard to controlling fire risks, controlling criticality and reinforced civil engineering. However, it demonstrated the need for improved incorporation of the hazards linked to dangerous substances into the safety case of the fuel cycle facilities, while ensuring a level of stringency at least equivalent to that of Seveso classified upper-tier facilities. In 2020, ASN therefore issued a binding requirement in its resolution associated with this periodic safety review, for updating of the safety case with regard to the risks resulting from dangerous substances.

The periodic safety reviews show the importance of an *in situ* verification of the conformity of the Protection Important Componant (PIC) that is as exhaustive as possible, or as representative as possible of the PIC 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.

In the context of the faster-than-anticipated corrosion of the fission products evaporators-concentrators and other equipment in the La Hague plant, the management of ageing is a priority issue for ASN with regard to the cycle back-end facilities, which are the subject of dedicated inspections and increased vigilance in the examination of the ongoing periodic safety reviews.

2.4 Particular regulatory actions conducted in consultation with the Defence Nuclear Safety Authority

The upcoming declassification of the Tricastin DBNI to a BNI will mean that ASN will take over responsibility for oversight of a part of the facilities it contains. Together with the Defence Nuclear Safety Authority (ASND), ASN ensures that consistency is maintained in the application of the safety and radiation protection requirements for the facilities under their respective responsibility on the Tricastin site. Most of the facilities regulated by the ASND have in fact been shut down or are being decommissioned and no longer play a role in national defence. They should therefore no longer 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 of 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. In 2020, ASN informed the Minister in charge of nuclear safety of its opinion on Orano's proposal to reorganise the platform following declassification of the DBNI.

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.

CHAPTER 12

NUCLEAR RESEARCH AND MISCELLANEOUS INDUSTRIAL FACILITIES

12 Nuclear research and miscellaneous industrial facilities

Nuclear research or industrial facilities differ from the Basic Nuclear Installations (BNIs) involved directly in the generation of electricity (nuclear power reactors and fuel cycle facilities) or waste management. Traditionally, most of these BNIs are operated by the Alternative Energies and Atomic Energy Commission (CEA), but also by other research organisations (for example the Laue-Langevin Institute – ILL, the International Thermonuclear Experimental Reactor (ITER) organisation and the National large heavy ion accelerator – Ganil) or by industrial firms (for instance CIS bio international, Steris and Ionisos, which operate facilities producing radiopharmaceuticals, or industrial irradiators).

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 (NPPs). Some of these facilities also produce radionuclides[1] 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 NPPs, the energy produced by research reactors is not recovered and is in fact a "by-product" removed by cooling. The quantities of radioactive substances used are smaller than in nuclear power reactors.

An overview of the various types of research reactors present in France and the main corresponding risks is presented below.

In their design, these reactors take account of reference accidents, both core melt "under water" (failure of the cooling system) and core melt "in air" (after uncovering of the core or during handling). They also take account of accidents specific to certain research reactors.

Neutron beam reactors

Neutron beam reactors are pool type. They are mainly designed for fundamental research (solid physics, molecular physico-chemistry, biochemistry, etc.), using the neutron diffraction method to study matter. The neutrons are produced in the reactor, at different energy levels and are captured by channels in the reactor before being routed to experimentation areas.

In France, there is now only one neutron beam reactor in service: the High-Flux Reactor – RHF (BNI 67) operated by the Laue-Langevin Institute (ILL) in Grenoble (rated power limited to 58 Megawatts thermal – MWth). The RHF operates in cycles of about 50 to 100 days. The main safety issues are reactivity control, cooling and containment. The Orphée reactor (BNI 101), operated by the CEA in Saclay (rated power limited to 14 MWth), was finally shut down at the end of 2019.

"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" reactor in service: the Cabri reactor (BNI 24) operated by the 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

The irradiation reactors are pool type. They are used to study the physical phenomena linked to the irradiation of materials and fuels, as well as their behaviour. As the neutron fluxes obtained by these facilities are more powerful than those in a Pressurized Water Reactor (PWR) type nuclear power reactor, the experiments enable ageing studies to be performed on 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 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 Megawatts thermal. 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 (JHR – BNI 172), which is to replace it, is currently under construction in Cadarache.

Fusion reactors

Unlike the research reactors previously described and which use nuclear fission reactors, some research facilities aim to produce nuclear fusion reactions.

1. The use of radionuclides offers medical analysis and treatment possibilities: to diagnose cancers by scintigraphy and tomography, allowing detailed examination of functioning organs, or to treat tumours with radiotherapy, which uses radiation from the radionuclides to destroy the cancer cells (see chapter 7).

Research facilities in France

▲ **Research reactors**
Cadarache: Cabri
Grenoble: High-Flux Reactor (RHF)

▲ **Research reactors under construction**
Cadarache: ITER,
Jules Horowitz Reactor (JHR)

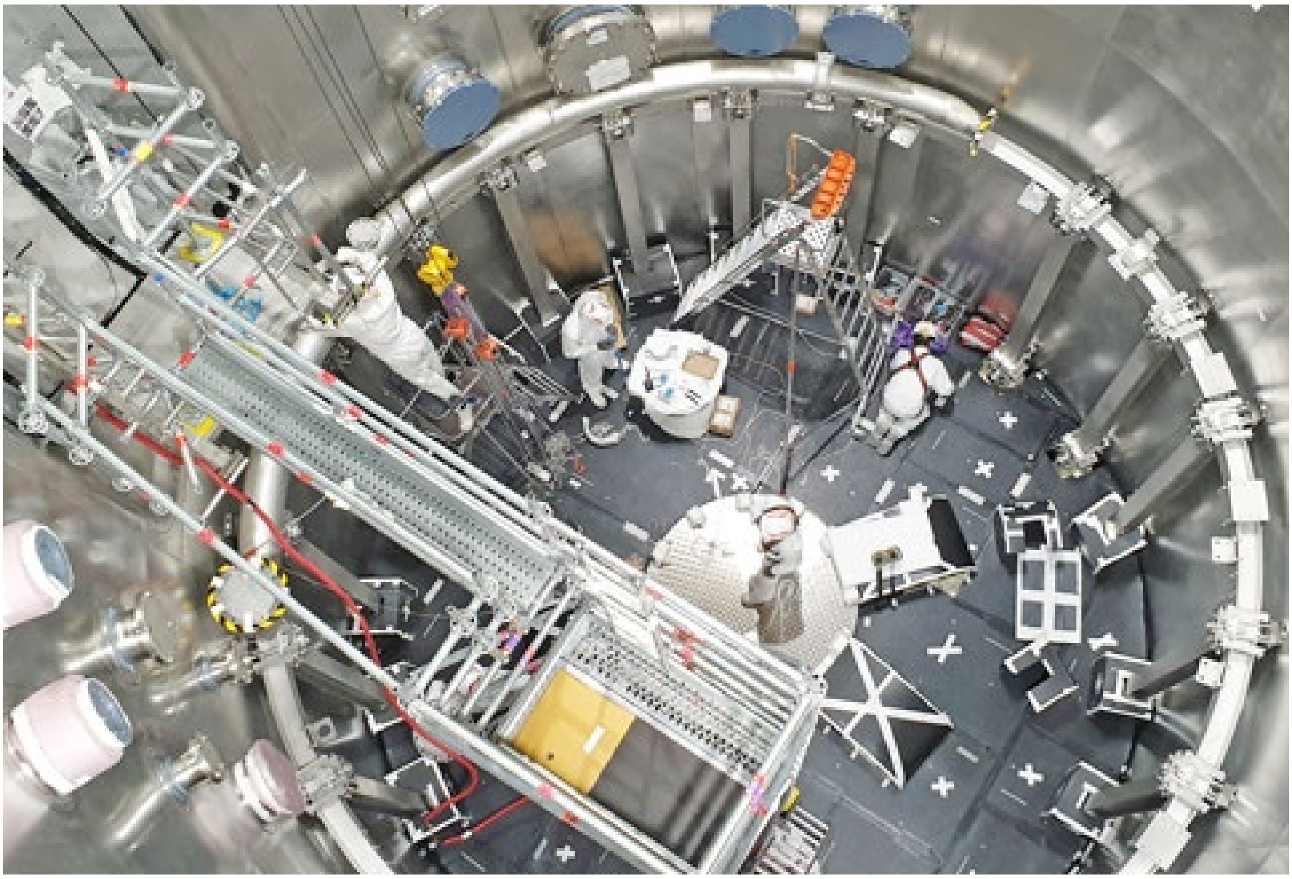
■ **Particle accelerators**
Caen: Ganil
Genève: CERN

● **Laboratories and miscellaneous industrial facilities**
Cadarache: LECA/STAR, Lefca
Saclay: LECI, UPRA
Marcoule: Atalante

● **Materials storage**
Cadarache: Magenta

✦ **Industrial ionisation facilities**
Dagneux, Pouzauges,
Sablé-sur-Sarthe: Ionisos
Marseille: Gammaster
Marcoule: Gammatec
Saclay: Poséidon

Jules Horowitz (JHR) nuclear research reactor – installing the pool floor



In France, the International Thermonuclear Experimental Reactor (ITER) facility (BNI 174) is an international fusion reactor project currently under construction in Cadarache. The purpose of ITER is to scientifically and technically demonstrate control of thermonuclear fusion by magnetic confinement of a deuterium-tritium plasma, during long-duration experiments with significant power – 500 Megawatts (MW) for 400 seconds.

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 criticality risk is controlled by strict instructions regarding the handling, storage and monitoring of the materials being studied. Finally, the fire risk is managed using technical systems (fire doors, dampers, detectors, fire fighting equipment, etc.) and an organisation limiting the fire loading. Personnel training and rigorous organisation are also essential factors in controlling these four main risks.

Fuels and materials test laboratories

Some of these laboratories, operated by the 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;
- the Laboratory for Research and Experimental Fabrication of Advanced Nuclear Fuels (Lefca, BNI 123), located in Cadarache;
- the Spent Fuel Testing Laboratory (LECI, BNI 50), located in Saclay.

Research and development (R&D) 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

The Artificial Radionuclides Production Facility (UPRA), situated in Saclay and operated by CIS bio international, is a nuclear facility designed according to the same principles as a laboratory (special areas for handling and experimenting with radioactive substances, using appropriate means), for the purposes of research and to develop radionuclides for medical uses. CIS bio international is a subsidiary of the Curium group, a manufacturer of radiopharmaceuticals.

1.2.2 Particle accelerators

Some particle accelerators are BNIs. These installations use electrical or magnetic fields to accelerate charged particles. The accelerated particle beams produce strong fields of ionising radiation, activating the materials in contact, which then emit ionising radiation even after the beams have stopped. Exposure to ionising radiation is thus the primary risk in this type of facility.

The Ganil

The Large National Heavy Ion Accelerator (Ganil – BNI 113), located in Caen, carries out fundamental and applied research work, more particularly in atomic physics and nuclear physics. This research facility produces, accelerates and distributes ion beams with various energy levels to study the structure of the atom.

The CERN

The European Organization for Nuclear Research (CERN) is an international organisation situated between France and Switzerland, whose role is to carry out purely scientific fundamental research programmes concerning high energy particles. The CERN does not operate just one particle accelerator to study the structure of matter, but an entire chain of devices (sometimes called injectors). This chain currently comprises several linear and circular accelerators. Owing to its cross-border location, the CERN is subject to particular verifications by the French and Swiss Authorities.

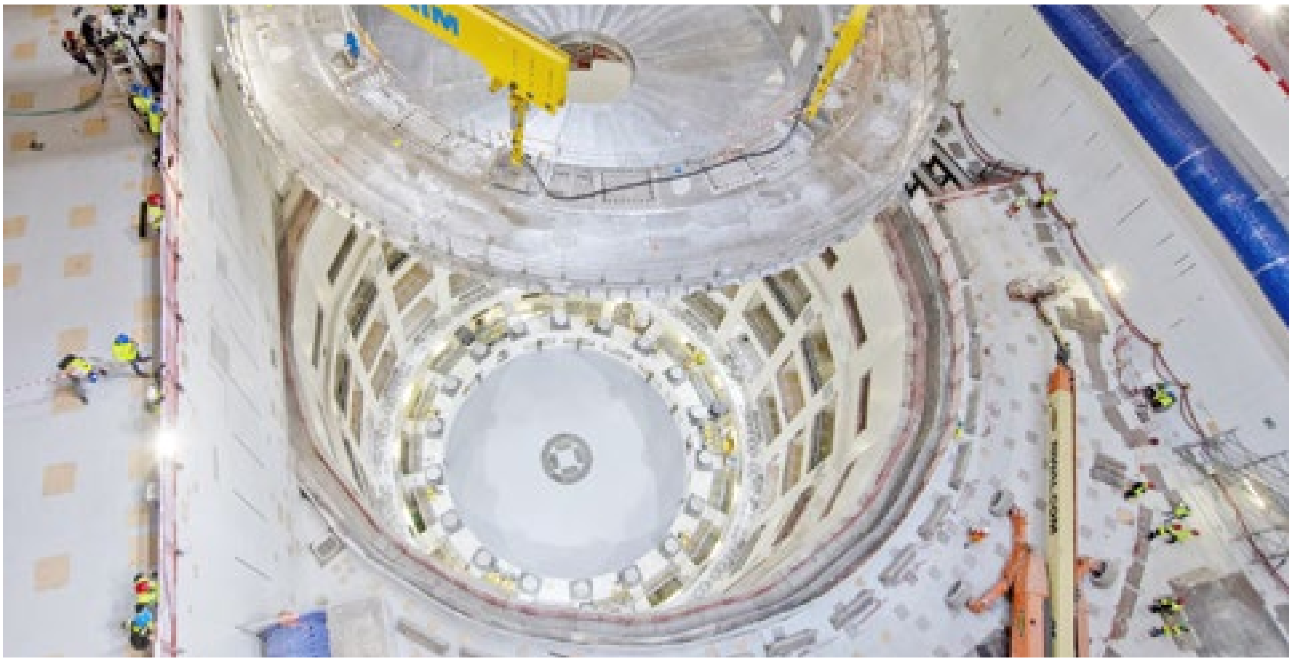
1.2.3 Industrial ionisation installations

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, agrifood products and pharmaceutical raw materials. Irradiators can also be used to study the behaviour of materials under ionising radiation, notably to qualify materials for the nuclear industry.

These irradiators are used by:
- the Ionisos Group, which operates three facilities located in Dagneux (BNI 68), Pouzauges (BNI 146) and Sablé-sur-Sarthe (BNI 154);
- the Steris group, which operates the Gammaster (BNI 147) and Gammatec (BNI 170) facilities in Marseille and Marcoule;
- the CEA, which operates the Poséidon irradiator (BNI 77) on the Saclay site.

ITER installation – base of the cryostat being lowered into the Tokamak



1.3 Materials storage facilities

The materials storage facilities operated by the CEA are primarily devoted to the conservation of non-irradiated (or slightly irradiated) uranium and plutonium-bearing fissile materials from other CEA facilities. This activity enables the laboratories (Atalante, Lefca, etc.) to be supplied according to the needs of the experiments being conducted. More recently, they have become a temporary storage solution for the fissile materials which were present in facilities that are now shutdown, such as the research reactors (Éole, Minerve, Osiris, Masurca, etc.).

Principles and safety issues

The main challenges inherent in these facilities are to prevent the dispersal of radioactive substances and to control the chain reaction (criticality).

The safety of these facilities is based on a series of static physical barriers (walls and doors of rooms and buildings) to prevent the dispersal of radioactive substances. When operations are carried out on these substances, static confinement is also provided by the equipment (glovebox, shielded cell) in which these operations are performed. This static confinement is supplemented by dynamic confinement consisting on the one hand of a cascade of negative pressure environments between the rooms where there is a risk of radioactive substance dissemination and, on the other, filtration of the gaseous releases into the environment. The chain reaction is controlled by strict instructions regarding the handling, storage and monitoring of the materials being stored.

Dedicated storage facilities

The Magenta facility (BNI 169), commissioned in 2011 and operated by the CEA on its Cadarache site, is dedicated to the storage of non-irradiated fissile material and the non-destructive characterisation of the nuclear materials received. It is more particularly replacing the Central Fissile Material Warehouse (MCMF – BNI 53), which was finally shut down at the end of 2017.

Materials storage areas in BNIs

Other radioactive material storage areas, located within a BNI, are authorised to store radioactive materials on the site, but in quantities far lower than those stored in Magenta. This is for example the case with BNI 55, called STAR, which stores spent fuels and fuels irradiated following reprocessing and/or conditioning.

2. ASN actions concerning research facilities: a graded approach

2.1 The graded approach according to the risks in the facilities

The BNI System applies to more than about a hundred facilities in France. This System concerns various facilities with widely differing nuclear safety, radiation protection and environmental protection challenges: nuclear research or power reactors, radioactive waste storage or disposal facilities, fuel fabrication or reprocessing plants, laboratories, industrial ionisation facilities and so on.

The safety principles applied to nuclear research or industrial facilities are similar to those adopted for nuclear power reactors and "nuclear fuel cycle" facilities, while taking account of their specificities with regard to risks and detrimental effects. ASN has implemented an approach that is proportional to the extent of the risks or drawbacks inherent in the facility. In this respect, ASN has divided the facilities 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 enables the oversight of the facilities to be adapted and thus focused on those with the highest risks, in terms of the inspections and the examinations carried out by ASN. For example, the RHF and Cabri research reactors are placed in categories 1 and 2 respectively, while the Ganil particle accelerator is placed in category 3.

2.2 The periodic safety reviews

The Environment Code requires that the licensees carry out a periodic safety review of their facilities every ten years. This periodic safety review is designed to assess the status of the facility with respect to the applicable regulations and to update the assessment of the risks or detrimental effects inherent in the facility, notably taking into account the condition of the facility, acquired operating experience, changes in knowledge and the rules applicable to similar facilities. They are thus an opportunity for upgrades or improvements in fields in which the safety requirements have changed, in particular seismic resistance, protection against fire and confinement.

To date, all the nuclear research and miscellaneous facilities have undergone a periodic safety review. For facilities which had not yet undergone a first review, the Decree of 2 November 2007 required that the licensees submit their first periodic safety review report no later than November 2017. ASN subsequently implemented an examination method commensurate with the issues in the facilities: some facilities require particular attention due to the risks they present, while for others presenting a lower level of risk, the extent of the inspections and examinations is adapted accordingly. The technical examination of all the periodic safety review reports will take several years, owing to the specific nature of each of the facilities concerned.

For example, on 1 November 2017, the CEA transmitted 16 periodic safety review reports to ASN. The CEA then informed ASN that it wished to even out the workload involved in these reviews, in terms of its organisation and its resources, by bringing forward the submission of the periodic safety review reports for certain facilities in the coming decade. ASN is in favour of this approach.

In 2020, ASN continued with on-site inspections specifically devoted to the periodic safety review of the facilities. It finds that the 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 this process.

2.3 Lessons learned from the Fukushima Daiichi accident

In the wake of the Fukushima Daiichi NPP accident, ASN initiated a stress tests approach for the nuclear facilities. The approach consists in assessing the safety margins in the facilities with regard to their ability to withstand a loss of electrical power, or cooling, and extreme natural hazards.

In May 2011, ASN required that stress tests be carried out on the BNIs with the highest level of risk in the light of the Fukushima Daiichi accident (batch 1). For the CEA BNIs (Masurca, Osiris and JHR) and the ILL's RHF, in batch 1, ASN in 2012 ordered the implementation of organisational and material provisions, called the "hardened safety core" in the light of the conclusions of the stress tests. ASN notably observes that the large-scale work on the RHF research reactor was carried out rapidly and satisfactorily, notably with the construction of new and robust emergency management premises, reinforcement of the tightness of the reactor building to extreme flooding and the installation or modification of back-up systems to prevent risks relating to the loss of cooling.

The stress tests were continued for a second group (batch 2) of 22 facilities with lesser safety implications. These include the UPRA, CEA research facilities (Atalante, Cabri, LECA and Orphée) and ITER. The emergency management resources in the CEA centres in Cadarache, Marcoule and Saclay were reviewed under the second batch of stress tests. In 2015, ASN ordered the implementation of new emergency management means, more particularly the construction or reinforcement of the "hardened safety core" emergency centres so that they could withstand extreme climatic conditions. It finds that these projects are behind schedule on all the CEA centres, for various reasons, and that the initial deadlines were not met. With regard to the Cadarache centre, ASN agreed to the request for postponement of construction of the emergency centre buildings, given that the main risk considered for the site is associated with the JHR reactor, for which commissioning has been delayed. For the Saclay centre, after formal notice from ASN on 6 September 2019, the CEA transmitted the file justifying the sizing of the future emergency management buildings in December 2019, with commissioning scheduled for the end of 2021. Finally, for the Marcoule centre, ASN is still waiting for additional data regarding the strength of the existing emergency management buildings (confinement, accessibility, operability, habitability, etc.).

Finally, of the thirty other Laboratories, Plants, Decommissioning and Waste (LUDD) facilities with the lowest safety implications (batch 3), ASN issued a binding requirement in 2013 on the CEA facilities (Lefca, LECI, Poséidon, Magenta and STAR), the Ganil and the irradiators of the Ionisos and Steris groups, regarding a calendar for submission of the stress tests reports running until 2020. For these facilities, the stress tests will be examined as part of a periodic safety review, as is currently the case for the irradiators of the Ionisos group.

CHAPTER 13

DECOMMISSIONING OF BASIC NUCLEAR INSTALLATIONS

13 Decommissioning of Basic Nuclear Installations

The term 'decommissioning' covers all the technical and administrative activities carried out after the final shutdown of a nuclear installation, on completion of which the installation can be delicensed, an administrative operation which consists in removing the installation from the list of Basic Nuclear Installations (BNIs). These activities include removal of the radioactive materials and waste still present in the installation and disassembly of the equipment, components and facilities used during operation. The licensee then proceeds with Post-Operational Clean-Out (POCO) of the premises, remediation of the soils, and possibly the destruction of civil engineering structures.

The aim of the decommissioning and POCO operations is to achieve a predetermined final state in which all the hazardous substances, non-radioactive substances included, have been removed from the nuclear installation.

The decommissioning of a nuclear installation is prescribed by Decree issued after consulting ASN, the French 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 2020 in France, 36 nuclear facilities of all types (power and research reactors, laboratories, fuel reprocessing plants, waste treatment facilities, etc.) were either shut down or undergoing decommissioning, which represents more than one quarter of the BNIs in operation. As at 31 December 2020, ASN was examining 18 decommissioning files for definitively shut down facilities whose decommissioning has not yet been prescribed or whose decommissioning conditions have been substantially changed.

The year 2020 was marked in particular by the shutdown of the two reactors of the EDF's Fessenheim Nuclear Power Plant (NPP) in February and June 2020, followed by the submission of the BNI decommissioning file.

1. Technical and legal framework for decommissioning

1.1 Decommissioning challenges

Accomplishing the decommissioning operations – which are often long and costly – within the set time frames is a challenge for the licensees in terms of project management, skills maintenance and the coordination of the various operations which involve numerous specialist companies. Decommissioning is effectively characterised by a succession of operations rather than a production state, and therefore by changing risks. Some risks, particularly the risk of significant off-site discharges, decrease because the quantity of radioactive substances gets smaller. But the work carried out, sometimes in close contact with the radioactive substances, presents serious radiation exposure risks for the workers. Other risks increase such as the risks of dispersion of radioactive substances into the environment or certain conventional risks such as the risks of falling loads when handling large components on worksites situated at height, fires or burns during hot work in the presence of combustible materials, anoxia when working in confined areas, instability of partially dismantled structures, chemical risks during decontamination operations.

One of the major challenges in the decommissioning of an installation is linked to the very large volumes of waste produced compared with the operational waste. The scale and the difficulty of the work must be assessed as early as possible in the life of the installation (as of the design stage if possible) in order to ensure completely safe decommissioning in as short a time frame as possible.

Correct performance of the decommissioning operations is also dependent on the availability of the decommissioning "support" facilities (waste storage, processing and conditioning facilities, effluent treatment facilities) and of appropriate management routes for all the types of waste likely to be produced. When the availability of the final waste disposal outlets on the stated dates is called into question, the licensees must, with due caution, organise the facilities necessary for the interim storage of their waste pending opening of the corresponding disposal route. 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 Alternative Energies and Atomic Energy Commission (CEA), EDF and Orano (see point 4).

Decommissioning of CEA's old installations and Orano's first-generation plants (especially the plants that played a role in the French deterrence policy, such as the gaseous diffusion plants of the Pierrelatte Defence Basic Nuclear Installation (DBNI) at Tricastin and the UP1 plant of the Marcoule (DBNI) is going to produce extremely large quantities of very-low-level (VLL) waste.

This massive production of waste in the decades to come, which was not anticipated and which is incompatible with the current capacities of Cires[1], was addressed by a PNGMDR working group resulting in several lines of reflection, including the creation of a new centralised repository, the possible recycling of some of the waste or its disposal on site. ASN issued a position statement in 2020 on the studies submitted by the licensees on this subject (see chapter 14).

1.2 The ASN decommissioning doctrine

Many factors can influence the choice of one decommissioning strategy rather than another: national regulations, social and economic factors, financing of the operations, availability of waste disposal routes, decommissioning techniques, qualified personnel, personnel present during the operating phase, exposure of the personnel and the public to ionising radiation resulting from the decommissioning operations, etc. Consequently, practices and regulations differ from one country to another.

1.2.1 Immediate dismantling

Decommissioning in the shortest time-frame possible is a core principle in the regulations applicable to BNIs (Order of 7 February 2012 setting the general rules relative to BNIs). This principle, which ASN has affirmed since 2009 as regards decommissioning and delicensing, has been enshrined in legislation by Act 2015-992 of 17 August 2015 relative to Energy Transition for Green Growth. This strategy moreover avoids placing the technical and financial burden of decommissioning on future generations. It also provides the benefit of retaining the knowledge and skills of the personnel present during operation of the installation, which are vital during the first decommissioning operations.

The aim of the strategy adopted in France is that:
- The licensee prepares the decommissioning of its installation as of the design stage.
- The licensee anticipates decommissioning and sends the 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 which can vary from a few years to a few decades, depending on the complexity of the installation.

1.2.2 Complete clean-out

The decommissioning and post-operational clean-out operations for a nuclear facility must lead to the gradual elimination of any hazardous substances, in particular radioactive substances, resulting from the activation or deposition phenomena, as well as any migration of contamination in the structures of the facility's premises or the soil of the site, with a view to delicensing the facility.

The ASN reference approach, as stated in its doctrine, requires that the licensees deploy decommissioning and clean-out practices taking into account the best scientific and technical knowledge available at the time and in economically acceptable conditions, with the aim of achieving a final state in which all the hazardous and radioactive substances have been removed from the BNI. Should it be difficult to apply this approach due to the nature of the contamination, ASN considers that the licensee must go as far as reasonably possible in the clean-out process. Whatever the case, the licensee must provide technical or economic justification that this reference management approach cannot be applied and that the clean-out operations cannot be taken further under acceptable economic conditions using the best technical clean-out and decommissioning methods available.

In accordance with the general principles of radiation protection, the dosimetric impact of the site on the workers and public after delicensing must be as low as reasonably possible (ALARA principle[2]). ASN is not in favour of introducing general thresholds and considers that it is preferable to adopt a case-by-case approach according to the intended subsequent use of the site. More specifically, reaching a threshold with exposure leading to an effective annual dose of 300 microsieverts (μSv) – *i.e.* one third of the annual dose limit of 1 millisievert (mSv) for the public – in all the envisaged and envisageable situations is only acceptable after demonstrating the integration of an optimisation process, in accordance with the International Atomic Energy Agency (IAEA) texts on the unconditional release of a site contaminated by radioactive substances.

In 2016, ASN thus updated and published a guide on structure clean-out operations (Guide No. 14, available on *asn.fr*). The provisions of this Guide have already been implemented on numerous installations with varied characteristics, such as research reactors, laboratories, fuel manufacturing plants, etc. In 2016, ASN also published a guide relative to the management of polluted soils at nuclear installations (Guide No. 24, available on *asn.fr*).

1.3 Decommissioning regulatory framework

Once a BNI is definitively shut down, it must be decommissioned. Its purpose therefore has to change as it is no longer that for which its creation was authorised, as the Creation Authorisation Decree notably specifies the operating conditions of the installation. Furthermore, the decommissioning operations imply a change in the risks presented by the installation. Consequently, these operations cannot be carried out within the framework set by the Creation Authorisation Decree. The decommissioning of a nuclear installation is prescribed by a new decree issued on the basis of an opinion from ASN. This decree sets out, among other things, the main decommissioning steps, the decommissioning end date and the final state. As part of its oversight duties, ASN monitors the implementation of the decommissioning operations as directed by the Decommissioning Decree.

In order to avoid fragmentation of the decommissioning projects and improve their overall consistency, the decommissioning file must explicitly describe all the planned operations, from final shutdown to attainment of the targeted final state and, for each step, describe the nature and scale of the risks presented by the facility as well as the envisaged means of managing them. This file is subject to a public inquiry.

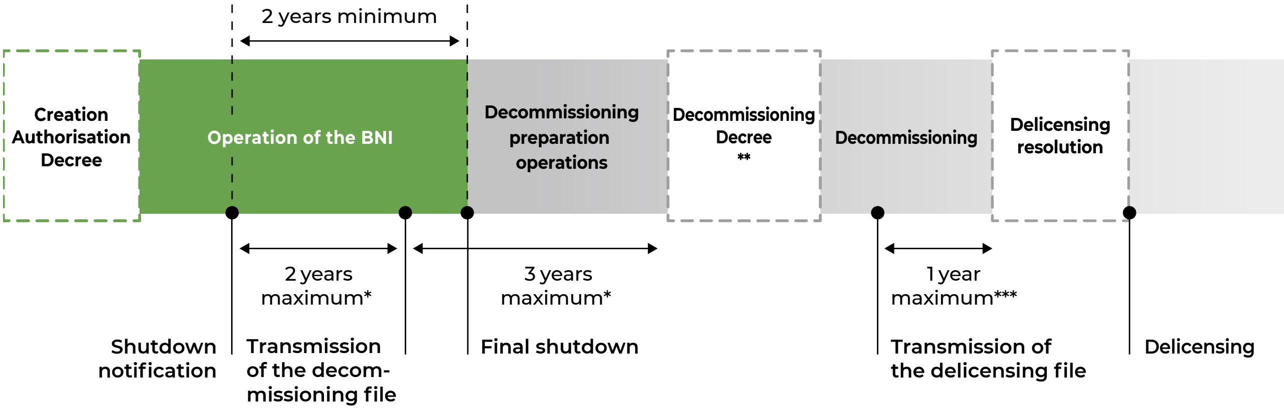
Given that installation decommissioning operations are often very long, the Decommissioning Decree can stipulate that some steps will be subject to prior approval by ASN on the basis of specific safety analysis files.

The Diagram below describes the corresponding regulatory procedure.

The licensee must demonstrate in its decommissioning file that the decommissioning operations will be carried out in as short a time-frame as possible.

1. *French acronym standing for "Industrial centre for grouping, storage and disposal". Located in Morvilliers (Aube* département*) and renamed Cires in October 2012, it was originally commissioned in 2003 under the name CSTFA, standing for "Very low level waste disposal facility".*
2. *ALARA principle (As Low As Reasonably Achievable).*

Phases in the life of a Basic Nuclear Installation



* Deadline extendable by two 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.
*** Deadline extendable by one year.

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 the installation characterisation operations can be carried out (radiological maps, collection of pertinent data such as the operating history) with a view to decommissioning. The fuel in a nuclear reactor can be removed during this phase.

The Environment Code requires – as is the case for all other BNIs – that the safety of a facility undergoing decommissioning be reviewed periodically and at least every 10 years. ASN's objective with these safety reviews is to ascertain that the installation com-plies 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 delicensing application, the licensee must provide a file containing a description of the state of the site after decommissioning (analysis of the state of the soils, remaining buildings or facilities, etc.) and demonstrating that the planned final state has been reached. Depending on the final state reached, ASN may require the implementation of active institutional controls as a condition of delicensing. These may set a number of restrictions on the use of the site and buildings (use limited to industrial applications for example) or precautionary measures (radiological measurements to be taken in the event of undermining[3], etc.).

1.4 The financing of decommissioning and radioactive waste management

Articles L. 594-1 to L. 594-10 and D. 594-1 to D. 594-18 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 the Order of 21 March 2007 relative to securing the funding of the nuclear costs.

It aims to secure the funding for nuclear costs in compliance with the "polluter-pays" principle. It is therefore up to the nuclear licensees to take charge of this financing by setting up a dedicated portfolio of assets capable of covering the expected costs. They are obliged to submit triennial reports on these costs and annual update notices to the Government. Provisioning is ensured under direct control of the State, which analyses the situation of the each licensee and can prescribe the necessary measures should it be found to be insufficient or inappropriate. The administrative authority with competence for this control is the General Directorate of the Treasury (DGT) and the General Directorate for Energy and the Climate (DGEC). Whatever the case may be, the nuclear licensees remain responsible for the satisfactory financing of their long-term costs.

These costs are divided into five categories:
- decommissioning costs, excluding long-term management of radioactive waste packages;
- spent fuel management costs, excluding long-term management of radioactive waste packages;
- cost of retrieving and conditioning legacy waste, excluding long-term management of radioactive waste packages;
- costs of long-term management of radioactive waste packages;
- costs of surveillance following closure of the disposal facilities.

The costs involved must be assessed using a method based on: 1) an analysis of the options that could be reasonably envisaged for the operation, 2) a conservative choice of reference strategy, 3) consideration of residual technical uncertainties and performance contingencies, and 4) consideration of operating experience feedback.

A Convention, signed by ASN and the DGEC for oversight of long-term costs by ASN, defines:
- the conditions in which ASN produces the opinions it is required to issue pursuant to Article D. 594-13 of the Environment Code, on the consistency of the strategies for decommissioning and management of spent fuels and radioactive waste;
- the conditions in which DGEC can call on ASN's expertise pursuant to Article L. 594-4 of the said Code.

3. Undermining means the intentional excavation of a plot of land by soil extraction to conduct works (for example, digging the foundations of a construction).

2. Situation of nuclear facilities undergoing decommissioning – specific challenges

At the end of 2020, 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 page 349). These facilities are varied (nuclear power reactors, research reactors, fuel cycle facilities, support facilities, etc.) and the decommissioning challenges can differ greatly from one facility to the next. These challenges are, however, all linked to the large quantity of waste to be managed during decommissioning. The risks for safety and radiation protection are all the higher if the facilities contain legacy waste; this is the case with the Orano former spent fuel reprocessing plants or the CEA's old storage facilities.

2.1 Nuclear power reactors

2.1.1 Pressurised water nuclear power reactors

The first Pressurised Water Reactor (PWR) undergoing decommissioning in France is the Chooz A reactor (BNI 163). This is a small model compared with the 56 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. Decommissioning of the PWRs is detailed in the box below.

2.1.2 Nuclear power reactors other than Pressurised Water Reactors

The nuclear power reactors that are not PWRs are all industrial prototypes. These comprise the first-generation Gas-Cooled Reactors (GCRs), the EL4-D heavy water reactor on the Brennilis site, and the sodium-cooled fast breeder reactors Phénix and Superphénix.

Some of these reactors have been shut down for several decades, which has led to loss of knowledge of the installation and its operation and loss of the skills associated with these reactors.

The decommissioning of these reactors is characterized by the lack of prior national or international experience.

As with the PWRs, decommissioning begins with the removal of the nuclear fuel, which removes 99% of the radioactivity present in the installation. As the thermal power of these reactors is relatively high – all greater than 250 Megawatts thermal (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 currently being determined, such as the graphite bricks, for which disposal appropriate for low-level long-lived nuclear waste (LLW-LL) is envisaged.

Decommissioning of the EL4-D reactor (prototype heavy water reactor) has been slowed, firstly due to the lack of prior experience in the decommissioning techniques to use, and secondly due to unforeseen setbacks concerning the Conditioning and Storage Facility for Activated Waste (Iceda, see the Regional Overview in the introduction to this report and chapter 14).

The decommissioning of the sodium-cooled reactors (Phénix and Superphénix) has met with no major technological obstacles. The specific challenges lie chiefly in the control of the fire risk due to the presence of sodium and the safety of its treatment processes.

2.2 Research facilities

2.2.1 Research laboratories

Four research laboratories are currently undergoing decommissioning or preparation for decommissioning. These are the High Activity Laboratory (LHA) at Saclay (BNI 49), the Chemical Purification Laboratory (LPC) at Cadarache (BNI 54), the Irradiated Materials Plant (AMI) at Chinon (BNI 94) and the "Process" laboratory at Fontenay-aux-Roses (BNI 165). These laboratories, which began operating in the 1960s, were dedicated to Research & Development to support the development of the nuclear power industry in France.

Research laboratory decommissioning operations prior to delicensing are typically carried out in several steps:
- removal of the legacy or old waste;
- disassembly of the electromechanical equipment and the reactor containments;
- cleaning out of the structures and remediation of the soils polluted by the activities of the BNI, if necessary.

Dismantling of the structures and civil engineering work, if applicable, can be carried out in the conventional manner after their complete clean-out. Nevertheless, in certain cases of highly contaminated structures, dismantling must be carried out during the decommissioning steps as their stability cannot be guaranteed once they have been cleaned out. In such cases, dismantling, which is carried out using techniques specific to the nuclear industry, is a step necessary for delicensing.

These very old facilities are all confronted with the issue of managing the "legacy" waste, stored on site at a time when the waste management routes had not been put in place, 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 the waste and the radiological status of the facility as accurately as possible 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

Decommissioning of Pressurised Water Reactors

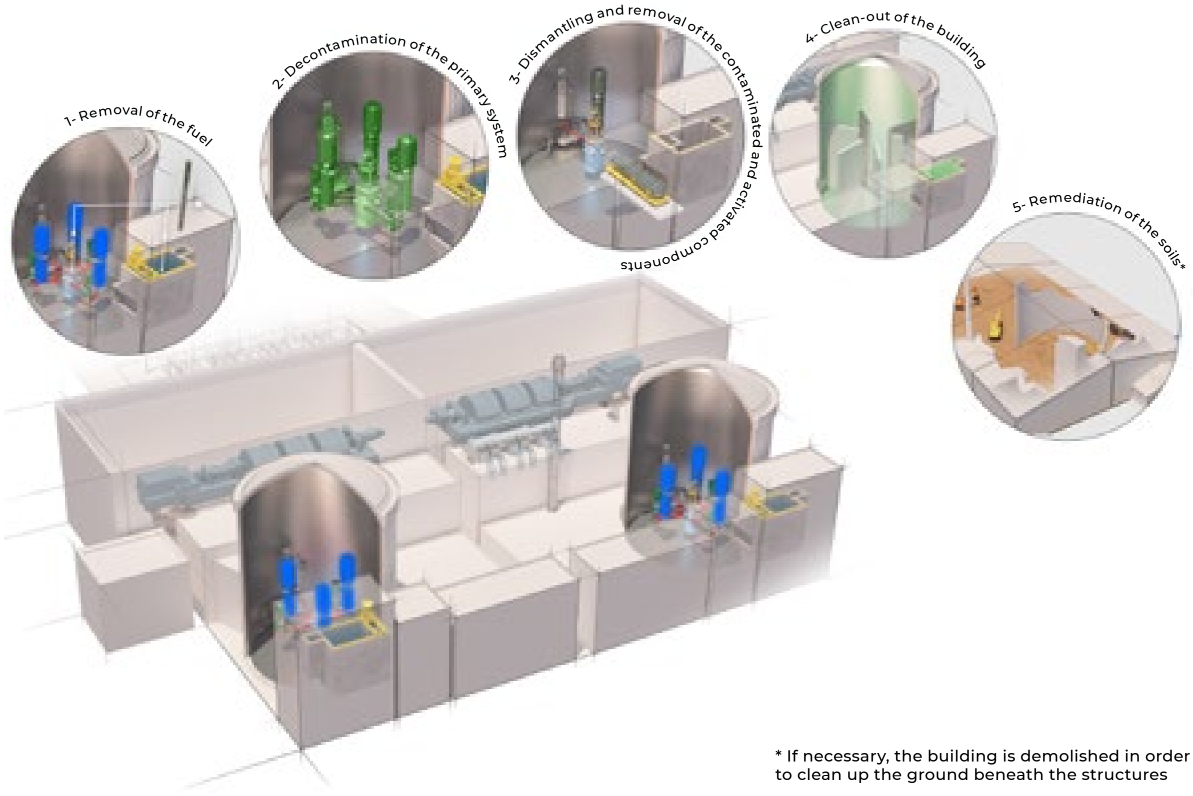
Considerable experience feedback from the decommissioning of Pressurised Water Reactors (PWRs) has been acquired through numerous projects internationally: 42 PWRs are currently undergoing decommissioning across the globe, and 6 have already been decommissioned in the United States. Furthermore, the design of these reactors facilitates their decommissioning compared with other reactor technologies, such as the first-generation Gas-Cooled Reactors (GCRs). The decommissioning of PWR facilities presents no major technical challenges and its feasibility is guaranteed: according to international experience feedback, the decommissioning of these reactors takes about 20 years.

The PWR nuclear island is made up of three main buildings (see chapter 10, part 1): the reactor building, the fuel building and the nuclear auxiliaries building, housing the effluent treatment, ventilation and air filtration facilities. The conventional island for its part comprises a turbine hall housing the alternator that produces electricity.

Decommissioning of the nuclear facilities is preceded by a phase of Decommissioning Preparation Operations (OPDEM). For a PWR, the main operation during this preparatory phase consists in unloading the fuel from the core, after which it will be stored in the spent fuel pool, then transferred from the facility to – in the case of France – the La Hague site for reprocessing (see chapter 11). The fuel represents the great majority of the radioactivity in the facility (approximately 95%): its removal therefore results in a significant reduction in the radiological risk. The residual radioactivity is then found chiefly in the primary system. For the decommissioning of the Fessenheim Nuclear Power Plant (NPP) whose, two reactors were definitively shut down in 2020 (see box in the Regional Overview in the introduction to this report – Grand Est region), EDF envisages decontaminating this system during the OPDEM with the aim of reducing radiological exposure during decommissioning. The decommissioning preparation phase will also include transforming the turbine hall into a waste treatment, packaging and storage facility.

The decommissioning operations will start after the publishing of the Decommissioning Decree which defines the main steps of the facility decommissioning process. Decommissioning of the reactor building begins with removal of the primary system, followed by decommissioning of the reactor pressure vessel. The systems of the other buildings of the nuclear island are also decommissioned at the same time. Once of the equipment has been decommissioned and the waste removed, the licensee proceeds with the post-operational clean-out of the various buildings, followed by their demolition with a view to delicensing the Basic Nuclear Installation (BNI) and rehabilitating the site.

In France, EDF is the sole licensee of the existing PWRs. Their decommissioning began in 2007 with the Chooz-A reactor, a limited power PWR situated in an excavated cavern. Whatever the service life of the reactors in operation, 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. Decommissioning of the Fessenheim NPP will provide useful feedback in this respect.



* If necessary, the building is demolished in order to clean up the ground beneath the structures

risks and can lead to dissemination of radioactive material, a potential source of internal and external contamination for the operators who work at close range and must be protected. This work can moreover be carried out near radiation sources, which increases the risk of external exposure for the workers.

2.2.2 Research reactors

Nine experimental reactors are in final shutdown status at the end of 2020: Rapsodie (sodium-cooled fast neutron reactor), Masurca (critical mock-up), Phébus (experimental reactor), Osiris, Orphée ("pool" type reactors), Éole and Minerve (critical mock-ups), Ulysse and Isis (training reactors). They are all in the decommissioning preparation phase, except for Ulysse, whose decommissioning was completed in August 2019. These reactors are characterised by a lower power output – from 100 Watts thermal (Wth) to 70 MWth – than the nuclear power reactors. When they were designed back in the 1960s to 1980s, the question of their decommissioning was not considered. One of the major decommissioning problems is the loss of memory of the design and operation of the installation. Therefore maintaining skills and the installation characterisation phase to determine its initial state (state of the installation at the start of decommissioning) are of vital importance. At the time of decommissioning, these installations usually present a low radiological source term, as one of the first operations consists in removing the spent fuel during the decommissioning preparation operations.

The risks involved in research reactor decommissioning operations evolve rapidly due to the numerous changes in the installation. The nuclear risks gradually give way to conventional industrial risks, such as the risk associated with the simultaneous management of several worksites, or the chemical risks during the clean-out-phase. One of the main challenges comes from the production and management of large volumes of VLL waste, which must be stored then disposed of *via* an appropriate route.

There is a considerable amount of decommissioning experience feedback for the research reactors, given the decommissioning of numerous similar installations in France (Siloé, Siloette, Mélusine, Harmonie, Triton[4], the Strasbourg University Reactor – RUS) and abroad. Their dismantling time-frames usually span about ten years. Most of these reactors were demolished with conventional disposal following clean-out.

2.3 The front-end "nuclear fuel cycle" facilities

Two front-end "nuclear fuel cycle" facilities are undergoing decommissioning. They are situated on the Tricastin site, one specialising in uranium enrichment by gaseous diffusion (BNI 93), the other in uranium conversion (BNI 105).

The only radioactive materials used in these plants were uranium-bearing substances. One of the particularities of these facilities lies in the presence of radioactive contamination associated with the presence of "alpha" particle-emitting uranium isotopes. The radiation exposure risks are therefore largely linked to the risk of internal exposure.

Furthermore, these are older facilities whose operating history is poorly known. Determining the initial state, particularly the pollution present in the soils beneath the structures, therefore remains an important issue. Furthermore, the industrial processes used at the time involved large quantities of toxic chemical substances (uranium, chlorine trifluoride and hydrogen fluoride, for example): the containment of these chemical substances is thus also an issue in these facilities.

2.4 The back-end "nuclear fuel cycle" facilities

The back-end facilities of the "nuclear fuel cycle" are the spent fuel storage pools, the spent fuel reprocessing plants and the facilities for storing waste from the treatment process. These facilities are operated by Orano 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 GCRs. This facility, BNI 33, called UP2-400 standing for "Production Unit No. 2-400 tonne" (the first reprocessing plant was UP1 situated in the DBNI of Marcoule and is currently being decommissioned), was definitively shut down on 12 January 2004 along with its support facilities, namely the effluent treatment station STE2 and the spent fuel reprocessing facility AT1 (BNI 38), the radioactive source fabrication facility ELAN IIB (BNI 47) and the "High Activity Oxide" facility (HAO), built for reprocessing the fuels from the "light water" reactors (BNI 80).

Unlike the direct on-line packaging of the waste generated by the UP2-800 and UP3-A plants in operation, most of the waste generated by the first reprocessing plant was stored without treatment or packaging. Decommissioning is therefore carried out concomitantly with the legacy Waste Retrieval and Packaging (WRP) operations. This waste is highly irradiating and comprises structural elements from fuel reprocessing, technological waste, rubble, soils and sludge. Some of the waste has been stored in bulk with no prior sorting. The retrieval operations therefore require remotely operated pick-up means, conveyor systems, sorting systems, sludge pumping and waste packaging systems. The development of these means and carrying out the operations under conditions ensuring a satisfactory level of safety and radiation protection represent a major challenge for the licensee. Given that these operations can last several decades, the management of ageing is also a challenge. Taking into account the quantities, the physical and chemical forms and the radiotoxicity of the waste contained in these facilities, the licensee must develop means and skills that involve complex engineering techniques (radiation protection, chemistry, mechanics, electrochemistry, robotics, artificial intelligence, etc.). At present about ten projects of this type are underway in the former facilities. They will span several decades and are a prerequisite to the complete decommissioning of these facilities, whereas the decommissioning of the process parts of the plant is continuing with more conventional techniques.

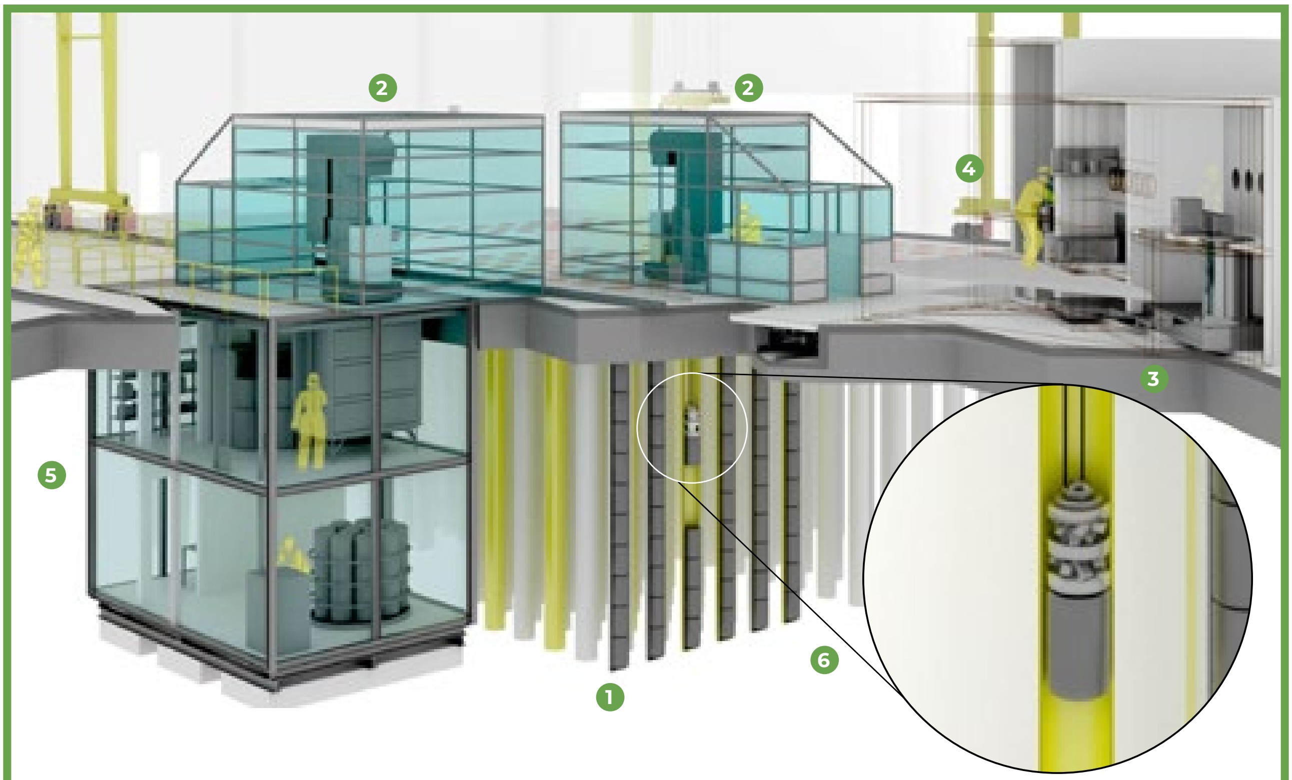
2.5 The support facilities (storage and processing of radioactive effluent and waste)

Many of these facilities, most of which were commissioned in the 1960's and whose level of safety does not comply with current best practices, have been shut down.

Old storage facilities were not initially designed to allow the removal of 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 plant silos in La Hague (silos 115 and 130 in BNI 38, the HAO silo in BNI 80), the pits and trenches of BNI 56 and the wells of BNI 72 and BNI 166. Retrieval of the waste from these facilities is complex and will span several decades. The waste must then be packaged and stored in safe conditions. New packaging and storage facilities are thus planned or under construction.

With regard to the Effluent Treatment Stations (STE) which also packaged the concentrates, they were shut down owing to

4. Triton was one of the first very compact and very flexible pool type research reactors called Material Test Reactor (MTR). Triton (6.5 MWth) was installed in Fontenay-aux-Roses in 1959.



New waste retrieval management at Saclay

Commissioned in 1971, Basic Nuclear Installation (BNI) 72 comprises the facilities for storing and treating the solid radioactive waste produced essentially by the reactors, laboratories and units situated in the Saclay centre.

Further to a meeting of the Advisory Committee of Experts in 2009, the Alternative Energies and Atomic Energy Commission (CEA) engaged a process to retrieve and remove the waste in order to reduce the source term of the facility. This complex process is currently continuing with the facility's Waste Retrieval and Packaging (WRP) project, which will last several decades. As BNI 72 is one of the CEA facilities containing the most significant potential source term in the event of an accident, the removal of this source term has been classified among the top priorities of the CEA decommissioning strategy.

The notable operation in this WRP phase is the future "EPOC" process, a French acronym standing for "Removal of the spent fuel drums", for which the project and the safety case were presented as part of the BNI 72 decommissioning file submitted in 2015.

The aim of this process is to retrieve, characterise, sort and package drums containing a mix of wastes and pieces of fuel, currently stored in 15 wells in building 114 (1).
In view of their deteriorated condition and their contents, the 144 drums in question cannot be treated by the facility with its current means.

EPOC is a complex process line consisting of a retrieval hood (2) positioned above the well, allowing the drums to be extracted and transferred to a shielded cell using a transfer trolley. The "retrieval hood" is equipped with a video camera which serves to determine the state of the drum and then the retrieval strategy, using different tools as appropriate for the condition of the drum.
The shielded line enables the drums to be treated and the fuel and waste they contain to be repackaged.

The retrieval hood positions itself vertically on the docking platform (3), the drum is lowered into the " chapel" (underground cavern), then transferred to the sorting cell where the fuel is placed in a can. This can is transferred to the adjacent fuel cell and the other waste is lowered back down into the cavern for treatment and packaging (4). The repackaged fuels are then introduced into a transport package for subsequent storage in a dedicated facility.

The maintenance and testing station (5), which is three storeys high, is used for the maintenance and decontamination of the retrieval equipment and for the equipment crane tests and operator training.

The method of drum retrieval will differ according to their condition (6). If a drum is intact, the retrieval hood picks it up as a single block and transfers it to the shielded cell. If the drum is damaged, the retrieval hood is equipped with a specific tool which cuts away the drum lid so that the contents can be retrieved. Lastly, if the drums are very severely damaged, the CEA has planned for specific equipment that enables the various containers to be cut up within the well, and a gripper to retrieve the container and its contents. The fragments are placed in small containers. Once filled, these containers are transferred to the shielded line for sorting and packaging. In this case, there is a large number of transfer operations which means that the retrieval time is increased. Removal from storage using EPOC will start around 2029 and is forecast to last 15 years.

THE IMPACT OF COVID-19

The Covid-19 pandemic caused the stoppage of many decommissioning worksites in spring 2020, due to the travel restrictions put in place by the Government. Some critical decommissioning and Waste Retrieval and Packaging (WRP) worksites, particularly in facilities operated by Orano, like the "High Activity Oxide" (HAO) facility, were nevertheless able to continue some of their activities. These stoppages or slowdowns have pushed back reaching certain milestones by several months, particularly in the taking of samples or the effective conducting of certain decommissioning operations.

Alongside this, the widespread recourse to remote working also induced delays in the performance of certain studies and the submission of files required by the regulations. At the end of the first lockdown, the work on the suspended worksites gradually resumed satisfactorily, in compliance with the health rules in effect. During the second lockdown, the licensees implemented protocols enabling the worksites to continue by restricting the number of people present on site, in accordance with the Government's instructions. This adapted way of functioning enabled the licensees to limit the impacts of the crisis on the course of the decommissioning operations.

the ageing of these facilities or the shutdown of the effluent-producing facilities.

Examples include the Radioactive Effluent and Waste Treatment Station (STED) at Fontenay-aux-Roses, BNI 37-B at Cadarache, STE2 at the La Hague plant and the Brennilis STE. The difficulties associated with the decommissioning of the STEs are closely dependent on their shutdown conditions, particularly the emptying and rinsing of their tanks.

The major difficulties associated with the decommissioning of the support facilities are as follows:
- poor knowledge of the operating history and the state of the facility to be decommissioned, which necessitates prior characterisation of the old waste and the analysis of samples of the sludge or deposits in the STE tanks. This characterisation necessitates firstly the development of methods and the use of specific equipment to take the samples, and secondly the availability of analysis laboratories;
- the difficulty in accessing the waste for retrieval was not taken into consideration in the design (silos, trenches, concrete-lined pits, cramped premises, etc.), necessitating the costly construction of infrastructures in conformity with current safety requirements and leading to long retrieval times and unforeseen events;
- the deterioration of the containment barriers, for example corrosion of waste drums or pollution of soils resulting from the occurrence of significant events during operation.

3. ASN actions related to facilities being decommissioned: a graded approach

3.1 The graded approach according to the risks of the facilities

ASN ensures the oversight of facilities undergoing decommissioning, as it does for facilities in operation. The BNI System also applies to definitively shut down facilities. ASN has implemented an approach that is proportional to the extent of the risks or drawbacks inherent to the facility. In this respect, ASN has divided the facilities under its oversight into three categories from 1 to 3 in descending order of the severity of the risks and drawbacks they present for the interests mentioned in Article L. 593-1 of the Environment Code (ASN resolution 2015-DC-0523 of 29 September 2015). This BNI classification enables the oversight of the facilities to be adapted, thus reinforcing oversight of the facilities with major implications in terms of inspections and the depth of the examinations conducted by ASN.

The risks with facilities undergoing decommissioning differ from those for facilities in operation. For example, the risks of significant off-site discharges decrease as decommissioning progresses because the quantity of radioactive substances decreases. The requirements concerning the systems for controlling the risks associated with the decommissioning operations therefore tend to decrease as decommissioning progresses. ASN considers that it is generally not appropriate to undertake reinforcement work to the same extent on a facility undergoing decommissioning as on a facility in operation, provided that the decommissioning is actually carried out and leads to a reduction in the hazard sources within a short period of time.

3.2 Lessons learned from the Fukushima Daiichi accident

To take into account the lessons learned from the nuclear accident that occurred at the Fukushima Daiichi NPP in Japan, ASN asked the BNI licensees to carry out stress tests, including on those facilities undergoing decommissioning.

The stress test procedure has been divided into three lots according to the safety risks inherent to the facilities. The facilities being decommissioned are essentially in lots 2 and 3.

For the facilities in lot 2, the post-Fukushima assessments have led ASN to request the removal of radioactive substances or the reinforcement of emergency management means on centres that often also have facilities in operation (see chapters 11 and 12).

For civil facilities undergoing decommissioning, the main challenges concern the La Hague site facilities. For example, the licensee has put in place operational provisions for extinguishing a fire in silo 130 following a "hardened safety core" earthquake[5]. Silo 115 must also be further protected against the fire risk and ASN has asked the licensee to study measures to speed up implementation of this programme.

Integration of the lessons learned from the Fukushima Daiichi accident for the facilities presenting more limited risks shall

5. Earthquake considered for the equipment constituting the "hardened safety core" of the facilities. The term "hardened safety core" was defined after the Fukushima Daiichi NPP accident to identify the ultimate equipment controlling the vital safety functions in an extreme situation (earthquake, winds, tornado, extreme flooding, etc.).

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

The conformity check aims to ensure that the changes in the facility due to the decommissioning work or to ageing do not call into question its conformity with the provisions of the regulatory texts and its technical baseline requirements.

Given the diversity of the facilities and the situations involved, each periodic safety review must be individually examined by ASN. ASN applies a method of examination that is adapted to the risks inherent to the facilities: some facilities warrant particular attention owing to the risks they present and may be reviewed by the Advisory Committee for Decommissioning (GPDEM) set up in 2018. For others presenting a lower level of risk, the extent of the inspections and examinations is adapted accordingly.

When a facility has been finally shut down and its decommissioning file has to be transmitted to the Minister in charge of nuclear safety and ASN, simultaneous filing of the decommissioning file and the periodic safety review conclusions report is considered to be good practice. The two files can thus be reviewed at the same time on the basis of technically consistent scenarios.

In 2020, ASN continued the examination of the safety review reports of some 20 facilities undergoing decommissioning that have been received since 2015. Inspections on the topic of the periodic safety review took place in 2020 on three facilities undergoing decommissioning. These inspections are used to check the means implemented by the licensee to carry out its review, as well as compliance with the action plan resulting from its conclusions. They led to several requests for corrective action and additional information.

3.4 Financing decommissioning: ASN's opinion on the triennial reports

The regulatory framework for ring-fencing the funds necessary for management of the long-term decommissioning and waste management expenses is presented in point 1.4.

On 13 August 2020, ASN published opinion CODEP-CLG- 2020-040124 of 6 August 2020 relative to the examination of the three-yearly reports submitted in 2019 by the licensees, concerning the accounts closed at the end of 2018.

ASN notes that the scope of evaluation of the expenses remains incomplete and omits certain high-stake financial operations. More specifically, the licensees are vague about the financing of the decommissioning preparation operations, and do not take into account in their cost assessment the characterisation and management of pollution of soils and structures, the complete clean-out and remediation operations, or the costs of works to maintain the facilities over their entire lifetime.

ASN also underlines that the assumptions adopted for evaluating the complete costs must be reassessed in order to show reasonable caution in the scheduling of the decommissioning projects and programmes, taking account of the risks related to the unavailability of storage, treatment and disposal facilities.

Furthermore, ASN considers that the project costs at completion must be more detailed and better substantiated, particularly in the light of the observed state of progress of the projects, as falling behind in the decommissioning schedules can raise the costs at completion.

Lastly, ASN considers that the proposed assumptions for evaluating the management of radioactive material and wastes are not sufficiently conservative. They do not systematically include either the management of legacy waste locations or the uncertainties regarding the management of LLW-LL waste. Similarly, the licensees tend to overestimate the prospects of reusing certain materials and to underestimate the actions necessary for bituminised waste.

In 2020, ASN examined the update of these three-yearly reports and sent its observations to the Ministry responsible for the environment in 2021.

4. Assessment of the licensees' decommissioning strategies

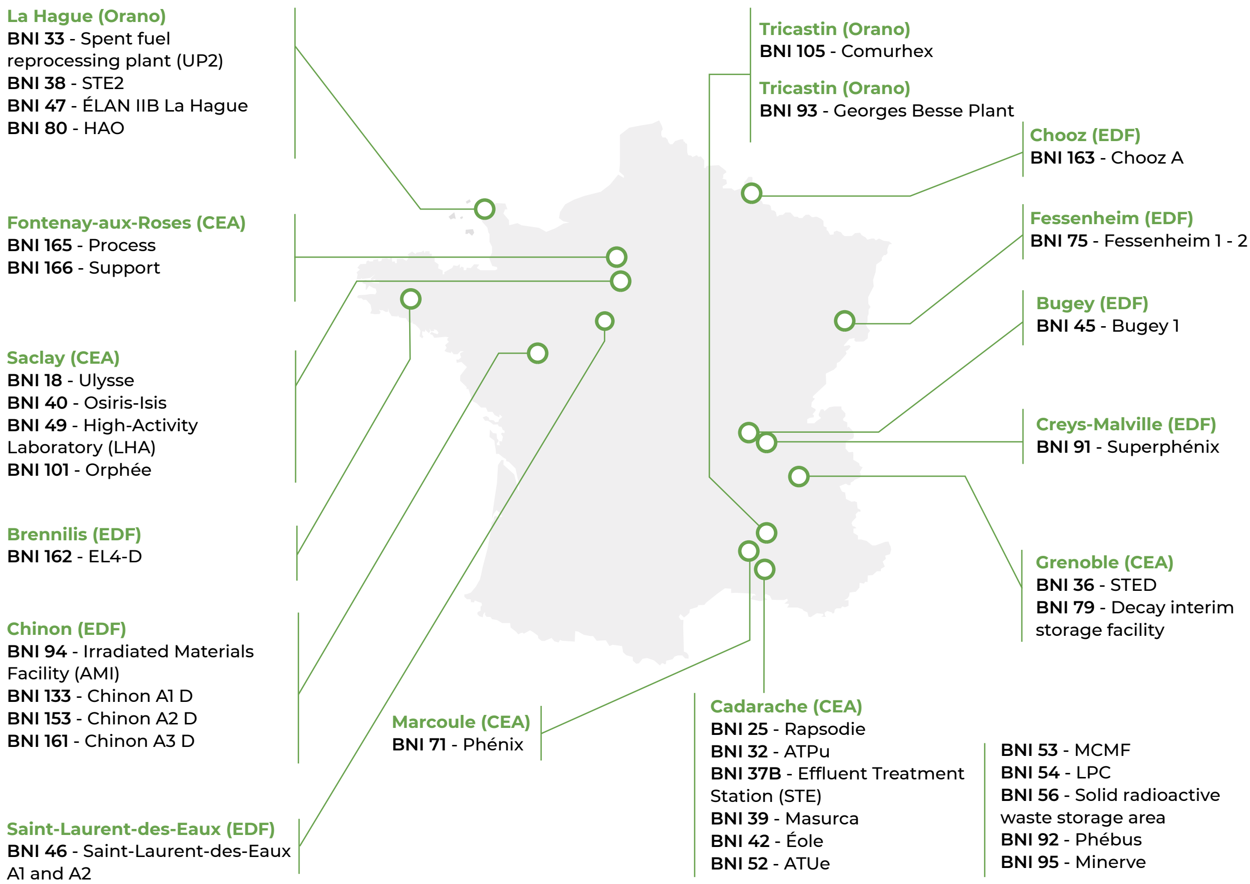
Given that numerous facilities have been shut down for several decades, with partial loss of knowledge of their operating histories, ageing structures and in some cases large quantities of waste still present, the advancement of decommissioning projects is one of the major issues for the safety of shut down facilities. Yet ASN has noted that the majority of the decommissioning projects are falling significantly behind schedule. ASN therefore asks the CEA, EDF and Orano to periodically present their decommissioning and radioactive waste management strategies, thereby providing an integrated view of the decommissioning projects and the disposal routes that are available or to be created for the waste resulting from the decommissioning operations.

As far as decommissioning is concerned, the licensees must justify the priority operations, principally through safety analyses. This prioritisation provides a means of checking that even if some projects are substantially behind schedule, the most significant resources will be devoted to operations with higher risk implications.

With regard to radioactive waste management, ASN checks the consistency with the regulatory framework and the guidelines of the French National Radioactive Materials and Waste Management Plan (PNGMDR). ASN examines with particular attention the defences against unforeseen events on a waste management facility and the plausibility of the 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 issued a position statement on the CEA's decommissioning and waste management strategy. In 2020, ASN issued a resolution requiring EDF to submit the decommissioning files for the GCRs and the framing of the operations to be carried out in the coming years (see Notable Events 2020 in the introduction to this report) given the examination of the change of

Map of the installations definitively shut down or in the process of decommissioning as at 31 December 2020



decommissioning strategy of EDF's GCRs. ASN also continued the examination of Orano's decommissioning and waste management strategy files. The context and the preliminary conclusions of these examinations are detailed below.

4.1 Assessment of EDF's decommissioning strategy

The first decommissioning strategy file for the EDF reactors definitively shut down (Chinon A1, A2, A3, Saint-Laurent A1 and A2, Bugey 1, EL4-D, Chooz A and Superphénix) was transmitted in 2001 at the request of ASN. Immediate dismantling was adopted as the reference strategy. This strategy has been updated regularly, in order, for example, to adjust the decommissioning schedule or incorporate the complementary studies requested by ASN and elements concerning the future decommissioning of the reactor fleet in service.

For the six first-generation GCRs (Chinon A1-A2 and A3, Saint-Laurent A1 and A2 and Bugey 1), EDF informed ASN in March 2016 of a complete change in strategy calling into question the technique ("under water") used for the decommissioning of these reactors and the rate of decommissioning, leading to the decommissioning of all the GCRs being pushed back by several decades (see Notable Events). The decommissioning time-frames presented by EDF will be reviewed periodically by ASN and may be revised if, in the coming decades, it is found that this scenario can be optimised. This decommissioning strategy for the GCRs is governed by two ASN resolutions, 2020-DC 686 and CODEP-CLG-2020-021253, published on 3 March 2020.

These resolutions establish the next steps necessary for the change in decommissioning strategy: submission of the decommissioning files corresponding to these new decommissioning techniques, the defining of a robust waste management strategy, the decommissioning operations to be continued, the putting into service of an industrial demonstrator and the information to be transmitted to ASN to monitor the effective implementation of the strategy.

ASN considers that it is justified for EDF to develop an industrial demonstrator before decommissioning the reactor pressure vessels, but decommissioning of the various reactors must nevertheless begin within reasonable time frames in view of the obligation for decommissioning to be carried out as rapidly as possible.

For the other EDF facilities shut down (notably Chooz A, the Chinon AMI, EL4-D, Superphénix), decommissioning is under way and the requirement to ensure decommissioning as rapidly as possible is satisfied on the whole.

4.2 Assessment of Orano's decommissioning strategy

Decommissioning the old installations is a major challenge for Orano, which has to manage several large-scale decommissioning projects in the short, medium and long term (UP2-400 facility at La Hague, Eurodif Production plant, individual facilities of the DBNI at Pierrelatte, etc.). Implementation of decommissioning is closely linked to the radioactive waste management strategy, given the quantity and the non-standard and hard to characterise nature of the waste produced during the prior operations phase and the new waste resulting from the decommissioning operations.

Furthermore, Orano must carry out special legacy Waste Retrieval and Packaging (WRP) operations in old waste storage facilities. The deadlines for completion have been stipulated by ASN, particularly for the La Hague site. Furthermore, completion of these WRP operations governs the progress of decommissioning on the UP2-400 plant, as WRP is one of the first steps of its decommissioning. The WRP work is of particular importance given the inventory of radioactive substances present and the age of the facilities in which they are stored, which do not meet current safety standards. WRP projects are becoming increasingly complex owing to the interactions with the plants in operation and the site.

In June 2016, at the request of ASN and ASND, Orano submitted its decommissioning and waste management strategy. The file also includes the application of this strategy on the La Hague and Tricastin sites. The Tricastin site accommodates one DBNI, hence the joint oversight of Orano by ASN and ASND, which mobilised substantial expertise for the joint examination of this strategy. The two Authorities consider that Orano must increase its ability to prioritise the operations according to the risks inherent to the facilities to decommission and to control the time frames. In addition, Orano's human and technical resources must also be increased in order to meet the deadlines for the operations.

4.3 Assessment of the CEA's decommissioning strategy

Given the number and complexity of the operations to be carried out for all the nuclear facilities concerned, CEA is giving priority to reducing the "Potential Source Term" (TSM[6]) which is currently at a very high level in certain facilities, in particular in some of the individual facilities of the Marcoule DBNI and in BNIs 72 and 56.

In their position statement letter of 27 May 2019, ASN and the ASND considered that, given the resources allocated by the State and the large number of facilities undergoing decommissioning, for which legacy waste retrieval and storage capacity will need to be built, it was acceptable for the CEA to envisage staggering the decommissioning operations and that priority be given to those facilities in which the safety issues were greatest. The Authorities have since observed changes in the WRP schedules presented by the CEA, particularly the pushing back of waste management deadlines, including for operations considered to be priorities. ASN, ASND and the DGEC shall be attentive to this in 2021 when examining the files submitted by the CEA, and will check the progress of the priority operations, particularly by conducting targeted inspections on the management of the WRP and decommissioning projects of the abovementioned facilities.

As concerns lower priority facilities, ASN and ASND also noted in 2020 that certain decommissioning deadlines announced by the licensee were pushed back significantly. The authorities will rule on the CEA's justifications for these schedule push-backs on reception of the facilities' decommissioning files.

6. The Potential Source Term ("TSM" from the French "Terme source mobilisable") corresponds to the quantity of radioactive activity that could be involved in an incident or accident. It is defined from the "source term" (activity of all the radioactive substances present in the facility) weighted by factors linked to:
- the dispersibility of the matrix (according to whether or not the radioactive substances are blocked in the materials and the nature of the blocking matrix),
- the effectiveness of the containment barriers (according to the seismic strength of the building and whether or not the ventilation is operational),
- the susceptibility of the source term to external hazards (the accident scenario adopted is an earthquake combined with a fire),
- the radiotoxicity of the inventory (β-γ, tritium or α spectrum).

Appendix

List of Basic Nuclear Installations undergoing decommissioning or delicensed as at 31 December 2020

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 list of BNIs and classified as ICPE(***)	Decommissioned
ZOÉ FAR	(Former BNI 11)	Reactor (250 kWth)	1948	1975	1978: Removed from list of BNIs and classified as ICPE(***)	Confined (museum)
Minerve FAR	(Former BNI 12)	Reactor (0.1 kWth)	1959	1976	1977: Removed from BNI list	Dismantled at Fontenay-aux-Roses 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 list of BNIs 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 solid and liquid waste	Before 1964	2006	2006: Removed from BNI list	Integrated in BNI 166
STED Cadarache	(Former BNI 37)	Transformation of radioactive substances	1964	2015	2015: Removed from BNI list	Integrated in 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 in BNIs 165 and 166
LCPu FAR	(Former BNI 57)	Plutonium chemistry laboratory	1966	1995	2006: Removed from BNI list	Integrated in BNIs 165 and 166
BAT 19 FAR	(Former BNI 58)	Plutonium metallurgy	1968	1984	1984: Removed from BNI list	Decommissioned
RM2 FAR	(Former BNI 59)	Radio-metallurgy	1968	1982	2006: Removed from BNI list	Integrated in BNIs 165 and 166
LCAC Grenoble	(Former BNI 60)	Fuels analysis	1975	1984	1997: Removed from BNI list	Decommissioned
LCAC Grenoble	(Former BNI 61)	Laboratory	1968	2002	2017: Removed from BNI list	Cleaned out
SICN Veurey-Voroize	(Former BNIs 65 and 90)	Fuel fabrication plant	1963	2000	2019: Removed from BNI list	Buildings demolished, active institutional controls

INSTALLATION LOCATION	BNI	TYPE OF INSTALLATION	COMMISSIONED	FINAL SHUTDOWN	LAST REGULATORY ACTS	CURRENT STATUS
STED FAR	(Former BNI 73)	Radioactive waste decay storage	1971	2006	2006: Removed from BNI list	Integrated in 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 progress
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 progress
Spent fuel reprocessing plant (UP2) (La Hague)	33	Transformation of radioactive substances	1964	2004	2013: Final shutdown and partial Decommissioning Decree	Partial decommissioning in progress
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 progress
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 station	1964	2004	2013: Final shutdown and partial Decommissioning Decree	Decommissioning in progress
Masurca	39	Reactor (5 kWth)	1966	2018		Preparation for decommissioning
Osiris-Isis	40	Reactor (70 MWth)	1966	2015		Preparation for decommissioning
Éole	42	Reactor (1 kWth)	1965	2017		Preparation for decommissioning
Bugey 1	45	Reactor (1,920 MWth)	1972	1994	2008: Final shutdown and Decommissioning Decree	Decommissioning in progress
Saint-Laurent-des-Eaux A1	46	Reactor (1,662 MWth)	1969	1990	2010: Decommissioning Decree	Decommissioning in progress
Saint-Laurent-des-Eaux A2	46	Reactor (1,801 MWth)	1971	1992	2010: Decommissioning Decree	Decommissioning in progress
ÉLAN IIB La Hague	47	Manufacture of caesium-137 sources	1970	1973	2013: Decommissioning Decree	Decommissioning in progress
High Activity Laboratory (LHA) Saclay	49	Laboratory	1960	1996	2008: Final shutdown and Decommissioning Decree	Decommissioning in progress
ATUe Cadarache	52	Uranium processing	1963	1997	2006: Final shutdown and Decommissioning Decree	Decommissioning in progress
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 progress

INSTALLATION LOCATION	BNI	TYPE OF INSTALLATION	COMMISSIONED	FINAL SHUTDOWN	LAST REGULATORY ACTS	CURRENT STATUS
Phénix Marcoule	71	Reactor (536 MWth)	1973	2009	2016: Decommissioning Decree	Decommissioning in progress
Fessenheim NPP	75	Reactor (1,800 MWth)	1977	2020	2020: Final shutdown	Preparation for decommissioning
High Activity Oxyde (HAO) facility (La Hague)	80	Transformation of radioactive substances	1974	2004	2009: Final shutdown and Decommissioning Decree	Decommissioning in progress
Superphénix Creys-Malville	91	Reactor (3,000 MWth)	1985	1997	2009: Final shutdown and Decommissioning Decree	Decommissioning in progress
Phébus	92	Reactor (40 MWth)	1978	2017		Preparation for decommissioning
Eurodif	93	Transformation of radioactive substances	1979	2012	2020: Decommissioning Decree	Partial decommissioning in progress
AMI Chinon	94	Utilisation of radioactive substances	1964	2015	2020: Decommissioning Decree	Decommissioning in progress
Minerve	95	Reactor (100 Wth)	1977	2017		Preparation for decommissioning
Orphée	101	Reactor (14 MWth)	1980	2019	2019: Final shutdown	Preparation for decommissioning
Comurhex Tricastin	105	Uranium chemical transformation plant	1979	2009	2019: Decommissioning Decree	Decommissioning in progress
Chinon A1 D (Former Chinon A1)	133 (Former BNI 5)	Reactor (300 MWth)	1963	1973	1982: Decree for confinement of Chinon A1 and creation of the Chinon A1 D storage BNI	Partially decommissioned, modified to storage BNI for waste left in place. Preparation for complete decommissioning
Chinon A2 D (Former Chinon A2)	133 (Former BNI 6)	Reactor (865 MWth)	1965	1985	1991: Decree for partial decommissioning of Chinon A2 and creation of storage BNI Chinon A2 D	Partially decommissioned, modified to storage BNI for waste left in place. 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 progress
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	Partial Decommissioning in progress. Preparation for complete decommissioning
Ardennes NPP (formerly Chooz A)	163 (Former BNI 1, 2, 3)	Reactor (1,040 MWth)	1967	1991	2007: Final shutdown and Decommissioning Decree	Decommissioning in progress
Process FAR	165	Grouping of former research installations (BNI 57 and 59) concerning reprocessing processes	2006	2006	2006: Final shutdown and Decommissioning Decree	Decommissioning in progress
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 progress

* Attila: reprocessing pilot located in a unit of BNI 57.
** Passive institutional controls.
*** Active institutional controls.
**** Installations Classified for Protection of the Environment.

CHAPTER 14

RADIOACTIVE WASTE AND CONTAMINATED SITES AND SOILS

14 Radioactive waste and contaminated sites and soils

This chapter presents the role and actions of the French Nuclear Safety Authority (ASN) in the management of radioactive waste and the management of sites and soils contaminated by radioactive substances. It describes in particular the actions taken to define and set the broad guidelines for radioactive waste management.

According to Article L. 542-1-1 of the Environment Code, radioactive waste consists of radioactive substances for which no subsequent use is planned or envisaged or which have been re-qualified as such by the administrative authority in application of Article L. 542-13-2 of this same Code. The waste comes from nuclear activities involving artificial or natural radioactive substances, from the moment this radioactivity justifies the implementation of radiation protection controls.

A site contaminated by radioactive substances is any site, either abandoned or in operation, on which natural or artificial radioactive substances have been or are employed or stored in conditions such that the site can present risks for health and the environment. Contamination by radioactive substances can result from industrial, craft, medical or research activities.

On 21 February 2020, further to the conclusions of the public debate held in 2019, the Minister of Ecological Transition and the Chairman of ASN published a resolution setting out the guidelines of the 5th French Radioactive Material and Waste Management Plan (PNGMDR). In the second half of 2020 and early 2021, ASN also published its opinions, for each management route, on the studies submitted under the PNGMDR 2016-2018.

In 2019, ASN and the Defence Nuclear Safety Authority (ASND), issued a joint position statement on the decommissioning and waste management strategy of the Alternative Energies and Atomic Energy Commission (CEA), submitted in 2016. In 2020, ASN and ASND, in collaboration with the General Directorate for Energy and Climate (DGEC), initiated an approach to monitor implementation of this strategy.

Lastly, in 2020 ASN continued, in collaboration with ASND, examining Orano's decommissioning and waste management strategy file. In order to verify Orano's ability to meet its strategy deadlines, ASN initiated an innovative project management inspection procedure in 2019 and 2020.

1. Radioactive waste

Pursuant to the provisions of the Environment Code, the producers of spent fuel and radioactive waste are responsible for these substances, without prejudice to the liability of those who hold these substances in their role as persons or entities responsible for nuclear activities. Radioactive waste must be managed in accordance with specific procedures. Waste producers must pursue the objective of minimising the volume and harmfulness of their waste, both before production by appropriate design and operation of the facilities, and after production by appropriate sorting, treatment and packaging.

The types of radioactive waste differ widely in their radioactivity (specific activity, nature of the radiation, half-life) and their form (scrap metal, rubble, oils, etc.).

Two main parameters can be used to assess the radiological risk that radioactive waste represents: firstly the activity, which contributes to the toxicity of the waste, and secondly the half-life of the radionuclides present in the waste which determines the required waste containment time A distinction is therefore made between very low, low, intermediate and high-level waste on the one hand and, on the other hand, very short-lived waste (whose activity level is halved in less than 100 days) resulting mainly from medical activities, short-lived waste (chiefly containing radionuclides whose activity level is halved in less than 31 years) and long-lived waste (which contains a large quantity of radionuclides whose activity level is halved in more than 31 years).

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 (except mining tailings and waste rock)

The management of radioactive waste is defined in Article L. 542-1-1 of the Environment Code. It comprises all the activities associated with the handling, preliminary treatment, treatment, packaging, storage and disposal of radioactive waste, excluding off-site transportation.

ASN oversees the activities associated with the management of radioactive waste from Basic Nuclear Installations (BNIs) or small-scale nuclear activities, other than those linked to national defence which are overseen by Defence Nuclear Safety Authority (ASND) and those relative to Installations Classified for Protection

TABLE 1

Classification of radioactive waste[1]

Activity scale	Level	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
0 Bq/g(*) – 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*)	
HUNDREDS Bq/g(*) – MILLIONS Bq/g(*)	**Low-level (LL)**		**Surface disposal** (Aube waste disposal repository)	**Near-surface disposal** (being studied pursuant to the Act of 28 June 2006)
MILLIONS Bq/g(*) – BILLIONS Bq/g(*)	**Intermediate-level (IL)**			
> BILLIONS Bq/g(*)	**High-level (HL)**	Not applicable(**)	**Deep geological disposal** (planned pursuant to the Act of 28 June 2006)	

(*) Becquerel per gramme (Bq/g).
(**) There is no such thing as high level, very short-lived waste.

of the Environment (ICPEs), which are placed under the oversight of the Prefects.

1.1.1 Management of radioactive waste in Basic Nuclear Installations

Two economic sectors are the major contributors to the production of radioactive waste in BNIs.

First, the nuclear power sector, with the 19 Nuclear Power Plants (NPPs) operated by EDF, and the plants dedicated to the fabrication and reprocessing of nuclear fuel operated by Orano and Framatome. Operation of the NPPs generates spent fuel, part of which is reprocessed to separate the recyclable substances from the fission products or minor actinides which are waste. Radioactive waste is also produced during the operational and maintenance activities in the NPPs and the fuel reprocessing plants, like the structural waste, the hulls and end-pieces constituting the nuclear fuel cladding, and the technological waste, and the waste from the treatment of effluents such as the bituminised sludge. Furthermore, decommissioning of the facilities produces radioactive waste.

Second, the research sector, which includes civil nuclear research, in particular the CEA's laboratory and reactor research activities, but also other research organisations. Radioactive waste is produced during the operation, maintenance and decommissioning of these facilities.

This radioactive waste is managed in accordance with specific provisions which take into account its radiological nature and are proportionate to the potential danger it represents.

1.1.2 Management of waste from small-scale nuclear activities authorised under the Public Health Code

The issues and implications

The use of unsealed radioactive sources[2] in nuclear medicine, biomedical or industrial research creates solid and liquid waste: small laboratory items used to prepare sources, medical equipment used to administer injections for diagnostic or therapeutic purposes, etc. Radioactive liquid effluents also come from source preparation as well as from patients who eliminate the administered radioactivity by natural routes.

The diversity of waste from small-scale nuclear activities, the large number of establishments producing it and the radiation protection issues involved, have led the public authorities to regulate the management of the waste produced by these activities.

Management of disused sealed sources considered as waste

Sealed radioactive sources[3] 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 both their concentrated activity and their potential attractiveness if found in the event of human intrusion after loss of the memory of a disposal facility. These two factors therefore limit the types of sources that can be accepted in disposal facilities, especially surface facilities.

1.1.3 Management of waste containing natural radioactivity

Some professional activities using raw materials which naturally contain radionuclides, but which are not used for their radioactive properties, may lead to an increase in specific activity in the products, residues or waste they produce. The term "Naturally Occurring Radioactive Material" (NORM) is used when its activity exceeds the exemption thresholds figuring in Table 1 of Appendix 13-8 of the Public Health Code. Consequently, NORM waste, for which there is no planned or envisaged use,

1. Appendix 1 of the Order of 9 October 2008 amended relative to the nature of the information that the entities responsible for nuclear activities and the companies mentioned in Article L. 1333-10 of the Public Health Code are obliged to establish, keep up to date and periodically communicate to the French National Agency for the Radioactive Waste Management (Andra).

2. Unsealed radioactive source: source for which the presentation and the normal conditions of use are unable to prevent all dispersion of the radioactive substance.

3. Sealed radioactive source: source for which the structure or packaging prevents all dispersion of radioactive materials into the ambient environment, in normal use.

is now considered as radioactive waste within the meaning of Article L. 542-1-1 of the Environment Code. Waste containing radioactive substances of natural origin but which do not exceed the abovementioned exemption thresholds is directed to conventional waste management routes.

NORM waste can be stored in two types of facility depending on its specific activity:
- in a waste disposal facility authorised by Prefectural Order, if the acceptance conditions stipulated in the Circular of 25 July 2006[4] relative to waste storage facilities, coming under sections 2760 of the ICPE nomenclature, are satisfied;
- in Cires[5] (Industrial centre for grouping, storage and disposal) intended for the disposal of very low-level (VLL) radioactive waste.

Some of this waste is however stored while waiting for a disposal route, in particular the commissioning of a disposal centre for low-level long-lived waste (LLW-LL).

Four hazardous waste disposal facilities are authorised by Prefectural Order to receive waste containing NORMs.

Furthermore, following the entry into effect on 1 July 2018 of Decree 2018-434 of 4 June 2018 introducing various provisions with regard to nuclear activities, the provisions of the Labour Code relative to the protection of workers against ionising radiation also apply to professional activities involving materials that naturally contain radioactive substances, which include the NORMs.

1.2 The legal framework for radioactive waste management

Radioactive waste management falls within the general waste management framework defined in Book V, Part IV, Chapter I of the Environment Code and its implementing decrees. Particular provisions concerning radioactive waste were introduced first by Act 91-1381 of 30 December 1991 on research into the management of radioactive waste, and then by Planning Act 2006-739 of 28 June 2006 on sustainable management of radioactive materials and waste, called the “Waste Act”, which gives a legislative framework to the management of all radioactive materials and waste A large part of the provisions of these Acts are codified in Book V, Part IV, Chapter II of the Environment Code.

The Act of 28 June 2006 more specifically sets a calendar for research into high and intermediate-level, long-lived (HL and IL-LL) waste and a clear legal framework for ring-fencing the funds needed for decommissioning and for the management of radioactive waste. It also provides for the preparation of the PNGMDR, which aims to carry out a periodic assessment and define the prospects for the radioactive substance management policy. It also consolidates the missions of the French National Radioactive Waste Management Agency (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 requalify materials as radioactive waste;
- reinforce the existing administrative and penal enforcement actions and provide for new enforcement actions in the event of failure to comply with the provisions applicable to the management of radioactive waste and spent fuel.

The conditions for creating a reversible deep geological repository for high-level and intermediate-level long-lived radioactive waste are detailed in Act 2016-1015 of 25 July 2016.

1.2.1 Legal framework for the management of radioactive waste produced in Basic Nuclear Installations

In France, the management of radioactive waste in BNIs is governed in particular by the Order of 7 February 2012 setting the general rules relative to BNIs, of which Part VI concerns waste management.

BNI licensees establish a waste zoning plan which identifies the zones in which the waste produced is or could be contaminated or activated. As a protective measure, the waste produced in these zones is managed as if it were radioactive and must be directed to dedicated routes. This absence of release thresholds for waste coming from a zone in which the waste is or could be contaminated or activated, constitutes a particularity of the French regulations. Waste from other areas, once confirmed as being free of radioactivity, is sent to authorised routes for the management of hazardous, non-hazardous or inert waste, depending on its properties.

The regulations also oblige licensees to present the wastes produced by the facility, whether radioactive or not, indicating the volumes, types, harmfulness and the envisaged disposal routes. The measures adopted by the licensees must consist in reducing the volume and the radiological, chemical or biological toxicity of the waste produced by recycling and treatment processes, so that only the ultimate waste has to go to final disposal.

ASN resolution 2015-DC-0508 or 21 April 2015 details the provisions of the Order of 7 February 2012, concerning in particular:
- the procedures for drawing up and managing the waste zoning plan;
- the content of the annual waste management assessment which each BNI must transmit to ASN.

ASN Guide No. 23 presents the conditions of application of this resolution with regard to the drawing up and modification of the waste zoning plan.

Further to a modification of the requirements of the procedures decree, codified in 2019 in the Environment Code, the the waste management study is no longer required as a specific document. The provisions of the regulations must now be carried over to the environmental impact study and the BNI general operating rules. In 2021, ASN will continue updating the resolution of 21 April 2015 to include this change in the regulations.

4. Circular of 25 July 2006 relative to classified installations – Acceptance of technologically enhanced or concentrated natural radioactivity in the waste disposal centres.
5. French acronym standing for “Industrial centre for grouping, storage and disposal”, name given in October 2012. It was commissioned in 2003 under the name CSTFA, standing for “Very low level waste disposal facility”, a facility licensed under section 2797 of the ICPE System.

1.2.2 Legal framework for the management of radioactive waste produced by activities authorised under the Public Health Code

Article R. 1333-16[6] of the Public Health Code states that the management of effluents and waste contaminated by radioactive substances originating from all nuclear activities involving a risk of exposure to ionising radiation must be examined and approved by the public authorities. This is the case in particular for activities using radioactive substances intended for medicine, human biology or biomedical research.

ASN resolution 2008-DC-0095 of 29 January 2008 lays out the technical rules applicable for the disposal of effluents and waste contaminated or potentially contaminated by radionuclides owing to a nuclear activity. ASN published a guide (Guide No. 18) to the application of this resolution in January 2012. ASN will have this regulatory framework updated by integrating the feedback from its application and new medical practices using radionuclides.

Management of disused sealed sources

Under the PNGMDR 2016-2018, Andra submitted a report in mid-2018 presenting a review of the situation regarding the acceptance of disused sealed sources considered as waste in the existing and planned disposal facilities.

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 provide proof 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 issued a position statement in early 2021 on the management of disused sealed sources. It considers that disused sealed sources which cannot be accepted in above-ground disposal facilities must be included in the inventories of projected disposal facilities, and that a complete inventory of the existing management routes must be established, indicating the responsibilities of the various actors. Moreover, ASN recommends that the notion of "last resort" mentioned in Decree 2015-231 must be specified.

Management by Andra of waste from small-scale nuclear activities

Article L. 542-12 of the Environment Code entrusts Andra with a public service mission for the management of waste produced by small-scale nuclear activities. Since 2012, Andra operates Cires, a collection centre and storage facility situated in the municipalities of Morvilliers and La Chaise for waste from small producers other than NPPs. ASN considers that the approach adopted by Andra is appropriate to meet the duties entrusted to it under Article L. 542-12 of the Environment Code and that this must be continued.

Nevertheless, the tritiated solid waste must be managed with the waste from 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 report provided in response to Article 61 of the Order of 23 February 2017, Andra proposes storing this waste on the CEA Valduc site pending commissioning of the abovementioned storage facilities.

6. Formerly Article R. 1333-12.

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 national 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:
- the French NPP fleet renewal scenario SR1 hypothesises the continued production of nuclear generated electricity, with an operating time for the current reactors of between 50 and 60 years and gradual replacement of the current reactors by European Pressurised Water Reactors (EPR) and then fast-neutron reactors;
- the French NPP fleet renewal scenario SR2 takes up the hypothesis of scenario SR1, but with a uniform 50-year operating time for the current reactors;
- the French NPP fleet renewal scenario SR3 takes up the hypotheses of scenario SR1, but with fleet renewal only by EPRs, which implies reprocessing the spent Enriched Natural Uranium (ENU) fuels only and no reprocessing of spent mixed uranium and plutonium oxide (MOX) and Enriched Reprocessed Uranium (ERU) fuels;
- the French reactor fleet Non-Renewal Scenario (SNR) takes the hypothesis of not renewing the fleet after 40 years of operation (60 years for the EPR), with early stopping of spent ENU fuel reprocessing in order not to produce separate plutonium, and stopping the reprocessing of spent MOX and ERU fuels.

This inventory constitutes an input database for preparing the PNGMDR. In its opinion of 8 October 2020, ASN considers it necessary to look ahead to the consequences of the possible change in energy policy on the management of material and waste, and points out that these forecasts must be based on various long-term hypotheses that are consistent with the multi-year energy programme forecasts adopted by a Decree of 21 April 2020.

1.2.4 The National Radioactive Materials and Waste Management Plan

Article L. 542-1-2 of the Environment Code, amended by the abovementioned Ordinance 2016-128 of 10 February 2016, defines the objectives of the PNGMDR:
- draw up the inventory of the existing radioactive material and waste management methods and the chosen technical solutions;
- identify the foreseeable needs for storage or disposal facilities and specify their required capacities and the storage durations;
- set the general targets, the main deadlines and the schedules enabling these deadlines to be met while taking into account the priorities it defines;
- determine the objectives to be met 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.

In view of the conclusions of the public debate of 2019, ASN and the DGEC have decided to change the governance of the PNGMDR. The 5th edition will be prepared by the Ministry of Ecological Transition, based in particular on the work of a "guidelines commission". Introduced by the resolution of 21 February 2020, this commission is chaired by an independent

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 French National Radioactive Material and Waste Management Plan (PNGMDR) but also by inspecting the facilities 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 consideration all the issues of safety, radiation protection, minimising waste volume and toxicity, 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 drawn up by the Ministry of Ecological Transition. The Ministry has opted, in the light of the public debate of 2019, to rely on a pluralistic "guidance commission", chaired by an independent qualified person, in which ASN participates. Monitoring of the technical and operational implementation of the PNGMDR is still ensured by a pluralistic working group co-chaired by ASN and the General Directorate for Energy and the Climate (DGEC), as described in chapter 2. ASN also publishes the PNGMDR, its synthesis, the minutes of the abovementioned working group's meetings, the studies required by the plan and the associated ASN opinions on its website.

qualified personality and brings together, in addition to the legacy members of the pluralistic working group mentioned in chapter 2, elected officials and representatives of the regional authorities. ASN participates actively in the guidelines commission – albeit without voting rights – to provide its guidance on the safety and radiation protection issues.

Implementation of the plan is then followed up at periodic meetings of the PNGMDR working group jointly chaired by ASN and the DGEC.

In 2020, ASN moreover assessed the studies submitted for the PNGMDR 2016-2018. For the preparation of the 5th PNGMDR, ASN has thus issued its opinions on the radioactive material and waste management routes in which it sets out a number of recommendations. It will issue an opinion on the regulatory texts adopted in application of the plan in the light of the nuclear safety and radiation protection challenges.

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, earth, sand) and metal waste. Its specific activity is usually less than 100 Bq/g (becquerels per gram) and can even be below the detection threshold of certain measuring devices.

The Cires includes a VLL waste disposal facility. This facility, which has ICPE status, has been operational since August 2003.

At end of 2020, Cires held 412,258 m^3 of VLL waste, which represents 63% of its authorised capacity. According to the national inventory produced by Andra, the quantity of VLL waste resulting from decommissioning of the existing nuclear facilities will be about 2,200,000 m^3. According to current forecasts, the facility could be filled to maximum capacity around 2028. Andra is currently working on the Acaci project, which aims to increase the facility's authorised capacity to more than 900,000 m^3, without changing its ground surface area.

In its opinion 2020-AV-0356 of 30 June 2020 on the management of VLL waste, ASN calls for the continuation and extension of the work undertaken in the 2016-2018 edition of the PNGMDR with the aim of improving current management methods and developing complementary management solutions which remain to be devised and implemented.

ASN reaffirms that the foundations of VLL waste management must be based on the place of origin of the waste and guarantee its traceability from production through to disposal, with the exception of metallic VLL waste that is to be recycled, thanks to specific routes as stated in the abovementioned resolution of 21 February 2020.

The recycling of certain types of waste which will be produced in large volumes, along with the setting up of a specific oversight framework for a metal recycling facility, is encouraged, consistently with the waste management hierarchy defined in the Environment Code. ASN recommends in particular the operational implementation of a rubble recycling route for use by the disposal facilities, and continuation of the metals recycling facility project, with the setting up of a specific oversight framework for this facility.

Furthermore, ASN considers it necessary for all the stakeholders, particularly the representatives of the regions concerned or likely to be concerned, to be more closely involved in the defining of the VLL waste management solutions.

Lastly, as saturation of the current disposal capacities for VLL waste could restrict the entire route and delay the decommissioning projects, ASN considers that solutions must be put forward to cater for the situation where a new centralised disposal facility is not available. It recommends that the studies for putting in place additional disposal facilities, whether centralised or decentralised, be continued and that the government should clarify Andra's responsibility in this respect.

1.3.2 Low and intermediate-level, short-lived waste

Low-level and intermediate-level short-lived waste (LL/ILW-SL) – in which the radioactivity comes primarily from radionuclides with a half-life of less than 31 years – comes essentially from the operation of nuclear facilities and more specifically as a result of maintenance work (clothing, tools, filters, etc.). It can also come from the post-operational clean-out and decommissioning of these facilities. The majority of LL/ILW-SL waste is placed in surface disposal facilities operated by Andra. Once these facilities are closed, they are monitored for a period set by convention at 300 years. The facility safety analysis reports – which are updated periodically, including during the monitoring phase – must show that at the end of this phase, the residual activity contained in the waste will have reached a residual level such that human and environmental exposure levels are acceptable, even in the event of a significant loss of the containment properties of the facility. There are two facilities of this type in France, the Manche repository (CSM – BNI 66), commissioned in 1969 and closed since 1994, and the Aube repository (CSA – BNI 149) in operation (see Regional Overview in the introduction to this report).

The quantity of LL/ILW-SL waste emplaced in the CSA repository totalled 353,147 m^3 at the end of 2020, which represents 35% of the facility's maximum authorised capacity. Added to this quantity is the waste emplaced in the Manche repository, which represents 527,214 m^3. The total quantity of LL/ILW-SL waste emplaced in the Andra facilities is therefore 880,361 m^3, to be compared with the quantity of 917,000 m^3 produced at the end of 2018. According to the data of the national inventory drawn up by Andra, this waste will represent a maximum volume of 2,000,000 m^3, on completion of decommissioning of the existing facilities. According to the estimates made by Andra in 2016 at the time of the periodic safety review of the CSA, this facility could reach its maximum filling capacity by 2060 instead of 2042 as initially forecast, this new estimate being based on better knowledge of the future waste and the waste delivery schedules.

1.3.3 Management of low-level long-lived waste

The low-level long-lived waste (LLW-LL) initially comprised two main categories: graphite waste resulting from operation of the Gas-Cooled Reactors (GCRs) and radium-bearing waste from the radium industry and its offshoots. Other types of waste have been added to this category such as certain bituminised effluents, substances containing radium, uranium and thorium with low specific activity, as well as certain disused sealed radioactive sources.

Furthermore, a fraction of the waste from the Orano Malvesi plant (Aude *département*) produced as from 1 January 2019 is now included in this waste category. The solid waste produced until 31 December 2018, on account of the large volumes it represents, is placed in a specific category of the national inventory called RTCU (French acronym standing for "Uranium Fuel Reprocessing Residues").

Putting in place a definitive management solution for this type of waste is one of the objectives defined by the Act of 28 June 2006. Finding such a management solution necessitates firstly having greater knowledge of LLW-LL waste and secondly conducting safety studies on the associated disposal solution. The successive editions of the PNGMDR have set out this objective. ASN also drafted a notice in 2008 giving general safety guidelines concerning the search for a site capable of accommodating LLW-LL.

The PNGMDR 2010-2012 opened up the possibility of separate disposal of graphite waste and radium-containing waste, and asked Andra to work on the two design options:
- reworked cover disposal in an outcropping geological layer by excavation followed by backfilling;
- intact cover disposal dug in underground layer of clay at a greater depth.

The PNGMDR 2013-2015 required the various actors involved to carry out studies (characterisation and waste treatment possibilities, geological investigations on a site identified by Andra, design studies and preliminary safety analyses) so that in 2016 the State can specify guidelines for the management of LLW-LL waste. Thus, the holders of LLW-LL waste have progressed in the characterisation of their waste and in the processing possibilities, particularly with regard to graphite waste and some bituminised waste packages. More specifically, the radiological inventory for chlorine-36 and iodine-129 has undergone a significant downward reassessment.

As part of the PNGMDR, Andra submitted a report in July 2015 containing:
- proposals of choices of management scenarios for graphite waste and bituminous waste;
- preliminary design studies covering the disposal options referred to as "intact cover disposal" and "reworked cover disposal";
- the inventory of the waste to be emplaced in it and the implementation schedule.

ASN issued an opinion 2016-AV-264 on Andra's interim report on the disposal project for LLW-LL waste on 29 March 2016. At the same time, ASN has started revising the general safety guidelines notice of 2008. A working group bringing together ASN the the French Institute for Radiation Protection and Nuclear Safety (IRSN), Andra, the LLW-LL waste producers and representatives of civil society was thus set up in Autumn 2018. A synthesis of the work carried out will be provided in an IRSN report in 2021. The recommendations of this report will be taken into account in the revision of the general safety guidelines for LLW-LL of 2008, which will be replaced by an ASN guide.

Lastly, in accordance with Article 7 of the Decree of 27 December 2013, Orano has submitted a study on the long-term management of the Malvési site waste already produced, stored in BNI 175 – Écrin. Various envisaged disposal concepts are presented.
- above-ground disposal;
- near-surface (40 m), reworked cover disposal, in the former open-cast mine pit;
- near-surface (40 m) reworked cover disposal, in a new pit as yet to be built.

Given the nature of the waste and the configuration of the site, ASN indicated in its opinion 2012-AV-0166 of 4 October 2012 that it is not in favour of continuing the development of this type of disposal as it considers that it does not meet the long-term safety requirements. The other two disposal options presented in the Areva study of December 2014 on the long-term management of legacy waste from the conversion process, are based on an identical concept, namely near-surface reworked cover disposal at a depth of about 40 m.

On 2 September 2019, ASN issued its opinion on the studies required by Article 7 of the Decree of 27 December 2013 relative to the implementation of a final management solution for the Malvési legacy waste in a near-surface repository. Orano's responses are currently being examined.

With the 5th edition of the PNGMDR in view, ASN issued its opinion 2020-AV-0357 of 6 August 2020 which details the work focuses it recommends for the management of LLW-LL waste.

It more particularly urges continuation of the work undertaken under the PNGMDR 2016-2018, such as the consolidation of the inventories of the various families of LLW-LL waste and the periodic reassessment of storage needs, notably in order to allow the decommissioning of the nuclear facilities.

ASN considers that, on the basis of a multi-criteria analysis, Andra should submit the outlines of various technical and safety options for the near-surface disposal facilities for LLW-LL waste, comparing the health and environmental effects of the various options envisaged. All of the stakeholders concerned, in particular the representatives of the localities actually or liable to be involved, must be involved more actively in defining LLW-LL waste management solutions. A pluralistic working group could notably be set up to establish concrete management solution proposals based on the work done by Andra.

ASN also recommends setting time milestones for Andra's next design stages (preliminary design study and then safety options file), for a near-surface disposal project for LLW-LL waste in the Vendeuvre-Soulaines municipality federation, which will be incorporated into this general strategy.

Finally, ASN considers that the RTCUs should be better integrated in the work on the LLW-LL waste management scenarios. It recommends that studies be continued on an RTCU disposal facility, involving the representatives of the localities actually or liable to be concerned. The aim is to provide the technical and safety options for this facility, at a date set by the next edition of the PNGMDR, with a level of maturity corresponding to the preliminary design stage.

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.

The report of the Special Public Debates Commission of 25 November 2019 concerning the public debate prior to the 5th edition of the PNGMDR concludes in particular that "*there are two options, each one defended by a portion of the actors: deep geological disposal and interim sub-surface storage for a sufficient length of time to allow progress to be made in transmutation research in order to reduce the radioactivity of the waste.*" In its opinion 2020-AV-0369 of 1 December 2020, ASN points out that the prospects of industrial-scale transmutation of the already-packaged waste of the *Cigéo* reference inventory are not credible. It considers that, although transmutation studies should be continued, they should concern radioactive substances currently qualified as materials or the waste produced by a future fleet of reactors and that they be carried out with a view to developing complete solutions, including the disposal of the waste resulting from transmutation and offering a high level of safety.

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 2035.

The Act of 28 June 2006 tasked Andra with coordinating the research and studies on the storage of HL and ILW-LL waste, which are therefore part of the approach of complementarity with the reversible repository. This law stipulated more specifically that the research and studies on storage should, by 2015 at the latest, allow new storage facilities to be created or existing facilities to be modified to meet the needs identified by the PNGMDR, particularly in terms of capacity and duration.

Progress in storage

In 2013, Andra submitted a report on the research and studies carried out. This report more particularly presented the established inventory of future storage needs, the exploration of the complementarity between storage and disposal, studies and research on engineering and on the phenomenological behaviour of the warehouses and a review of innovative technical options.

From 2013 to 2015, Andra conducted more in-depth studies into storage concepts linked to repository reversibility. This concerns facilities which, if necessary, would accept packages removed from the repository. For such facilities, Andra looked for versatility which would allow simultaneous or successive storage of packages of various types in their primary form or placed in disposal overpacks. In its study submitted in 2013, Andra stated that it had stopped its research on near-surface storage facilities. It justified abandoning this operation in particular because of the greater complexity of this type of facility (consideration of the presence of underground water and the need for ventilation if exothermal waste was emplaced, surveillance of the civil engineering structures) and the lower operating flexibility. The multi-criteria analysis submitted in 2018 did not call into question these conclusions.

In the light of industrial experience, research and its studies, Andra issued recommendations in 2014 for the design of future storage facilities that are complementary to disposal. They concern more specifically the service life of the facilities (up to about 100 years), their monitoring and surveillance and their modularity. Orano has integrated some of the recommendations in the design of the extension of the glass storage facilities at La Hague (E/EV-LH) intended for high-level waste and situated in BNI 116. This extension comprises two pits: 30 and 40, commissioned in 2015 and 2017 respectively.

Within the framework of the PNGMDR 2013-2015, and after presenting the inventory of HLW and ILW-LL waste packages intended for *Cigéo* as at the end of 2013 and the status of the existing storage locations, the producers more specifically analysed the fundamental elements enabling waste package storage needs to be identified.

The work carried out under the PNGMDR 2016-2018

The studies required by the PNGMDR 2016-2018 focus on the analysis of the storage needs for HL and ILW-LL waste packages and take up the broad lines of the ASN opinion of 25 February 2016.

Article D. 542-79 of the Environment Code, introduced by the Decree of 23 February 2017 relative to the provisions of the PNGMDR 2016-2018, stipulates that the holders of spent fuel and HL and ILW-LL radioactive waste must keep up to date the availability status of the storage capacities for these substances by waste category and identify the future storage capacity needs for the next 20 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 20 years. The CEA, EDF and Orano have also studied, within this context, how sensitive the storage needs are to shifts in the *Cigéo* schedule.

In its opinion 2020-AV-0369 of 1 December 2020, ASN considers in this respect that the dates at which existing storage facilities will reach maximum capacity and the future storage needs for the next 20 years have on the whole been identified by the producers.

Nevertheless, the storage capacity estimates must be consolidated by all the waste producers, integrating margins to cope with any contingencies affecting the waste management routes concerned and thereby be able to anticipate the needs for additional storage capacities and the corresponding licensing authorisation procedures.

Article 52 of the Order of 23 February 2017 requires Andra to substantiate the reasons that led it to reject the option of designing near-surface storage facilities. In response to this requirement, in 2018 Andra submitted a comparative study of the different types of storage it has studied. This analysis does not show a near-surface facility to have a decisive advantage with respect to an above-ground facility in terms of nuclear safety.

In its opinion 2020-AV-0369 of 1 December 2020, ASN considers that near-surface storage facilities do not have a decisive advantage over above-ground storage facilities with regard to nuclear safety and radiation protection.

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*.

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 (ASN Guide No. 1).

The conditions of creation of a reversible deep geological repository for HL and ILW-LL radioactive waste were specified by the Act of 25 July 2016, which defines the principle of reversibility, introduces the industrial pilot phase before complete commissioning of *Cigéo* and brings schedule adaptations concerning the deployment of *Cigéo*.

This Act defines reversibility as "*the ability, for successive generations, to either continue the construction and then the operation of successive sections of a disposal facility, or to reassess previous choices and change the management solutions. Reversibility is materialised by the progressive nature of the construction, the adaptability of the design and the operational flexibility of placing radioactive waste in a deep geological repository which can integrate technological progress and adapt to possible changes in waste inventory following a change in energy policy. It includes the possibility of retrieving waste packages from the repository under conditions and during a period of time that are consistent with the operating strategy and the closure of the repository*".

In its opinion 2016-AV-0267 of 31 May 2016 relative to the reversibility of the deep geological disposal of radioactive waste, ASN had considered that the principle of reversibility implied a requirement for adaptability of the facility and retrievability of the packages during a period governed by law.

The Decree of 23 February 2017 relative to the provisions of the PNGMDR details certain principles applicable to *Cigéo*, and more particularly in Articles D. 542-88 to D. 542-96 of the Environment Code. Article D. 542-90 stipulates in particular that: "*The inventory to be considered by the French National Agency for Radioactive Waste Management (Andra) for the studies and research conducted for the design of the repository provided for in Article L. 542-10-1 shall comprise a reference inventory and a reserve inventory. The reserve inventory shall take into account the uncertainties associated more specifically with putting in place new waste management routes or changes in energy policy. The repository shall be designed to accommodate the waste of the reference inventory. It shall also be designed by Andra, in consultation with the owners of the substances of the reserve inventory, to be capable of accommodating the substances figuring in that inventory, provided that changes in its design can be implemented if necessary during operation of the repository at an economically acceptable cost*".

Underground laboratory of Meuse/Haute-Marne

Studies on deep geological disposal necessitate research and experiments in an underground laboratory. Andra has been operating such an underground laboratory within the Bure municipality since 1999.

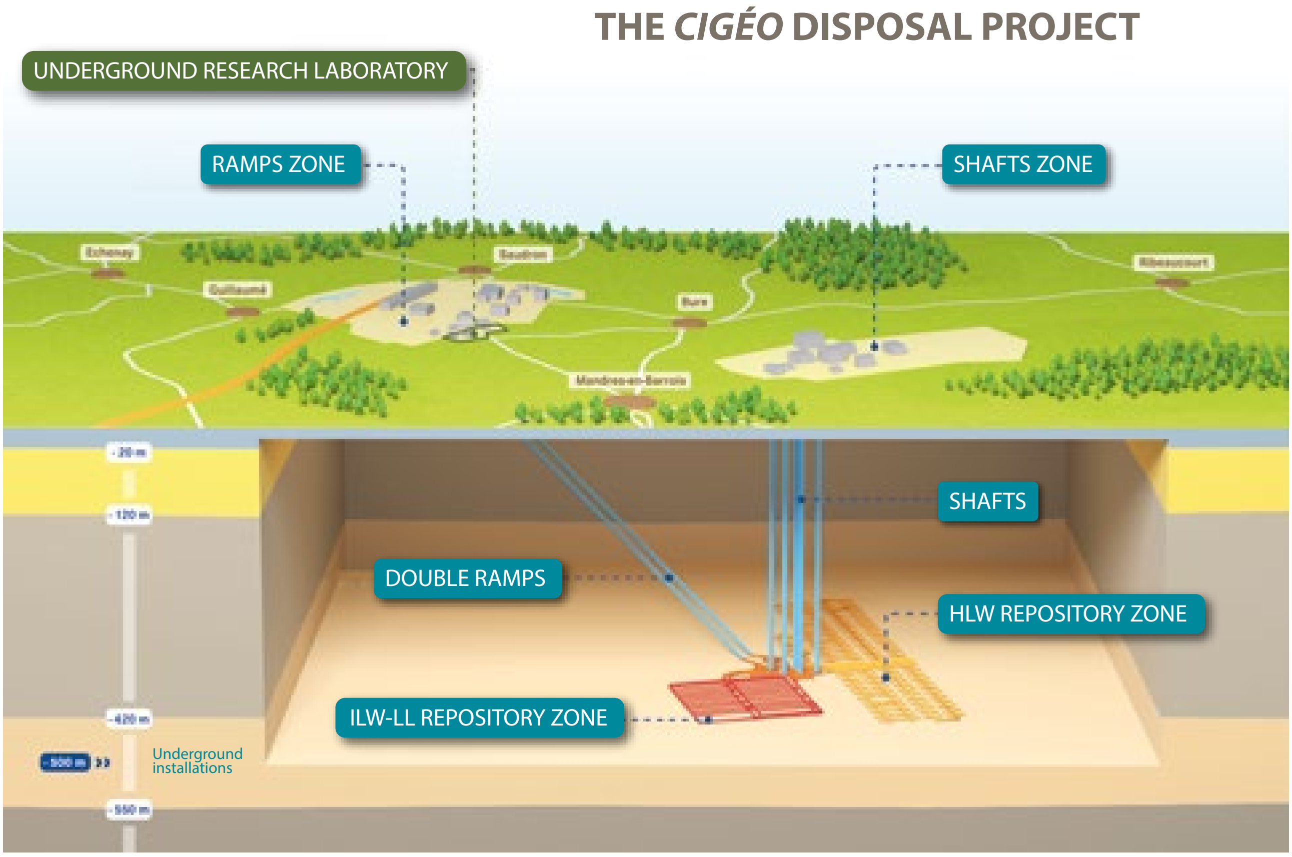
In the context of the studies on the deep geological disposal, ASN issues recommendations concerning the research and experiments conducted in the laboratory, and ascertains by random sampling during follow-up inspections, that they are carried out using processes that guarantee the quality of the results.

Technical instructions

Pursuant to the Act of 30 December 1991, and then pursuant to the Act of 28 June 2006 and the PNGMDR, Andra has carried out studies and submitted reports on deep geological disposal. 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 2009. It issued opinions on these reports on 1 February 2006 and 26 July 2011. Andra subsequently submitted

Schematic diagram of the *Cigéo* repository showing the surface and underground facilities



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 dossier.

The authorisation process

Examination of the creation authorisation application for a deep geological disposal facility will not start until formally requested by Andra and will be governed in particular by Book V, Title IX, Chapter III, Section 4 of the Environment Code and by Article L. 542-10-1 of the Environment Code, which is specific to deep geological disposal facilities.

Examination of the *Cigéo* Safety Options Dossier

The filing of a Safety Options Dossier (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 additional studies and justifications (corrosion phenomena, low-pH concretes, representativeness of the hydrogeological model, surveillance strategy, etc.). The demands made in this letter take into account the suggestions and comments received through the public consultation.

The examination of the *Cigéo* DOS highlighted several issues relating to specific aspects (architecture, defining of hazards, post-accident management, etc.). Among these issues ASN pointed out that the management of bituminised waste required special attention.

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).

7. *Article R. 593-14 of the Environment Code stipulates that* "any person who plans operating a BNI can, before initiating the creation authorisation procedure, ask ASN for an opinion on all or part of the options it has chosen to protect the interests mentioned in Article L. 593-1. ASN through an opinion rendered and published under the conditions determined by ASN, indicates the extent to which the safety options presented by the applicant are appropriate for preventing or limiting the risks for the interests mentioned in Article L. 593.1, given the prevailing technical and economic conditions. ASN may indicate the additional studies and justifications that will be required for a prospective creation authorisation application. It can set a validity period for its opinion. This opinion is communicated to the applicant and to the Minister responsible for nuclear safety".

In 2019, ASN made additional information requests[8] to the waste producers and to Andra further to the examination of the study submitted under Article 46. They focus more specifically on the effect of self-irradiation on the thermal behaviour of the bituminised waste packages, on the thermal reactivity of the bituminised coatings, on the long-term swelling considering the long-term behaviour of the *Cigéo* repository and on the design changes to control the risks associated with the disposal of packages of bituminised waste.

The Minister responsible for energy and ASN moreover wanted an independent multidisciplinary assessment drawing on international practices to be conducted on this issue. The conclusions of this assessment were presented to the working group which monitors the PNGMDR (see box page 360) in September 2019. ASN considers in this respect in its opinion 2020-AV-0369 of 1 December 2020 that in view of the conclusions of the third-party review of the management of bituminised waste and the studies on the changes in design of the *Cigéo* ILW-LL waste disposal cells, which highlight new technical factors since the publication of the opinion of 11 January 2018, it is essential for the waste producers to conduct an ambitious programme to characterise the bituminised waste packages in order to demonstrate that all or part of these packages could be emplaced with a high level of safety in the projected *Cigéo* facility without prior treatment.

ASN considers moreover that the bituminised waste packages whose safety once emplaced in the disposal facility could not be demonstrated must undergo further investigations.

From the Safety Options Dossier to the creation authorisation application

At present, Andra is continuing the *Cigéo* project design and preparing the requisite authorisation applications. Andra filed a Declaration of Public Utility (DUP) application in August 2020. Andra will acquire the status of nuclear licensee as soon as the creation authorisation application is filed. ASN and the IRSN make regular progress assessments with Andra to check that the key issues identified in the examination of the previous Andra files have been properly taken into account. Andra must also integrate the results of the bituminised waste review in its creation authorisation application file, particularly with regard to the architecture of the ILW-LL waste disposal cells.

In the public debate relative to the fifth edition of the PNGMDR, the question of *Cigéo* governance was identified as requiring closer examination, particularly with regard to the implementation of reversibility and the objectives of the industrial pilot phase. The Special Public Debate Committee (CPDP) concludes in particular that civil society must be involved in the governance of *Cigéo*, particularly during the industrial pilot phase. Furthermore, the CPDP considers that the public must also be involved in the steps that have an impact on the reversibility of the facility, particularly package retrievability.

The resolution of 21 February 2020 of the Minister of Ecological Transition and Solidarity and of the ASN Chairman further to the public debate provides in this respect that the PNGMDR will specify the conditions of reversibility of the facility, particularly regarding package retrievability, the decision-making milestones of the *Cigéo* project and the required method of governance in order to be able to review the choices made. It also specifies that the PNGMDR shall define the objectives and success criteria for the industrial pilot phase provided for in Article L. 542-10-1 of the Environment Code, the methods of informing the public between two successive updates of the operations master plan provided for in Article L. 542-10-1 of the Environment Code and the methods of involving the public in the decisive development steps of the *Cigéo* project.

The cost of the project

On 15 January 2016, in accordance with the procedure stipulated in Article L. 542-12 of the Environment Code and after consideration of ASN's opinion of February 2015 and the comments of the radioactive waste producers, the Minister responsible for energy issued an Order setting the reference cost of the *Cigéo* disposal project "*at €25 billion under the economic conditions prevailing on 31 December 2011, the year in which the cost evaluation work began*". This Order also specifies that the cost must be updated regularly and at least at the key stages of project development (creation authorisation, commissioning, end of "industrial pilot phase", periodic safety reviews).

1.4 Radioactive waste management support facilities

Treatment

Treatment is a fundamental step in the radioactive waste management process. This operation serves firstly to separate the waste into different categories to facilitate its subsequent management, and secondly to significantly reduce the volume of waste.

The La Hague plants which process the spent fuel assemblies are involved in this process because they apply a dissolution and chemical treatment process to separate the cladding and the fission products. The hulls and end-pieces are then compacted to reduce their disposal footprint.

The melting and incineration facility of Cyclife France, called "Centraco", significantly reduces the volume of the low-level and very-low-level waste that is treated there. This plant has a unit dedicated to the incineration of combustible waste, and a melting unit in which metal waste is melted down.

The radioactive effluents can also be concentrated by evaporation, like the operations carried out in Agate, the effluent advanced management and processing facility (BNI 171), with this same aim of volume reduction.

Packaging

Radioactive waste packaging consists in placing the waste in a package which provides a first containment barrier preventing radioactive substances being dispersed in the environment. The techniques used depend on the physical-chemical characteristic of the waste and their typology, which explains the large variety of packages used. These packages are subject to approvals by Andra if they are intended for existing disposal facilities, and to packaging agreements by ASN if they are intended to be directed towards disposal facilities still under study.

In some cases the packaging operations are carried out directly on the site of waste production, but they can also take place in dedicated facilities, like the La Hague plants, which package spent fuel hulls and end-pieces in CSD-C packages and fission products in CSD-V packages, and the effluent treatment stations such as the Stella station in BNI 35. The waste packages are sometimes packaged in the facilities in which they are to be stored, which will be the case for the ILW-SL waste packages in the Iceda facility, or directly in a disposal facility, such as Cires and CSA, which carry out these operations on a portion of the incoming packages.

8. *The follow-up letters are available on the ASN website:* asn.fr/Informer/Dossiers-pedagogiques/La-gestion-des-dechets-radioactifs/Plan-national-de-gestion-des-matieres-et-dechets-radioactifs/PNGMDR-2016-2018

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 below) are specifically dedicated to the storage of radioactive waste, such as Ecrin, commissioned in 2018, and Cedra and Iceda, commissioned in 2020. This will also be the case with Diadem once this facility is commissioned. 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's site conducts research and development work in low-level and intermediate-level objects and waste. This work primarily concerns aqueous waste treatment processes, decontamination processes, solid waste packaging methods and the expert assessment and inspection of waste packages.

2. Nuclear safety in waste management support facilities, role of ASN and waste management strategies of the major nuclear licensees

2.1 Nature of ASN oversight and actions

2.1.1 The 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 waste zoning, packaging or controls performed by the licensee), and on the other hand the safety of the facilities dedicated to radioactive waste management (waste treatment, packaging, disposal 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 the level of expertise required to examine certain files submitted by the licensees.

The various facilities and ASN's assessment of their safety are presented in the introduction of this report.

2.1.2 Oversight of the packaging of waste packages

Regulations
The Order of 7 February 2012 defines the requirements associated with waste packaging. Producers of radioactive waste are instructed to their waste taking into account the requirements associated with their subsequent management, and more particularly their acceptance at the disposal facilities.

ASN resolution 2017-DC-0587 of 23 March 2017 specifies the requirements regarding waste packaging for storage and the conditions of acceptance of waste packages in the disposal BNIs.

Production of waste packages intended for existing disposal facilities
The waste package producers prepare an approval application file based on the acceptance specifications of the disposal facility that is to receive the packages. Andra issues an storage 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 storage facilities currently being studied, the waste acceptance specifications have of course not yet been defined. Andra therefore cannot issue approvals to govern the production of packages for LLW-LL, HLW-LL or ILW-LL waste.

Under these conditions, the production of packages of these types of waste is subject to ASN approval on the basis of a file established by the waste producer called "packaging baseline requirements". This file must demonstrate that on the basis of existing knowledge and the currently identified requirements of the disposal facilities being studied, the packages present no unacceptable behaviour.

This provision also avoids delaying Waste Retrieval and Packaging (WRP) operations.

Checks and inspections
Alongside Andra's surveillance of approved packages, ASN checks the measures taken by the licensee to correctly implement the requirements of the authorisation and to master the packaging processes. For waste packages intended for disposal facilities still under study, ASN is particularly attentive to ensuring that the packages comply with the conditions of the issued packaging approvals.

ASN also ensures through inspections that Andra takes the necessary measures to verify the quality of the packages accepted in its disposal facilities. This is because ASN considers that Andra's role in the approvals issuing process and in monitoring the measures taken by the waste package producers is vital in guaranteeing package quality and compliance with the safety case of the waste repositories.

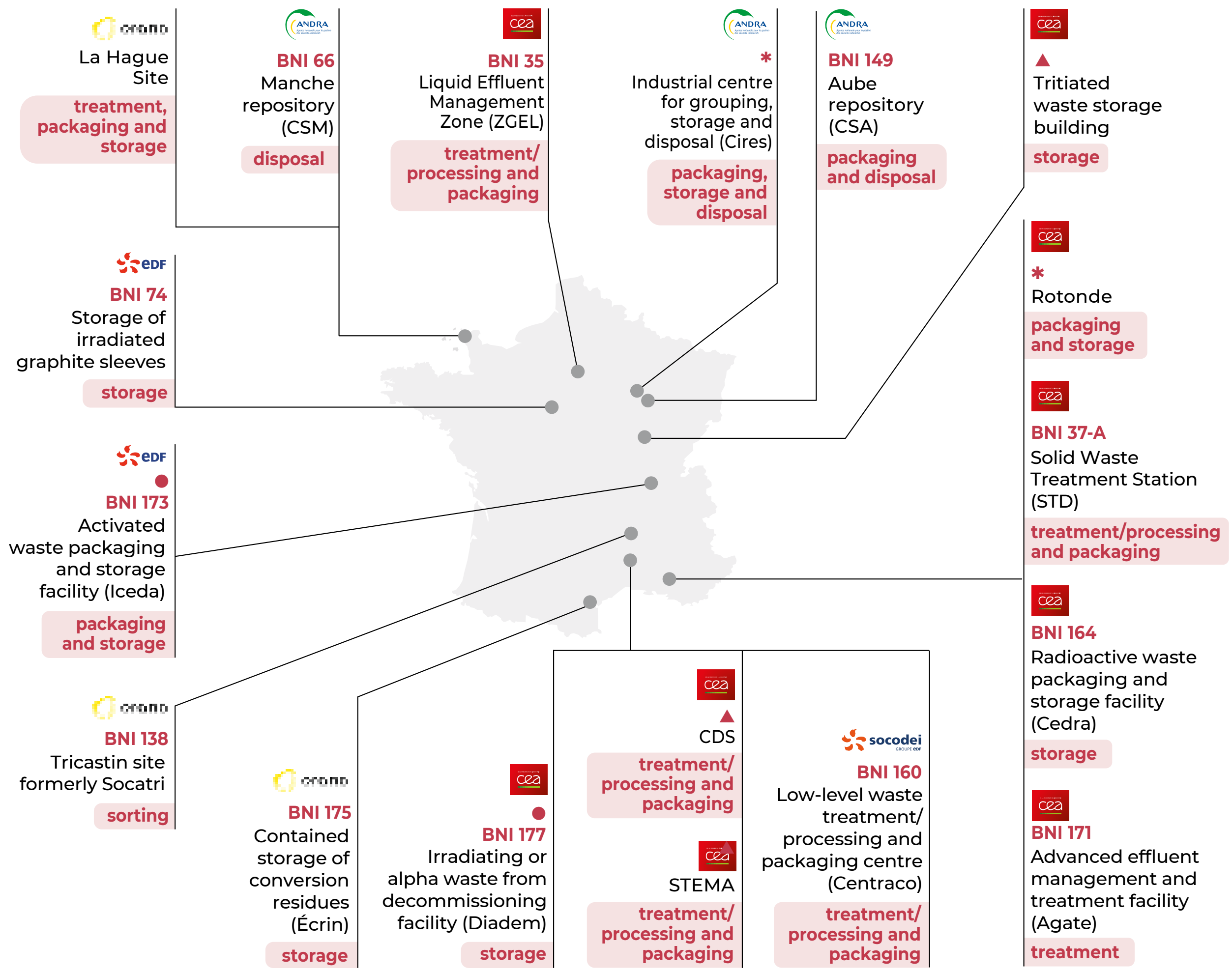
2.1.3 Developing recommendations for sustainable waste management

ASN issues opinions on the studies submitted under the PNGMDR. Between June 2020 and February 2021, ASN issued six opinions on the radioactive material and waste management routes, for the preparation of the 5th PNGMDR.

2.1.4 Developing the regulatory framework and issuing prescriptions to the licensees

ASN can issue regulations. Thus, the provisions of the Order of 7 February 2012 which concern the management of radioactive waste have been set out in ASN resolutions mentioned earlier relative to waste management in BNIs and the packaging of waste. To give an example, the resolution of 23 March 2017 addresses the packaging of radioactive waste and the conditions of acceptance of the radioactive waste packages in the storage BNIs. Its aim is to specify the safety requirements in the various stages of a management route. This

The main support facilities for radioactive waste management



● Waiting for commissioning * Comes under the status of ICPE ▲ Comes under the status of DBNI

resolution has been applicable since 1 July 2018. Moreover, to ensure a consistent approach to the management of waste in BNIs and Defence BNIs, ASN and ASND signed an agreement in January 2021 coordinating their actions in this area.

More generally, ASN issues requirements relative to the management of waste from the BNIs.

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 and 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 the Western European Nuclear Regulators Association (WENRA) which aims to harmonise nuclear safety practices in Europe by defining "reference safety levels" which must be transposed into the national regulations of its member countries. In this respect, the Working Group on Waste and Decommissioning (WGWD) is tasked with developing reference levels for the management of radioactive waste and spent fuel, and for the decommissioning of nuclear facilities. The ASN resolutions enable, among other things, these reference levels to be transposed into the general regulations applicable to BNIs. In 2017, following the work already carried out on storage, disposal and decommissioning, ASN participated in finalising the development of reference levels for the packaging of radioactive waste.

Since 2019, ASN has participated in a think-tank on the strategic orientations of the activities of the WGWD, which should submit its proposals in 2021.

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 the European Nuclear Safety Regulators Group (ENSREG) group 2 which is responsible for subjects relative to radioactive waste management.

In 2020, 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 is currently undergoing a peer review prior to the 7th Joint Convention Review Meeting planned for summer 2022. The peer review of the preceding report in 2018 revealed a distinct interest in the French approach. Aspects underlined in particular were the quality of its comprehensive regulatory framework, the coherence of its policy and the priority given to safety through the recognition of eight areas of good performance. It was 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 each European Union country's programme on these themes be assessed by a peer review. In France, this international assessment took place from 15 to 24 January 2018 as part of an Integrated Review Service for radioactive Waste and Spent Fuel Management, Decommissioning and Remediation (ARTEMIS) mission organised by the IAEA. A delegation of ten international experts met teams from the DGEC, ASN, the DGPR, the IRSN, Andra, and the radioactive waste producers.

ASN also participates in several working groups set up within the framework of European Union and IAEA actions, particularly concerning the deep geological disposal of radioactive waste.

Lastly, ASN collaborates with the authorities of the countries the most advanced in the deployment of deep geological disposal.

ASN's international actions are presented more generally in chapter 6.

2.2 Periodic safety reviews of radioactive waste management facilities

BNI licensees, including for radioactive waste management facilities, carry out periodic safety reviews of their facilities in order to assess the situation of the facilities with respect to the rules applicable to them and to update the assessment of the risks or adverse effects, taking into account, more specifically, the state of the facility, the experience acquired during operation, and the development of knowledge and rules applicable to similar facilities. The diversity and frequently unique nature of each radioactive waste management facility lead ASN to adopt an examination procedure that is specific to each facility.

In this context, ASN is currently examining eight safety reviews of radioactive waste management facilities. They concern:
- four BNIs operated by the CEA: the treatment and packaging facility (BNI 35) on the Saclay site, the storage area (BNI 56), the Chicade research and development facility (BNI 156), and the Cedra packaging and storage facility (BNI 164) on the Cadarache site;
- one BNI operated by Orano: BNI 118, the waste treatment, packaging and waste package storage facility on the La Hague site;
- two BNIs operated by Andra: the Aube radioactive waste repository – CSA (BNI 149), and the Manche radioactive waste repository – CSM (BNI 66);
- one BNI operated by EDF: BNI 74 comprising the Saint-Laurent-des-Eaux interim storage silos.

2.2.1 Periodic safety reviews of radioactive waste management support facilities

The periodic safety reviews of the oldest facilities such as BNI 35 and BNI 118 present particular challenges. These safety reviews must address the control of the waste storage conditions, including legacy waste, the retrieval and packaging of this waste with a view to removal *via* the dedicated route and scheduled post-operational clean-out of the buildings. In relation with these challenges, the safety reviews must ensure that the impacts of discharges into the environment (soils, groundwater, or seawater in the case of BNI 118) are controlled.

For the most recent facilities, as is the case with Cedra and Chicade, the periodic safety reviews highlight more generic problems. The resistance of the buildings to internal and external hazards (earthquake, fire, lightning, flooding, aircraft crash) is one of the important aspects.

2.2.2 Periodic safety reviews of radioactive waste disposal facilities

The CSA and the CSM are subject to the obligation to hold periodic safety reviews. Their safety reviews have the particularity of addressing control of the risks and adverse effects over the long term, in addition to reassessing their operational control. Their purpose is therefore, if necessary, to revise the scenarios, models and long-term assumptions in order to confirm satisfactory control of the risks and adverse effects over time. The periodic safety reviews of these two facilities, although they are at different stages of progress (for the CSM, the review report was submitted in April 2019; for the CSA, ASN is finalising its examination of the review report), thus highlighting the need for increased knowledge of the long-term impacts associated with the toxic chemicals contained in the waste and of the impacts of radionuclides on the environment

The successive safety reviews must also serve to detail the technical measures planned by the licensee to control the adverse effects of the facility over the long term, notably for the cover which contributes to the final containment of the disposal concrete blocks. The durability of the CSM cover is, along with the preservation of the site memory for future generations, the predominant theme of the periodic safety review of a radioactive waste disposal facility.

Furthermore, these safety reviews also serve to detail, over time, the measures the licensee plans to take to ensure the long-term monitoring and surveillance of the behaviour of the disposal facility.

2.3 CEA's waste management strategy and its assessment by ASN

Types of waste produced by CEA

The CEA operates diverse types of facilities covering all the activities relating to the nuclear cycle: laboratories and plants associated with fuel cycle research, as well as experimental reactors.

CEA also carries out numerous decommissioning operations.

Consequently, the types of waste produced by CEA are varied and include more specifically:
- waste resulting from operation of the research facilities (protective garments, filters, metal parts and components, liquid waste, etc.);
- waste resulting from legacy waste retrieval and packaging operations (cement-, sodium-, magnesium- and mercury-bearing waste);
- waste resulting from final shutdown and decommissioning of the facilities (graphite waste, rubble, contaminated soils, etc.).

The contamination spectrum of this waste is also wide with, in particular, the presence of alpha emitters in activities relating to fuel cycle research and beta-gamma emitters in operational waste from the experimental reactors.

The CEA has specific facilities for managing this waste (processing, packaging and storage). Some of them are shared between all the CEA centres, such as the liquid effluent treatment station in Marcoule or the solid waste treatment station in Cadarache.

The issues and implications

The main issues for the CEA with regard to radioactive waste management are:
- the renovation of existing facilities or commissioning of new facilities for the processing, packaging and storage of the effluents, spent fuel and waste under satisfactory conditions of safety and radiation protection and within time frames compatible with the commitments made for shutting down old facilities which no longer meet current safety requirements;
- the management of legacy waste retrieval and packaging projects.

ASN notes the difficulty the CEA has in fully managing these issues and conducting all the associated projects, especially decommissioning projects, at the same time.

ASN's examination of the CEA's waste management strategy

ASN's previous examination of the CEA's strategy, which was concluded in 2012, had shown that waste management on the whole had improved since the examination carried out in 1999. ASN nevertheless observed that certain aspects of the strategy required improvement, particularly with regard to the management of intermediate-level long-lived solid waste and low or intermediate-level liquid waste, which therefore had to be consolidated. At the joint request of ASN and ASND, the CEA conducted an overall review of its decommissioning and radioactive waste management strategy and submitted the results of this work in December 2016. After examining this report, the two Authorities gave a joint opinion on this strategy in May 2019.

ASN and ASND consider that the CEA's facility decommissioning strategy and its updating of the waste and material management strategy are the result of an in-depth review and analysis. It appears acceptable for the CEA to envisage staggering the decommissioning operations in view of the resources allocated by the State and the large number of facilities undergoing decommissioning, for which waste retrieval and storage capacities will have to be built.

With regard to the material and waste management strategy, the two Authorities observe several vulnerabilities in the CEA's strategy, due in particular to the envisaged sharing of resources between centres, for the management of liquid radioactive effluents or solid radioactive waste for example, which means that for some operations, only a single facility will be available. The two Authorities also note uncertainties concerning the management of spent fuels or irradiated materials, which will have to be clarified.

ASN and ASND have therefore addressed several demands of the CEA with the aim of limiting these vulnerabilities, consolidating its strategy and detailing the operations schedule.

They demanded that the CEA make regular progress reports on the decommissioning and waste management projects, and ensure regular communication with the public, applying procedures appropriate to the nature of the facilities, civil or defence. Lastly, they want special measures to be implemented to monitor the progress of these projects.

Monitoring implementation of the CEA waste management strategy

In 2019 and 2020, ASN had regular dedicated interchanges with the DGEC, ASND and the CEA to reinforce progress monitoring on the priority projects. ASN notes the difficulty the CEA has in fully managing these issues and conducting concomitantly all the associated projects, whether they concern decommissioning or waste management support facilities. ASN notes that the deadlines for a large number of priority projects have changed significantly since the file was submitted in 2016. It will therefore apply increased vigilance to the management and monitoring of these projects in 2021.

2.4 Orano's waste management strategy and its assessment by ASN

The spent fuel reprocessing plant at the La Hague site presents the main radioactive waste management issues for Orano. The waste on the La Hague site comprises on the one hand waste resulting from reprocessing of the spent fuel, which generally comes from NPPs 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 – whether French or foreign – who have their spent fuel reprocessed. French waste is directed to the management routes described earlier, whereas foreign waste is sent back to its country of origin. On the Tricastin site, Orano also produces waste associated with the front-end activities of the cycle (production of nuclear fuel), essentially contaminated by alpha emitters.

In mid-2016, Orano (formerly Areva) submitted to ASN and ASND a file presenting the decommissioning and waste management strategy for the group's installations in France and its practical application on the La Hague and Tricastin sites. This file, for which additional elements were received in 2017, is currently being examined. Moreover, Orano submitted general and particular commitments for the La Hague and Tricastin sites in 2018. In order to verify Orano's ability to meet the deadlines of its strategy, ASN initiated an innovative project management inspection procedure in 2019.

The issues and implications

The main issues relating to the management of waste produced by Orano concern in particular:
- the safety of the legacy waste storage facilities. On the La Hague site, the facilities dedicated to legacy waste retrieval, packaging and storage have to be designed, built and then commissioned. These complex projects meet with technical difficulties which can make it necessary to adjust deadlines set by ASN (see chapter 13). Furthermore, the on-site storage capacities must be estimated with conservative margins in order to prevent premature filling to capacity. The legacy waste stored on the Tricastin site necessitates a large amount of work to characterise it and find management solutions. The storage conditions in some of the Tricastin site facilities do not meet current safety requirements and must be improved;
- the defining of solutions for waste packaging, in particular the legacy waste. These solutions require the prior approval of ASN in accordance with Article 6.7 of the Order of 7 February 2012 (see point 2.2.2). Keeping control of the packaging deadlines is a particularly important aspect, which requires the development of characterisation programmes to demonstrate the feasibility of the chosen packaging processes and to identify sufficiently early the risks that could significantly affect the project. If necessary, when the feasibility of the defined packaging cannot be determined within times compatible with the prescribed deadlines, the licensee must plan for an alternative solution, including in particular interim storage areas allowing the retrieval and characterisation of the legacy waste as rapidly as

possible. For information, Article L. 542-1-3 of the Environment Code requires that the ILW-LL waste produced before 2015 be packaged by the end of 2030 at the latest.

Within the framework of the WRP operations, Orano is examining packaging solutions that necessitate the development of new processes, particularly for the following ILW-LL waste:
- the radioactive sludge from the La Hague STE2 facility;
- the alpha-emitting technological waste which comes primarily from the La Hague and Melox plants (Gard *département*) and is not suitable for above-ground disposal.

For other types of ILW-LL waste resulting from the WRP operations, Orano is examining the possibility of adapting existing processes (compaction, cementation, vitrification). Some of the associated packaging baseline requirements are currently being examined by ASN.

2.5 EDF's waste management strategy and its assessment by ASN

The radioactive waste produced by EDF comes from several distinct activities. It mainly comprises waste from the operation of the NPPs, which consists of activated waste from the reactor cores, and waste from their operation and maintenance. Some legacy waste and waste resulting from ongoing decommissioning operations can be added to this. EDF is also the owner, for the share attributed to it, of HLW and ILW-LL waste resulting from spent fuel reprocessing in the Orano La Hague plant.

Activated waste

This waste notably comprises control rod assemblies and poison rod assemblies used for reactor operation. This is ILW-LL waste that is produced in small quantities. At present this waste is stored in the NPP fuel storage pools pending transfer to the Iceda facility.

Operational and maintenance waste

Some of the waste is processed by melting or incineration in the Centraco facility, in order to reduce the volume of ultimate waste. The other types of operational and maintenance waste are packaged on the production site then shipped to the CSA or Cires repositories for disposal (see points 1.3.1 and 1.3.2). This waste contains beta and gamma emitters, and few or no alpha emitters. At the end of 2013, EDF submitted a file presenting its waste management strategy. After examining this file, ASN in 2017 asked EDF to continue its measures to reduce the uncertainties concerning the activity of the waste sent to the CSA, to improve its organisational arrangements to guarantee the allocation of sufficient resources to radioactive waste management, and to present the most appropriate process for the treatment of used steam generators. Lastly, the spent Fuel Cluster Guide Tubes (TGG)[9] of the EDF fleet (about 2,000) should be treated by Cyclife France at the Centraco facility. This project would comprise three successive stages (interim storage, treatment before melting, then packaging for transfer to the CSA repository operated by Andra). The various license applications relative to this project are currently being examined by ASN.

The issues and implications

The main issues related to the EDF waste management strategy concern:
- the management of legacy waste. This mainly concerns structural waste (graphite sleeves) from the graphite-moderated GCR fuels. This waste could be disposed of in a repository for LLW-LL waste (see point 1.3.4). It is stored primarily in semi-buried silos at Saint-Laurent-des-Eaux. Graphite waste is also present in the form of stacks in the GCRs currently being decommissioned. In the context of the PNGMDR 2016-2018, EDF conducted a study of the reliability of the activity predictions for this waste and submitted its conclusions in December 2019. ASN will examine this report;
- the changes linked to the fuel cycle. EDF's fuel use policy (see chapter 10) has consequences for the fuel cycle installations (see chapter 11) and for the quantity and nature of the waste produced. ASN issued an opinion on the coherence of the "nuclear fuel cycle" in October 2018 (see chapter 11).

3. Management of mining residues and mining waste rock from former uranium mines

Uranium mines were worked in France between 1948 and 2001, producing 76,000 tons of uranium. Some 250 sites in France were involved in exploration, extraction and processing activities. The sites were spread over 27 *départements* in the eight regions: Auvergne-Rhône-Alpes, Bourgogne-Franche-Comté, Bretagne, Grand Est, Nouvelle-Aquitaine, Occitanie, Pays de la Loire and Provence-Alpes-Côte d'Azur. Ore processing was carried out in 8 plants. The former uranium mines are now almost all under the responsibility of Orano.

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 170 million tonnes;
- static or dynamic processing tailings, which are the products remaining after extraction of the uranium from the ore. In France, these tailings represent 50 million tonnes distributed among 17 disposal sites. These sites are ICPEs and their environmental impact is monitored.

The regulatory context

The uranium mines, their annexes and their conditions of closure are covered by the Mining Code. The disposal facilities for radioactive mining tailings are governed by section 1735 of the ICPE nomenclature. The mines and the mine tailings disposal sites are not subject to ASN oversight.

In the specific case of the former uranium mines, an action plan was defined by Circular 2009-132 of 22 July 2009 from the Minister responsible for the environment and the Chairman of ASN, based on the following work themes:
- monitor the former mining sites;
- improve the understanding of the environmental and health impact of the former uranium mines and their monitoring;
- manage the mining waste rock (better identify the uses and reduce impacts if necessary);
- reinforce information and consultation.

The long-term behaviour of the sites

Redevelopment of the uranium processing tailings disposal sites was made possible by placing a solid cover over the tailings to provide a geochemical and radiological protective barrier to

9. *The Fuel Cluster Guide Tubes (TGGs) currently stored in the pools of the NPPs serve to guide the control rod clusters inside the reactors. These parts are significantly activated, especially in their bottom section. EDF considers the removed TGGs to be radioactive waste, to be processed* via *dedicated disposal or treatment routes.*

limit the risks of intrusion, erosion, dispersion of the stored products and the risks of external and internal exposure of the neighbouring populations.

The studies submitted for the PNGMDR have enhanced knowledge of:
- the dosimetric impact of the mine tailing disposal areas on man and the environment, in particular through the comparison of data obtained from monitoring and the results of modelling;
- the evaluation of the long-term dosimetric impact of the mining waste rock piles and the mining waste rock in the public domain in relation to the results obtained in the context of the Circular of 22 July 2009;
- the strategy chosen for the changes in the treatment of water collected from former mining sites;
- the relation between the discharged flows and the accumulation of marked sediments in the rivers and lakes;
- the methodology for assessing the long-term integrity of the embankments surrounding tailings disposal sites;
- transport of uranium from the waste rock piles to the environment;
- the mechanisms governing the mobility of uranium and radium within uranium-bearing mining tailings.

In accordance with ASN opinion 2016-AV-0255 of 9 February 2016, these various studies are continuing under the PNGMDR 2016-2018, as is the work of the two technical working groups focusing on:
- maintaining the functions of the structures surrounding the disposal facilities for uranium ore treatment residues; the interim report on this work was published on the ASN website;
- management of the water from the former uranium mining sites, for which the interim report drawn up from 2018 to 2019 was published on the ASN website.

The studies required under the PNGMDR 2016-2018 were carried out following on from the previous PNGMDRs.

Orano thus submitted eleven studies between January 2017 and February 2020, supplementing those submitted previously.

ASN opinion 2021-AV-0374 of 4 February 2021 on the PNGMDR specifies the studies still to be carried out to meet the challenges associated with the former mining sites reiterated above. It recommends continuation of the work of the two working groups mentioned above, and proposes the creation of a third group dedicated to updating the methodology for assessing the long-term impact of the disposal facilities for mining processing residues. It details more specifically the long-term deterioration scenarios for the cover of mining processing residue disposal facilities, in relation with the radioactive waste disposal site development scenarios and the work carried out by the GEP Limousin, a pluralistic expert assessment group for the uranium mining sites of the Limousin region.

Management of reused mining waste rock

Most of the mining waste rock has remained on its site of production (mine in-fill, redevelopment work or spoil heaps). Nonetheless, 1 to 2% of the mining waste rock may have been used as backfill, in earthworks or for road beds in public places situated near the mining sites. Although the reuse of waste rock on public land has been traced since 1984, knowledge of reuses prior to 1984 remains incomplete. ASN and the Ministry responsible for the environment, in the framework of the action plan drawn up further to the Circular of 22 July 2009, asked Orano Mining to inventory the mining waste rock reused on public land in order to verify compatibility of the uses and to reduce the impacts if necessary.

Orano Mining has thus deployed a plan of action comprising three broad phases:
- aerial overflight around the former French mining sites to identify radiological singularities;
- inspection on the ground of areas identified in the overflight to confirm the presence of waste rock;
- treatment of areas of interest incompatible with the land usage.

The second phase of this action plan was completed in 2014. The Ministry responsible for the environment defined the procedures for managing cases of confirmed presence of mining waste rock in an Instruction to Prefects of 8 August 2013 and a complementary Instruction of 4 April 2014. This 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.

In January 2018, under the PNGMDR 2016-2018, Orano submitted an assessment of the actions taken when inventorying the mining waste rock on public land, which was supplemented in October 2019. ASN considers that the survey of waste rock piles and mining waste rock in the public domain is now complete. Based on this survey, corrective measures have been applied for situations presenting an average annual exposure exceeding 0.6 mSv/year in the public domain, or, in the case of radon exposures that could be of man-made origin, to levels exceeding 2,500 becquerels per cubic metre (Bq/m^3).

4. Management of sites and soils contaminated by radioactive substances

A site contaminated by radioactive substances is defined as a site which, due to the presence of old deposits of radioactive substances or waste, or to the utilisation or infiltration of radioactive substances or radiological activation of materials, presents radioactive contamination that could cause adverse effects or a lasting risk for people or the environment.

Contamination by radioactive substances can result from industrial, craft, medical or research activities involving radioactive substances. It can concern the places where these activities are carried out, but also their immediate or more remote vicinity. The activities concerned are generally either nuclear activities as defined by the Public Health Code, or activities concerned by natural radioactivity.

However, most of the sites contaminated by radioactive substances and today requiring management have been the seat of past industrial activities, dating back to a time when radioactive hazards were not perceived in the same way as at present. The main industrial sectors that generated the radioactive contamination identified today were radium extraction for medical and parapharmaceutical needs, from the early 1900s until the end of the 1930s, the manufacture and application of luminescent radioactive paint for night vision, and the industries working ores such as monazite or zircons. Sites contaminated by radioactive substances are managed on a case-by-case basis, which necessitates having a precise diagnosis of the site.

Article L.125-6 of the Environment Code provides for the State to create soil information sectors in the light of the information

ASN actions concerning the various uranium mining sites and soils contaminated by radioactive substances

The uranium mines, their annexes and their conditions of closure are covered by the Mining Code. The disposal facilities for radioactive mining tailings are governed by section 1735 of the nomenclature of Installations Classified for Protection of the Environment (ICPEs). Oversight of the conditions of management of the mine tailings or mining waste rock outside the production or disposal sites is the responsibility of the Prefect, on proposals from the Regional Directorate for the Environment, Planning and Housing (Dreal).

Consequently, the mines, the disposal areas, the mine tailings, the conditions of management of mine tailings or mining waste rock on public land and the management of sites and soils with no solvent responsible entity which are polluted by radioactive substances are not subject to ASN oversight. ASN assists the State departments at their request in the areas of radiation protection of workers and the public, and the management routes for mining waste, tailings and waste rock. In addition, under the French National Radioactive Material and Waste Management Plan (PNGMDR), ASN issues opinions on the studies submitted in order, for example, to improve knowledge of the development of the long-term radiological impact of the former mining sites on the public and the environment.

ASN can, at the request of the competent authority, issue an opinion regarding the management of these sites. In October 2012, ASN finalised its doctrine specifying the fundamental principles it has adopted for the management of sites contaminated by radioactive substances. In the event that, depending on the characteristics of the site, this procedure would be difficult to apply, it is in any case necessary to go as far as reasonably possible in the remediation process and to provide elements, whether technical or economic, proving that the remediation operations cannot be taken further and are compatible with the actual or planned use of the site.

The ASN doctrine defines the measures to take if complete remediation is not achieved. ASN has initiated a critical review of this doctrine, on the basis of experience feedback and the regulatory developments of 2018.

at its disposal. These sectors must comprise land areas in which the knowledge of soil contamination justifies – particularly in the case of change of use – carrying out soil analyses and taking contamination management measures to preserve safety, public health and the environment. Decree 2015-1353 of 26 October 2015 defines the conditions of application of these measures.

The Regional Directorates for the Environment, Land Planning and Housing (Dreals) coordinate the soil information sector development process under the authority of the Prefects. The ASN regional divisions contribute to the process by informing the Dreals of the sites they know to be contaminated by radioactive substances. The soil information sector development process is progressive and is not intended to be exhaustive. Ultimately these sites are to be registered in the urban planning documents.

Several inventories of contaminated sites are available to the public and are complementary: Andra's national inventory, which is updated every three years and comprises the sites identified as contaminated by radioactive substances (the 2018 edition is available on *andra.fr*) and the databases of the Ministry responsible for the environment dedicated to contaminated sites and soils.

ASN 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.

In application of the "polluter-pays" principle written into the Environment Code, those responsible for the contamination finance the operations to rehabilitate the contaminated site and to remove the waste resulting from these operations. If the responsible entities default, Andra, on account of its public service remit and by public requisition, ensures the rehabilitation of radioactive contaminated sites.

In cases where contaminated sites and soils have no known responsible entity, the State finances their clean-out through a public subsidy provided for in Article L. 542-12-1 of the Environment Code. The French National Funding Commission for Radioactive Matters (CNAR) gives opinions on the utilisation of this subsidy, as much with respect to fund allocation priorities as to polluted site treatment strategies and the principles of assisted collection of waste.

Under Article D. 542-15 of the Environment Code, the CNAR comprises:
- "members by right": representatives of the Ministries responsible for the environment and energy, of Andra, the French Environment and Energy Management Agency (Ademe), the 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).

By order of 21 March 2019, the mandated members have been appointed to the CNAR. The Commission met four times in 2020, focusing in particular on the files concerning the retrieval of radioactive objects held by private individuals, the management of contaminated sites and the management of soils from the remediation of legacy sites, such as the soils from the Bayard factory.

When contamination is caused by an installation that is subject to special policing (BNI, ICPE or nuclear activity governed by the Public Health Code), the sites are managed under the same oversight system. Otherwise, the Prefect oversees the measures taken regarding management of the contaminated site.

With regard to the management of radioactive contaminated sites coming under the ICPE system and the Public Health Code, when the responsible entity is solvent or defaulting, the Prefect uses the opinions of the classified installations inspectorate, of ASN and the Regional Health Agency (ARS) to validate the site rehabilitation project and supervises the implementation of the rehabilitation measures by Prefectural Order. ASN may thus be called upon by the services of the Prefect and the classified installation inspectors to give its opinion on the clean-out objectives of a site.

APPENDIX

LIST OF BASIC NUCLEAR INSTALLATIONS AS AT 31 DECEMBER 2020

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

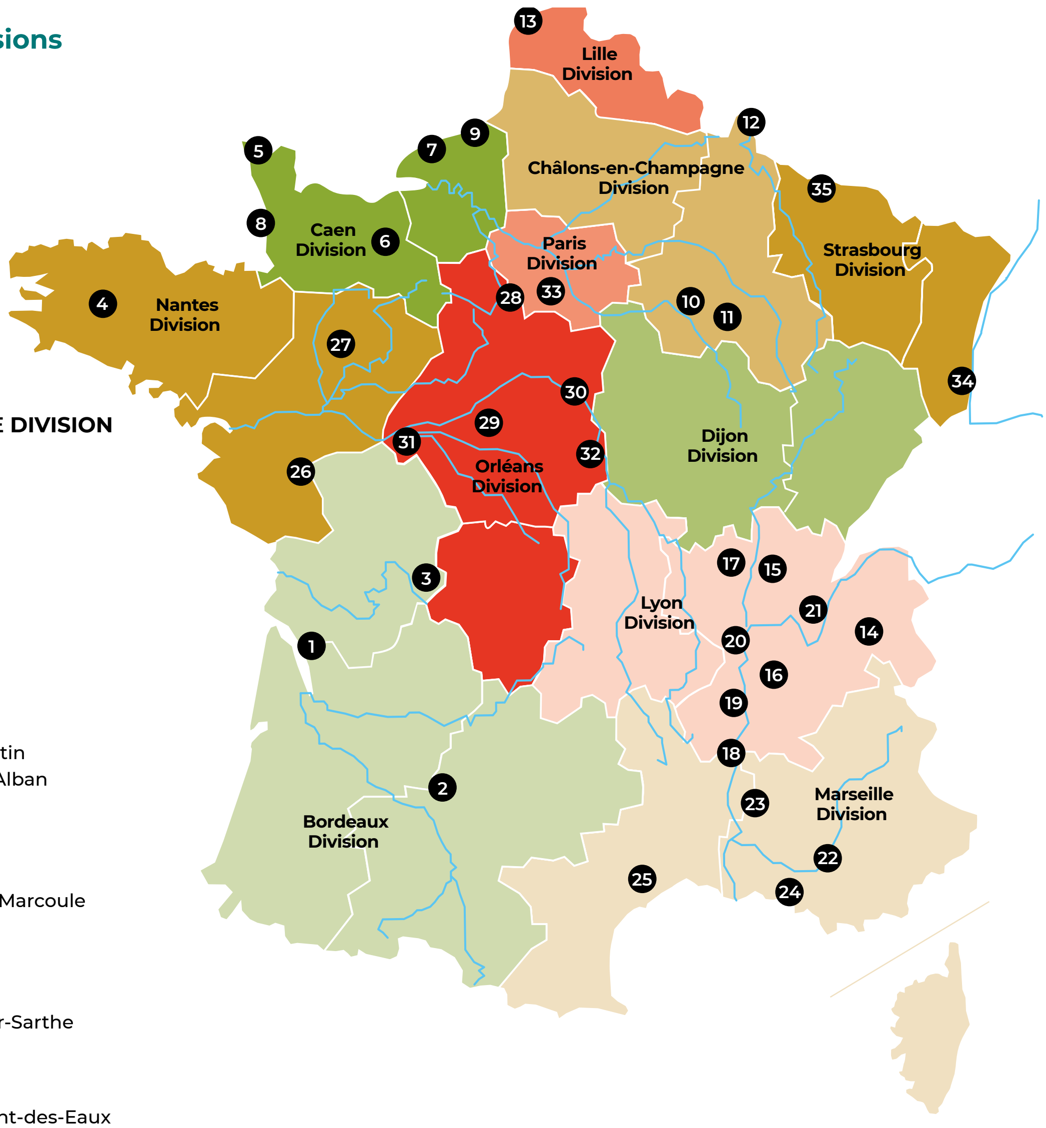
LYON DIVISION
14 Grenoble 15 Bugey
16 Romans-sur-Isère
17 Dagneux 18 Tricastin
19 Cruas-Meysse 20 Saint-Alban
21 Creys-Malville

MARSEILLE DIVISION
22 Cadarache 23 Marcoule
24 Marseille 25 Malvési

NANTES DIVISION
26 Pouzauges 27 Sablé-sur-Sarthe

ORLÉANS DIVISION
28 Saclay 29 Saint-Laurent-des-Eaux
30 Dampierre-en-Burly 31 Chinon
32 Belleville-sur-Loire
33 Fontenay-aux-Roses

STRASBOURG DIVISION
34 Fessenheim 35 Cattenom



TYPE OF INSTALLATION
- Nuclear Power Plant
- Factory
- Research installations
- Disposal of Waste
- Others

To regulate all civil nuclear activities and installations in France, the French Nuclear Safety Authority (ASN) has set up a regional organization comprising 11 regional divisions based in Bordeaux, Caen, Châlons-en-Champagne, Dijon, Lille, Lyon, Marseille, Nantes, Orléans, Paris and Strasbourg.

The Caen and Orléans divisions are responsible for Basic Nuclear Installation (BNI) regulation in the Bretagne (Brittany) and Île-de-France regions respectively. The Paris division oversees the overseas regions and the *département*[1] of Mayotte, while the Marseille division oversees radiation protection and radioactive substance transport in the Corse collectivity.

A BNI is an installation which, due to its nature or the quantity or activity of the radioactive substances it contains, is subject to a specific regulatory system as defined by the Environment Code (Title IX of Book V). These installations must be authorised by decree issued following a public inquiry and an ASN opinion. Their design, construction, operation and decommissioning are all regulated.

The following are BNIs:
1. nuclear reactors;
2. large installations for the preparation, enrichment, fabrication, treatment or storage of nuclear fuels or the treatment, storage or disposal of radioactive waste;
3. large installations containing radioactive or fissile substances;
4. large particle accelerators;
5. deep geological repositories for radioactive waste.

With the exception of nuclear reactors and the possible future deep geological repositories for radioactive waste, which are all BNIs, Section 1 entitled “Nomenclature of Basic Nuclear Installations” of Chapter III of Title IX of Book V of the Environment Code sets the threshold for entry into the BNI System for each category.

For technical or legal reasons, the concept of a BNI can cover a number of different physical situations: for example in a Nuclear Power Plant (NPP), each reactor may be considered as a separate BNI, or a given BNI might in fact comprise two reactors. Similarly, a fuel cycle plant or a French Alternative Energies and Atomic Energy Commission (CEA) centre can comprise several BNIs. These different configurations do not alter the regulatory conditions in any way.

The following are subject to the BNI System:
- facilities under construction, provided that they are the subject of a Creation Authorisation Decree;
- facilities in operation;
- facilities shut down or undergoing decommissioning, until they are delicensed by ASN.

As at 31 December 2020, there were 124 BNIs (legal entities).

The notified BNIs are those which existed prior to the publication of Decree 63-1228 of 11 December 1963 concerning nuclear facilities and for which neither said Decree nor the Environment Code required authorisation but simply notification on the basis of the acquired rights (see Articles L.593-35 and L. 593-36 of the Environment Code).

The missing BNI numbers correspond to facilities that figured in previous issues of the list, but which no longer constitute BNIs further to their delicensing (see chapter 13) or their licensing as new BNIs.

1. Administrative region headed by a Prefect.

SITE NAME	NAME AND LOCATION OF THE INSTALLATION	LICENSEE	TYPE OF INSTALLATION	BNI
LOCATION OF INSTALLATIONS REGULATED BY THE BORDEAUX DIVISION				
1 Blayais	BLAYAIS NUCLEAR POWER PLANT (reactors 1 and 2) 33820 Saint-Ciers-sur-Gironde	EDF	Reactors	86
1 Blayais	BLAYAIS NUCLEAR POWER PLANT (reactors 3 and 4) 33820 Saint-Ciers-sur-Gironde	EDF	Reactors	110
2 Golfech	GOLFECH NUCLEAR POWER PLANT (reactor 1) 82400 Golfech	EDF	Reactor	135
2 Golfech	GOLFECH NUCLEAR POWER PLANT (reactor 2) 82400 Golfech	EDF	Reactor	142
3 Civaux	CIVAUX NUCLEAR POWER PLANT (reactor 1) BP 1 – 86320 Civaux	EDF	Reactor	158
3 Civaux	CIVAUX NUCLEAR POWER PLANT (reactor 2) BP 1 – 86320 Civaux	EDF	Reactor	159
LOCATION OF INSTALLATIONS REGULATED BY THE CAEN DIVISION				
4 Brennilis	MONTS D'ARRÉE (EL4D) 29530 Loqueffret	EDF	Reactor	162
5 La Hague	SPENT FUEL REPROCESSING PLANT (UP2-400) 50107 Cherbourg Cedex	Orano Recyclage	Transformation of radioactive substances	33
5 La Hague	EFFLUENT AND SOLID WASTE TREATMENT STATION (STE2) AND SPENT NUCLEAR FUELS REPROCESSING FACILITY (AT1) 50107 Cherbourg Cedex	Orano Recyclage	Transformation of radioactive substances	38
5 La Hague	ELAN IIB FACILITY 50107 Cherbourg Cedex	Orano Recyclage	Transformation of radioactive substances	47
5 La Hague	MANCHE WASTE REPOSITORY (CSM) 50440 Digulleville	Andra	Disposal of radioactive substances	66
5 La Hague	HIGH LEVEL OXYDE (HAO) FACILITY 50107 Cherbourg Cedex	Orano Recyclage	Transformation of radioactive substances	80
5 La Hague	REPROCESSING PLANT FOR SPENT FUEL ELEMENTS FROM LIGHT WATER REACTORS (UP3 A) 50107 Cherbourg Cedex	Orano Recyclage	Transformation of radioactive substances	116
5 La Hague	REPROCESSING PLANT FOR SPENT FUEL ELEMENTS FROM LIGHT WATER REACTORS (UP2-800) 50107 Cherbourg Cedex	Orano Recyclage	Transformation of radioactive substances	117
5 La Hague	LIQUID EFFLUENT AND SOLID WASTE TREATMENT STATION (STE3) 50107 Cherbourg Cedex	Orano Recyclage	Transformation of radioactive substances	118
6 Caen	NATIONAL LARGE HEAVY ION ACCELERATOR (GANIL) 14021 Caen Cedex	G.I.E. GANIL	Particle accelerator	113
7 Paluel	PALUEL NUCLEAR POWER PLANT (reactor 1) 76450 Paluel	EDF	Reactor	103
7 Paluel	PALUEL NUCLEAR POWER PLANT (reactor 2) 76450 Paluel	EDF	Reactor	104
7 Paluel	PALUEL NUCLEAR POWER PLANT (reactor 3) 76450 Paluel	EDF	Reactor	114
7 Paluel	PALUEL NUCLEAR POWER PLANT (reactor 4) 76450 Paluel	EDF	Reactor	115
8 Flamanville	FLAMANVILLE NUCLEAR POWER PLANT (reactor 1) 50340 Flamanville	EDF	Reactor	108
8 Flamanville	FLAMANVILLE NUCLEAR POWER PLANT (reactor 2) 50340 Flamanville	EDF	Reactor	109
8 Flamanville	FLAMANVILLE NUCLEAR POWER PLANT (reactor 3 – EPR) 50340 Flamanville	EDF	Reactor	167
9 Penly	PENLY NUCLEAR POWER PLANT (reactor 1) 76370 Neuville-lès-Dieppe	EDF	Reactor	136
9 Penly	PENLY NUCLEAR POWER PLANT (reactor 2) 76370 Neuville-lès-Dieppe	EDF	Reactor	140
LOCATION OF INSTALLATIONS REGULATED BY THE CHÂLONS-EN-CHAMPAGNE DIVISION				
10 Nogent-sur-Seine	NOGENT-SUR-SEINE NUCLEAR POWER PLANT (reactor 1) 10400 Nogent-sur-Seine	EDF	Reactor	129
10 Nogent-sur-Seine	NOGENT-SUR-SEINE NUCLEAR POWER PLANT (reactor 2) 10400 Nogent-sur-Seine	EDF	Reactor	130
11 Soulaines-Dhuys	AUBE WASTE REPOSITORY (CSA) 10200 Bar-sur-Aube	Andra	Radioactive waste surface repository	149
12 Chooz	CHOOZ B NUCLEAR POWER PLANT (reactor 1) 08600 Givet	EDF	Reactor	139
12 Chooz	CHOOZ B NUCLEAR POWER PLANT (reactor 2) 08600 Givet	EDF	Reactor	144
12 Chooz	ARDENNES CENTRALE NUCLÉAIRE CNA-D (CHOOZ A) 08600 Givet	EDF	Reactor	163

SITE NAME	NAME AND LOCATION OF THE INSTALLATION	LICENSEE	TYPE OF INSTALLATION	BNI
	LOCATION OF INSTALLATIONS REGULATED BY THE LILLE DIVISION			
13 Gravelines	GRAVELINES NUCLEAR POWER PLANT (reactors 1 and 2) 59820 Gravelines	EDF	Reactors	96
13 Gravelines	GRAVELINES NUCLEAR POWER PLANT (reactors 3 and 4) 59820 Gravelines	EDF	Reactors	97
13 Gravelines	GRAVELINES NUCLEAR POWER PLANT (reactors 5 and 6) 59820 Gravelines	EDF	Reactors	122
	LOCATION OF INSTALLATIONS REGULATED BY THE LYON DIVISION			
14 Grenoble	EFFLUENT AND SOLID WASTE TREATMENT STATION (STED) 38041 Grenoble Cedex	CEA	Transformation of radioactive substances	36
14 Grenoble	HIGH FLUX REACTOR (RHF) 38041 Grenoble Cedex	Max Von Laue Paul Langevin Institute (ILL)	Reactor	67
14 Grenoble	DECAY INTERIM STORAGE FACILITY (STD) 38041 Grenoble Cedex	CEA	Storage of radioactive substances	79
15 Bugey	BUGEY NUCLEAR POWER PLANT (reactor 1) BP 60120 – 01150 Saint-Vulbas	EDF	Reactor	45
15 Bugey	BUGEY NUCLEAR POWER PLANT (reactors 2 and 3) BP 60120 – 01150 Saint-Vulbas	EDF	Reactors	78
15 Bugey	BUGEY NUCLEAR POWER PLANT (reactors 4 and 5) BP 60120 – 01150 Saint-Vulbas	EDF	Reactors	89
15 Bugey	BUGEY INTER-REGIONAL WAREHOUSE (MIR) BP 60120 – 01150 Saint-Vulbas	EDF	Storage of new fuel	102
15 Bugey	ACTIVATED WASTE PACKAGING AND STORAGE INSTALLATION (ICEDA) 01150 Saint-Vulbas	EDF	Packaging and interim storage of radioactive substances	173
16 Romans-sur-Isère	NUCLEAR FUELS FABRICATION UNIT (FBFC) 26104 Romans-sur-Isère Cedex	Framatome	Fabrication of radioactive substances	98
16 Romans-sur-Isère	NUCLEAR FUELS FABRICATION UNIT (CERCA) 26104 Romans-sur-Isère Cedex	Framatome	Fabrication of radioactive substances	63
17 Dagneux	DAGNEUX IONISATION PLANT Z.I. Les Chartinières 01120 Dagneux	Ionisos	Utilisation of radioactive substances	68
18 Tricastin	TRICASTIN NUCLEAR POWER PLANT (reactors 1 and 2) 26130 Saint-Paul-Trois-Châteaux	EDF	Reactors	87
18 Tricastin	TRICASTIN NUCLEAR POWER PLANT (reactors 3 and 4) 26130 Saint-Paul-Trois-Châteaux	EDF	Reactors	88
18 Tricastin	GEORGES BESSE PLANT FOR URANIUM ISOTOPE SEPARATION BY GASEOUS DIFFUSION (EURODIF) 26702 Pierrelatte Cedex	Orano Chimie-Enrichissement	Transformation of radioactive substances	93
18 Tricastin	URANIUM HEXAFLUORIDE PREPARATION PLANT (COMURHEX) 26130 Saint-Paul-Trois-Châteaux	Orano Chimie-Enrichissement	Transformation of radioactive substances	105
18 Tricastin	URANIUM CLEAN-UP AND RECOVERY FACILITY (IARU) 26130 Saint-Paul-Trois-Châteaux	Orano Chimie-Enrichissement	Factory	138
18 Tricastin	TU5 AND W FACILITIES BP 16 – 26700 Pierrelatte	Orano Chimie-Enrichissement	Transformation of radioactive substances	155
18 Tricastin	TRICASTIN OPERATIONAL HOT UNIT (BCOT) BP 127 – 84500 Bollène	EDF	Nuclear maintenance	157
18 Tricastin	GEORGES BESSE II PLANT FOR CENTRIFUGAL SEPARATION OF URANIUM ISOTOPES (GB II) 26702 Pierrelatte Cedex	Orano Chimie-Enrichissement	Transformation of radioactive substances	168
18 Tricastin	AREVA TRICASTIN ANALYSIS LABORATORY (ATLAS) 26700 Pierrelatte	Orano Chimie-Enrichissement	Laboratory for the utilisation of radioactive substances	176
18 Tricastin	TRICASTIN URANIUM-BEARING MATERIAL STORAGE YARD 26700 Pierrelatte	Orano Chimie-Enrichissement	Storage of radioactive materials	178
18 Tricastin	P35 26700 Pierrelatte	Orano Chimie-Enrichissement	Storage of radioactive materials	179
19 Cruas-Meysse	CRUAS-MEYSSE NUCLEAR POWER PLANT (reactors 1 and 2) 07350 Cruas	EDF	Reactors	111
19 Cruas-Meysse	CRUAS-MEYSSE NUCLEAR POWER PLANT (reactors 3 and 4) 07350 Cruas	EDF	Reactors	112
20 Saint-Alban	SAINT-ALBAN NUCLEAR POWER PLANT (reactor 1) 38550 Le Péage-de-Roussillon	EDF	Reactor	119
20 Saint-Alban	SAINT-ALBAN NUCLEAR POWER PLANT (reactor 2) 38550 Le Péage-de-Roussillon	EDF	Reactor	120
21 Creys-Malville	SUPERPHÉNIX REACTOR 38510 Morestel	EDF	Reactor	91
21 Creys-Malville	FUEL STORAGE FACILITY (APEC) 38510 Creys-Mépieu	EDF	Storage of radioactive substances	141

SITE NAME	NAME AND LOCATION OF THE INSTALLATION	LICENSEE	TYPE OF INSTALLATION	BNI
	LOCATION OF INSTALLATIONS REGULATED BY THE MARSEILLE DIVISION			
22 Cadarache	TEMPORARY DISPOSAL FACILITY (PEGASE) AND SPENT NUCLEAR FUEL DRY STORAGE INSTALLATION (CASCAD) 13115 Saint-Paul-lez-Durance Cedex	CEA	Storage of radioactive substances	22
22 Cadarache	CABRI 13115 Saint-Paul-lez-Durance Cedex	CEA	Reactor	24
22 Cadarache	RAPSODIE 13115 Saint-Paul-lez-Durance Cedex	CEA	Reactor	25
22 Cadarache	PLUTONIUM TECHNOLOGY FACILITY (ATPu) 13115 Saint-Paul-lez-Durance Cedex	CEA	Fabrication or transformation of radioactive substances	32
22 Cadarache	SOLID WASTE TREATMENT STATION (STD) 13115 Saint-Paul-lez-Durance Cedex	CEA	Transformation of radioactive substances	37-A
22 Cadarache	EFFLUENT TREATMENT STATION (STE) 13115 Saint-Paul-lez-Durance Cedex	CEA	Transformation of radioactive substances	37-B
22 Cadarache	MASURCA 13115 Saint-Paul-lez-Durance Cedex	CEA	Reactor	39
22 Cadarache	ÉOLE 13115 Saint-Paul-lez-Durance Cedex	CEA	Reactor	42
22 Cadarache	ENRICHED URANIUM PROCESSING FACILITY (ATUE) 13115 Saint-Paul-lez-Durance Cedex	CEA	Fabrication of radioactive substances	52
22 Cadarache	ENRICHED URANIUM AND PLUTONIUM WAREHOUSE (MCMF) 13115 Saint-Paul-lez-Durance Cedex	CEA	Storage of radioactive substances	53
22 Cadarache	CHEMICAL PURIFICATION LABORATORY (LPC) 13115 Saint-Paul-lez-Durance Cedex	CEA	Transformation of radioactive substances	54
22 Cadarache	ACTIVE FUEL EXAMINATION LABORATORY (LECA) AND SPENT FUEL REPROCESSING, CLEAN-OUT AND REPACKAGING STATION (STAR) 13115 Saint-Paul-lez-Durance Cedex	CEA	Utilisation of radioactive substances	55
22 Cadarache	SOLID RADIOACTIVE WASTE STORAGE YARD 13115 Saint-Paul-lez-Durance Cedex	CEA	Storage of radioactive substances	56
22 Cadarache	PHÉBUS 13115 Saint-Paul-lez-Durance Cedex	CEA	Reactor	92
22 Cadarache	MINERVE 13115 Saint-Paul-lez-Durance Cedex	CEA	Reactor	95
22 Cadarache	LABORATORY FOR RESEARCH AND EXPERIMENTAL FABRICATION OF ADVANCED NUCLEAR FUELS (LEFCA) 13115 Saint-Paul-lez-Durance Cedex	CEA	Fabrication of radioactive substances	123
22 Cadarache	CHICADE BP 1 – 13115 Saint-Paul-lez-Durance Cedex	CEA	Research and development laboratory	156
22 Cadarache	CEDRA 13115 Saint-Paul-lez-Durance Cedex	CEA	Packaging and interim storage of radioactive substances	164
22 Cadarache	MAGENTA 13115 Saint-Paul-lez Durance Cedex	CEA	Reception and shipment of nuclear materials	169
22 Cadarache	EFFLUENT ADVANCED MANAGEMENT AND PROCESSING FACILITY (AGATE) 13115 Saint-Paul-lez Durance Cedex	CEA	Packaging and interim storage of radioactive substances	171
22 Cadarache	JULES HOROWITZ REACTOR (JHR) 13115 Saint-Paul-lez Durance Cedex	CEA	Reactor	172
22 Cadarache	ITER 13115 Saint-Paul-lez-Durance Cedex	International organisation ITER	Nuclear fusion reaction experiments with tritium and deuterium and deuterium plasmas	174
23 Marcoule	PHÉNIX 30205 Bagnols-sur-Cèze Cedex	CEA	Reactor	71
23 Marcoule	ATALANTE 30200 Chusclan	CEA	Research and development laboratory and study of actinides production	148
23 Marcoule	NUCLEAR FUELS FABRICATION PLANT (MELOX) BP 2 – 30200 Chusclan	Orano Recyclage	Fabrication of radioactive substances	151
23 Marcoule	CENTRACO 30200 Codolet	Cyclife France	Radioactive waste and effluent processing	160
23 Marcoule	GAMMATEC 30200 Chusclan	Synergy Health Marseille	Ionisation treatment of materials, products and equipment, for industrial purposes and for research and development	170
23 Marcoule	DIADEM 30200 Chusclan	CEA	Storage of solid radioactive waste	177
24 Marseille	GAMMASTER IONISATION PLANT M.I.N. 712 13323 Marseille Cedex 14	Synergy Health Marseille	Ionisation installation	147
25 Malvési	CONTAINED STORAGE OF CONVERSION RESIDUES (ÉCRIN) 11100 Narbonne	Orano Chimie-Enrichissement	Storage of radioactive substances	175

SITE NAME	NAME AND LOCATION OF THE INSTALLATION	LICENSEE	TYPE OF INSTALLATION	BNI
	LOCATION OF INSTALLATIONS REGULATED BY THE NANTES DIVISION			
26 Pouzauges	POUZAUGES IONISATION PLANT Z.I. de Monlifant 85700 Pouzauges	Ionisos	Ionisation installation	146
27 Sablé-sur-Sarthe	SABLÉ-SUR-SARTHE IONISATION PLANT Z.I. de l'Aubrée 72300 Sablé-sur-Sarthe	Ionisos	Ionisation installation	154
	LOCATION OF INSTALLATIONS REGULATED BY THE ORLÉANS DIVISION			
28 Saclay	ULYSSE 91191 Gif-sur-Yvette Cedex	CEA	Reactor	18
28 Saclay	ARTIFICIAL RADIONUCLIDES PRODUCTION FACILITY (UPRA) 91191 Gif-sur-Yvette Cedex	CIS bio international	Fabrication or transformation of radioactive substances	29
28 Saclay	LIQUID EFFLUENT MANAGEMENT ZONE (STELLA) 91191 Gif-sur-Yvette Cedex	CEA	Transformation of radioactive substances	35
28 Saclay	OSIRIS-ISIS 91191 Gif-sur-Yvette Cedex	CEA	Reactors	40
28 Saclay	HIGH-ACTIVITY LABORATORY (LHA) 91191 Gif-sur-Yvette Cedex	CEA	Utilisation of radioactive substances	49
28 Saclay	SPENT FUEL TEST LABORATORY (LECI) 91191 Gif-sur-Yvette Cedex	CEA	Utilisation of radioactive substances	50
28 Saclay	SOLID RADIOACTIVE WASTE MANAGEMENT ZONE (ZGDS) 91191 Gif-sur-Yvette Cedex	CEA	Storage and packaging of radioactive substances	72
28 Saclay	POSEIDON IRRADIATION FACILITIES 91191 Gif-sur-Yvette Cedex	CEA	Utilisation of radioactive substances	77
28 Saclay	ORPHÉE 91191 Gif-sur-Yvette Cedex	CEA	Reactor	101
29 Saint-Laurent-des-Eaux	SAINT-LAURENT-DES-EAUX NUCLEAR POWER PLANT (reactors A1 and A2) 41220 La Ferté-Saint-Cyr	EDF	Reactors	46
29 Saint-Laurent-des-Eaux	IRRADIATED GRAPHITE SLEEVE STORAGE SILOS 41220 La Ferté-Saint-Cyr	EDF	Storage of radioactive substances	74
29 Saint-Laurent-des-Eaux	SAINT-LAURENT-DES-EAUX NUCLEAR POWER PLANT (reactors B1 and B2) 41220 La Ferté-Saint-Cyr	EDF	Reactors	100
30 Dampierre-en-Burly	DAMPIERRE-EN-BURLY NUCLEAR POWER PLANT (reactors 1 and 2) 45570 Ouzouer-sur-Loire	EDF	Reactors	84
30 Dampierre-en-Burly	DAMPIERRE-EN-BURLY NUCLEAR POWER PLANT (reactors 3 and 4) 45570 Ouzouer-sur-Loire	EDF	Reactors	85
31 Chinon	IRRADIATED MATERIAL FACILITY (AMI) 37420 Avoine	EDF	Utilisation of radioactive substances	94
31 Chinon	CHINON INTER-REGIONAL WAREHOUSE (MIR) 37420 Avoine	EDF	Storage of new fuel	99
31 Chinon	CHINON NUCLEAR POWER PLANT (reactors B1 and B2) 37420 Avoine	EDF	Reactors	107
31 Chinon	CHINON NUCLEAR POWER PLANT (reactors B3 and B4) 37420 Avoine	EDF	Reactors	132
31 Chinon	CHINON A1 D 37420 Avoine	EDF	Reactor	133
31 Chinon	CHINON A2 D 37420 Avoine	EDF	Reactor	153
31 Chinon	CHINON A3 D 37420 Avoine	EDF	Reactor	161
32 Belleville-sur-Loire	BELLEVILLE-SUR-LOIRE NUCLEAR POWER PLANT (reactor 1) 18240 Léré	EDF	Reactor	127
32 Belleville-sur-Loire	BELLEVILLE-SUR-LOIRE NUCLEAR POWER PLANT (reactor 2) 18240 Léré	EDF	Reactor	128
33 Fontenay-aux-Roses	PROCÉDÉ 92265 Fontenay-aux-Roses Cedex	CEA	Research installation	165
33 Fontenay-aux-Roses	SUPPORT 92265 Fontenay-aux-Roses Cedex	CEA	Effluent treatment and waste storage installation	166
	LOCATION OF INSTALLATIONS REGULATED BY THE STRASBOURG DIVISION			
34 Fessenheim	FESSENHEIM NUCLEAR POWER PLANT (reactors 1 and 2) 68740 Fessenheim (Haut-Rhin)	EDF	Reactors	75
35 Cattenom	CATTENOM NUCLEAR POWER PLANT (reactor 1) 57570 Cattenom	EDF	Reactor	124
35 Cattenom	CATTENOM NUCLEAR POWER PLANT (reactor 2) 57570 Cattenom	EDF	Reactor	125
35 Cattenom	CATTENOM NUCLEAR POWER PLANT (reactor 3) 57570 Cattenom	EDF	Reactor	126
35 Cattenom	CATTENOM NUCLEAR POWER PLANT (reactor 4) 57570 Cattenom	EDF	Reactor	137

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